DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-37-NH

DATE: **July 3, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Guidance - Revisions to State Operations Manual (SOM), Appendix PP-Guidance to Surveyors for Long-Term Care (LTC) Facilities and Chapter 4

Memorandum Summary

- **Revisions to Appendix PP of the SOM:** We have revised the Interpretive Guidelines and, where appropriate, Investigative Protocols for the following F Tags to incorporate Survey & Certification (S&C) policy memos issued from October 2003 through May 2014. Specifically, the guidelines have been updated for the following F Tags:

  F161 - Assurance of Financial Security
  F202 - Documentation for Transfer and Discharge
  F208 - Admission Policy
  F221 - Physical Restraints
  F278 - Accuracy of Assessment/Coordination/Certification/Penalty for Falsification
  F281 - Services Provided Meet Professional Standards of Quality
  F286 - Maintaining 15 Months of Resident Assessments (Use)
  F332 - Medication Errors/Free of Medication Errors of 5% or Greater
  F333 - Medication Errors/Residents are Free of Significant Medication Errors
  F371 – Sanitary Conditions
  F387 - Frequency of Physician Visits/Timeliness of Visits
  F388 - Personal Visits by the Physician
  F390 - Physician Delegation of Tasks in SNFs/Performance of Physician Tasks in NFs
  F425 - Pharmacy Services
  F428 - Drug Regimen Review
  F431 - Service Consultation/Labeling of Drugs and Biologicals/Storage of Drugs and Biologicals
  F441 - Infection Control
  F492 - Compliance with Federal, State and local laws and Professional Standards
  F514 - Clinical Records
  F516 - Resident Identifiable Information/Safeguard against loss, destruction, or unauthorized use

- **Revisions to SOM Chapter 4:** Section 4132.1E Waiver of Program Prohibition has been revised to incorporate information consistent with CFR 483.151(c)(1). Section 4542.2 State Agency (SA) Expenses for Training of SA Personnel has been revised to include Association of Health Facility Survey Agencies (AHFSA) to the list of annual meetings.

A. Background

The Centers for Medicare & Medicaid Services (CMS) is committed to revising and updating the SOM by incorporating published S&C policy memos. This includes clarification of guidance, and/or changes to acceptable standards of practice related to the regulatory guidance.

In this transmittal, revisions have been made to Appendix PP based on the following:

- F161- Assurance of Financial Security and F208 - Admission Policy are related to S&C memo 04-17, "Clarification of Nursing Homes Requiring Promissory Notes or Deposit Fees as a Condition of Admission and Implications related to Surety Bonds" dated Jan.8, 2004.

- F202 - Documentation for Transfer and Discharge is related to S&C memo 03-10, "Binding Arbitration in Nursing Homes" dated Jan. 9, 2003.

- F221- Physical Restraints is related to S&C memo 07-22, "Clarification of Terms Used in the Definition of Physical Restraints as Applied to the Requirements for Long Term Care Facilities" dated June 22, 2007.

- F281 - Services Provided Meet Professional Standards of Quality , F332 - Medication Errors/Free of Medication Errors of 5% or Greater, F333- Medication Errors/Residents are Free of Significant Medication Errors, F425- Pharmacy Services, F428- Drug Regimen Review, F431- Service Consultation/Labeling of Drugs and Biologicals/Storage of Drugs and Biologicals and the Investigative Protocols for F428 and F431 are related to S&C memo 13-02, "Nursing Homes - Clarification of Guidance related to Medication Errors and Pharmacy Services" dated Nov. 2, 2012.

- F278 - Accuracy of Assessment/Coordination/Certification/Penalty for Falsification, F286 - Maintaining 15 Months of Resident Assessments (Use), and F514 - Clinical Records are related to S&C memo 05-14, "Electronic Signature Guidance – Clarification" published on Jan. 13, 2005 (which replaced S&C memo 04-46, "Electronic Signature Guidance" dated Sept. 9, 2004).

- F332 - Medication Errors/Free of Medication Errors of 5% or Greater and F333 - Medication Errors/Residents are Free of Significant Medication Errors related to S&C policy memos 07-39, "Medication Pass Clarification for Surveying F Tags F332 and 333 During Nursing Home Surveys," published on Sept. 28, 2007 and 06-30 "Exceptions to the Observation Requirement When Determining Significant Medication Errors" dated Sept. 29, 2006.

- F371- Sanitary Conditions and the associated investigative protocol related to S&C policy memo11-38 "Compliance with Food Procurement Requirements for Nursing Homes with Gardens" dated Sept. 7, 2011 and S&C policy memo 14-34 "Advance Copy of Revised F371; Interpretive guidance and Procedures for Sanitary Conditions, Preparation of Eggs in Nursing Homes" dated May 20, 2014.

- F387- Frequency of Physician Visits/Timeliness of Visits, F388- Personal Visits by the Physician, and F390 - Physician Delegation of Tasks in SNFs/Performance of Physician Tasks in NFs related to S&C policy memo 13-15 Physician Delegation of Tasks (which replaced S&C policy memos 04-08 and 03-18 titled Physician Delegation of Tasks in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs).

- F425- Pharmacy Services related to S&C policy memo 06-06 "Use of Foreign Acquired Drugs in LTC Facilities" published Nov. 14, 2005 and S& C policy memo 13-02 "Nursing Homes – Clarification of Guidance related to Medication Errors and Pharmacy Services." dated November 2, 2012.

- F441- Infection Control and the associated Investigative Protocol related to S&C policy memo 12-30 "Use of Insulin Pens in Health Care Facilities" dated May 18, 2012, S&C policy memo 12-35 "Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections" dated June 15, 2012, S&C policy memo 10-28 "Point of Care Devices and Infection Control in Nursing Homes" dated August 27, 2010, S&C policy memo 13-09 "Clarification of Interpretive Guidance at F Tag 441 – Laundry and Infection Control" dated January 25, 2013 and "Advance Copy – Single-Use Device Reprocessing under Tag F441. Revisions to Interpretive Guidance in Appendix PP, State Operations Manual (SOM) on Infection Control" dated May 9, 2014.

- F492- Compliance with Federal, State and local laws and Professional Standards related to S&C policy memo 12-34 "Clarification and revisions to Interpretive Guidance at F Tag 492, as Part of Appendix PP, State Operations Manual (SOM) for Long Term Care (LTC) Facilities" dated June 1, 2012.

- F514- Clinical Records and F516 - Resident Identifiable Information/Safeguard against loss, destruction, or unauthorized use related to S&C policy memo 09-53 "Surveying Facilities that use Electronic Health Records (EHR)" dated August 14, 2009.

In this transmittal, we have also revised Section 4132.1E, Waiver of Program Prohibition, to incorporate information consistent with 42 CFR 483.151(c)(1).

An advance copy of the guidance revisions is attached. The final version of this document, when published in the online SOM, may differ slightly from this advanced copy.

If you have any questions regarding this memorandum, please contact Alisa Overgaard at 410-786-2167 or via e-mail at Alisa.Overgaard@cms.hhs.gov.

Effective Date: Immediately. This information should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachments: (19)

Advance Copy, SOM Interpretive Guidance Revisions for Appendix PP and Chapter 4

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)

Transmittal ADVANCE COPY **Date: ----------**

SUBJECT: Revisions to Appendix PP – "Guidance to Surveyors for Long Term Care Facilities" and State Operations Manual (SOM) Chapter 4 – "Program Administration and Fiscal Management"

I. SUMMARY OF CHANGES: This instruction revises the Interpretive Guidelines and, in some instances, associated Investigative Protocols for several F Tags to reflect incorporation of S&C policy memo guidance issued from FY03 through May 2014. SOM Chapter 4 Section 4132.1E - Waiver of Program Prohibition has been revised to incorporate information consistent with CFR 483.151 (3)(c)(1).

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/F tag 161/ §483.10(c)(7)
R	Appendix PP/F tag 202/§483.12(a)(2)(3)
R	Appendix PP/F tag 208/§483.12(d)(3)
R	Appendix PP/F tag 221/§483.13(a)
R	Appendix PP/F tag 278/§483.20(g) & (i)
R	Appendix PP/F tag 281/§483. 20(k)(3)
R	Appendix PP/F tag 286/§483.20(d)
R	Appendix PP/F tag 332/§483.25(m)(1)
R	Appendix PP/F tag 333/§483.25(m)(2)
R	Appendix PP/F tag 371/§483.35(i)(1)(2)
D	Appendix PP/F tag 371/§483.35 (i)(l)(2) Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety: Delete last bulleted paragraph – "The facility purchased unpasteurized shell eggs for all cooking purposes. The cook prepared…..

R	Appendix PP/F tag 387/§483.40(c)(1)(2)
R	Appendix PP/F tag 388/§483.40(c)(3)(4)
R	Appendix PP/F tag 390/§483.40(e) (f)
R	Appendix PP/F tag 425/§483.60, §483.60 (a) & (b)(1)
R	Appendix PP/F tag 428/§483.60(c)(1)(2)
R	Appendix PP/F tag 431/§483.60(b)(2)(3)(d)(e)
R	Appendix PP/F tag 441/§483.65
R	Appendix PP/F tag 492/§483.75(b)(c)
R	Appendix PP/F tag 514/§483.75(l)(1)
R	Appendix PP/F tag 516/§483.75(l)(3)
R	Chapter 4/Section 4132/Subsection 4132.1E/Waiver of Program Prohibition
R	Chapter 4/ Section 4542/ Subsection 4542.2 - SA Expenses for Training of SA Personnel

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Chapter 4 - Program Administration and Fiscal Management

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4000 - Federal/State Relationship for Provider Certification

(Rev. 1, 05-21-04)

4000A - Title XVIII - Medicare Regulations

(Rev. 1, 05-21-04)

Section 1864 of the Social Security Act (the Act) outlines the functional role of State survey agencies (SAs) in the Medicare program, and provides for establishing an administrative relationship based upon a formal agreement negotiated between the governor of the State and the Secretary of HHS.

4000B - Title XIX - Medicaid Regulations

(Rev. 1, 05-21-04)

Pursuant to Title XIX, the SA is a grantee of Federal funds, and is required under §1902 of the Act to develop and adhere to its own administrative "State plan," for which HHS provides the major share of financing through grants, the terms of which are spelled out in §1903 of the Act. The Federal share is termed Federal financial participation (FFP). If the Secretary finds that a State is not complying with its plan (as approved by the Secretary), §1904 of the Act provides that FFP can be reduced or withheld.

Extensive regulatory standards for the development and terms of the State plans, for the management of the grants, and for the standards limiting participation of health care institutions are found in 42 CFR Chapter IV, Subchapter C. However, those regulations which directly affect the State component administering the Medicaid program (known as the State Medicaid agency or the single State agency) are widely dispersed through Subchapter C. Provisions of Federal grant laws other than title XIX also impinge upon the financial administration of the SA.

4001 - Federal Administrative Responsibilities

(Rev. 1, 05-21-04)

Among the responsibilities of the parties to the agreements are obligations imposed upon the Federal government (delegated to CMS) dealing with the States' program administration, which include:

- Setting policy and providing policy interpretations on the provider and supplier certification program standards;

- Providing consultation to agencies involved in administering the Federal requirements;

- Paying the appropriate and allowable costs of the SA functions relating to administration of regulations and provisions of the agreement and State Plan;

- Making determinations of allowable State costs to submit for Federal payment;

- Controlling payment of Federal trust funds (and grant awards) to appropriate SA for survey and certification costs incurred in administering title XVIII and title XIX programs; and

- Approving qualified State personnel used in the provider certification program.

4002 - Nature and Source of Payments to States

(Rev. 1, 05-21-04)

4002A - Trust Funds for Title XVIII-Related Activities

(Rev. 1, 05-21-04)

Execution of an agreement with a SA under §1864 of the Act involves the assumption by CMS of the obligation to meet the necessary and reasonable expenses of performing services provided for in the agreement. Payments to States under §1864 of the Act are made from the Federal Hospital and Supplementary Medical

Insurance Trust Funds to cover the costs of services performed under the agreement are authorized by §1864 of the Act. The costs of health insurance benefits and the administrative costs of the program are charged to the Trust Funds. Administrative expenses (including advances or payment to States under §1864 of the Act) are authorized for expenditure from the Trust Funds only through the regular appropriation process of Congress.

4002B - Grant Funds for Title XIX-Related Activities

(Rev. 1, 05-21-04)

Sections 1903(a)(4) and (a)(7) provide that to the extent the SA is performing certification activities pursuant to an approved State plan, the Federal financial grant mechanisms are used to pay the State for a percentage of the cost of those activities during each quarter of the year. The matching grants come from appropriated general revenues of the United States. The Secretary is authorized to pay a percentage against these costs for the proper and efficient administration of the State plan. Whereas the title

XVIII trust funds are controlled under terms of the State agreement, the grant funds are controlled by the established rules of Federal grant laws and regulations.

4003 - SA Administrative Responsibilities

(Rev. 1, 05-21-04)

The SA is responsible for:

- Establishing and maintaining organizational relationships with other State and local governmental groups as necessary for attaining program or related program goals;

- Keeping CMS advised of program needs and trends, and of responsive actions taken;

- Providing the material, equipment, and the training and support of personnel to perform the above functions; and

- Furnishing necessary records and accounting to provide justification for costs claimed for payment by the Secretary.

4003.1 - SA Responsibility for Records and Reports

(Rev. 1, 05-21-04)

The SA establishes and maintains basic records and prepares operating reports to reflect essential administrative and fiscal data of mutual concern to the SA and CMS. These records and reports provide:

- Evaluation of the effectiveness of program operations;

- Analysis of workloads;

- Identification of administrative or technical problem areas;

- Development and justification of budget estimates; and

- Supporting documentation for the expenditure of Federal and State funds.

For the most part, the SA responsibility for records and reports, on a continuing or special request basis, is limited to those pertinent to the managing of agency operations and those that reflect the agency's workload. To the extent possible, these will be designed to fit within the framework of the SA operations. The CMS requirement for a minimum of

specific records and reports is not intended to limit in any way the SA fiscal and administrative practices.

4003.2 - SA Responsibility for Staff Training and Development

(Rev. 1, 05-21-04)

4003.2A - Staff Training

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

All health facility surveyors employed in the Medicare and/or Medicaid programs must successfully complete the Basic Health Facility Surveyor Training Course within the first year of employment. When applicable, the surveyor must also attend laboratory, LSC, ESRD, and other specified training as necessary or required by the Federal government.

Each State is responsible for providing continuing education to its surveyors. In conjunction with and subject to the approval of the Regional Training Administrator, each SA must have a procedure for identifying the training needs of its surveyors. Each SA provides the appropriate training through in-service education, State, regional, and/or national conferences, seminars and workshops, and related courses as needed and appropriate within fiscal limitations approved by CMS. The SAs are to assure that surveyors are trained to survey for all regulatory requirements and have the necessary skills to perform the survey.

For surveyors of long term care facilities, i.e., nursing homes, CMS is implementing a computer-assisted survey process, the Quality Indicator Survey (QIS), in selected State Survey Agencies to determine if Medicare and Medicaid certified nursing homes meet the Federal participation requirements. In addition to completion of any other requirements, surveyors of nursing homes in States implementing the QIS are required to successfully complete the additional QIS training requirements described below at §4009F.

4003.2B - In-Agency Training

(Rev. 1, 05-21-04)

Each SA must have its own program of staff development that responds to the needs of new employees for orientation and basic training, and to the needs of experienced employees for continuing development and education.

4003.2C - Outside-of-Agency Training

(Rev. 1, 05-21-04)

In evaluating the appropriateness of any outside training activity for survey and certification funding, the SA and CMS must consider the degree to which the benefit to the trainee is applied toward his/her service to the survey and certification program. This is especially important where personnel are serving on a part-time basis.

4004 - SA Reporting of Possible Certification Fraud

(Rev. 1, 05-21-04)

Section 1128.B of the Act and P.L. 104.191, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) contains specific penalties for fraud and abuse under Medicare and Medicaid. It provides criminal penalties for:

- Making false statements or representation for any benefit or payment under Medicare and Medicaid;
- Soliciting or receiving any kickback, bribe, or rebate;
- Making false statements or representations with respect to the conditions or operation of any institution, facility, or entity in order to qualify (either initial certification or recertification) for participation in Medicare or Medicaid;
- Charging for any services provided to a patient under Medicaid at a rate in excess of the established State rate, or charging, soliciting, accepting, or receiving in addition to any amounts otherwise required to be paid under Medicaid, any gift, money, donation, or other consideration as a precondition of admitting a patient to a hospital, NF, or ICF/MR, or a requirement for the patient's continued stay in such a facility;
- Charging for services not rendered; and
- Physicians and suppliers who agree to accept assignment and violate the terms of that agreement.

When the SA believes that there may be certification fraud, it should immediately notify the RO via memorandum. This memorandum should include the name and provider number of the facility, together with a statement of the relevant facts. In addition, the SA should make no further contacts with the offending individual or facility with respect to this matter unless requested to do so by the appropriate RO personnel. This is necessary because any unauthorized contacts may compromise the potential or pending

investigation, including chances for successful prosecution of any criminal violation that has occurred.

4005 - Reliance Upon States to Initiate Budget - Coordinated Activity Plans for Carrying Out Program Action

(Rev. 1, 05-21-04)

States are encouraged to conduct their administrative affairs to harmonize, within broad Federal guidelines, with their own programmatic resources, recognized needs, and accustomed methods of operation. State-initiated proposals are considered within certain limits for adoption or approval by the CMS. They are evaluated for efficiency in attaining program objectives, and for general administrative prudence and accountability.

4006 - Interagency Subagreements

(Rev. 1, 05-21-04)

4006A - Authority

(Rev. 1, 05-21-04)

When an SA wishes to assign part of its responsibility to another State or local public agency or a private agency, the authority to seek such assignment is found in the agreements of State plans negotiated by the States and the Secretary of HHS in Article IV of the §1864 Agreement.

> With prior written authorization of the Secretary, the State may utilize the services, facilities, and records of any other State agency or any local governmental agency to assist the State survey agency in carrying out its functions authorized by this Agreement. Only the reasonable and necessary costs incurred by such agencies in furnishing to the State survey agency such services, facilities, or records, may be allowed under this Agreement, in accordance with Article IX.

4006B - Need for Subagreements With Public Entities

(Rev. 1, 05-21-04)

The consideration contained in subsection A.3 of the §1864 Agreement does not apply where use of individuals or services not an integral part of the SA are generally obtained by detail or reassignment within State government. Neither would the consideration contained in subsection A.3 apply where licensure responsibility is delegated to local entities, when a pattern of close administrative relationships has been established. In such situations, no formal agreement is necessary, except where required by State

practice. The necessary costs of services are identified in the normal manner used by the SA for survey and certification activities.

The fact that the activities are decentralized would not in itself require an assignment of responsibility, provided decentralization is an integral part of the SA. If the SA has already established operating arrangements with the local agency under State law and supervises local health department activities, or generally oversees these activities through conditional financial assistance similar to Federal-State grants-in-aid, no formal agreement is needed, and the costs of the services should be identified and reported in the normal manner.

There may be situations, however, in which the SA finds it desirable to arrange for services which it would not directly supervise, but over which it would maintain a certain amount of control. This might occur when the SA wishes to delegate survey functions to a local health department, yet retain the authority to make final evaluation of recommendations and forward certifications to CMS.

The SA would need to enter into an agreement with the local health department setting forth the responsibilities of both entities and enabling the department to be paid the necessary costs incurred in furnishing such services. The SA includes such costs in estimates for advance of funds and in reports of its actual expenditures.

4006C - Program Specialization of Tasks Performed by Subagreement Entity

(Rev. 1, 05-21-04)

Section 1902(a)(9) of the Act requires that the same SA that performs title XVIII certification functions must also be responsible for pursuing compliance in title XIX institutional standards. Section 1902(a)(33) of the Act provides that the State health licensing agency (which may or may not be the same agency) determines for title XIX whether institutions meet the standards for participation. The combined practical effect of these provisions is to require that the same SA make certifications for both titles XVIII and XIX. However, in no way does this preclude division of functions for inspecting and providing consultation between different State components. The important thing is that the SA designated in the §1864 State Agreement has control and responsibility for both title XVIII certification recommendations and title XIX approval decisions in all cases. As long as this is the case, it does not matter that another State or local agency is designated to perform field functions as long as the following provisions are included:

- A clear delineation of responsibilities and duties to be carried out by both parties;
- Provision for the degree of supervision and control to be exercised by the SA;
- Provision for payment by the SA on an approved cost basis;

- A termination clause specifying the length of the agreement (normally one year, with provision for extensions as necessary); and

- A statement acknowledging the applicability of the §1864 Agreement or State plan to the other agency which includes the following:

> All of the terms and provisions of the agreement or State plan between the State of (insert State) and the Secretary of Health and Human Services entered into (insert date), pursuant to §1864 or §1902, respectively, of the Social Security Act, as amended, which are applicable to the (insert title of State agency) also shall be applicable to the (insert title of other agency) in its performance on behalf of the (insert title of State agency) of the functions herein enumerated.

In conformity with usual State practice, the format should make provision for signatures of representatives of the two contracting agencies. Since the document relates to understandings reached at the State-local level, a representative of CMS should not make provision in the agreement for signature.

When a suitable title XVIII agreement is negotiated, two copies of the agreement are forwarded to the CMS. The CMS approval will be in the form of a separate letter from CMS and will constitute authorization for utilization of the other agency's services as provided in the agreement. Approval from CMS must be obtained whenever such an agreement is renewed or renegotiated.

4006.1 - Negotiating Subagreements With Non-Public Entities

(Rev. 1, 05-21-04)

This represents an unusual situation because arrangements with non-public organizations such as universities, hospital associations, etc., may create difficulties of program control. A unique problem might compel using a non-public agency. However, an agreement with a non-public agency would require a more precise contract than the agreement that is considered sufficient with other governmental agencies. Agreements with such agencies are not to be considered within the scope of the above sections. This is due to their complexity, and the need to ensure that the results from such non-public services are acceptable from an appeals standpoint. Not all SA agreements specify in §4006.A (A.3) that the services of non-public agencies can be utilized. Accordingly, where this is lacking, the §1864 agreement must be modified before such a request could be approved.

4007 - Assistance of CMS in SA Program Administration

(Rev. 1, 05-21-04)

The CMS RO is the representative of CMS Central Office (CO) in all certification functions and is responsible for:

- Reviewing and recommending action on SA budget submittals;
- Furnishing program guidance and policy interpretation to SA officials;
- Coordinating communications with SAs, providers, and intermediaries on certification activities; and
- Consulting on a regular basis with SAs for mutual assessment of program activities, achievement of stated objectives, and establishment of future goals.

These functions are in addition to the CMS RO Director's responsibility for assessing the adequacy of SA documentation of title XVIII certification recommendations, monitoring SA title XIX certification decisions, making the determination of acceptance for participation, denial, and termination in the title XVIII program, and for recommending the same to the RO division responsible for Medicaid.

Before approving State budget submittals, the RO considers the following:

- Is the SA's plan of program activities appropriately related to the national aims and needs of CMS programs?
- Is adequate provision made for deploying staff to accomplish these aims, and are the professional qualifications for these positions appropriate to the functions to be performed?
- Do the workload and activity plans and the staffing estimates properly distribute emphasis upon recertification, administrative and coordinative planning, and efficient agency administration in terms of supervision, training, records control, and interdivisional relationships?
- Does the budget request represent a consistent application and understanding of approved principles of reasonable cost to the SA's specific circumstances, are the requested funds proper, and has adequate provision been made for validating the costs to be charged to certification?
- Have activities not falling under the purview of survey and certification functions, such as State licensure and medical review, been appropriately excluded?

- Has the SA provided for the appropriate State match for title XIX FFP?

4008 - Conflicts of Interest of SA Employees

(Rev. 1, 05-21-04)

(Also see §7202)

Conflicts of interest may arise within the Medicare/Medicaid certification program when public employees utilize their position for private gain or to secure unfair advantages for outside associates. The gain involved may or may not be monetary. Abuses of privileged information, abuses of influence, and other abuses of trust are included, regardless of whether a monetary advantage is gained or sought. Almost all States have laws or regulations prohibiting, and providing punishment for, overt specific violations of public trust.

It is not possible to list all situations which could be construed as potential conflicts of interest in the certification process, but many would be among the examples in subsection A, below. SA administrators should require employees to make a declaration of any such outside interests and update this declaration periodically. The SA should evaluate the need for preventive measures to protect the integrity of the certification program. In cases where certification work is performed by agencies other than the designated SA, the SA administrators and the subagency administrators have a shared responsibility for such surveillance.

It is not necessary for the SA to inform the RO of all potential and apparent conflict situations. However, if an overt abuse requires corrective action, the SA should inform the RO as described in subsection B, below.

4008A - Examples of Potential Conflicts of Interest

(Rev. 1, 05-21-04)

The following are typical situations that may raise a question of possible conflicts of interest on the part of an agency employee representing the Medicare/Medicaid survey and certification program:

- Participation in ownership of a health facility located within the employing State;
- Service as a director or trustee of a health facility;
- Service on a UR committee;
- Private acceptance of fees or payments from a health facility, group of health facilities, or association of health facility officers for personal appearances,

personal services, consultant services, contract services, referral services, or for furnishing supplies to a health facility;

- Participation in a news service disseminating trade information to a segment of the health industry; and/or

- Having members of one's immediate family engaged in any of the above activities, other than non-managerial employees of health facilities.

4008B - Report and Investigation of Improper Acts

(Rev. 1, 05-21-04)

State codes should provide judicial or administrative remedies for abuses of influence, privileged information, or trust arising through conflicts of interest. Any acts of employees in violation of State laws or regulations should be handled in accordance with applicable State procedures. When there appears to be Medicare/Medicaid program involvement, the SA immediately reports this to CMS and keeps it advised of corrective actions. Also, the SA requests assistance or advice on any case of an impropriety involving conflicts of interest that cannot be handled immediately under an applicable State procedure. The regional OIG, along with the RO, will work in close cooperation with the responsible State officials to resolve the matter.

4009 - Federal Surveyor Qualifications Standards

(Rev. 1, 05-21-04)

(Also see §7201)

In accordance with the "Personnel" clause of the State agreement, SA personnel must be under a merit system that meets Federal standards. Minimum standards specifically applicable to surveyors for Medicare and Medicaid Programs are as follows:

4009A - Persons Covered

(Rev. 1, 05-21-04)

The term "surveyor" means a person who investigates, evaluates, and/or makes official reports of situations and conditions in a health facility, and who determines the degree to which the facility meets specific criteria contained in regulations issued pursuant to titles XVIII and XIX of the Act.

4009B - Health Professional Qualifications

(Rev. 1, 05-21-04)

To perform the surveyor functions requires an appropriate background in the health professions or health administration, in addition to basic investigative skills. Therefore, one element in the standard is that the surveyor be qualified in one of the following professions:

- Hospital administrator;
- Industrial hygienist;
- Laboratory or medical technologist, bacteriologist, microbiologist, or chemist;
- Medical record librarian;
- Nurse;
- Nursing home administrator;
- Nutritionist;
- Pharmacist;
- Physical Therapist;
- Physician;
- Qualified Mental Retardation Professional;
- Sanitarian;
- Social worker; or
- Any other professional category used within State merit systems for health professional positions, provided the State has determined the position classification skill level to be commensurate with any of the above professions.

This does not mean that the surveyor must belong to a professional organization or have prior work experience in the profession. It means that he/she must satisfy necessary requirements to be employed in one of these specialties by the State.

4009C - Education, Training, and Experience

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

To assure that individuals have the necessary knowledge, skills, and abilities to carry out survey functions, the following prerequisites apply:

- The amount of academic education required is that which is necessary to qualify in a profession listed in §4009B;

- Newly hired surveyors must successfully complete an orientation program approved by CMS that includes the core elements of the CMS-developed orientation program. (See Exhibit 42.) The CMS provides this program for Federal surveyors and the States provide it for theirs;

- The CMS and States assure that the health facility surveyors, laboratory surveyors, and Life Safety Code (LSC) surveyors have successfully completed, within the first 12 months of employment, the basic surveyor training course developed under CMS auspices, including all course prerequisites. LSC surveyors are required to complete a LSC basic course (there is self-paced training on a CD-ROM as a prerequisite). No individual may serve on a survey team until he or she fulfills this requirement, except as a trainee who is accompanied onsite by a surveyor, who has successfully completed the required training and testing program;

- In States implementing the Quality Indicator Survey (QIS) process to determine if Medicare and Medicaid certified nursing homes meet the Federal participation requirements, additional training in QIS as described below at §4009F must be completed.

- Before any State or Federal surveyor may serve on a survey team (except as a trainee) for an ICF/MR, ESRD facility, HHA, or Hospice survey, he/she must have successfully completed the relevant provider-specific Basic course and any course prerequisites;

- Some State position classifications may require additional education, training, and experience as State minimums, as requirements for promotion, or entry at a higher scale of position classification; and

- SAs must have a mechanism to identify and respond to the in-service training needs of the surveyors.

4009D - Evaluation

(Rev. 1, 05-21-04)

The surveyor must demonstrate ability to perform the essentials of the survey function, including knowledge of new or changing Federal regulations as obtained through continuing education sponsored by CMS or the State. All survey and certification staff must attend job-related training courses annually.

4009E - Implementation

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

Surveyors are considered qualified if:

- They undergo the training prescribed in the second and third bullets and, if applicable, in the fourth bullet for QIS States in §4009C. Personnel are regarded as being in an associate or apprentice capacity until such time as they meet these training requirements; and

- They either devoted 50 percent or more of their working time to Medicare and/or Medicaid survey activities or meet the professional qualifications for positions described in §4009B;

- Associates and others who are not qualified surveyors may continue to participate as members of survey teams. However, teams must include one qualified surveyor who has responsibility for completing and signing the survey report and for the accuracy of the surveys conducted by associate or apprentice surveyors.

4009F - Quality Indicator Survey (QIS) Training Process

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

CMS is implementing the Quality Indicator Survey (QIS) which is a computer-assisted long term care survey process used by selected State Survey Agencies and CMS to determine if Medicare and Medicaid certified nursing homes meet the Federal requirements. The QIS is a federally-approved process for surveying nursing homes and it includes the use of computer technology that is not utilized in the traditional survey process. National implementation of the QIS is progressing State-by-State as resources are available to conduct training of State and Federal surveyors. Once a State is selected by CMS to implement the QIS, the time frame for achieving statewide QIS implementation can range from one to three years. The rate at which implementation occurs is dependent upon the number of surveyors needing QIS training and other issues as determined by the State. Therefore, until all nursing home surveyors in a selected State have received training in the QIS process, some nursing homes will continue to

receive the traditional survey to determine compliance with Federal participation requirements.

The standards outlined in this section apply to all State Survey Agencies (SAs) implementing the QIS and their respective CMS Regional Offices (ROs). Only CMS-approved QIS surveyor training course material will be used to train surveyors and trainers. The CMS-approved QIS training materials (with CMS logo) include the procedures, processes, and forms that are used to support the QIS process.

CMS has approved the training entity to conduct the initial QIS training of selected State and CMS RO surveyors and the subsequent training of a State's designated QIS trainers. Surveyors who successfully complete all QIS training components will be recognized as "Registered QIS Surveyors." From the pool of initial Registered QIS Surveyors who have successfully completed at least six QIS surveys of record, individuals will be selected by the SA to receive additional training to become "CMS-Certified QIS Trainers." (The approved CMS training entity certifies to CMS that these individuals have met the requirements to train surveyors on the QIS process.) The CMS-Certified QIS Trainers provide QIS training to the remaining nursing home surveyors in their State.

4009F.1 - Orientation and Training of Newly Employed Surveyors in a State Implementing the QIS

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

Each QIS State determines if a newly hired surveyor will be trained in the QIS process or the traditional survey process, and this determination will be based on the manner in which a QIS State is implementing the QIS. Implementation of the QIS process in a State does not replace or alter the requirements that a newly employed surveyor must be oriented to the nursing home survey process, successfully complete the Basic Long Term Care Health Facility Surveyor Training Course (BLTCC), and receive a passing score on the Surveyor Minimum Qualifications Test (SMQT).

In a QIS State, if a newly hired surveyor is being oriented to the QIS process, the preceptor assigned to this surveyor is both SMQT qualified and a Registered QIS Surveyor. The preceptor performs the same responsibilities as a preceptor of a newly hired surveyor in a State using the traditional survey process.

As part of the field experience in the State's orientation to the QIS process of a newly hired surveyor and prior to attending the formal QIS classroom training, the newly hired surveyor in a QIS State should:

- Receive training in basic computer skills (including data management using Folders, Import/Export functions and Microsoft Word);

- Observe one or more QIS surveys to gain exposure to the QIS process;

- Complete QIS survey tasks under the direct supervision of the preceptor to the extent that the preceptor is confident that the newly employed surveyor understands the QIS process; and

- Attend the formal QIS training at the point in time that the State determines the newly employed surveyor is prepared to begin QIS training.

The QIS training includes several required components described below. It is not a requirement that the newly hired surveyor be SMQT qualified prior to participating in QIS training components. Successful completion of all QIS training components will culminate in the student becoming a Registered QIS Surveyor. The designation as "Registered QIS Surveyor" indicates that the newly hired surveyor successfully completed the QIS training and is registered in the CMS Survey & Certification Learning Management System (LMS). The newly hired Registered QIS Surveyor continues to work as part of the team under an SMQT qualified and Registered QIS Surveyor preceptor.

The newly hired surveyor who is a Registered QIS Surveyor meets the same requirements as a newly hired surveyor in a State that is not yet implementing the QIS process. Specifically, the newly hired surveyor must successfully complete the Basic Long Term Care Course (BLTCC) within the first year of employment and receive a passing score on the SMQT to independently (that is, without supervision of an SMQT qualified surveyor) survey nursing homes to determine compliance with the requirements of participation.

In a QIS State that has fully implemented the QIS process or has otherwise determined that the newly hired surveyor would be oriented to the nursing home survey process via the QIS and not the traditional process, it is expected that newly employed surveyors would complete the requirements and become Registered QIS Surveyors before attending the BLTCC.

4009F.2 - Training Process: Registered QIS Surveyor

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

The initial QIS training process in a newly selected State begins with the training of two core survey teams of four surveyors each. The initial QIS training is conducted by the CMS-approved training entity. The initial core group selected in a State Survey Agency (SA) implementing the QIS must:

- Have a minimum of two years of recent long term care (LTC) survey experience;

- Have received a passing score on the SMQT*;*

- Possess strong leadership ability and/or prior experience as a trainer or teacher; and

- Possess intermediate computer skills.

Every SA or CMS RO surveyor must successfully complete prescribed training components to be considered a Registered QIS Surveyor whether the training is provided initially by the CMS-approved training entity or subsequently by a SA or RO CMS-Certified QIS Trainer. The training of surveyors in the QIS process includes all of the following components:

- Web-based Lessons - Surveyors will initially complete a short series of Web-based learning modules prior to participation in the classroom training. The designated Web-based modules provide background information, a general overview of the QIS process, and an introduction to the QIS specific software.

- Classroom Training - The classroom training uses the CMS-approved QIS surveyor training course manual, which incorporates various media presentations, lectures, exercises, computer tutorials, and discussions. Generally, each class will be comprised of 8 surveyor-students (2 teams of 4 surveyors each). In the case that a SA wishes to have more than 8 surveyors in one class at a time, consideration should be given to constructing teams of 4 surveyors each to assure there are a sufficient number of instructors to accompany each team on its mock survey and surveys of record. Class size will be determined by the State in consultation with the CMS training entity. If the State wishes to train additional survey teams initially, the State is expected to bear the expense and to make arrangements with the CMS training entity.

  During the initial round of QIS training of core surveyors in a State, the State will assure that at least one first-line supervisor/manager with responsibility for QIS surveys and an informational technology (IT) staff person receives training in the QIS training process. Additional training for the IT staff member is provided. The QIS utilizes the QIS Data Collection Tool (DCT) software. Therefore, it is essential that the State's IT staff be available immediately either on site at the nursing home or by telephone to support the training activities conducted in the field. In addition, the CMS-Certified QIS Trainer must be able to assist students in resolving technical issues.

- Mock Training Survey - Immediately upon completion of the QIS classroom training portion, surveyors will be organized into two survey teams (of about four surveyors each) and each team will participate in a mock, or simulated, survey in a nursing home using the QIS process.

  The mock training survey is a learning opportunity and <u>not</u> a survey of record. During the mock training survey, two trainers (the trainers may be CMS-Certified

QIS Trainers or the CMS-approved training entity) are present and work with the survey teams to assure that the surveyors understand and implement the QIS process correctly. The trainers will identify problems, if any, in the surveyors' adherence to the procedures and correct any problems identified. If there is a concern with the implementation of the QIS process by the surveyors, an additional mock survey would be conducted. A surveyor would not conduct surveys of record until instructor staffs are satisfied that the surveyor can independently conduct survey activities using the QIS. If necessary, additional classroom training or mock surveys would be conducted as a remediation activity before conducting surveys of record using the QIS process. The State Survey Agency bears the expense of any further remediation activities required beyond the first remediation visit provided in the CMS contract with the CMS training entity.

- Surveys of Record with Compliance Assessments - Surveys of record will be conducted following the successful completion of the mock survey(s). During the first survey of record, two trainers (the trainers may be CMS-Certified QIS Trainers or the CMS-approved training entity) are present to assess the surveyors' compliance with the QIS process and evaluate the extent to which surveyors are adhering to QIS procedures. The first compliance assessment will be conducted during each surveyor's first survey of record. The second compliance assessment will be conducted usually during the second survey of record or, after one intervening survey (that is, during the third survey of record).

  There should be no more than one intervening survey of record between the first and second compliance assessment. Surveyors must pass two consecutive compliance assessments to become Registered QIS Surveyors. If a surveyor fails either of the two compliance assessments, additional compliance assessments will be conducted until there are two successful consecutive assessments. If additional compliance assessments are conducted by the CMS training entity, the State will bear the additional expense of this activity.

The rate of a State's QIS implementation and the availability of State resources may allow a State the ability to provide experienced and SMQT qualified surveyors an opportunity to observe an actual QIS survey before attending the required QIS training.

4009F.3 - Training Process: CMS-Certified QIS Trainer

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

Trainer-candidates will be selected from the two core survey teams initially trained in QIS by the CMS- approved training entity. The CMS-Certified QIS Trainers function as a training team of two persons and provide QIS training to the State's remaining nursing home surveyors. CMS expects that each State will have a minimum of two training teams composed of two CMS-Certified QIS Trainers on each team. If a State wishes to

have more than the initial 4 trainers, the State bears the expense of training the additional two person teams as QIS trainers for the State. In the event that a trainer-candidate fails any component of the training, the costs associated with remediation training for QIS trainer-candidates are the responsibility of the SA.

Those selected to become CMS-Certified QIS Trainers must:

- Be Registered QIS Surveyors;
- Have participated in at least six QIS surveys of record; and
- Developed sufficient mastery of the QIS process to serve as an instructor/trainer.

To become a CMS-Certified QIS Trainer, the selected Registered QIS Surveyors must successfully complete the following training components, under the tutelage of the CMS training entity:

- Train-the-Trainer Workshop - Trainer-candidates will participate in a 4-day train-the-trainer workshop, which will be held in a classroom setting by the State. Led by the CMS-approved training entity, this workshop will provide trainer-candidates specialized background information and knowledge of the QIS, including in-depth training on the QIS Data Collection Tool (DCT), classroom and onsite facilitation techniques, optimal use of the QIS process, protocols for assessing onsite compliance with the QIS process, and preparation for questions frequently asked by surveyors.

- Instruct One Class of Surveyor-Students - Generally, four trainer-candidates will provide classroom training to a class of approximately eight surveyor-students with CMS training entity staff observer(s) participating at the classroom session. The class size may vary; however, the number of surveyors trained in the QIS process is dependent on the trainers' ability to perform all of the training steps in a timely manner. The training components include classroom instruction, mock survey, two successful compliance assessments, and remediation training, if necessary. The QIS classroom training session will be conducted as follows:

    - Presentations and instruction are rotated to provide the CMS training entity staff multiple opportunities for observation and evaluation of the trainer-candidates' delivery of the QIS training to surveyor-students.

    - Each trainer-candidate's performance during the classroom training will be evaluated on knowledge of the QIS, QIS computer skills, ability to articulate QIS concepts to the group, and ability to answer questions from the class.

- The surveyor-students will evaluate the trainer-candidates and these evaluations will be considered in addition to the CMS training entity's evaluation of each trainer-candidate.

- Each of the four components of performance will be rated on a Pass/Fail basis. If a trainer-candidate fails any one of the four topic areas, he/she fails the classroom training component of the trainer certification process.

- Evaluations of Surveyor-Students During Mock Surveys – Each mock survey will include two trainer-candidates and four surveyor-students (generally), accompanied by the CMS training entity staff. Each trainer candidate will be evaluated by the CMS training entity on QIS knowledge, QIS computer skills, ability to answer individual questions, and organizational skills. Evaluations will be rated on a Pass/Fail basis; and failure of any of the four components will result in failure on the mock survey training component of the trainer certification process.

- Oversight of First Survey of Record with Compliance Assessment – The first survey of record will be comprised of two trainer-candidates, usually four surveyor-students, and one or two CMS training entity staff. Each trainer-candidate will be evaluated by the CMS training entity based on individual QIS knowledge, QIS computer skills, and the ability to apply the CMS-approved compliance assessment and use of forms to conduct the first compliance assessment of surveyor-students. Evaluations of the trainer-candidates will be rated on a Pass/Fail basis, and failure on any of the three components will result in failure on the survey of record component of the trainer certification process.

In summary, as described above, the training approach developed for QIS requires surveyors in each State to first master the QIS process and become Registered QIS Surveyors. The trainer-candidates must have conducted QIS surveys of record and achieved proficiency with the QIS. The trainer-candidates must have completed an intensive train-the-trainer workshop. Through these processes, the States' trainer-candidates have developed a unique body of knowledge and achieved a level of expertise that they will pass on to surveyor-students in the classroom and in the other training components.

Many QIS surveyor-students participating in the training process are seasoned SMQT-qualified surveyors, supervisors, or RO staff, all with proven proficiency in the traditional survey process. However, in the QIS classroom training, mock survey, and survey of record with compliance assessment, the QIS surveyor-students are the learners. To optimize the learning experience, it is essential that the surveyor-students be open-minded about the QIS process and respect the leadership and expertise of the CMS-Certified QIS Trainers and QIS trainer-candidates. The training process includes the requirement that the QIS trainer-candidates conduct evaluations of the surveyor-students' use of the QIS

process. These evaluations are not intended to critique the surveyor-students skills but rather to ensure the consistent and accurate implementation of the QIS process as approved by CMS.

The CMS-Certified QIS Trainer status awarded to each individual who has successfully completed the QIS trainer program remains in effect as long as the individual is actively involved in the QIS process. To be considered actively involved, the CMS-Certified QIS Trainer is expected to conduct a minimum of two SA QIS trainings of all components (classroom, mock, compliance assessments) per year or participate as a survey team member in at least one QIS survey per quarter. A trainer's name will be removed from the LMS as a "CMS-Certified QIS Trainer" if the individual is not actively involved.

4009F.4 - Documentation of Successful Completion of Training

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

The CMS Survey and Certification Learning Management System (LMS) tracks the successful completion of training as a "Registered QIS Surveyors" and the successful completion of training as a "CMS-Certified QIS Trainers." Completion of the QIS training requirements for surveyors and trainers must be timely documented in the LMS so that surveyors can conduct QIS surveys.

4009F.5 - CMS Regional Office Staff Participation in QIS Training

(Rev. 39, Issued: 12-19-08, Effective: 12-19-08, Implementation: 12-19-08)

The number of States implementing the QIS in each particular CMS Regional Office (RO) will determine the number of RO surveyors to receive QIS training. At least two RO SMQT-qualified long term care surveyors are expected to participate as students in a State's QIS training; however, the two RO surveyors need not participate at the same QIS training session. The selected RO surveyor(s) will travel to the State within their region that is conducting the QIS training. The CMS training entity is present during the first cycle of QIS training conducted by the State's trainer-candidates and this may be an opportune time for RO surveyor participation.

The RO surveyors nominated to complete QIS training to become Registered QIS Surveyors should have:

- Have a minimum of 2 years of recent long term care survey experience;
- Have received a passing score on the SMQT;
- Possess strong leadership ability and/or prior experience as a trainer or teacher; and
- Possess intermediate computer skills.

The RO surveyors are students and participate in all components of the QIS training process including classroom, mock survey, compliance assessments, and six surveys of record (conducted consecutively if possible, to maximize learning and minimize disruption). The two compliance assessments of the RO surveyors will be conducted by the State's QIS trainer-candidates. It is expected that the two RO surveyors will each be embedded with a different State survey team (one RO surveyor per State QIS team). By being embedded, the RO surveyor will participate as a member of the team, receiving survey assignments and carrying out the same survey functions as other members of the team. The RO surveyor who is learning the QIS process will also need to become proficient performing some of the team coordinator functions such as, using the primary laptop. The RO surveyors will receive the same QIS training as SA surveyors to become Registered QIS Surveyors.

In the future, the RO's Registered QIS Surveyors must complete the same QIS training process as the States' Registered QIS Surveyors to become CMS-Certified QIS Trainers. A CMS consortium may decide to develop a blended training team consisting of two RO Registered QIS Surveyors from different ROs within the consortium to receive training to be CMS-Certified QIS Trainers.

As the CMS training entity instructs initial core teams of surveyors, supervisors, and IT staff in new States, a CMS RO informational technology (IT) expert should participate with the State's IT experts in receiving the specialized QIS IT training.

4009.1 - Federal Minimum Qualification Standards for LTC Facility Surveyors

(Rev. 1, 05-21-04)

Sections 1819(g)(2)(C)(ii), 1819(g)(2)(E)(iii), 1919(g)(2)(C)(ii), and 1919(g)(2)(E)(iii) of the Act require that individual members of long term care (LTC) survey teams meet minimum qualifications established by the Secretary and successfully complete a training and testing program in survey and certification techniques. In addition, LTC surveyors must successfully complete a training and testing program, which includes the Surveyor Minimum Qualifications Test (SMQT).

4009.1A - Purpose

(Rev. 1, 05-21-04)

The SMQT is part of the training and testing program and addresses the knowledge, skills, and abilities (KSAs) needed to conduct standard and extended surveys in LTC facilities.

4009.1B - Prerequisites

(Rev. 1, 05-21-04)

Prior to taking the SMQT, a LTC surveyor must complete the CMS Orientation Program, and the Basic Long Term Care Health Facility Surveyor Training Course.

4009.1C - Test Composition

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

- The Surveyor Minimum Qualifications Test (SMQT) is a 1 day 4 hour automated test which focuses on the LTC facility, the survey process, related laws, regulations and guidelines, environmental quality, sanitation, resident assessment and care plans, facility records, medicine, nursing, rehabilitation, gerontology, disability, chronic disease, resident rights, quality of life, nutrition, pharmacy, infection control, scope, and severity. The test also focuses on skill in documenting, gathering, and integrating information.

4009.1D - Successful Performance

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

Successful Completion

An individual must successfully complete the SMQT in order to survey independently. A surveyor can serve as a member of a survey team with at least one surveyor who has successfully completed the required training, but cannot survey independently until the surveyor has successfully completed the SMQT.

4009.1E - Unsuccessful Performance

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

1. Unsuccessful Completion

Individuals who do not successfully complete the SMQT must retake the examination until they are successful. Alternate procedures for meeting surveyor minimum qualifications in rare and extraordinary circumstances are specified in §4009.l.E.3. If a surveyor fails to successfully complete the SMQT, the State Survey Agency (or, if a federal surveyor, the RO) must develop an individual training plan (ITP) for the surveyor to correct deficiencies. The components of the ITP are specified in §4009.1.E.2. During this period, the surveyor may participate in surveys as a trainee, i.e., the surveyor must be

accompanied onsite by a surveyor who has successfully completed the training and testing program.

2. Individual Training Plan (ITP)

The ITP must have the following components:

- Individual training objectives that address the area of deficiency identified by the training and testing program;
- A plan to meet training objectives;
- A schedule for meeting these objectives; and
- Someone designated to monitor the progress of the individual toward meeting these objectives.

Upon completing the ITP, the surveyor must retake the SMQT.

3. Rare and Extraordinary Circumstances

If the SA considers an individual to be a highly qualified LTC surveyor and that individual does not successfully complete the SMQT after three attempts, the State Survey and Certification Director may petition the RO for an exception to the requirement of passing the SMQT for the individual. The State must include at least the following documentation in its request for an exception:

- A rationale as to why this individual has not successfully completed the SMQT;
- Attestation by the State Survey and Certification Director that the individual for whom the request is being made is a highly qualified LTC surveyor; and

Evidence that the individual has full understanding of LTC requirements, guidelines, and survey procedures, and has applied them accurately, consistently, and effectively when conducting LTC surveys or accompanying the survey team. This evidence may consist of documentation of onsite evaluations of the surveyor's performance by experienced surveyors, including supervisors.

4009.2 - Test Administration/Registration

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

The SMQT is administered at over 200 testing centers located throughout the United States. Each testing center determines their specific hours of operation; however, all testing centers are open at least 16 hours each week, with most open 32 to 40 hours.

4009.2A - State Agency (SA) Registration Responsibilities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

State Agency (SA) registration responsibilities areas are as follows:

- SAs work with the surveyors to determine when and where they will take the SMQT;

- At least 4 weeks before the preferred test date, the SA submits surveyor information on the State Candidates' SMQT Roster Sheet to the SMQT contractor and the RO and lists three possible dates and times for each surveyor to take the test;

- At least 3 weeks before the test date, and once the SA is notified that the SMQT contractor has contacted the testing center and put the surveyors' names on the eligible list, the SA calls the testing center to schedule the SMQT for surveyors;

- Within 24 hours of registration, the SA notifies the surveyor of the date, time, and location of their test; and

States must ensure that surveyors or surveyors' supervisors call the testing center to cancel the appointment at least 24 hours before the scheduled testing time if the surveyor cannot take the SMQT at the designated time. If cancelled less than 24 hours in advance, CMS will be charged. The contractor and the RO must be notified of all cancellations.

4009.2B - Regional Office (RO) Registration Responsibilities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

Regional Office (RO) registration responsibilities are as follows:

- ROs must ensure that they receive the SMQT State Candidates Roster Sheet when surveyors are registered to take the SMQT;

- ROs must ensure that States follow the established procedures for registering surveyors to take the SMQT; and

ROs must share with the States any updates or changes to the SMQT procedures or policies conveyed to them.

4009.2C - Contractor Registration Responsibilities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

Contractor registration responsibilities are as follows:

- Within 3 days of receipt of the SMQT State Candidates Roster Sheet, the SMQT contractor registers surveyors listed on the roster with the testing center; and

- The SMQT contractor notifies the SA of successful registration.

4009.2D – Testing Center Registration Responsibilities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

Testing center registration responsibilities are as follows:

- When the SMQT contractor contacts the testing center to register a surveyor as eligible, the testing center representative puts the surveyor's name on the list of eligible surveyors; and

The testing center and the SA immediately notify surveyors of the date, time, and location for testing.

4009.3 - Additional Responsibilities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

4009.3A - Additional SA Responsibilities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

The SA has the following additional responsibilities:

- Approving, training, and monitoring training programs;

    - Distributing SMQT related materials, including any updates or changes to the SMQT procedures and policies as conveyed to them by the RO;

- Distributing test results to individual surveyors;

    - Approving, coordinating, and monitoring training programs for individuals who do not successfully complete the test; and

Maintaining records of the State surveyor's progress toward successful completion of the training and testing program in each LTC surveyor's personnel file. This record should include information specified in §4009.4.A. Do not destroy SMQT records.

4009.3B - Additional RO Responsibilities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

The RO has the following additional responsibilities:

- Distributing SMQT related materials to Federal surveyors;
- Notifying Federal surveyors of dates, times, and locations for testing;
- Informing Federal surveyors of test results;
    - Approving, coordinating, and monitoring implementation of training programs for RO surveyors who do not successfully complete the test; and
    - Maintaining records of Federal surveyors' progress toward successful completion of the training and testing program in each RO LTC surveyor's personnel file. This record should include information specified in §4009.4.A. Do not destroy SMQT records.

4009.3C – Surveyor Responsibilities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

Test Procedures and Security

Each individual participating in the test must adhere to testing procedures established by the testing center, the RO, and the State.

4009.4 - Test-Related Activities

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

4009.4A – Recordkeeping

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

The SA will use a standardized format to structure an SMQT record for each LTC surveyor. The SA uses this format to track implementation of the training and testing program and the progress of individual surveyors toward its completion. The RO will use this format for Federal surveyors. Each record must include at least the following:

- Full name;
- Surveyor identification number;
- Entry on duty date;
- Date the individual completed prerequisite requirements for the SMQT;
- Date(s) the individual took the SMQT, dates of retests; and
- Date of successful completion of the SMQT.

These records should not be destroyed under any circumstances and are confidential.

4009.4B – Training of Surveyors That Do Not Pass the SMQT

(Rev. 23, Issued: 01-19-07; Effective/Implementation Dates: 02-20-07)

The SA develops a standardized plan to provide training for those surveyors who do not successfully complete the SMQT, (e.g., onsite observation of survey team, independent study, continuing education). The plan should address how the SA identifies the most effective approach for each individual in training, and how it manages the individual's progress.

4010 - SA Annual Activity Plan

(Rev. 1, 05-21-04)

The SA with its budget request submits the annual activity plan; a description of planned program activities for the ensuing fiscal year. This enables CMS to assess the adequacy and appropriateness of the programs planned by the State and match those activities against the accompanying State budget.

4011 - SA Planning Annual Workload

(Rev. 1, 05-21-04)

The need for professional skills and additional personnel can only be ascertained after the workload is identified and a plan for accomplishing the work is outlined. Since the survey and certification program requires that health facilities be surveyed according to an established coverage level (with leeway permitted to spread the workload, and to integrate it with other programs, where feasible), the SA should find it helpful to set goals by numbers and categories of facilities. The activity plan should establish a program that will permit survey and certification work to be done on an orderly basis throughout the year with a workload distribution as even as possible. Additional workloads caused by

amendments to title XVIII or title XIX of the Act are to be treated as separate workload items.

The SA checks the range of activities projected for the budget year to identify possible questions relating to survey and certification requirements. If it appears questions would arise, include sufficient details in the activity plan on activities to show justification for survey and certification program support.

The "State Survey Agency Certification Workload Report," Form CMS-434 (see Exhibit 52), is the vehicle for identifying the number of facilities to be surveyed during the year. It must be furnished by the SA as a supplement to the narrative activity plan in order to permit evaluation of the plan in recognition of the quantity and types of work to be accomplished.

In addition to the numbers of surveys entered on Form CMS-434, there is data available on the number of instances of certification deficiencies that the SA has identified relative to each of the Conditions of Participation (CoPs). The SA cites the data in the narrative work plan, as appropriate, to show the SA's need to engage consultants in particular specialty areas or to explain why the SA requests the Secretary's concurrence to give selective emphasis to particular facets of program activity.

4018 - Regulatory Role of Surveyor and Consultant

(Rev. 1, 05-21-04)

(Also see §2727, and Appendix P – Section 9)

The survey and certification process is intended to ascertain whether providers and suppliers meet program participation requirements. Therefore, the primary role of the surveyor is to assess the quality of care and services and relate those findings to statutory and regulatory requirements.

When deficiencies are found in the course of a survey, the surveyor should explain to the provider what the deficiency is in terms specific enough to allow a reasonably knowledgeable person to understand why the requirement is not met. In many situations, the explanation of the deficiency itself provides the necessary information needed to correct the problem. This is not considered to be consultation.

However, in some instances there may be several possible causes for the deficiency, and it is for these situations that the policy for not providing consultation is intended. It is not the surveyor's job to examine the facility's policies and procedures to determine or speculate on the root cause of deficiencies, or to sift through various alternatives to prescribe one acceptable remedy. In these situations, the provider is responsible for determining the most feasible and economical way of achieving compliance.

On resurvey, the surveyor's task is to ascertain whether compliance has been achieved and not whether the provider did what the surveyor recommended. Thus, in reviewing a proposed PoC, the SA reviews the plan only for effectiveness and timeliness.

Surveyors should be willing to explain the requirements and why something is a deficiency. For example, if a provider is cited for maintaining incomplete clinical records, the surveyor is to specify what is missing, not why it is missing or what process is best for ensuring that the records are complete in the future. Under no circumstances should a data tag or a reiteration of the regulations be used as a substitute for an explanation.

The SA staff should be willing to work with all groups in its State if such discussions or meetings lead to more meaningful surveys or an overall improvement in compliance by providers and suppliers.

4055 - Ordering CMS Forms and Literature

(Rev. 1, 05-21-04)

The Chief of the Printing Management Branch at CMS CO sends an order form to each SA every 6 months. The SA head may request a supply of forms and CMS literature sufficient to meet anticipated needs within the agency and for any necessary redistribution by the agency. Also, as new forms are devised, he/she arranges for a simultaneous advance shipment. Estimate the number of copies of new materials needed before the next regular six-month supply period and request that number directly. Shipments are by parcel post or bill of lading (never C.O.D.).

The SA should maintain an adequate supply of each required form and publication until it becomes obsolete. The SA submits interim orders any time that a supplemental supply is needed. However, since it takes approximately four weeks to fill and ship an order, the SA should submit a reorder while an eight or ten-week supply is on hand.

Address any contacts regarding the ordering of public literature or forms to:

Centers for Medicare & Medicaid Services
7500 Security Boulevard - South Building
Elizabeth Ostrowski
Form Management Specialist
Baltimore, Maryland 21244-1850

Phone: (410) 786-7863

NOTE: If the SA receives any shipment or mailing of materials in error, do not return them without first contacting the Forms Management Specialist for instructions.

Address any contacts regarding the ordering of the SOM to:

Centers for Medicare & Medicaid Services
7500 Security Boulevard - South Building
Linda Douglas
Baltimore, Maryland 21244-1850

Phone: (410) 786-7860

Office of Management and Budget (OMB) Approval of Information Collected from the Public

4060 - Approval of Information Collected From Public by SAs - General

(Rev. 1, 05-21-04)

The Paperwork Reduction Act (PRA) was enacted on December 11, 1980. Section 3512 of the Act stipulates that no member of the public may be penalized for failing to maintain or provide information to any agency if the information collection request does not display an approval number from OMB or does not state that such request is not subject to the PRA. The term "agency" includes executive departments (such as CMS) and their contractors (such as intermediaries, carriers, and SAs). The term "public" includes all entities that are not employees of or contractors to the Federal government. For CMS purposes, the public includes health care providers, suppliers, physicians, beneficiaries, QIOs, and SMAs.

The CMS forms originating from CO which reference information collection should already have OMB approval. The OMB approval number (e.g., 0938-XXXX) is printed in the upper right-hand corner of these forms. Over the years, SAs developed other forms subject to the PRA in response to instructions contained in CMS' program issuances. Thus, the actual requirement for the information resides in the program issuance manuals approved by OMB.

In some categories, the specification of data elements may unduly limit the performance of SAs. In these cases, OMB approval will be obtained for a more generalized collection of information, such as an "area of inquiry." The area of inquiry would be accompanied by examples of data elements, typical of the area of inquiry. The SAs' forms could use these data elements or others of a similar nature, as long as they fall within the area of inquiry as described in the program issuance manual and approved by OMB.

As the categories are reviewed and defined in terms of their data elements or areas of inquiry, the program issuance will convey this information. The SAs' forms will then be limited to the routine collection of the data so specified.

In the future, as CMS identifies new categories of information that SAs should collect, two areas of the program issuance manuals will be updated and reapproved by OMB. First, the forms in the exhibits will identify the new OMB approval number and the data elements that are to be collected. Secondly, the SA's responsibility in collecting this information will be described in the appropriate section of the manual.

The PRA requires the display of the OMB approval number on each form. It should be printed in the top right-hand corner of each page as shown below. No special typesetting is required.

Form Approved
OMB No. 0938-XXXX

4062 - Information That Does Not Require OMB Approval

(Rev. 1, 05-21-04)

There are a number of forms that do not come under the provisions of the PRA. The following definitions and discussion identify the types of forms that do not require OMB approval nor the display of an OMB approval number.

4062.1 -Verification or Correction Information

(Rev. 1, 05-21-04)

If a form that has OMB approval is filled out incompletely or incorrectly, the request for the missing or corrected data does not require OMB approval.

NOTE: The follow-up request is limited to those items present on the OMB-approved form. If additional items are included, the form cannot be considered approved by OMB.

This is an exception to the PRA that was granted by OMB. It has particular relevance to claims development activities, but can be invoked by OMB.

4062.2 - Certifications

(Rev. 1, 05-21-04)

A certification attests to the accuracy of a statement or the receipt of articles or services. It is limited to identifying information and a signature. A certification may include, at a maximum, the following information:

- The name, title, address, and phone number of the individual or entity making the certification;

- Any number identifying the certifier, such as the provider number, physician number, social security number, license number, tax number, or health insurance number;

- An identification of the article received, for instance, a benefit check;

- An authorization statement which, for instance, names a representative to act on one's behalf, or which identifies an entity to whom the information may be revealed;

- The statement to be certified. The statement must be printed on the form. The certifier cannot write it. It is acceptable to have more than one certification statement printed with a line/box to be checked off by the certifier; and

- A date and a signature line.

Information in excess of that described above would make the form subject to OMB review and approval.

Survey and Certification Related Activities

4100 - Basis for Determining Health Insurance Relatedness of Activity Costs

(Rev. 1, 05-21-04)

Sections 1864 and 1902 of the Social Security Act (the Act) provide the basis for agreements and plans with States under which CMS pays States for costs incurred in performing survey and certification functions The primary State function may be characterized as "certification" of health facilities, and the costs of SA activities that are an integral part of this process are appropriate for survey and certification funding.

This manual discusses the procedures involved in the certification function. The criteria contained in §§4100-4109 are controlling in terms of the nature and extent of activity that may be charged to the survey and certification program within the limits of the approved budget.

The operating procedures contained in Part Two outline activities that are required to support an initial certification that a facility does or does not qualify to participate in, or have their services covered under the survey and certification program, or a certification recommending continuing participation, coverage, or termination.

Such activities are certification-related and are funded under the survey and certification program In those agencies where activities are performed for survey and certification only, the survey and certification program pays the entire costs. In many States, these activities serve other programs in addition to survey and certification (e.g., certification as well as licensure). When this situation exists, the SA establishes a method of determining the survey and certification share of the cost. (See §§4500-4544.) Where the SA has responsibility for performing survey-related activities under title XVIII and title XIX, establish appropriate safeguards to ensure that proper charges are made to each program and that duplicate charges are avoided.

4101 - Survey-Related Activities - General

(Rev. 1, 05-21-04)

In addition to survey activity which identifies and documents deficiencies, the SA communicates CMS guidelines and explains the CoPs (or requirements for SNFs/NFs, to:

- Nonparticipating facilities or agencies that have either filed a Request to Establish Eligibility or a Request for Approval or have otherwise expressed interest in

participating in the appropriate title XVIII or title XIX certification program and which have a reasonable potential for qualifying, when surveyed; and

- Those participating providers and suppliers that have correctable deficiencies.

The information provided should be concerned with specific steps the facility must take to meet program requirements, for example, advising that medical staff bylaws need to describe the organization of the medical staff. However, the SA does not provide direct assistance (e.g., helping the facility to actually rewrite the bylaws), since direct assistance is not an agency function under §§1864 (the Agreement) or 1902 (State plan) of the Act.

The services that may be offered to facilities are subject to limitations that prohibit the program from assuming responsibilities and costs that are properly those of the facility, another agency, or another program.

4102 - Activities With Accredited Entities Deemed to Meet Participation Requirements

(Rev. 1, 05-21-04)

Section 1865 of the Act allows CMS to find that if the accreditation of the following entities by any national accreditation organization provides reasonable assurance that the CoPs or Conditions for Coverage(CoCs), or requirements for SNFs, are met for these entities, then CMS may deem these entities by virtue of their accreditation as meeting the Medicare conditions. The entities covered by the law that can be deemed are hospitals, psychiatric hospitals, ASCs, RHCs, laboratories, hospices, HHAs, SNFs, CORFs, and clinic rehabilitation agencies or public health agency providers of OPT (including speech pathology services) or occupational therapy services. Section 353 of the Public Health Service Act (PHSA) also provides the same recognition for accreditation organizations and State licensure programs of CLIA laboratories. The CMS published a notice in the Federal Register" to notify the public of any organizations whose accredited specified types of providers or suppliers are deemed to meet Medicare or CLIA participation requirements. Sample validation or substantial allegation surveys of entities accredited by accreditation organizations approved by CMS are acceptable reimbursement activity. See §1018 for those facilities that may participate by virtue of their accreditation by an approved accrediting body.

4111 - Higher Than National Standards

(Rev. 1, 05-21-04)

Section 1863 of the Act permits, at the request of a State, higher requirements for that State than the Federal Conditions or Requirements if approved under a State plan. If approved by the Secretary, the Secretary will impose like requirements in entities within that State. When a State has higher standards (approved by the Secretary) than those

imposed nationally, the costs of certification activities necessary to apply the higher requirements are paid by Federal trust fund and grant monies.

4115 - Non-Facility-Related Activities

(Rev. 1, 05-21-04)

In addition to activities that are related to individual facilities, there are other activities necessary to the proper functioning of the survey and certification program. These activities include relationships with other programs and organizations that permit effective accomplishment of program goals as they relate to individual facilities.

4116 - SA Promotional and Public Informational Activities

(Rev. 1, 05-21-04)

Most of the promotional and public informational activities are carried out by CMS, primarily through CO and ROs and, to a lesser extent, by intermediaries. However, §§1819(g)(1)(B) and 1919(g)(1)(B) of the Act require each State to conduct periodic educational programs for the staff and residents (and their representatives) of SNFs and NFs in order to present current regulations, procedures, and policies. Persons having general questions about Medicare and/or Medicaid are referred to the RO for information. Certain professional relations activities on the part of the SA's personnel are necessary and proper for maintaining ongoing relationships in the health professions. Participation by SA employees as speakers, panelists, or consultants at meetings of professional organizations (hospital associations, medical societies) in the interest of furthering compliance with Medicare and/or Medicaid standards and objectives would be proper activities for survey and certification funding.

4116.1 - Medical Societies

(Rev. 1, 05-21-04)

Contacts by SA officials with medical societies are desirable to clarify the objectives of survey and certification program and enlist the cooperation of the medical societies in meeting those objectives that are certification-related.

Objectives may relate to a specific CoP or CoC or to broader objectives such as effective use of the different levels of care offered through hospitals, LTC facilities, HHAs, and other medical facilities.

4117 - Relations with Other Programs

(Rev. 1, 05-21-04)

It is incumbent on each State to maintain effective liaison with other programs having activities similar to those performed for the survey and certification program. The need for establishing and maintaining relationships is particularly obvious with reference to licensure programs. In addition to licensure, examples of other programs with goals closely related to those of certification are hospital survey and construction programs, health facilities planning programs, and mental health and chronic ESRD programs. These programs, while not bearing the same relationship to survey and certification as does licensure, include activities that approximate health insurance activities. Additionally, the SA should consider joint activities with mutually benefiting programs on an "ad hoc" basis. This assumes that each State makes protracted and frequent contacts at an administrative level in the interest of the survey and certification program.

4131 - Deeming and Waiver of Nurse Aide Training and Competency Evaluation (NATCEP) Requirements

(Rev. 1, 05-21-04)

The Omnibus Budget Reconciliation Act (OBRA) of 1987 prohibits SNFs and NFs from using as nurse aides any individuals who have not successfully completed a nurse aide training and competency evaluation program (NATCEP) or competency evaluation program (CEP) approved by the State. The OBRAs 1987 and 1989 deemed some individuals to meet this requirement and permitted States to waive this requirement for others. All individuals who are deemed to meet the nurse aide NATCEP requirements, or for whom the State waives the requirement to complete a CEP, must be included in the nurse aide registry described in §4141.

A nurse aide is deemed to satisfy the requirement of completing a NATCEP if, before July 1, 1989, he or she completed a nurse aide training and CEP of at least 60 hours and made up at least the difference between the number of hours in the program he or she completed and 75 hours in supervised practical nurse aide training, or in regular in-service nurse aide education.

A nurse aide is deemed to satisfy the requirement of completing a NATCEP if, before July 1, 1989, the individual was found competent (whether or not by the State) after completing nurse aide training of at least 100 hours duration.

The State may deem an individual to have completed a NATCEP if the individual completed, before July 1, 1989, a NATCEP that it determines would have met the requirements for approval at the time it was offered.

The State may waive the requirement for an individual to complete a CEP for any individual who can demonstrate to its satisfaction that he or she has served as a nurse aide at one or more facilities of the same employer in the State for at least 24 consecutive months before December 19, 1989.

Any individual described above may be employed as a nurse aide by a nursing home if that individual is also competent to perform nursing or nursing-related services.

4132 - NATCEPs and CEPs

(Rev. 1, 05-21-04)

The OBRA of 87 requires the State to specify those NATCEPs and CEPs it approves. The State should follow the requirements detailed in §4132.1 - 4132.3 when reviewing and approving programs, and when withdrawing approval from programs. The State may offer its own NATCEP and/or CEP as long as the program meets these requirements.

4132.1 - Approval of NATCEPs and CEPs

(Rev. 1, 05-21-04)

If the State does not offer a NATCEP or CEP, the State should review and approve or disapprove all NATCEPs, upon request. The State should approve NATCEPs and CEPs offered by any entity as long as the requirements for approval are met.

4132.1A - Requirements for Program Approval

(Rev. 1, 05-21-04)

Before approving a NATCEP or CEP, the State should:

- For NATCEPs, determine whether the requirements of §4132.2 are met;
- For CEPs, determine whether the requirements of §4132.3 are met; and
- In all reviews other than the initial review, visit the entity providing the program.

4132.1B - Time Frames for Review

(Rev. 1, 05-21-04)

Within 90 days of a request to review a program or receipt of additional information from a requester, the State must:

- Advise the requestor whether the program has been approved; or
- Request additional information.

The State may not grant approval of a program for more than 2 years. The State should require programs to notify the State when there are substantive changes to the program within the two-year period, and the State should review programs to which substantive changes are made.

4132.1C - Prohibition of Program Approval

(Rev. 1, 05-21-04)

Unless program disapproval is waived in accordance with subsection E below, the State must not approve a NATCEP or nurse aide CEP offered by or in a nursing home if, in the 2 years prior to the State's review, that facility:

- In the case of a skilled nursing facility, has operated under a waiver under §1819(b)(4)(C)(ii)(II) of the Act;
- In the case of a nursing facility, has operated under a waiver under §1919(b)(4)(C)(ii) of the Act that was granted on the basis of a demonstration that the NF is unable to provide nursing care required under §1919(b)(4)(C)(i) of the Act for a period in excess of 48 hours a week;
- Has been subject to an extended (or partial extended) survey under §§1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act;

Has been assessed a civil money penalty described in §§1819(h)(2)(B)(ii) or 1919(h)(2)(A)(ii) of the Act of not less than $5,000. This requirement applies to civil money penalties for Federal citations only after the facility has had an opportunity to a hearing as specified in §1128A of the Act and the penalty is determined due and payable; or

- Has been subject to a remedy described in §§1819(h)(2)(B)(i) or (iii), 1819(h)(4), 1919(h)(1)(B)(i), or 1919(h)(2)(A)(i), or (iii), or (iv) of the Act.

4132.1D - Withdrawal of Program Approval

(Rev. 1, 05-21-04)

Unless the State waives program disapproval in accordance with subsection E below, the State must withdraw approval from:

- Any NATCEP or CEP described in subsection C; and

- Any NATCEP or CEP if the entity offering the program refuses to permit unannounced State visits. (Also, any facility that refuses to permit unannounced State visits is subject to having its provider agreement terminated, and being excluded from the program by the Office of the Inspector General.)

The State may withdraw approval of a NATCEP or CEP if the State determines that any of the requirements described in §§4132.2 and 4132.3 are not met by the program. The State may also withdraw approval from any program that does not meet any requirements the State may have in excess of the minimum Federal requirements, or that otherwise fails to meet State standards.

When withdrawing approval from a NATCEP or a CEP, the State should:

- Notify the program in writing, indicating the reason(s) for withdrawal of approval; and

- In the case of a NATCEP, permit students who have already started the program to finish it.

4132.1E - Waiver of Program Prohibition

(Rev.)

A facility may request that CMS waive the disapproval of its nurse aide training program when the facility has been assessed a civil money penalty of no less than $5,000 if the civil money penalty was not related to the quality of care furnished to residents in the facility.

While the waivers should be submitted to the State, CMS will make the final determination on a case by case basis after considering the recommendation and facts of the case as provided by the State.

Duration of Waiver - A waiver may not exceed 2 years, but must be withdrawn earlier if the facility is subsequently found to no longer meet the waiver criteria. If 2-year disapproval periods overlap, any non-waived disapproval in the earlier period will control

waiver rights in the second until the two periods no longer overlap. Below are examples describing the effect of a series of survey findings on a facility's ability to have a waiver.

EXAMPLE:

Year 1:

A survey conducted at Facility X identifies substandard quality of care. The finding of substandard quality of care results in nurse aide training and competency evaluation program disapproval for 2 years. The facility requests and is granted a waiver after the State has confirmed that the facility has removed the substandard quality of care. The waiver may not exceed 2 years.

Year 2:

The survey of Facility X identifies substandard quality of care. Based on this current finding of substandard quality of care, the facility loses its existing waiver. This nurse aide training and competency evaluation program disapproval, based on this survey, is effective for 2 years. Additionally, the facility forfeits the waiver granted in year 1 due to its inability to continue to meet waiver criteria at E.1.b. (i.e., to be free of deficiencies which constitute substandard quality of care.

Year 3:

The survey of Facility X identifies deficiencies that do not constitute substandard quality of care, but result in the imposition of denial of payment for new admissions. The imposition of this remedy results in nurse aide training and competency evaluation program disapproval for 2 years. The facility requests and is granted a waiver. The waiver may not exceed 2 years. However, since the facility is currently operating under a nurse aide training and competency evaluation program disapproval for 2 years, based on its year two survey, the waiver resulting from this current survey will not apply until the remainder of the disapproval period (which overlaps with part of the waiver period) is satisfied.

4132.1F - Conflicts of Interest

(Rev. 1, 05-21-04)

States are governed by their respective conflict of interest laws and are free to develop their own policies or rules about what may or may not constitute a conflict of interest relative to nurse aide training and competency evaluation programs. This gives States the ability to define their programs so that they can meet their needs relative to NATCEPs while meeting the intent of the law. Factors States may consider in making conflict of interest determinations may include, but are not limited to, the following:

- Whether the training program being offered is owned and operated independently of the ownership and operation of the nursing home that has lost its ability to train;

- Whether facility staff, who are also employees of an approved outside training program, should be permitted to train in the facility (as employees of the outside training program) if the facility loses its ability to train; and

- Any other factors the State believes to be relevant in making conflict of interest determinations.

4132.2 - Requirements for NATCEPs

(Rev. 1, 05-21-04)

(S&C01-20)

4132.2A - Hours of Training

(Rev. 1, 05-21-04)

A NATCEP must consist of a minimum of 75 clock hours of training in order to be approved by the State. The State has the discretion to require additional hours of training.

NOTE: Transporting residents is the only nursing home service that does not require the use of nurse aides with 75 hours of training. It was never the intent that transporting residents by driving a van or pushing a wheelchair would require 75 hours of nurse aide training. However, transferring residents, for example from bed to wheelchair, from wheelchair to the toilet or bath does require the services of a nurse aide who has completed the NATCEP.

4132.2B - Restrictions on Activities of Students in a NATCEP

(Rev. 1, 05-21-04)

The State should not approve a program unless it ensures that:

- Students do not perform any services for which they have not trained and been found proficient by the instructor; and

- Students providing services to residents are under the general supervision of a licensed nurse or an RN.

4132.2C - Instructor Qualifications

(Rev. 1, 05-21-04)

The training of nurse aides must be performed by or under the general supervision of a registered professional nurse who possesses a minimum of 2 years of nursing experience, at least one year of which must be in the provision of long-term care facility services. Instructors of nurse aides must have completed a course in teaching adults or have experience in teaching adults or supervising nurse aides. In a facility-based program, the training of nurse aides may be performed under the general supervision of the Director of Nursing, who is prohibited from performing the actual training.

Other individuals may supplement the instructor. Following are examples of those who might be useful in a NATCEP:

- RNs;
- Licensed practical/vocational nurses;
- Pharmacists;
- Dietitians;
- Social workers;
- Sanitarians;
- Fire safety experts;
- Nursing home administrators;
- Gerontologists;
- Psychologists;
- Physical and occupational therapists;
- Activities specialists;
- Speech/language/hearing therapists; and
- Resident rights experts.

The program may utilize individuals from fields other than those listed as examples if needed to meet the planned program objectives for a specific unit. Supplemental personnel must have a minimum of one year of experience in their fields. The State may require that these individuals be, where applicable, licensed, registered, and/or certified in their field.

4132.2D - Minimum Curriculum Requirements

(Rev. 1, 05-21-04)

The objective of NATCEPs is to enable nurse aides to provide quality services to residents. Therefore, a NATCEP must contain at least these minimum curriculum requirements for it to be approved. The State may also specify additional areas to be included.

Within the minimum 75 hours of training, at least 16 hours must be devoted to supervised practical training. Supervised practical training is defined as training in a laboratory or other setting in which the student demonstrates knowledge while performing tasks on an individual under the direct supervision of an RN or LPN. A program must also include at least 16 hours of classroom instruction prior to a trainee's direct involvement with a resident. This instruction must include the following:

- Communication and interpersonal skills;
- Infection control;
- Safety/emergency procedures, including the Heimlich maneuver;
- Promoting residents' independence; and
- Respecting residents' rights.

The curriculum must also include training in the following areas:

1. Basic nursing skills:
    a. Taking and recording vital signs;
    b. Measuring and recording height and weight;
    c. Caring for the residents' environment;

d. Recognizing abnormal changes in body functioning and the importance of reporting such changes to a supervisor. Some examples of abnormal changes are:

- Shortness of breath;
- Rapid respiration;
- Fever;
- Coughs;
- Chills;
- Pains in chest;
- Blue color to lips;
- Pain in abdomen;
- Nausea;
- Vomiting;
- Drowsiness;
- Excessive thirst;
- Sweating;
- Pus;
- Blood or sediment in urine;
- Difficulty urinating;
- Frequent urination in small amounts;
- Pain or burning on urination; and
- Urine has` dark color or strong odor.

e. Caring for residents when death is imminent.

2. Personal care skills:

    a. Bathing;

    b. Grooming, including mouth care;

    c. Dressing;

    d. Toileting;

    e. Assisting with eating and hydration;

    f. Proper feeding techniques;

    g. Skin-care; and

    h. Transfers, positioning, and turning.

3. Mental health and social service needs:

    a. Modifying aide's behavior in response to resident's behavior;

    b. Awareness of developmental tasks associated with the aging process;

    c. How to respond to resident behavior;

    d. Allowing residents to make personal choices, providing and reinforcing other behavior consistent with the resident's dignity; and

    e. Utilizing resident's family as a source of emotional support.

4. Care of cognitively impaired residents:

    a. Techniques for addressing the unique needs and behaviors of individuals with dementia (Alzheimer's and others);

    b. Communicating with cognitively impaired residents;

    c. Understanding the behavior of cognitively impaired residents;

    d. Appropriate responses to the behavior of cognitively impaired residents; and

    e. Methods of reducing the effects of cognitive impairments.

5. Basic Restorative Services - The nurse aide should be able to demonstrate skills which incorporate principles of restorative nursing, including:

    a. Training the resident in self-care according to the resident's abilities;

    b. The use of assistive devices in transferring, ambulation, eating, and dressing;

    c. Maintenance of range of motion;

    d. Proper turning and positioning both in bed and chair;

    e. Bowel and bladder training; and

    f. Care and use of prosthetic and orthotic devices.

6. Residents' Rights - The nurse aide should be able to demonstrate behavior that maintains residents' rights, including but not limited to:

    a. Providing privacy and maintenance of confidentiality;

    b. Promoting the resident's right to make personal choices to accommodate their needs;

    c. Giving assistance in resolving grievances and disputes;

    d. Providing needed assistance in getting to and participating in resident and family groups and other activities;

    e. Maintaining care and security of resident's personal possessions;

    f. Providing care which maintains the resident free from abuse, mistreatment, and neglect, and reporting any instances of such treatment to appropriate facility staff; and

    g. Avoiding the need for restraints in accordance with current professional standards.

4132.2E - Competency Evaluation Component

(Rev. 1, 05-21-04)

All NATCEPs must contain competency evaluation procedures that meet the requirements specified in §4132.3.

4132.2F - Prohibition of Charges

(Rev. 1, 05-21-04)

No nurse aide who is employed by, or who has an offer of employment from, a facility on the date on which the aide begins a NATCEP may be charged for any portion of the program (including any fees for textbooks or other required course materials). If an individual who is not employed or does not have an offer to be employed as a nurse aide becomes employed by or receives an offer of employment from a facility not later than 12 months after completing a NATCEP, the State must provide payment for costs incurred in completing the program on a pro rata basis during the period in which the individual is employed as a nurse aide.

4132.3 - Requirements for CEP

(Rev. 1, 05-21-04)

4132.3A - Notification to Individual

(Rev. 1, 05-21-04)

The State provides advance notice to any individual who takes the competency evaluation that a record of the successful completion of the evaluation will be included in the nurse aide registry (NAR).

4132.3B - Content of CEP

(Rev. 1, 05-21-04)

Competency evaluations must consist of two components: a written or oral examination and a skills demonstration program. The written or oral examination must:

- Allow aides to choose between a written and an oral examination;
- Address each item specified in §4132.2.D;
- Be developed from a pool of test questions, only a portion of which is used in any one examination;
- Use a system that prevents disclosure of both the test questions and the individual competency evaluations; and
- If oral, must be read from a prepared text in a neutral manner.

The skills demonstration must consist of a demonstration of randomly-selected items drawn from a pool consisting of tasks generally performed by nurse aides. This pool of skills must include all of the personal care skills listed in §4132.2.D.

4132.3C - Administration of NACEP

(Rev. 1, 05-21-04)

The competency evaluation may be administered and evaluated only by:

- The State directly; or
- A State-approved entity which is not the SNF which provided the training.

The skills demonstration component of the evaluation must be:

- Performed in a facility or laboratory setting similar to the setting in which the individual functions as a nurse aide; and
- Administered and evaluated by an RN with at least one year's experience in providing care for the elderly or the chronically ill of any age.

4132.3D - Proctoring

(Rev. 1, 05-21-04)

The competency evaluation may, at the nurse aide's option, be conducted at the facility in which the nurse aide is or will be employed unless the facility is described in §4132.1.C.

The State may permit the competency evaluation to be proctored by facility personnel if it finds that the procedure adopted by the facility assures that the NATCEP:

- Is secure from tampering;
- Is standardized and scored by a testing, educational, or other organization approved by the State; and
- Requires no scoring by facility personnel.

The State retracts the right to proctor nurse aide competency evaluations from facilities in which it finds any evidence of impropriety or tampering by facility staff.

4132.3E - Successful Completion of CEP

(Rev. 1, 05-21-04)

The State establishes a standard for successful completion of the competency evaluation. To complete the competency evaluation successfully, an individual must pass both the written or oral examination and the skills demonstration. A record of successful completion of the competency evaluation must be included in the NAR described in §4141 within 30 days of the date the individual is found to be competent.

4132.3F - Unsuccessful Completion of Competency Evaluation

(Rev. 1, 05-21-04)

If an individual does not complete the evaluation satisfactorily, the individual must be advised:

- Of the areas in which he or she did not pass; and
- That he or she has at least three opportunities to take the evaluation.

The State may impose a maximum on the number of times an individual may attempt to complete the competency evaluation successfully, but the maximum may be no less than three.

4140 - Guidance to States for Medicaid NF Remedies

(Rev. 1, 05-21-04)

(See also Chapter 7)

4140A - Background

(Rev. 1, 05-21-04)

Section 1919(h) of the Act requires the State Medicaid Agency (SMA) to establish, by statute or regulation, remedies for NFs that do not meet the requirements of participation. The State must design remedies to result in faster correction of deficiencies and ensure the health or safety of residents of NFs. The SMA imposes these remedies for those NFs that are not operated by the State or those found noncompliant by the CMS validation process. The SA sends recommendations to the SMA for remedies under SMA jurisdiction, and to the RO for remedies under RO jurisdiction.

4140B - Required State Remedies

(Rev. 1, 05-21-04)

The SMA specifies the criteria as to when and how each remedy is applied, the amounts of any fines, and the severity of each remedy. The SMA designs the procedures to minimize the time between identification of violations and final imposition of remedies. Denial of payment for new admissions, appointment of temporary management, and closure are remedies that may be imposed during the pending of any hearing.

The criteria for all remedies are to provide for incrementally more severe fines for repeated or uncorrected deficiencies. In determining what action to take, the SMA will consider the NF's compliance history, change of ownership, and the number and gravity of the deficiencies. The SMA may also specify additional remedies, as long as the SMA can demonstrate are as effective in deterring non-compliance and correcting deficiencies as those that follow:

The SMA will follow regular procedures to amend it's approved State plan to establish at least the following remedies:

4140C - Alternative Remedies

(Rev. 1, 05-21-04)

The SMA will include the specified remedies in subpart B in its approved State plan for any quarter beginning after October 1, 1989. However, the SMA may establish remedies alternative to the specified State remedies (except for the remedy of termination) if the SMA can demonstrate to the satisfaction of CMS that their alternative remedies are as effective in deterring noncompliance and correcting deficiencies as those under §1919 (h)(2)(A) of the Act. For example, the SMA may already have alternative remedies in place for the licensure program or for the Medicaid program under State law, such as:

- Civil or administrative fines (different from the specified OBRA remedy);
- Court-appointed receiver;
- Conditional/provisional licensing, probationary license, or license revocation; and
- Withholding of payments.

If the SMA has alternative remedies in place, it will summarize its past experience with alternative remedies, indicating that they are effective in deterring noncompliance and correcting deficiencies.

The SMA will provide the following types of documentation to indicate the effectiveness of its alternative remedies, such as:

- Procedures for implementing the remedies including explanations of what type of deficiencies trigger the remedies, a method or ranking the seriousness of violations and corresponding remedies, timing of remedies and appeals and specific rules designating responsibility for the violation and liability for the remedies;

- Identification of the agency responsible for ensuring imposition of the remedies and the amount of resources being devoted to this effort, including legal and other enforcement-related staff; and

- Method of evaluation and supporting data for alternative remedies that have proved to be effective in deterring noncompliance and correcting deficiencies including the number of facilities in evaluation and the rate of recidivism.

Alternatives to the specified remedies must be submitted under the established procedures for approval of State plan amendments.

4140D - Incentives for High Quality Care

(Rev. 1, 05-21-04)

In addition to the remedies specified under §1919(h)(2) of the Act, the SMA may establish in it's approved State plan a program to reward NFs that provide the highest quality care to Medicaid residents. The reward may be in the form of public recognition, incentive payments, or both.

The expenses incurred in carrying out such a program are considered expenses necessary for the proper and efficient administration of the State plan under Medicaid. (See §1903(a)(7) of the Act.)

If the SMA elects to use an incentive payment, the State plan amendment must define highest quality care, state the criteria to be met, and the measurements to be used in awarding an incentive payment. To be considered as "efficient" in the administration of the State plan, the incentive payment must be reasonable, as determined by the RO in its State plan review process.

4140E - Federal Financial Participation (FFP)

(Rev. 1, 05-21-04)

Reasonable State expenditures for the proper and efficient administration of the State plan, such as temporary management, closing a NF, transfer of residents to another NF,

and other expenses associated with implementing these remedies, are subject to Federal matching payment at the rate of 50 percent. The SMA establishes procedures to prevent claiming FFP for expenditures which have been funded by the CMPs discussed in subpart B.

4141 – Nurse Aide Registry (NAR)

(Rev. 1, 05-21-04)

The State establishes and maintains a NAR of individuals who have successfully completed a NATCEP or CEP approved by the State, **or** are deemed to have completed a NATCEP, **or** have had the competency evaluation requirement waived. (See §4131.)

4141A - Registry Function

The State ensures that the NAR:

- Lists all individuals who have successfully completed a NATCEP or CEP approved by the State;
- Lists all individuals who are deemed to have completed a NATCEP;
- Lists all individuals for whom the requirement to complete a CEP has been waived by the State;
- Lists all nurse aides who are found by the State to have abused or neglected a resident or misappropriated resident property;
- Removes entries for all individuals who have performed no nursing or nursing-related services for monetary compensation for a period of 24 consecutive months, **except** those individuals who are found to have abused or neglected residents or misappropriated resident property;
- Discloses to everyone requesting information about an individual on the registry, the date of eligibility for placement on the registry, **and** any information pertaining to a finding of resident abuse or neglect, or misappropriation of resident property. (The State may disclose any additional information it deems necessary.);
- Provides individuals on the registry with all information in the registry on them when findings of resident abuse or neglect or misappropriation of resident property are made, or upon request;
- Permits all individuals on the registry sufficient opportunity to correct any misstatements or inaccuracies contained in the registry;

- Is sufficiently accessible to meet the needs of the public and health care providers;
- Provides requested information promptly; and
- Does not impose any charges related to registration on individuals listed in the registry.

The NAR may include information on home health aides who have successfully completed a home health aide training and competency evaluation program approved by the State **if** home health aides are differentiated from nurse aides.

4141B - Registry Information

(Rev. 1, 05-21-04)

The following items must be maintained and retrievable from the NAR for each individual who has completed a NATCEP or CEP approved by the State, who has been deemed to have completed a NATCEP, or for whom the State has waived the competency evaluation requirement:

1. The individual's full name;
2. Information necessary to identify the individual;
3. The date the individual became eligible for placement in the registry; and
4. Any finding by the SA of resident abuse or neglect or misappropriation of resident property by an individual documenting:
    - The SA investigation, including the nature of the allegation and the evidence that led it to conclude that the allegation was valid;
    - The date of the hearing (if the individual chose to have one) and its outcome; and
    - A statement disputing the allegation, if the individual chose to make one.

Findings of resident abuse or neglect or misappropriation of resident property against a nurse aide must be included in the registry within 10 working days of the finding and must remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death.

4141C - Responsibility for NAR

(Rev. 1, 05-21-04)

The State may contract the daily operation and maintenance of the registry to a non-State entity. However, the State must maintain overall accountability for operation of the registry and compliance with regulations, **and** only the SA is permitted to place findings of resident abuse or neglect or misappropriation of resident property on the registry.

4145 - Specification of Resident Assessment Instruments (RAIs) for Use in Long Term Care Facilities

(Rev. 1, 05-21-04)

4145.1 - Statutory Requirements

(Rev. 1, 05-21-04)

Sections 1819(b)(3), 1819(e)(5), 1819(f)(6)(B), 1919(b)(3), 1919(e)(5), and 1919(f)(6)(B) of the Act specify assessment requirements for SNFs for Medicare and NFs for Medicaid, which provide nursing, medical, and rehabilitative care to Medicare and/or Medicaid beneficiaries. These provisions require facilities to conduct comprehensive, accurate, standardized, and reproducible assessments of each resident's functional capacity using an RAI that has been specified by the State. Facilities are required to examine their residents no less frequently than once every three months.

These provisions place specific responsibilities on the Department of Health and Human Services, the State, and providers. The CMS is responsible for designating the minimum data set (MDS), common definitions and utilization guidelines, and for designating one or more RAIs for use by the States. The States are responsible for specifying the RAI for use by facilities in the State. The State may use an RAI designated by CMS or specify it's own instrument provided that it includes the MDS and that it has been approved by CMS. All State RAIs must include the MDS of core elements, common definitions and utilization guidelines specified by CMS. (See §4145.2.) Providers are responsible for using the specific assessment instrument that has been specified by the State and approved by the Secretary.

4145.2 - Definitions

(Rev. 1, 05-21-04)

- **Minimum Data Set (MDS) -** A core set of screening and assessment elements, including common definitions and coding categories, that forms the foundation of the comprehensive assessment for all residents of long term care facilities certified

to participate in Medicare and/or Medicaid. The items in the MDS standardize communication about resident problems and conditions within facilities, between facilities, and between facilities and outside agencies.

- **Common Definitions** - Standardized instructions for how to interpret each element specified in the MDS.

- **Coding Categories** - Levels of measurement for each element included in the MDS.

- **Triggers** - Specific resident responses for one or a combination of MDS elements. These triggers identify residents who require further evaluation using resident assessment protocols designated within the State specified RAI.

- **Resident Assessment Protocols (RAPs)** - A component of the utilization guidelines, the RAPs are structured, problem-oriented frameworks for organizing MDS information, and additional clinically relevant information about an individual that identifies medical problems and forms the basis for individualized care planning.

- **Resident Assessment Instrument (RAI)** - An instrument which requires for completion the performance of a standardized assessment system, comprised of the MDS and utilization guidelines (including the RAPs and triggers). This assessment system provides a comprehensive, accurate, standardized, reproducible assessment of each long-term care facility resident's functional capabilities and identifies medical problems.

- **Utilization Guidelines** - Instructions concerning when and how to use the RAI. These include instructions for completion of the RAI as well as structured frameworks for synthesizing MDS and other clinical information.

- **Quarterly Review** - Part of the Secretary's designated instrument. The quarterly review is a subset of MDS items reviewed (i.e., reassessed) no less frequently than once every three months (92 days) to assure the continued accuracy of the care plan.

4145.3 - RAI by CMS

(Rev. 1, 05-21-04)

The CMS is responsible for designating the MDS, its common definitions and utilization guidelines, and for designating one or more RAI(s). The CMS' RAI is specified in Appendix R and is comprised of the utilization guidelines (including the RAPs), the MDS of core elements and common definitions, and the quarterly review items. The utilization guidelines for completion of the RAI are specified in Appendix R, Part I; the core

elements of the MDS, common definitions, and quarterly review items are specified in Part II; and the utilization guidelines pertaining to the RAPs, triggers and instructions are specified in Part III.

4145.4 - Specification of a State RAI

(Rev. 1, 05-21-04)

The State must specify an RAI for use in long term care facilities that participate in Medicare and/or Medicaid. The State must either specify:

- The RAI designated by CMS, which is comprised of the MDS with common definitions, the utilization guidelines, including CMS' RAPs, triggers and a documentation format (see Appendix R), and quarterly review items; or

- An alternate instrument for use in the State. An alternate instrument must be approved by CMS prior to the State specifying it to facilities. To receive approval, an alternate instrument must contain:

  a. The Utilization Guidelines for Completion of the RAI - See Appendix R, Part I.

  b. The MDS - See Appendix R, Part II. All data elements and corresponding coding categories specified in the MDS must be contained in the State's instrument. A State agency may not alter the MDS definitions or the coding categories used with each MDS element. The State may not rearrange the sequence of core MDS items or introduce new items within the core set of MDS items specified by CMS.

  - The State agency may add data elements additional to those in the MDS that are needed to meet unique State operational needs. Include these elements at the end of the core MDS in "Section S," which is designated for State supplemental items. These additional items will be reviewed by CMS to assure there is no conflict with elements included in the MDS. However, CMS will not evaluate the merits of those elements. Under the SNF Prospective Payment System (PPS) requirement, for residents in a Medicare part A covered stay, Section T must be completed with each MDS that is required for payment purposes. In addition, States may specify MDS sections T and/or U as part of the State-specified RAI.

  - **Discharge Tracking** - Includes section AA Items 1 - 9, (but only the three discharge codes from Item 8, Reasons for Assessment), Items AB1 - 2, A6, and R3 - 4. This form is completed when a resident dies or leaves the facility and is actually admitted to another health care

facility, regardless of whether the long-term care facility formally discharges the resident. (Refer to Appendix R for additional detail regarding the Discharge Tracking form and its use.)

- **Reentry Tracking** - This form contains Section AA Items 1 - 9, (but only one Reentry code from Item 8, Reasons for Assessment), and Items A4 and 6. This form is completed whenever a resident reenters the nursing home following temporary admission to a hospital or other health care setting, even if the resident's clinical record was not formally closed, and regardless of whether the resident was formally discharged from the facility. (Refer to Appendix R for additional detail regarding the Reentry Tracking form and its use.)

c. Utilization Guidelines Pertaining to the RAPs – At a minimum, State's RAI must include CMS' RAPs. As CMS develops new RAPs or revises RAP triggers or guidelines, a State agency must develop comparable changes.

To develop a new RAP, provide the following documentation to CMS when requesting approval to add the RAP to the State-specified RAI:

- Assessment triggers, based on MDS elements or other information requirements that screen which residents are subject to additional assessment;

- Guidelines, which provide a framework for additional assessment or structured investigation of issues to facilitate clinical decision-making for care planning; and

- Supporting documentation for clinical validation of RAP content (e.g., literature citations, expert consensus, research studies, results of field testing).

- States wishing to pursue RAP development are encouraged to seek consultation and assistance from CMS during the planning phase. Additionally, States are encouraged to volunteer to participate in CMS-sponsored RAP development/revision activities.

d. RAP Summary Form - Information from Section V of the MDS is documented on the RAP Summary Form. Each State's RAI must include CMS' RAP Summary Form or another standardized format for documentation of the RAP assessment. States may request approval of an alternate format for inclusion in the State RAI which:

- Identifies the location of information derived from RAPs about the resident's status in the triggered area. As appropriate for the resident,

information may include the nature of problems, complications and risk factors, the need for referral to appropriate health professionals, and the reasons for deciding to proceed or not to proceed with care planning specific to the triggered problems;

- Provides a means for collecting data on triggered RAPs and care plan decisions; and

- Provides a method for staff to certify the accuracy and completeness of the RAP assessment (i.e., signature and date).

e. Quarterly Review – States must specify a Quarterly assessment form, for use by facilities that include at least the items on the CMS-designated form (See Section R). The Quarterly assessment form contains the mandated subset of MDS items from Section A (Identification and Background Information) through Section R (Assessment Information) that serve as the minimum requirement within each State's RAI. Some States have mandated an expanded Optional Quarterly assessment form. The CMS has published two optional versions that States may require. A State may also require a full assessment on a quarterly basis. Contract your state RAI coordinator for State specifics. States have the following options for the Quarterly Assessment:

- Minimum Required MDS Quarterly Assessment;

- MDS Quarterly Assessment Form Optional Version for RIG-III;

- Full MDS Assessment;

- Medicare Prospective Payment Assessment Form (MPAF).

The State may require facilities to use the full MDS or may add MDS elements to the quarterly review but may not omit or reorder any elements in CMS' designated form. States may add items to their quarterly review form in one of two ways:

- Items that are part of CMS' MDS should be added within the same area of the quarterly review form that it falls on the full MDS (e.g., the State would add item H4, Change in Urinary Continence, after item H3 on the quarterly review form); or

- Items that are part of the State supplement (i.e., MDS Section S) should be added at the end of the State quarterly review form.

4145.5 - Variations in Formatting the State-Specified RAI

(Rev. 1, 05-21-04)

The CMS' approval of a State-specified RAI covers those items included on the instrument, the working and sequence of those items, and all definitions and instructions for the RAI. Approval of the State-specified instrument does not address the attributes of the instrument related to formatting (for example, print type, color coding, or changes, such as integrating triggers into the instrument). States are encouraged to permit some flexibility in form design (e.g., print type, color, shading, or integrated triggers) or through use of a computer-generated printout of the RAI. The CMS' approval is not required for a State to permit such formatting variations. However, a State must assure that any RAI form or printout in the resident's record accurately and completely represents the State-specified RAI as approved by CMS, in accordance with 42 CFR 483.20(b). In other words, it includes all and only the items on the State-specified instrument with the exact wording and in the same sequence.

4145.6 - Approval Process

(Rev. 1, 05-21-04)

A State agency must not revise its specified RAI without first notifying CMS and receiving CMS' approval. All State agencies must adopt any revisions to the RAI that are specified by CMS.

All State agencies must inform CMS whether they intend to specify the RAI designed by CMS, or request approval for an alternative State instrument.

When specifying CMS' instrument, a State agency must include the following in its letter to CMS:

- A plan for implementation that includes time frames (e.g., effective dates) and plans for training the facilities; and

- The name, address, phone number, and e-mail address (if known) of the State RAI coordinator (i.e., the individual responsible for liaison and training of providers and State agency staff).

When requesting approval for an alternative instrument, or modifications to an existing specified instrument, a State agency must include the following in its request to CMS:

- A copy of the proposed instrument and any instructions that exceed CMS' utilization guidelines;

- A short narrative specifying how the instrument conforms with CMS' designated MDS and utilization guidelines (including the RAPs);

- A description of the items and their definitions that will appear in the State supplement section of the MDS;

- A plan for implementation that includes time frames and plans for training the facilities;

- The name, address, phone number, and e-mail address (if known) of the State RAI coordinator (i.e., the individual responsible for liaison and training of providers and State agency staff); and

- The name, address, phone number, and e-mail address (if known) of the State agency's contact for technical questions on the proposed alternate instrument.

Please send all correspondence to:

Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations
Survey and Certification Group
Technical Director, Division of Nursing Homes
7500 Security Boulevard
Mail Stop S2-12-25
Baltimore, Maryland 21244

Once CMS has received a State agency's request for use of an alternate instrument, or modifications to an existing specified instrument, CMS will review the proposed instrument to determine whether it is an acceptable alternate, and will communicate directly with the State agency's representatives to clarify information, if necessary. The CMS will work with the State agency to meet its needs for resident assessment information.

Once a State agency has received approval from CMS for the alternate instrument, the State agency must implement the approved alternate. Within 60 days of receiving CMS' approval of the alternate RAI, the State agency must notify all long term care facilities participating in the Medicare and/or Medicaid programs in its State of the alternate instrument. This notification must include a copy of the approved specified instrument and the procedures for using the instrument.

States that have specified the CMS-designated RAI as their specified instrument must notify all long-term care facilities participating in the Medicare and/or Medicaid programs in their States of the specified instrument and any updates issued by CMS, with sufficient time for the facilities to meet the effective implementation date.

The State agency must ensure that all long-term care facilities participating in the Medicare and/or Medicaid programs in its State are using specified instrument within 90 days after a State agency has notified its providers of the specified instrument. To ensure that facilities are properly trained, each State agency must provide periodic educational programs for facility staff to assist with implementation of the specified RAI.

4146 - Minimum Data Set (MDS) System

(Rev. 1, 05-21-04)

The MDS system in each State is the cornerstone for a comprehensive, Quality Improvement and Evaluation System (QIES) that will not only fulfill MDS administration requirements, but also support other assessment-based programs (such as the Outcome and Assessment Information Set (OASIS) for home health agencies (HHAs), quality and performance indicators; and new, integrated survey and certification data systems. The State must use the MDS system for editing, storing, and processing MDS data to support CMS' MDS operating requirements within the State and to transmit the required MDS data to the CMS MDS repository. The State may not add additional software applications to the MDS system without a specific directive from CMS.

The automated MDS system is a critical component of State agency and CMS operations, and provides the means for transmission of assessment data to CMS for validating payments under the Medicare SNF Prospective Payment System (SNF PPS) for nursing homes.

The initial phase of the MDS system implementation involved a CMS-funded installation of standardized computer hardware and data management software at each State Agency to allow electronic transfer of MDS data elements from all Medicare and Medicaid nursing homes to the State. The data management software:

1. Validates the basic accuracy of the data and rejects submission files (batches) with **Fatal File Errors**, such as a missing or invalid Facility ID, incorrect record length, or missing headers or trailers;

2. Validates individual assessment records and rejects those records with **Fatal Record Errors**,

3. Stores and reports **Non-Fatal Errors** on records that are accepted by the database; and

4. Builds a database of MDS information for all residents in each nursing home in the State.

The MDS system implemented electronic transmission of MDS data by all Medicare and Medicaid nursing homes beginning with the regulation's effective date of June 22, 1998.

This provides for enhanced analytical capabilities at the State agencies; electronic transmission from the State databases to a national repository; integration with performance indicators for quality oversight and survey planning by the State Agency; use of MDS data as a basis for prospective payment of nursing homes; research directed at improving quality of care; feedback to providers; and dissemination of information to purchasers, beneficiaries, and others.

The following procedures describe MDS system operations.

4146.1 - System Description

(Rev. 1, 05-21-04)

The CMS has provided each State with an MDS system composed of standardized hardware and software platforms scaled to meet each State's anticipated processing volumes. The hardware is comprised of a communications server, database server, modems and other peripheral devices. The QIES system software includes an Oracle database, Netscape Enterprise Server, Netscape Personal Edition, Microsoft Windows NT, the MDS/OASIS Data Management Application, and all required software licenses. The MDS system deployed to each State was specifically engineered and purchased to fulfill the MDS requirements of 42 CFR 483.20(f) and 483.315(h), additional CMS provider assessment processes as they become effective, and operational support of Medicare and Medicaid survey and certification pursuant to §1864 of the Social Security Act. The system was designed with an emphasis on flexibility and integration, so that additional software components could be easily added to provide the States with new MDS-related functionality (such as new or revised quality indicators and expanded analytical reports), as well as applications that support future assessment processes for other provider types, and new capabilities to support survey and certification operations or any other entity using the MDS data or system. Since each State's system was specifically sized to accommodate these planned functions, the SA or any other entity using the MDS data or system must not add other, non-CMS prescribed, applications or databases to the MDS system.

4146.2 - Administration Requirements

(Rev. 1, 05-21-04)

The States are directly responsible for fulfilling requirements to operate the State MDS system. However, the State may enter into an agreement with the SMA, another State component, or a private contractor to perform day-to-day operations of the system.

The State must obtain RO approval prior to entering an agreement with another agency**.** Criteria for approval are provided at Exhibit 259. Under any such arrangement, the State must be guaranteed real-time, priority access to this system to fully support all MDS functions specified in the MDS procedures and this manual. All CMS privacy and

confidentiality requirements must be met. Off-site operation of the MDS system will require high capacity, fault-tolerant network connections to ensure reliable support for the State's daily operations that will be affected by this system. The State also must use the MDS system for reporting MDS data to the CMS central repository.

To promote national consistency in MDS system operations and troubleshooting, each State must designate one individual as the MDS automation project coordinator. This person is CMS' key contact within each State for managing MDS system issues. This person must be familiar with the use of the RAI and the MDS automation and transmission process. Technical knowledge of information systems is useful but far less critical than an understanding of the RAI and MDS processes, good communications and project management skills, and the ability to educate and work with providers and vendors to ensure successful implementation of an automated process for all providers. The State should designate additional staff, including a system administrator to manage the technical aspects of running the MDS system, and support staff to assist in answering routine user questions, assigning passwords, etc.

With respect to systems maintenance, the MDS system installed in each State is comprised of commercial off-the-shelf hardware and software components that are generally covered under typical umbrella service agreements that the State may already have in place for maintenance of data processing equipment. Those MDS software components that are developed and distributed by CMS will be maintained and upgraded centrally by CMS. The State will not be responsible for these software upgrades.

To the extent that the State has developed customized external applications for using information obtained from the MDS database (e.g., to support Medicaid payment), the costs of developing and maintaining these additional software applications (and any related hardware components) will not be funded through the survey and certification budget.

4146.3 - Validation and Editing Process

(Rev. 1, 05-21-04)

Each time a facility accesses the State MDS system and transmits an assessment file, the State system performs a series of three levels of validations:

1. **Fatal File Errors -** The first check examines the basic structure and integrity of the submission file. If there are fatal flaws in the file (batch of records), the entire file is rejected and the facility is notified of the reason for rejection in the "Initial Feedback Report." In the event that a batch is rejected due to **Fatal File Errors**, the facility will not receive a "Final Validation Report." Rejected files must be corrected and retransmitted. **Fatal File Errors** are described in a document named spdoc110.pdf, that is posted at the CMS website, http://www.cms.hhs.gov/medicaid/mds20/ under "MDS Software and Data

Specifications" and then under "Version 1.10 Files Available for Downloading." The spdoc.pdf document is in a "zip" file names MDS 110.zip.

2. **Fatal Record Errors** - If the file structure is acceptable, then each MDS record in the file is examined individually for **Fatal Record Errors**. These errors include out of range responses (this edit applies to most, but not all fields), selected inconsistent relationships between fields, or errors which made identifying a resident or record type difficult. Fatal Record Errors result in rejection of individual records by the State MDS database. The facility is informed of **Fatal Record Errors** on both the "Initial Feedback Report" and the "Final Validation Report." An overview of **Fatal Record Errors** is provided in a document called spdoc110.pdf, available in a "zip" file names mds 110.zip at http://www.cms.hhs.gov/medicaid/mds20 under "MDS Software and Data Specification" and then under "Version 1.10 Files Available for Downloading." A detailed listing of **Fatal Record Errors** is provided in the item-by-item MDS record specifications, Document names d_dt120.pdf, available in a "zip" file names mds 120.zip at http://www.cms.hhs.gov/medicaid/mds20 under "MDS Software and Data Specifications" and then under "Data Specifications Version 1.20 for the QIES MDS July 2002 Release." One additional Fatal Record Error is based on the submission requirement under which the MDS record is submitted by the facility. There is a data field called SUB_REQ that deals with this issue. **Fatal Record Errors** based upon the SUB_REQ field are described in a special document named subreqspecs.pdf at http://www.cms.hhs.gov/medicaid/mds20 under "MDS Software and Data Specifications" and then under Data Specifications and Instructions for the QIES MDS November 26, 2001 Release." At this level of validation, the MDS standard system at the State is designed to reject individual records with **Fatal Record Errors** and to accept records with no **Fatal Record Errors**. An electronic "final validation report" is made available to the facility and includes error messages for individual records found to have errors, and a statement of record status (accepted or rejected), with associated error statements for any rejected records. Rejected records must be corrected and retransmitted.

3. **Non-Fatal Errors** - If there are no **Fatal Record Errors**, the record is loaded into the State database and the record is further examined for **Non-Fatal Errors**. Any **Non-Fatal Errors** are reported to the facility in the "Final Validation Report." **Non-Fatal Errors** include missing or questionable data of a non-critical nature, field consistency errors of a non-critical nature, and record sequencing and timing errors.

The Initial Feedback Report is available for the facility to download immediately following the submission of a file. Since the Final Validation Report will not be available as quickly as the Initial Feedback Report, the facility may, based on experience, choose to obtain this report on a subsequent logon.

The validations and edits described above fulfill all of CMS' editing requirements under 42 CFR 483.315(h)(1)(iv). Also, as specified at 42 CFR 483.315(h)(2)(ii), States or other data/system users may not modify any aspect of the CMS MDS standard system, including these validations and edits, the Standard Record Layout, and the software code and specifications on which the system is based.

States that use MDS data for Medicaid payment may require additional assessment information not required by CMS' MDS system. Section S (the State-specific section) of the MDS system was designed for this purpose. Moreover, some States may impose additional edits on Medicaid assessments. However, a State or other data system users may not interfere with, modify, or delay the transmission of records, meeting CMS edit standards, from a Medicare and/or Medicaid certified facility to the CMS MDS standard system.

Furthermore, the State or other data system users may not impose any requirements that modify the clinical accuracy of CMS prescribed MDS records, reports, or calculations.

4146.4 - Reports

(Rev. 1, 05-21-04)

The MDS system provides the following reports to both the State and the provider. These reports, which focus on errors in MDS submissions, are key to working with facilities to ensure successful transmission of MDS data.

1 - Initial Feedback Report

During a submission session, the facility will be informed of file submission status in an Initial Feedback Report. The Initial Feedback Report may indicate that the batch was "accepted," "received" (for a test file), or that it was "rejected." Since the Initial Feedback Report is not automatically saved by the system, it must be reviewed prior to logging off after a batch submission.

The top section of this report gives general information about the entire batch of records.

- Report Date/Time;

- Batch Status - Status is "Rejected" if a file had **Fatal File Errors** and the entire batch of records was rejected. Status is "Accepted" if a file had **no Fatal File Errors** and individual records were processed for loading into the State database. For **test** files only, status is "Received" if the test submission had no **Fatal File Errors**. Test records are not inserted in the database;

- Submission Date/Time - Date/time that the MDS file was submitted; may be needed for troubleshooting any problems with a batch;

- Submission Batch ID - Unique ID assigned to each batch used for troubleshooting problems with a batch;

- Facility ID - The standard system logon ID for the facility;

- Facility Name;

- Number of Records Processed - Number of data records in the file (batch)--value will be 0 if the entire file is rejected;

- Number of Records Rejected - Number of data records that contained **Fatal Record Errors** and were not accepted into the State database. If the entire file was not **rejected**, this value will be 0 on the Initial Feedback Report. This value and the Report Detail will be provided in the Final Validation Report upon validation of all records in the file;

- Number of Records with Errors - Number of records that were accepted into the State database but that also contained **Non-Fatal Errors**. If the entire file was not **rejected**, this value will be 0 on the Initial Feedback Report. This value and the Report Detail will be provided in the Final Validation Report upon validation of all records in the file; and

- Total Number of Errors - Total number of **Non-Fatal Errors** across all records accepted into the State database. If the entire file was not **rejected**, this value will be 0 on the Initial Feedback Report. This value and the Report Detail will be provided in the Final Validation Report upon validation of all records in the file.

Detail concerning any file header and trailer errors will appear in the lower portion of the Initial Feedback Report, under "Report Detail." The Report Detail section includes the following information (clarification of labels is given in parentheses):

- Record Type, Effective Date - The record type field can contain "Header" for a header record, "Trailer" for a trailer record;

- Field - Field in error;

- Invalid Data - Data that caused the error; and

- Error Description - Descriptive error message.

2 - Final Validation Report

If there are **Fatal File Errors** with the MDS submission file, the entire batch of records is rejected and the only feedback that the facility will receive during the submission session

is the Initial Feedback Report. However, if there are no **Fatal File Errors**, a Final Validation Report will also be received by the facility. The Final Validation Report has exactly the same layout as the Initial Feedback Report. The "Report Detail" section of the Final Validation Report details all errors found in the data records in the batch. These errors can be **Fatal Record Errors** (resulting in record rejection) or **Non-Fatal Errors**. The following information is displayed in the record detail section:

- SSN, Name - Resident SSN and name;

- Record Type, Effective Date - The Record Type field contains "Header" for a header record, and "Trailer" for a trailer record. For data records, the record type field contains the data record types as defined in definitions section (e.g., "A" for an initial admission assessment record, "Q" for a quarterly update assessment, etc.). For a data record, the Effective Date for the record follows the record type. The effective date A4a for a reentry record R2b for an assessment record, and R4 for a discharge record.

- Target Date.- The target date field contains the date that the reentry, assessment or discharge event occurred. The target date is A4a for a reentry record. A3a for an assessment record, and R4 for a discharge record.

- Field or MDS Items. - Field or fields in error. A single field or item will be present for data range or formatting errors. Two fields will be present for errors involving required consistency between pairs of MDS items.

- Invalid Data Submitted - Data values that caused the error. There will be single value for errors involving data range or formatting errors. Two values will be present involving consistency between pairs of MDS items.

- Message Number.- The system numeric code for the error detected. The numeric codes are negative numbers. After the numeric code the report indicates if the error is "Fatal" or Non-Fatal."

- Message. - Descriptive error message.

The additional reports listed below are available to the State for the MDS system, but not directly to the provider. The State may provide copies of these reports to the facilities as they deem appropriate.

- **Assessment Field Information -** Displays information about each assessment field in the database including field name, start position, field length, valid values, start and end ranges (for numeric fields), field data type, field description, and which assessment section contains the field;

- **Assessment Primary Reason -** (MDS Item A8a or AA8a) - Displays information about primary reason for assessment;

- **Assessment Sections** - Displays which assessment sections are included for each combination of Primary Reason for Assessment (MDS Item A8a or AA8a) and Special Reason for Assessment (MDS Item AA8b) values;

- **Assessment Special Reason -** (MDS Item A8b or AA8b) - Displays information about these values;

- **Case Mix Codes -** Displays details of each CMI set that is in the database. Information includes CMI sequence, set name, ADL values, CMI codes, CMI values, and descriptions;

- **Discharges in Previous Month** - A list of residents who had discharge assessments (as the last assessment) submitted in the last 30 days. Report can be generated for a single facility or all facilities;

- **Duplicate Resident Names** - A list of residents with identical first and last names. Useful for finding duplicate residents in a facility;

- **Duplicate Resident SSN** - A list of residents who are listed as having the same SSN. All residents for a particular SSN are listed. This report is also useful for finding duplicate residents;

- **Error Summary -** This report lists the errors that have occurred in submissions, the number of occurrences, and the percentage of assessments with each error. The report is for a single facility, all facilities, for a single vendor, all vendors, or for an entire State for a specified time period;

- **Error Message** - Displays all of the error message codes and descriptions;

- **Error Detail -** List of all errors for all submissions grouped by assessment. The report can be generated for a single facility, all facilities, a single vendor, or all vendors for a specified time period;

- **Errors by Field** - Lists, by field, the number of assessments that had an error in that field, the number of assessments successfully processed, and the percentage of assessments with each error. Can be generated for a single facility, all facilities, a single vendor, all vendors, or the entire State for a specified period of time**;**

- **Facility Accounts Report -** Lists all facilities and their logon ID and password;

- **Facility List** - Listing of all facilities in a State that submit MDS assessments;

- **Facility List, No Recent Submissions** - Listing of all facilities in the State that have not submitted assessments since a specified date;

- **Facility List - Non-Submitted Data** - Listing of all facilities that have not submitted assessments;

- **Overdue Assessments** - Listing of all residents who have not had assessments submitted within the required timeframe. Report includes which assessment type(s) is/are expected. Available for a single facility or all facilities;

- **Quarterly Assessment Fields** - Listing of all fields that are included for each quarterly assessment type grouped by each MDS Item AA8a/AA8b combination;

- **Roster Report** - Lists all residents who are currently in a facility. Can be generated for a single facility or all facilities;

- **Roster Timeframe Report** - List all residents who are in a facility within a specified date range. Can be generated for a single facility or for all facilities;

- **Sequencing Report -** Displays invalid sequences between assessments. Displayed by two sets of MDS Item A8a/A8b or AA8a/AA8b combinations and Record Types (current and previous);

- **State Customization -** List the values for the active CMI set for the State, State optional fields (if any), and the validation engine options set by the State;

- **Summary Statistics -** List the number of files received, number of records processed (by record type), number of records rejected, and number of records received with errors (by record type). Available for a single facility or all facilities for a specified time period;

- **Validation Codes** - A reference report that lists valid codes for various fields in the assessment;

- **Vendor List -** A list of facilities that have used a particular vendor. This report can be generated for a single vendor or multiple vendors; and

- **Ad Hoc Reports -** Various user-defined reports can also be generated using structured query language within the Data Management Application.

In addition, the MDS system has made other reports available to both the States and providers, based on the deployment of analytical and quality indicator software.

4146.5 - Correction of Errors in MDS Records That Have Been Accepted by the Standard MDS System at the State

(Rev. 1, 05-21-04)

The standard MDS system in each State includes a mechanism by which facilities can electronically submit corrections to MDS data that have already been accepted into the State MDS database. Depending on the circumstances surrounding the error, corrections may include modification or inactivation of MDS records (assessments, Discharge Tracking forms and Reentry tracking forms). The MDS system provides management reports to the State that analyze the type, nature and frequency of corrections submitted by facilities to the MDS database at the State. For information about the process of correcting errors in MDS records in the State database, refer to "Correction Policy for MDS Records" in Appendix R, Part IV.

4146.6 - Replication to the CMS Repository

(Rev. 1, 05-21-04)

Each State's MDS database will be transmitted to CMS' Central Repository at least monthly using a data replication process initiated by CMS. Since the process will be managed by CMS through an automatic polling process, the States will not actually have to transmit the data. However, the State must ensure that the CMS data-line established for this purpose is accessible to CMS at all times for testing and monitoring purposes. Actual replication access to the Oracle assessment data tables may be controlled by the States but, in such cases, a fixed schedule must be established with CMS Central Office.

The MDS system and CMS data line meet all industry security standards. However, if the State is concerned about security, it may establish a firewall (an electronic block) to restrict access to the State's portion of the network. Access must not be restricted to the CMS-supplied MDS System.

4146.7 - Privacy and Confidentiality

(Rev. 1, 05-21-04)

4146.7A - System of Records

(Rev. 1, 05-21-04)

The MDS database is operated and maintained by States as a Federal database and, as such, is subject to the requirements of the Federal Privacy Act. The text of the System of Records notice for the MDS, which follows, describes the legal requirements regarding privacy and disclosure of information by CMS or the State.

> The purpose of the Long Term Care Minimum Data Set (LTC MDS) System NO. 09-70-1517 is to aid in the administration of the survey and certification of Medicare/Medicaid long term care facilities and to study the effectiveness and quality of care given in those facilities. This system supports regulatory, reimbursement, policy and research functions. In addition, this system will enable Federal and State regulators to provide long term care facility staff with outcome data for provider's internal quality improvement activities.

This system shall contain clinical information found in the comprehensive assessments of persons residing in long term care facilities that are certified to participate in the Medicare and/or Medicaid programs (including private pay individuals). This information is found in the Long Term Care Minimum Data Set for Nursing Home Resident Assessment."

The CMS established this system in accordance with the principles and requirements of the Privacy Act. The Privacy Act allows the disclosure of information from this system without an individual's consent if the information is to be used for a purpose that is compatible with the purposes for which the information was collected. Any such compatible use of data is known as a "routine use." The proposed routine uses for this system meet the compatibility requirement of the Privacy Act since they are consistent with the purpose of analyzing data on the physical, mental, functional, and psychosocial status of nursing facility residents living in the State.

The routine uses specify the circumstances under which CMS and the State in their roles as contractors representing CMS may release information from the long-term care MDS system without the consent of the individual to whom such information pertains. The CMS System Manager must evaluate each proposed disclosure of information under the routine uses and/or an individual authorized by CMS. The authority to release data is limited to the System Manager or authorized designee.

4146.7B - Procedures for Disclosure of Information Pursuant to Data Use Agreement

(Rev. 1, 05-21-04)

Releases of information **must be** evaluated to determine if disclosure is **legally permissible** by the CMS System Manager or authorized designee, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. Releases are generally only made for the routine uses specified in the system notice. The CMS System Manager or authorized designee **must require** each prospective recipient of LTC MDS system information to agree in writing to certain conditions to ensure the continuing confidentiality and to physically

safeguard of the information. For each disclosure it is necessary for the System Manager or authorized designee to, as necessary and appropriate:

1. Determine that no other Federal statute specifically prohibits disclosure of the information;

2. Determine that the use or disclosure does not violate legal limitations under which the information was provided, collected, or obtained;

3. Determine the purpose for which the disclosure is to be made:

    a. Cannot reasonably be accomplished unless the information is provided in individually identifiable form;

    b. Is of sufficient importance to warrant the effect on or the risk to the privacy of the individual(s) that additional exposure of the record(s) might bring;

    c. There is a reasonable probability that the purpose of the disclosure will be accomplished; and

    d. The purpose is within the scope of a routine use.

4. Require the recipient of the information to:

    a. Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized access, use, or disclosure of the record or any part thereof. The physical safeguards shall provide a level of security that is at least equivalent to the level of security contemplated in OMB Circular No. A-130 (revised), Appendix III, Security of Federal Automated Information Systems, which sets forth guidelines for security plans for automated information systems in Federal agencies; contemplated in OMB Circular No. A-130 (revised), Appendix III, Security of Federal Automated Information Systems, which sets forth guidelines for security plans for automated information systems in Federal agencies;

    b. Remove or destroy the information that allows subject individual(s) to be identified at the earliest time at which removal or destruction can be accomplished, consistent with the purpose of the request;

    c. Refrain from using or disclosing the information for any purpose other than the stated purpose under which the information was disclosed; and

d. Make no further use or disclosure of the information except:

- To prevent or address an emergency directly affecting the health or safety of an individual;
- For use on another project under the same conditions, provided the System Manager or authorized designee has authorized the additional use(s) in writing; or
- When required by law.

5. Secure a written statement or agreement from the prospective recipient of the information whereby the prospective recipient attests to an understanding of, and willingness to abide by the foregoing provisions and any additional provisions that the System Manager deems appropriate in the particular circumstance. The System Manager or authorized designee must use a CMS-approved Data Release Agreement that cannot be modified; and

6. Determine whether the disclosure constitutes a computer "matching program" as defined in 5 U.S.C. §552a(a)(8). If the disclosure is determined to be a computer "matching program" the instructions regarding preparation and transmission of a matching agreement as stated in 5 U.S.C. §552a(o) must be followed.

4146.7C - Routine Uses

(Rev. 1, 05-21-04)

The following lists the routine uses published in the LTC MDS System NO. 09-70-1517 (current as of February 2002).

Disclosure may be made:

1. To Agency contractors, or consultants who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this system and who need to have access to the records in order to assist CMS;

2. To another Federal or state agency, agency of a state government, and agency established by state law, or its fiscal agent to:

   a. Contribute to the accuracy of CMS' proper payment of Medicare benefits;

   b. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefit program funded in whole or in part with Federal funds, and/or;

c. Assist Federal/state Medicaid programs within the state.

3. To QIOs in connection with review of claims, or in connection with studies or other review activities, conducted pursuant to Part B of Title XI of the Act and in performing affirmative outreach activities to individuals for the purpose of establishing and maintaining their entitlement to Medicare benefits or health insurance plans;

4. To insurance companies, underwriters, third parties administrators (TPA), employers, self-insurers, group health plans, health maintenance organizations (HMO), health and welfare benefit funds, managed care organizations, other supplemental insurers, non-coordinating insurers, multiple employer trusts, liability insurers, no-fault medical automobile insurers, workers compensation carriers or plans, other groups providing protection against medical expenses without the beneficiary's authorization, and any entity having knowledge of the occurrence of any event affecting (a) an individual's right to any such benefit or payment, or (b) the initial right to any such benefit or payment, for the purpose of coordinating of benefits with Medicare program and implementation of MSP provision at 42 U.S.C. 1395y(b). Information to shall be limited to Medicare utilization data necessary to perform that specific function. In order to receive the information, they must agree to:

    a. Certify that the individual about whom the information is being provided is one of its insured or employees, or is insured and/or employed by another entity for whom they serve as a TPA;

    b. Utilize the information solely for the purpose of processing the individual's insurance claims; and

    c. Safeguard the confidentiality of the data and prevent unauthorized access.

    Other insurers may require LTCMDS information in order to support evaluations and monitoring of Medicare clams, information of beneficiaries, including proper reimbursement for services provided.

5. To an individual or organization for research, evaluation, or epidemiological projects related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects;

6. To a Member of Congress or congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained;

7. To the Department of Justice (DOJ), court or adjudicatory body when:

    a. The Agency or any component thereof;

    b. Any employee of the Agency in his or her official capacity;

    c. Any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

    d. The United State Government, is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation.

8. To a CMS contractor (including, but not limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such program;

9. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local government agency), that administers, or that has the authority to investigate potential fraud or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in such programs. Other agencies may require LTCMDS information for the purpose of combating fraud and abuse in such Federally funded programs; and

10. To a national accrediting organization whose accredited facilities are presumed to meet certain Medicare requirements fro inpatient hospital (including swing beds) services; e.g., the Joint Commission for the Accrediting of Healthcare Organizations (JCAHO). Information will be released to accrediting organizations only for those facilities that they accredit and that participate in the Medicare program.

4146.7D - Access by an Individual to His or Her Own Records

(Rev. 1, 05-21-04)

Upon request by any individual with records contained in the system of records, the System Manager or authorized designee shall permit the individual to review his/her records and obtain a copy of all or any portion thereof (in a form comprehensible to the individual) unless an exemption under the Privacy Act applies. Fees may be charged only

for the cost of copying the records, and not for time spent searching for the records or determining whether to release the records. The individual may have another person accompany him/her while reviewing the records, but must furnish a written statement authorizing disclosure and discussion of the records in the accompanying person's presence. The individual may request amendment of any portion of his/her records which is not accurate, relevant, timely or complete.

4146.7E - Criminal Penalties for Improper Disclosure

(Rev. 1, 05-21-04)

Under the Federal Privacy Act, the following criminal penalties may be applicable:

- Any officer or employee of the State who intentionally discloses individually identifiable information prohibited from disclosure under the Privacy Act, shall be guilty of a misdemeanor and fined not more than $5,000;

- Any officer or employee of the State who willfully maintains a system of records without meeting the notice requirements of the Privacy Act shall be guilty of a misdemeanor and fined not more than $5,000; and

- Any individual who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000.

4146.8 - System Security

(Rev. 1, 05-21-04)

As distinguished from confidentiality and privacy, which primarily focus on the rules for release on information when it is authorized, security relates to the means by which the information is protected from unauthorized access, disclosure and misuse. The State must ensure that the electronic data in the MDS system is protected to the same degree that paper records containing any identifiable data must be safeguarded. Additionally, any printed copies of reports from the system must be maintained in a secure locked area while they are needed and shredded when no longer needed.

The State must issue a policy that delimits the qualifications for an individual to access the MDS system and the system administrator must issue passwords and user IDs in strict adherence to those requirements. Those who receive passwords must be aware of the requirement of the State's security policies and those of the System of Records and the Privacy Act. The system administrator and those who have received passwords must protect passwords. Passwords must be disabled at the time an individual leaves a position requiring MDS system access.

No one should leave the MDS system in a logged-on status when leaving the area. If possible, the system hardware should be located in an enclosed area, with a door having interior hinges that can be locked. Keys or a combination should be available to only a minimal group of individuals with a need for access to the system.

In addition to the specific guidance above, the safeguards must provide a level of security at least equivalent to that required by the Office of Management and Budget Circular A-130 (revised) Appendix III, Security of Federal Automated Systems.

4146.9 - RO Roles and Responsibilities

(Rev. 1, 05-21-04)

ROs must provide the States with the program guidance and technical assistance critical to successful implementation of MDS and subsequent programs and ensure that the States have the necessary resources to accomplish these goals.

The following activities must be performed by the RO:

1. **Budget Process -** The RO must review each State agency's budget request and the required MDS Implementation Plans in accordance with the Budget Call Memorandum and reasonable and prudent expenditure of funds to ensure that States receive a fair and reasonable allocation. The RO must monitor Quarterly Expenditure Reports against the States' allocation;

2. **Review State Implementation Plans** - The RO must review all annual MDS Implementation Plans from the States and ensure that the States have reasonable plans for ensuring facilities have the technical information, training, and assistance they need to comply with MDS submission and accuracy, privacy and security requirements, and that the States are monitoring facility compliance with MDS requirements;

3. **Review Contracts and Agreements** - The RO must ensure that the State survey agency has executed an agreement with another entity if that other entity is operating the MDS system on behalf of the State survey agency responsible for nursing home survey and certification;

4. **Provide Training and Technical Assistance** - The RO must provide training and technical assistance to the States in MDS implementation requirements and continuing education in the MDS program;

5. **Perform Focused Reviews/Federal Surveys** - The RO will use the National MDS Repository assessment and quality indicator data to select facilities for focused reviews, and in preparation for Federal surveys; and

6. **Take Enforcement Action** - The RO will process and effectuate enforcement actions for non-compliance with MDS requirements.

4146.10 - Provider Relations

(Rev. 1, 05-21-04)

With CMS technical support and guidance, the States must work closely with the provider community and their MDS 2.0 software vendors in providing information on specific requirements related to the submission of MDS assessments to the State MDS system. The standardization of the State MDS system extends back to the provider because a common data communications software package is used by providers to transmit MDS assessments to the State.

The CMS expects that a facility's software vendor will provide primary support to the facility in terms of MDS encoding and transmission to the State repository. The State, however, must work with facilities and software vendors in educating them about this process and in working out some of the initial problems in getting provider data through the vendor software and into the State MDS system. The States must also provide training and technical assistance in interpretation of MDS reports provided to facilities. The State will also fund the monthly telephone line charges associated with transmission of the MDS data from the facilities to the State.

SA Analysis Activity

4149 - OSCAR System

(Rev. 1, 05-21-04)

4149A - Summary

(Rev. 1, 05-21-04)

The Online Survey Certification and Reporting System (OSCAR) collects provider and supplier certification information and generates reports which compile this information into a workable format. The SA has primary responsibility for entering all recertification and Medicaid initial survey data, except for nursing homes and home health agencies, into the Online Data Input and Edit (ODIE) subsystem of OSCAR via computer terminals. The RO is responsible for entering all Medicare initials and terminations unless this has been delegated to the SA. Nursing homes and home health agencies data must now be entered through ASPEN Central Office (ACO) by SAs and ASPEN Regional Office (ARO) for ROs. The data will move from ASPEN to OSCAR. Entered deficiency data is compared against a list of critical requirements (flags) in order to identify surveys that require submittal to the RO by the SA for substantive professional review prior to approval for continued program participation. After a compliance determination is made, additional information is entered into the system to complete the certification record. Standard reports are available from OSCAR and can be produced on an as-needed basis. User designed reports can be set up and saved in a user library for future use. Each standard and user designed report pertains to a particular aspect of the certification process. The intended use of these reports is to help SAs understand and manage their workload and identify processing problems for correction.

4149B - Availability of OSCAR Data

(Rev. 1, 05-21-04)

Provider information abstracted from the certification documents is maintained in OSCAR data records and produced in various formats to assist the SA, RO, and CO in managing and assessing their respective areas of responsibility in the certification process. It is the responsibility of each SA, the ROs, and CO to generate the reports necessary to monitor and manage their certification workload.

The SA/RO should generate OSCAR Report 2 (Facilities Scheduled for Survey) on a regular basis for those provider/supplier types currently being surveyed on an annual basis. They should obtain history profile of deficiencies for these facilities by running OSCAR Report 3 (Facility History Profile). Here, they can target their search on

Condition, standard, lesser requirements, or all deficiencies. Other OSCAR reports that would be useful to the SA, RO, or CO and can be generated on an as-needed basis are:

- OSCAR Report 9 (Average Certification Work Processing Times) which calculates the average processing times to complete the certification of each category of participating providers and suppliers;

- OSCAR Report 9R (Recap of Certification Work Processing Times) compares the average processing times by certification processing steps and type of certification action;

- OSCAR Reports 18 through 20 provide a Comparison of Deficiency Patterns by tag number sequence, by State, region, and frequency of occurrence. This information is displayed either by State, region, and nation; and

- OSCAR report 5 and 6 provide a listing of all Medicare/Medicaid facilities in alphabetical order by type of facility, chronological survey date order, zip code, or State region code.

Through the user defined features of OSCAR, users can customize and design their own reports as well as extract data and download that data to a PC where it can further be analyzed with the available PC tools.

OSCAR has on-line information retrieval. Its inquiry option provides the ability to search by name, provider number, provider type, or ZIP code.

4149C - Review of Certification Data

(Rev. 1, 05-21-04)

It is crucial that the SA and RO review all certification documents for completeness and accuracy prior to data entry to maintain the integrity of the OSCAR database. To avoid processing delays, make sure the appropriate forms, as listed below, are at hand. The ODIE and ACO systems are programmed to accept data from complete certification kits that contain all required forms. Some documents are common to all initial and recertification kits including the "Medicare/Medicaid Certification and Transmittal" (Form CMS-1539), the appropriate Request for Certification form, the "Statement of Deficiencies and Plan of Correction" (Form CMS-2567), and the Crucial Data Extract (CDE). The SA and RO may enter the data from the "Post-Certification Revisit Report" (Form CMS-2567B) detailing the status of the deficiencies on the revisit either at the time of initial data entry or, if the facility record is already in OSCAR, at a later time. The CDE must be present in every kit. The CDE for each type of institution corresponds to the respective Survey Report and abstracts certain compliance and deficiency information for data collection purposes.

The following list includes all the basic certification documents (including their provider number series that follows the 2-digit State code) required for ODIE or ASPEN Central Office input in all routine initial and recertification packages:
(See also §2779.)

1. **Nonaccredited Acute Hospital** (0001 to 0879)
    - "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
    - "Request to Establish Eligibility," Form CMS-1514
    - "Statement of Deficiencies and Plan of Correction," Form CMS-2567
    - Crucial Data Extract for Form CMS-2786
    - "Survey Team Composition and Workload Report," Form CMS-670
2. **Nonaccredited Psychiatric Hospital** (4000 to 4499)
    - "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
    - "Request to Establish Eligibility," Form CMS-1514
    - "Statement of Deficiencies and Plan of Correction," Form CMS-2567
    - Crucial Data Extracts for Form CMS-2786
    - "Survey Team Composition and Workload Report," Form CMS-670
3. **Accredited Acute Hospital** (0001 to 0879)
    - "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
    - "Request to Establish Eligibility," Form CMS-1514
4. **Accredited Psychiatric Hospital** (4000 to 4499)
    - "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
    - "Request to Establish Eligibility," Form CMS-1514
    - "Statement of Deficiencies and Plan of Correction," Form CMS-2567
    - "Survey Team Composition and Workload Report," Form CMS-670

5. **Home Health Agency** (7000 to 8499 and 9000 to 9499)

    - "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
    - "Home Health Agency Survey and Deficiencies Report," Form CMS-1572(A)
    - "Statement of Deficiencies and Plan of Correction," Form CMS-2567
    - "Survey Team Composition and Workload Report," Form CMS-670

6. **Portable X-Ray** (X0000001 to X9999999)

    - "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
    - "Request to Establish Eligibility," Form CMS-1880
    - "Portable X-Ray Survey Report," Form CMS-1882
    - "Statement of Deficiencies and Plan of Correction," Form CMS-2567
    - "Survey Team Composition and Workload Report," Form CMS-670

7. **Rehabilitation Agency (OPT/SP)** (6500 to 6989)

    - "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
    - "Request to Establish Eligibility," Form CMS-1856
    - Crucial Data Extract for Form CMS-1893
    - "Statement of Deficiencies and Plan of Correction," Form CMS-2567
    - "Survey Team Composition and Workload Report," Form CMS-670

8. **Rural Health Clinic** (3400 to 3499, 3800 to 3999 and 8500 to 8999)

    - "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
    - "Request to Establish Eligibility," Form CMS-29
    - "Statement of Deficiencies and Plan of Correction," Form CMS-2567

- Crucial Data Extract for Form CMS-30(E)
- "Survey Team Composition and Workload Report," Form CMS-670

9. ESRD (2300 to 2999 and 3500 to 3799)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- "Statement of Deficiencies and Plan of Correction," Form CMS-2567
- Crucial Data Extract for Form CMS-3427
- "Survey Team Composition and Workload Report," Form CMS-670

10. SNF and SNF/NF - Titles XVIII and XVIII/XIX (5000 to 6399)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- "Long Term Care Facility Application for Medicare/Medicaid," Form CMS-671
- "Resident Census and Conditions of Residents," Form CMS-672
- "Statement of Deficiencies and Plan of Correction," Form CMS- 2567
- "Fire Safety Survey Report Crucial Data Extract," Form CMS-2786
- "Survey Team Composition and Workload Report," Form CMS-670

11. NF (A001 to A999, 00-B001 to B999, E001 to E999, and F001 to F999)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- "Long Term Care Facility Application for Medicare/Medicaid," Form CMS-671
- "Resident Census and Conditions of Residents," Form CMS-672
- "Statement of Deficiencies and Plan of Correction," Form CMS-2567
- "Fire Safety Survey Report Crucial Data Extract," Form CMS-2786
- "Survey Team Composition and Workload Report," Form CMS-670

12. **Intermediate Care Facilities for the Mentally Retarded** (GOO1 to G999, H001 to H999)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- "Intermediate Care Facility for the Mentally Retarded Survey Report," Form CMS-3070G
- "Statement of Deficiencies and Plan of Correction," Form CMS-2567
- "Fire Safety Survey Report Crucial Data Extract," Form CMS-2786
- "Survey Team Composition and Workload Report," Form CMS-670

13. **Ambulatory Surgical Centers** (C0000001 to C9999999)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- "Ambulatory Surgical Center Request for Certification in the Medicare Program," Form CMS-377
- "Statement of Deficiencies and Plan of Correction," Form CMS-2567
- "Ambulatory Surgical Center Survey Report," Form CMS-378 and "Ambulatory Surgical Center Report -- Crucial Data Extract," Form CMS-378E
- "Fire Safety Survey Report," Form CMS-2786H
- "Survey Team Composition and Workload Report," Form CMS-670

14. **Comprehensive Outpatient Rehabilitation Facilities** (4500 to 4599, 3200 to 3299, 4500 to 4599 and 4800 to 4899)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- "Request to Establish Eligibility," Form CMS-359
- "Statement of Deficiencies and Plan of Correction," Form CMS-2567
- "Survey Team Composition and Workload Report," Form CMS-670

15. Hospice (1500 to 1799)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- "Request to Establish Eligibility," Form CMS-417
- "Statement of Deficiencies and Plan of Correction," Form CMS-2567
- Crucial Data Extract for Form CMS-643
- "Survey Team Composition and Workload Report," Form CMS-670

16. Community Mental Health Centers (4600 to 4999 and 1400 to 1499)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- "Community Mental Health Center Crucial Data Extract (No CMS number.)

17. Federally Qualified Health Centers (1800 to 1989)

- "Medicare/Medicaid Certification and Transmittal," Form CMS-1539
- Federally Qualified Health Center Crucial Data Extract

18. CLIA Laboratories (D0000001 to D9999999)

- "Medicare/Medicaid Certification and Transmittal Form CMS-1539
- "Survey Report Form (CLIA)," Form CMS-1557
- "Statement of Deficiencies and Plan of Correction," Form-2567
- "Survey Team Composition and Workload Report," Form CMS-670

4149D - OSCAR Input Considerations

(Rev. 1, 05-21-04)

After the kit is reviewed to ensure that the appropriate certification documents are complete and the data is entered into ODIE or ACO, it undergoes a series of edit and consistency checks programmed into the system to screen input errors and data inconsistencies. Depending upon the nature of the error, the data may be rejected or placed in a pending transaction file until corrected information is received and accepted to

the record. To assure efficient operation of the system, the SA should be careful that all certification data are completed properly, keyed accurately, and transmitted promptly.

4149E - Suggested Output Utilization

(Rev. 1, 05-21-04)

1 - SA

The SA produces the OSCAR reports identified in subsection B on a regular basis. These reports provide pertinent information concerning the ongoing management of the certification process. The SA uses these as tools in monitoring the status of individual providers and suppliers in the State. Preliminary analysis of facility deficiency profiles (OSCAR Report 17) can help the SA determine the appropriate survey team composition for resurveys. The survey team can use the profiles to familiarize themselves with the histories and characteristics of facilities scheduled for forthcoming surveys based on previous findings and reported corrective actions. For HHA and NH surveys, surveyors should also review the appropriate quality indicator and quality measures reports. OSCAR Report 2 can be utilized to verify internal controls and existing records for scheduling resurveys. Additional management information can be derived from OSCAR Report 5 or 6 since each lists all participating providers and suppliers in alphabetical order by facility name for reference purposes. Also, OSCAR Report 5 or 6 can sort the facilities by provider number order, zip code, or State region code. These reports should help the SA maintain a balanced survey schedule and avoid certification backlogs.

The SA, through careful analysis of OSCAR Reports 18 through 20, can uncover significant State deficiency patterns and reflect a possible need for additional surveyor training or provider consultation in problem areas. The SA can then investigate the causative factors that underlie frequently occurring deficiencies and institute plans for corrective action. Similarly, if a State consistently shows few deficiencies for requirements often out of compliance nationwide, it can explore whether the facilities are strong in that area or if there are problems with the survey process. OSCAR reports may also be used to track selected deficiencies over a specified time period and enable the SA to monitor any changes in deficiency patterns.

2 - RO Usage

Evaluation of SA performance is the most important responsibility of the RO and use of OSCAR data is an integral part of this evaluation. Analysis of data derived from the various OSCAR reports can provide the RO with insights into such areas of SA performance as timeliness of certification actions (OSCAR Reports 9 and 9R) and facility deficiency patterns as compared to other States, regions, and the nation (OSCAR Reports 18-20). OSCAR reports can specifically provide the RO with the tools to:

- Identify overdue recertifications;

- Prepare for SA visits; and

- Monitor SA processing times.

3 - CO Usage

CO calls upon OSCAR to answer informational requests from interested parties (e.g., Congress, public interest groups, governmental agencies) and to supply statistical information to the Administrator of CMS. The data from OSCAR is also used extensively in the general oversight of the certification process on the national level.

4150 - RO Oversight of SA Surveyor Training

(Rev. 1, 05-21-04)

Responsibilities of RO staff for the surveyor training program fall into the following four groupings:

A. To enforce and interpret the SA surveyor qualifications and training statement. The RO:

    1. Determines whether surveyors hired by SAs meet the Federal qualifications requirements;

    2. Assures that new surveyors complete the orientation program and attend the appropriate Basic surveyor Training Course; and

    3. Maintains an updated roster of SA surveyors.

B. To review, approve, and monitor the SA orientation programs for new surveyors. The RO:

    1. Assists States in adapting CMS orientation program to State needs;

    2. Reviews and approves State's proposed orientation program;

    3. Monitors the implementation of the program assuring that each new surveyor completes the orientation program;

    4. Informs new surveyor in training (either when several trainees can come to the RO at one time, or when the regional training administrator visits a State or at some other convenient time and place), regarding the responsibilities of ROs as they relate to their State;

5. Confers and advises the preceptor and/or coordinator on the administrative and technical issues regarding the orientation program;

6. Participates in the evaluation of new surveyors' development;

7. Plans, conducts, and coordinates the RO orientation program;

8. Issues a certificate to each surveyor satisfactorily completing the orientation program;

9. Acts as a liaison between CO and the SA in overall implementation, monitoring and evaluation of the orientation program; and

10. Evaluates the in-service training program in the SA as it relates to the continued development of the skill knowledge of the new surveyor.

C. To provide nominations of eligible surveyors for basic and specialty courses. The RO:

1. Maintains accurate information on surveyors who need to attend the basic Surveyor Training Course;

2. Provides CO with nominations for the Basic Course on a timely basis; and

3. Selects attendees to specialty courses and provides the names to CO.

D. To design and carry out surveyor training programs that meet special needs of individual States in the region. The RO:

1. Assists Central Office in assessing training needs of surveyors and participates in task forces developing nationally offered specialty courses; and

2. Based upon analytical studies, identifies training needs of SA surveyors and develops training programs to meet those needs.

4151 -RO Program Analysis Activity

(Rev. 1, 05-21-04)

Program analysis may be focused in the following areas:

4151A - Analysis of Administrative Factors

(Rev. 1, 05-21-04)

Analyze administrative data. This data includes (but is not limited to):

- Level of expenditures;
- Number of surveyors;
- Surveyor turnover rates;
- Number of providers;
- Time and effort statistics; and
- OSCAR reports.

The manipulation of this data may lead to the identification of the causes of performance problems, or help explain differences in survey-related costs.

4151B - Analysis of SA Reviews

(Rev. 1, 05-21-04)

The major focus of analysis of SA evaluations concerns areas where a State shows persistent substandard performance. This may not be evident through periodic reviews, since the reviews do not encompass the same functions. A focus on the results of each area may impact other areas. For example, a high surveyor turnover rate will be evident in financial data (increased training costs) and in 670 data (increased survey completion time). The important element is that several areas of data can be used to demonstrate and support a request for SA corrective action.

SA reviews should also be studied to each other (State-to-State) to determine common areas of success as well as difficulty. These areas should be clearly delineated since difficulties common to most States represent areas where major programmatic efforts should be made to improve program processes.

4151C - Analysis of Individual Special Programs

(Rev. 1, 05-21-04)

The special program or innovation must be directly evaluated. The approach must be one that studies interrelationships among the agency's components. The analysis should determine what work the agency produces, how well and quickly it's produced, and its

cost. These considerations must also be studied to determine effects in each area. For example, a program aimed at cost-reduction through a decrease in survey team size may show a trend toward the citing of fewer deficiencies. The results of any analysis should be discussed with the SA with the common goal of improving the quality of survey and certification activities.

4152 – State Performance Measures for All Providers and Suppliers

(Rev. 1, 05-21-04)

(Refer to §7801)

4157 - Federal Monitoring Surveys - Definition and Purpose

(Rev. 1, 05-21-04)

4157A - Definition

(Rev. 1, 05-21-04)

A Federal Monitoring Survey (FMS) is a survey performed by the RO or designated contractors under the authority of the Central or Regional Offices, of any Medicare/Medicaid participating provider and/or supplier (see Chapter 6 for Labs).

4157B - Purpose

(Rev. 1, 05-21-04)

The RO conducts the survey to:

- Monitor SA performance in interpreting and applying Federal standards;
- Identify training and/or technical assistance needs of surveyors;
- Identify problems that surveyors and/or providers encounter in implementing Federal regulations; and
- Require correction of problems that exist in individual facilities or in individual surveys.

4157C - Scope of Survey

(Rev. 1, 05-21-04)

1. Full Survey

A survey of all applicable CoPs and standards for all types of Medicare/Medicaid providers and/or suppliers except SNFs, NFs and ICFs/MR. SNFs, NFs are described separately in 3 below, and ICFs/MR are described separately in 4 below.

2. Partial Survey

A survey of selected Conditions and/or standards for any type of Medicare/Medicaid provider and/or supplier, except SNFs and/or NFs and ICFs/MR. SNFs and/or NFs are described separately in 3 below, and ICFs/MR are described separately in 4 below.

3. SNF and/or NF Surveys

a. **Standard Survey** - A standard survey is composed of Tasks 1-7, and is a resident-centered, outcome-oriented inspection which relies on a case-mix stratified sample of residents to gather information about the facility's compliance with participation requirements. Based on the specific procedures detailed in Appendix P, a standard survey assesses:

- Compliance with residents' rights and quality of life requirements;
- The accuracy of residents' comprehensive assessments and the adequacy of care plans based on these assessments;
- The quality of services furnished, as measured by indicators of medical, nursing, rehabilitative care and drug therapy, dietary and nutrition services, activities and social participation, sanitation and infection control; and
- The effectiveness of the physical environment to empower residents, accommodate resident needs, and maintain resident safety.

If in conducting the information gathering tasks of the standard survey the RO identifies a possible noncompliant situation related to any requirement, it investigates the situation to determine whether the facility is in compliance with the requirements.

b. **Extended Survey** - The extended survey is conducted after substandard quality of care is found during a standard survey. When, based on performing the resident-centered tasks of the standard survey the RO makes a determination that the facility has provided substandard quality of care in 42 CFR 483.13, Resident

Behavior and Facility Practices; 42 CFR 483.15, Quality of Life; and/or 42 CFR 483.25, Quality of Care, then an extended survey must be conducted within 14 days after completion of a standard survey. (See Appendix P, Part I, Section III, the extended and partial extended survey.)

c. Partial Extended Survey - A partial extended survey is always conducted after substandard quality of care is found during an abbreviated standard survey. When, based on performing the abbreviated standard survey, the RO makes a determination that the facility has provided substandard quality of care in 42 CFR 483.13, Resident Behavior and Facility Practices; 42 CFR 483.15, Quality of Life; and/or 42 CFR 483.25, Quality of Care, it must conduct a partial extended survey. (See Appendix P, Part I, Section III, the extended and partial extended survey.)

4. ICF/MR Surveys

a. **Fundamental Survey** - Conducted to determine the quality of services and supports received by individuals, as measured by outcomes for individuals and essential components of a system which must be present for the outcomes of active treatment to occur. Certain requirements are designated as fundamental and are reviewed first. The remaining requirements (that are not designated as fundamental) are supporting structures or processes that the facility must implement. A decision that a provider is in compliance with the fundamental requirements indicates an outcome-reviewed compliance with the non-fundamental requirements and associated Conditions of Participation. (Reference Transmittal No. 278 for specific tag numbers included primarily under 42 CFR 483.420, Client Protections, 42 CFR 483.440, Active Treatment Services, 42 CFR 483.450, Client Behavior and Facility Practices, 42 CFR 483.460, Health Care Services).

b. **Extended Survey** - Conducted when standard-level deficiencies are found during the fundamental survey and the survey team has determined or suspects that one or more CoP examined during the fundamental survey are “not met.” The team needs to gather additional information in order to identify the structural and process requirements that are “not met” and to support their condition-level compliance decision. The team reviews all of the requirements within the CoP(s) for which compliance is in doubt.

c. **Full Survey** - A survey of all applicable CoPs and standards. A full survey is conducted by the State Agency at an initial survey and at the discretion of the RO, based on the RO’s identification of concerns related to the provider’s capacity to furnish adequate services.

4157D - Survey Definitions

(Rev. 1, 05-21-04)

1. Comparative Survey

A Federal survey conducted within 60 days of the State survey to assess SA performance in the interpretation, application, and enforcement of Federal requirements. Whenever possible, the RO conducts comparative surveys within 30 days of the State survey.

2. Direct/Federal Jurisdictional Survey

A Federal survey to assess provider performance and to determine whether a provider/supplier meets all applicable program requirements. It is used as the basis for approving a provider where the SA lacks jurisdiction. Federal personnel conduct surveys of health facilities of the Indian Health Services, Commonwealth of the Virgin Islands, and participating ESRD facilities in VA hospitals.

3. Validation Survey for Accredited Facilities

A survey of an accredited entity, e.g., hospital, HHA, ASC, to validate the presumed compliance of the entity's deemed status and the survey process of the accrediting organization, recognized by CMS.

4. - Validation Survey of SNFs or NFs

An on-site survey of a representative sample of SNFs or NFs in each State (at least 5 percent of the number of SNFs and NFs surveyed by the State in the year, but in no case less than 5 SNFs and NFs in the State) within 2 months of the date of a State's standard or an extended survey. The sample is of a sufficient size to allow inferences about the adequacy of the State's surveys, and, in conducting a validation survey of SNFs and NFs, CMS uses the same survey protocols the State used.

5. Federal Oversight Support Survey (FOSS)

An on-site SNF/NF survey where the Federal surveyor(s) attends the State survey (initial, recertification, revisit and/or complaint) to observe and assess State surveyor team performance. The RO surveyor(s) may provide training and/or technical assistance to address identified performance needs while on-site as a result of the evaluation of outcomes. The outcomes include:

- Concern Identification
- Sample Selection

- General Investigation
- Kitchen and Food Service Investigation
- Medication Investigation
- Deficiency determination

The Form CMS-2567 is also evaluated to identify whether deficient practices identified on-site are reflected in the Form CMS-2567.

4158 - Federal Oversight Support Survey (FOSS) Expectations and Responsibility

(Rev. 1, 05-21-04)

4158A - SA Responsibility

(Rev. 1, 05-21-04)

Once the survey schedule has been prepared, the SA should forward this schedule to the RO at least two weeks prior to the earliest survey date. This schedule should include:

- Survey dates (including projected end date)
- Facility name and provider number
- SA surveyor names or initials, with the identification of the team leader
- Any use of specialty surveyors
- Type of survey (initial, recertification, complaint, etc)

Once the survey schedule has been forwarded to the RO, and/or the SA has been notified of the selection for Federal oversight, the SA must notify the RO prior to the survey regarding any survey changes (for those selected for FOSS surveys). Changes may be defined as increasing or decreasing team size and composition, altering the survey date, and changing locations. SA justification should accompany the communication of such changes.

During a FOSS, the SA surveyors must inform the RO surveyors when they are or will be conducting certain functions during the survey process. These include, at a minimum:

- Interviews (with staff, family and/or residents)

- Team meetings
- Observations of care delivery

The SA team will share all survey documentation with the RO surveyor(s) for review.

The SA team must determine if Harm, Substandard Quality of Care and/or Immediate Jeopardy are present during the information gathering tasks of the survey and/or during information analysis and decision-making.

Once the FOSS and SA survey have concluded and the SA has documented the compliance decisions, the SA must forward the CMS-2567 to the RO at the same time the CMS-2567 is forwarded to the facility.

4158B - RO Responsibility

(Rev. 1, 05-21-04)

The RO, in preparation for the survey, shall review the survey schedule provided by the SA and notify the State Agency when a survey has been selected for a FOSS. However, an RO may select a survey for an unannounced FOSS.

The RO, in conducting a FOSS will generally perform several steps in gathering information about survey team performance. These include:

- Observing surveyors
- Talking with SA surveyors to clarify observations and interpretations
- Reviewing facility documentation and surveyor notes
- Conducting limited fact finding
- Attending survey team meetings.

The RO surveyor must be able to be present at as many interviews as possible with residents and key facility staff. In addition, the evaluator must be able to be present during all team meetings, investigative activities and during resident care observations as appropriate for their discipline.

The RO surveyor(s) may perform limited fact finding in order to assess the SA survey team's achievement of outcome measures associated with assessing a provider's compliance with Federal regulations. (See FOSS Manual for guidance)

The RO team must provide evaluators to ensure RO to SA ratios of 1:2, but no less than 1:3. The RO surveyors shall not remain on-site if the SA survey team has ended that day's observations and investigations. When the SA leaves the facility, the RO should also depart.

The RO team will debrief the SA survey team regarding the effectiveness of it's survey behaviors in achieving the goals and outcomes of the survey following the completion of the survey, or within the first week the State survey team and RO surveyors return to the office. The RO team will also document the SA team's performance on each outcome that was observable during the survey, and rate that performance by assigning the team a numerical score on each outcome. If appropriate, the RO team will identify SA team training needs.

Upon the conclusion of the FMS (FOSS), the RO team will provide SA management with written feedback on the FOSS at two key points:

- Within 30 days after the completion of the survey, the FOSS Rating and Documentation Form will be provided to the SA.

- Within 30 days after receipt of the facility copy of the Form CMS-2567 by the RO, the FOSS Evaluation Form for Form CMS-2567 will be provided to the SA.

4159 - Selecting and Scheduling Facilities for Monitoring Surveys

(Rev. 1, 05-21-04)

Provider and supplier institutions selected for RO monitoring surveys are usually selected from those the SA recently surveyed. Other criteria for the number and types of institutions chosen include the SA workload, whether the SA is regionalized or centralized, and unique survey problems known to exist in the State. The RO notifies the SA in advance, advising it of those institutions selected for a survey. In cases where the RO wishes the SA to announce the survey beforehand, the SA uses Exhibit 62 to notify the provider or supplier of the date and purpose of the survey.

The SA surveyor may be invited to accompany the Federal surveyors or the Federal surveyors may accompany a SA team, e.g., OSPATS. If LSC enforcement in the State is handled by a subcontracting agency, someone from that agency maybe asked to accompany the Federal LSC inspector.

4160 - Conduct of Monitoring Surveys

(Rev. 1, 05-21-04)

To prevent any misunderstanding about the purpose of the survey, the Federal RO team leader explains the purpose of the survey to provider personnel as the survey begins. The

survey usually covers all CoPs. All survey reports are fully completed, but some partial surveys may be conducted to cover selected Conditions or standards.

At a brief exit conference, the RO team gives the provider a general appraisal of it's operation. If deficiencies were found that would significantly affect patient health and safety, the provider is made aware of those particular deficiencies and is cautioned that such deficiencies could result in adverse action by the RO.

Provider Certification Files and Program Reporting

4200 - SA Provider Certification Files

(Rev. 1, 05-21-04)

The certification files the SA maintains can be used as:

- Working files to enable it to carry on correspondence with the providers and suppliers;
- A repository for its copies of the investigative reports and records supporting certification recommendations; and
- A source for statistical and narrative report data that may be requested by the RO.

4205 - Materials Forwarded to RO

(Rev. 1, 05-21-04)

The SA forwards all documents supporting its certifications to the RO as outlined in §2760. To retain a copy of the file, the SA duplicates or obtains multiple copies of the material. When CMS forms are copied, the SA sends the original to the RO. Copies of other material sent to the RO must be legible and must contain the appropriate signature(s), if required.

The files in the RO may be needed to substantiate terminations, reconsiderations, hearings, and appeals. The RO may ask the SA to supply supplementary evidence to support the decisions in these cases. However, whenever an appeal action is pending and the SA obtains additional evidence relating to the certification deficiencies, it immediately forwards copies of this material to the RO without waiting for a request.

4210 - SA Files Used for Case Control and Reporting

(Rev. 1, 05-21-04)

The RO may also need more specific information about an aspect of the certification operations in a State, or may need other special tabulations and reports concerning an area of program activity. Some items of information that may be needed are:

- The status of a facility's Request to Establish Eligibility;
- The number of initial surveys pending;

- The number of applications pending for various lengths of time;
- The reasons that action has not been completed on a certification, e.g., a revisit scheduled;
- Survey schedules; and
- The progress made with a facility.

The SA can use this additional data for its own purposes as well. All such data should be readily available from its records.

4225 - Establishment of SA Case Folders and Controls

(Rev. 1, 05-21-04)

The SA must have an effective case control system. The system of control should be used to maintain a record of every action taken by the SA. The system may be either manual or electronic and must provide easy access to those in the office.

Necessary SA Expenses

4500 - General

(Rev. 1, 05-21-04)

Any class or kind of administrative expenditure that is properly chargeable to Federal funds under plans approved by the Department of Health and Human Services (DHHS) could generally be properly chargeable to State provider certification program funds provided the expenditure is essential to certification functions and in a proper amount. The SA exercises due care in the expenditure of funds, as these funds must be effectively and economically used in carrying out the provisions of the Social Security Act (the Act) for survey and certification activities.

Necessary expenses can include a portion of the cost of operations that serve the certification program and one or more other programs. The SA is required to submit a specific plan for determining the certification program's cost for such multi-program activities as part of the overall plan and budget. Include in the budget both the basis on which the certification program share or ratio is determined and the expenses to which this ratio is applied.

The CMS' current policy is that the total survey costs must be allocated to each benefiting program or activity to determine the payable costs for that program or activity. Knowledge of the State's licensure requirements is necessary in formulating the budget to ensure that cost shares are equitable and in line with current CMS policy. (See §4514.D and E.)

In many States, two or more programs are served by the SA activities, e.g., those relating to certification versus licensure. However, there may be activities that are required by the State survey program only. Under these circumstances, the total cost of these activities would be an appropriate charge to the State survey program.

A State is entitled to receive FFP for Medicaid activities by way of payment or advances to support the reasonable cost of performing services provided for in the agreement with the Secretary or State plan. The "reasonable cost" includes all necessary expenses involved, i.e., expenses that are in accord with these standards and within the limits of the approved SA budget.

4502 - SA Cost of Studies of Distribution of Staff Time

(Rev. 1, 05-21-04)

An important administrative objective is to explore alternative methods of budgeting to facilitate budget preparation, approval, and execution. Studies of the distribution of SA staff time to various definable areas of State activity within the State survey program may be required. The cost of all studies, recording, and reporting that a State may be requested to do by CMS is considered a necessary expense. The results of such studies are made available to the States.

4504 - Pro Rata Costs - General Rule

(Rev. 1, 05-21-04)

The general rule for prorating costs is that the share apportioned to the State survey program shall not exceed an amount that reflects the ratio of total monies disbursed for personnel services in the State survey program to the total monies disbursed for personnel services in the agency's total program. This total includes the total monies disbursed for personnel services in the State survey program and is based on the calendar quarter for which a report is prepared. This general rule applies except as expressly modified elsewhere.

The basis for apportioning shared costs is a matter of record. All pro rata allocations are to be supported by documentation maintained by the SA. (See §§4508.B and 4510.B.)

4508 - SA Goods, Facilities, Services from Other State Agencies or From Local Agencies

(Rev. 1, 05-21-04)

4508A - Definition

(Rev. 1, 05-21-04)

The definitions of the terms "goods," "facilities," and "services," and the criteria for application of the standards are those in effect for State grant-in-aid relationship with DHHS.

4508B - Centralized State Services

(Rev. 1, 05-21-04)

In some States, services of an administrative nature (including certain commodities) such as accounting, printing, civil service, or central purchasing are furnished to the various operating agencies of the State by specialized service departments outside the health department (or other agency having an agreement and/or State plan with DHHS under §§1864 and/or 1903 of the Act). An equitable part of such charges may be allocated to the State survey and certification program if the services are necessary and are ones from which the program derives a benefit similar to that accruing to other units of the agency, and provided that:

- The pro rata share charged to the State survey program does not include costs attributable to the general expense of State government in carrying out the coordinating, fiscal, and administrative functions of government;

- The charge is based on cost; and

- The costs are extra, identifiable, and readily ascertainable either by segregation or as a pro rata share of the cost of such facilities or services.

The basis of the service agency's charge must be described, including the method of proration and the services provided, and the description submitted for approval to CMS. Such costs should be separately identified in the SA budget.

4510 - SA Personnel Services

(Rev. 1, 05-21-04)

4510A - Selection of Personnel

(Rev. 1, 05-21-04)

Personnel employed for, or assigned to, duties the cost of which may appropriately be charged to DHHS must meet the qualification requirements of, and be appointed and paid in accordance with, the personnel standards contained in the approved State plan, the provisions of the State civil service or other merit system of personnel administration in effect for the designated SA, or the "Standard for a Merit System of Personnel Administration" issued by DHHS.

The costs of all personnel services required to effectively carry out the SA's responsibility under its agreement are proper charges to DHHS. In accordance with prevailing State practice, the SA may include fees for consultants and experts as direct personnel service

charges in the personnel services detailed in the budget submittal, or as a contractual arrangement under "other direct charges." (See §4542.)

4510B - Charges for Director and Secretary of State Survey Activities Determined by Pro Rata Method

(Rev. 1, 05-21-04)

In some agencies a director of survey and certification activities is shared with one or more other agency programs. In such cases, the State survey program's share of the director's salary and that of his/her secretary may be determined by a proration method other than time records, provided such method can be shown to be equitable to the State survey program and to the other programs involved. One acceptable method is based on the ratio of the total monies disbursed for personnel services in the State survey program to the total monies disbursed for personnel services in that segment of the agency having the programs for which this director is responsible (including the State survey program). Quarterly charges for this position would be derived by multiplying the salary paid to the incumbent(s) during the quarter by this pro rata percentage. For purposes of this computation, both the amount representing salary paid to the incumbent(s) and the pro rata percentage would be based on actual expenses in each report quarter.

4514 - SA Determination of Necessary Staff

(Rev. 1, 05-21-04)

4514A - Full-Time

(Rev. 1, 05-21-04)

"Full-time staff" as used here means persons who devote their entire time to the State survey program, and who are employed by the State on a full-time basis.

The number and composition of the full-time staff identified with survey and certification activities should be sufficient to provide for timely and efficient program direction and coordination. The determination of necessary full-time staff is to be based on organizational arrangements and workload in each agency. At a minimum, each agency whose workload requires two or more staff-years of activity in a fiscal year should consider establishing a "full-time" professional position. The incumbent of this position would provide continuous program direction and, as appropriate in the context of agency workload, might also perform line functions.

Neither this section nor Subsection B apply to full-time equivalent positions described in Subsection C.

4514B - Limitation of Full-Time Identifiable Positions

(Rev. 1, 05-21-04)

The number of persons on duty at the end of a monthly reporting period who occupy full-time identifiable positions in the State survey program is limited in any category (professional or clerical) to the number of such positions approved in the budget for that period, unless prior authorization to exceed that number is obtained from CMS.

4514C - Part-Time and Temporary

(Rev. 1, 05-21-04)

To augment the full-time State survey staff with the appropriate professional specialties required to perform State survey activities, the SA is authorized to:

- Recruit part-time or temporary State employees; or

- Arrange for part of the working time of full-time State employees (multi-program staff).

Both types of employees are considered part-time employees to the survey program. As a general rule, consultants are not included in this category unless they are employees of the State. See §4611 for instructions relating to budget requests for consultants' fees.

Provision is made for "equivalent" positions to allow regular agency personnel to perform State survey functions where the agency's regular personnel are already fully occupied and unable to devote time to this function unless the equivalent of the human resources used is added to their regular staff.

Under this concept, an agency that estimated that the aggregate total time of multi-program personnel to be devoted to the State survey program would equal the time of one (or more) full-time person, could hire, with CMS approval, one (or more) full-time person as an "equivalent." In such cases, the agency with approval could also purchase equipment needed by the persons hired. However, it is essential that the individual's time be fully offset by time spent on the State survey program by other staff of the agency. The SA must maintain time records to validate charges to the State survey program.

4514D - Charging for Multi-Program Staff - Program Activities Readily Identifiable

(Rev. 1, 05-21-04)

In agencies where the function performed is separate and readily identifiable as serving the State survey program only, charges for multi-program staff performing State survey

functions might be based on daily estimates of time spent on these functions, periodic sample time studies, or continuous time records. Periodic sample time studies must be approved by CMS in advance before the SA can use them as a basis for making charges under this section.

4514E - Charging for Multi-Program Staff - Program Activities Not Separate

(Rev. 1, 05-21-04)

Where some or all of the State survey activities are shared with other on-going agency programs so that a common function, e.g., survey of a hospital, will serve for State survey and certification as well as for licensure or other State programs and the work involved cannot be separated into program elements, time records may not be an appropriate basis for determining cost to the State survey program. The SA may use one of the following methods or submit another proposal for apportioning costs between the State survey program and the other agency program(s) involved.

1 - Cost Due to Acceleration of Usual Agency Functions

Where the agency can identify an increase in its usual workload that is caused by such program requirements as recertification deadlines, the State survey program share would be equivalent to the cost of accomplishing this incremental workload. Charges would be substantiated by records indicating that the usual workload as well as the increase for the State survey program was, in fact, accomplished. If possible, substantiate charges by agency data on human resource requirements necessary for this workload, e.g., previous studies of time or human resources required for surveys of facilities in other agency programs.

2 - Ratio of Specific Workload Requirements of State Survey Program to Total Workload Requirements of All Agency Programs Involved

This method may be used when the SA can identify countable activities (standards) for each type of survey which:

- Need to be evaluated because of the requirements of the State survey program, and

- Others that are related more to the requirements of another program.

The ratio of countable activities required by the State survey program to the sum of the countable activities required by all programs could then be applied to the cost of the multi-program activity. Specific applications of this general principle would have to be developed jointly to allow for circumstances a particular agency may encounter and take into account the comparability of such activities between programs. All such proposals

require approval by CMS before charges can be made under them. In some instances the comparability of activities or adjustments made in treating countable activities may have to be verified by later operational studies.

4518 - Use of Overtime in SAs

(Rev. 1, 05-21-04)

The CMS expects the SA to take the initiative in bringing about the adoption of such special measures as it believes necessary to meet workload objectives. To provide the productive capacity to meet certification workloads on a timely basis, all agencies should take steps to secure authority for future use of paid overtime for State survey program staff.

4518.1 - Payment for Overtime

(Rev. 1, 05-21-04)

In the absence of specific State laws or State-wide regulations concerning payment for overtime services, consideration will be given to a State's rules as well as established State practice. Funds advanced to an SA may be used for expenditures for overtime services performed by its personnel under conditions (including rate of pay) authorized by State regulations.

4530 - SA Non-Personnel Services

(Rev. 1, 05-21-04)

Non-personnel services costs, to a substantial degree, will be chargeable directly to the State survey program. Expenses not charged directly may be prorated as indicated in the sections that follow. Generally, each object of expenditure should be either a direct charge in its entirety or a joint charge subject to proration. In justifiable circumstances, however, a portion of expense in an object classification may be charged as a direct cost and the remainder prorated e.g., charges for office space may be based on both direct and indirect costs where one or more rooms are occupied by individuals whose entire time is devoted to State survey activities, and other space is occupied by individuals whose time is devoted only in part to this activity. The basis for apportioning shared costs should be a matter of record and all pro rata allocations should be supported by documentation maintained in the agency.

4531 - Travel by SA Personnel

(Rev. 1, 05-21-04)

The cost of travel, including, where appropriate, per diem or subsistence in lieu of per diem, in the State survey program should be charged in accordance with provisions of State law, regulations, and administrative procedure applicable to travel of State employees.

4531A - Certification and Administrative Travel

(Rev. 1, 05-21-04)

Certification travel includes travel to a facility for initial certification, resurveys for continuing compliance, consultation with a facility applying for certification, and meetings with CMS personnel.

Administrative travel is defined as travel within the State for management purposes related to the State survey program to attend agency administrative staff meetings, State survey program meetings or activities conducted or sponsored by CMS, and planning or liaison visits to other agencies having to do with certification.

Travel expenses for an employee performing activities for the State survey program and other agency programs may be prorated on the basis of individual trips in accordance with distribution of direct personal service time spent on each program involved as recorded for each trip.

Alternatively, such trip records may be accumulated to prorate for an accounting period. For example, if at the end of the period such records showed that a third of the employee's productive time while in travel status was devoted to the State survey program, then the agency would charge a third of the total travel cost to Federal funds (including transportation, per diem, etc.).

In lieu of the proration described above, travel expenses for employees performing activities for the State survey program and one or more other agency programs may be prorated in accordance with the proration of the salary costs of the traveler, or in accordance with the general pro rata formula outlined in §4504, as appropriate.

4531B - Training and Conference Travel

(Rev. 1, 05-21-04)

This category of travel includes travel that is not directly related to line operations of certification, consultation, and administration. Examples are travel performed:

- Incident to orientation and basic training of new employees in areas appropriate to activities in the survey and certification program; and

- To meet the needs of experienced employees for retraining.

Also included is travel related to conferences, meetings, training institutes, workshops, and seminars, if agenda material is directly related to survey functions. Travel for such purposes may be funded by CMS in accordance with the guidelines on training contained in §4542.2. Travel expenses related to training are to be included in the "Training" line item on the Form CMS-435, line 11.

4532 - SA Communications and Supplies

(Rev. 1, 05-21-04)

4532A - Communications

(Rev. 1, 05-21-04)

Communication expenses include such items as telephone services, telegraph messages (except such items as are payable on travel expense accounts), postage, postage meter charges, printed stamped envelopes, registry and special delivery fees, insurance charges on fourth class mail, or postage-due charges.

4532B - Supplies

(Rev. 1, 05-21-04)

Supply charges include such expenses as:

- General office supplies such as paper, pencils, folders, unstamped envelopes, clips;

- Non-consumable supplies, such as staplers, pencil sharpeners, file baskets, and books, which do not exceed a $25 cost per unit;

- Printing, duplicating expense, and the cost of procuring forms such as printed or duplicated general office forms; and

- Costs of transportation or shipment of any of the above items.

The $25 cost per unit under non-consumables applies unless a different amount is specified by State law, in which case the amount so specified shall control.

4532C - Basis for Charges

(Rev. 1, 05-21-04)

Communications and supplies should be direct charges if separable and identifiable as to unit cost. These expenses may be charged on a pro rata basis (see §4504) or, if equitable, there may be a combination of both direct charges and pro rata charges. For example, if long distance calls are routed through a switchboard or can otherwise be identified as to program, the State survey program calls can be made a direct charge. Otherwise, all long distance charges should be prorated.

Further, it would not be equitable to charge State survey program for installation and rental of telephones used by the State survey staff and in addition charge a pro rata share of the corresponding telephone costs of other components of the agency.

4534 - SA Office Space

(Rev. 1, 05-21-04)

The cost of office space essential for State survey functions is a proper charge against CMS funds. Such charges may take the form of:

- Rent, service, and maintenance cost in privately-owned buildings;

- Monthly rental charges based on the cost of initial construction or purchase of publicly-owned buildings; and

- Meeting the costs of service and maintenance in lieu of rent in publicly-owned buildings.

In addition, charges may be made for repairs and alterations to either privately or publicly-owned buildings. Payment will be made only for periods of occupancy unless approval is received from CMS for payment for periods of non-occupancy.

4534.1 - Standard of Comparable Rental

(Rev. 1, 05-21-04)

Charges against CMS funds for office space must not exceed the rental rate of comparable privately-owned space in the same or similar locality. Although the rental rate of comparable privately-owned space is not a fixed amount for any particular locality, and the rental rates may vary within a locality as well as between localities, it is expected that a realistic determination of the rental rate of comparable privately-owned space be made. Keep on file the basis and documentation for establishing the rental rate of comparable privately-owned space.

4535 - Rent in Privately-Owned Space

(Rev. 1, 05-21-04)

Charges against CMS funds for privately-owned space, including expenses for services and maintenance, repairs, and alterations, must not exceed the rental rate of equivalent space and facilities in the same or similar locality.

In contracting a lease for privately-owned space, include cancellation or conditional clauses in rental agreements.

The following guides are applicable with respect to the rental of space in privately-owned buildings when renewing an existing lease or when obtaining new or additional space under a lease:

4535A - Cancellation Clause

(Rev. 1, 05-21-04)

When executing or renewing leases, the SA should make every effort to include a reasonable right of cancellation (30 days, if possible) for the State, if such right can be included in the light of rental rates, probable permanency of occupancy, and other pertinent factors. Secure a cancellation clause in all rental agreements covering space for more than one year, if possible.

4535B - Lease Not Exceeding One Year

(Rev. 1, 05-21-04)

When the SA is unsuccessful in securing a cancellation clause, secure leases not to exceed one year’s duration, if possible, with an annual renewal option for an extended period such as 3 or 5 years.

4535C - Consulting RO

(Rev. 1, 05-21-04)

Where neither of the above is possible, consult the RO at least 30 days in advance of the date the lease will be signed.

4536 - Space in Publicly-Owned Buildings

(Rev. 1, 05-21-04)

The following standards apply to charges for office space in a publicly-owned building:

A. Actual Cost - The amount charged for office space in a publicly-owned building must not exceed actual costs over a long-run period. The agency is required to produce records of actual costs for examination, as necessary.

The cost of land may not be included as part of the cost of initial construction or purchase of publicly-owned buildings in determining rental charges. This exclusion is based on the fact that land has no actual physical depreciation. The State would always have the land as an asset long after the building had become obsolete or demolished and value could be realized.

The estimated useful life of the building should be established if depreciation is included as an element of cost. In case the building is vacated before the end of its useful life, past claims for amortization must be adjusted to a reasonable depreciation basis.

B. Cost After Building Amortization - After the initial cost of a building has been amortized, only the costs of service and maintenance may be charged.

C. 75 Percent Rule - The amount charged for office space in a publicly-owned building may not exceed 75 percent of the lowest comparable rental for privately-owned space, unless there are special considerations justifying a greater charge. Use of this standard as an expedient interim measure, in the absence of actual cost data, enables you to claim costs that are not in excess of 75 percent of the lowest cost of privately-owned space without prior review or approval by CMS.

D. Ratio of Charge To Rental Rates In Privately-Owned Space - Experience gained in analyzing the elements of rental rates in privately-owned space shows that approximately 75 percent of the rate represents the expenses of service, maintenance, and depreciation. The portion in excess of 75 percent of the rental rate of comparable privately-owned space generally represents taxes and profit on investment that would ordinarily accrue. Therefore, whenever a charge is made for space in a publicly-owned building that is not in excess of 75 percent of the

lowest cost of comparable privately-owned space in the same or similar locality, it may be assumed that such charge is reasonably related to the expense of service, maintenance, and depreciation. The reasonable relationship of such charges to actual costs over a long-run period, however, would be subject to verification.

When a monthly rental charge based on the cost of initial construction or purchase of publicly-owned buildings exceeds 75 percent of lowest comparable rental for privately-owned space, or when the cost of service and maintenance in lieu of rent in publicly-owned buildings exceeds 75 percent, obtain prior approval from CMS.

E. Charge Based on Cost of Initial Construction or Purchase - When rental charges are based on costs of initial construction or purchase of a publicly-owned building, and such charges exceed 75 percent of the lowest comparable rent for privately-owned space, prior to acquisition or occupancy of the space, the SA submits justification for review and approval by CMS.

F. Charges Based on Meeting Cost of Service and Maintenance - When the total charges for service and maintenance in a publicly-owned building exceed 75 percent of the lowest comparable rental for privately-owned space, the SA must submit, prior to its claim, the following data for review and approval by CMS:

- Total useable floor space and the amount of space allocated to the State survey program unit;
- Total costs of service and maintenance and the portion to be charged to CMS funds;
- The elements of cost; and
- The rental cost of comparable privately-owned space, with at least three statements of appraisals.

4537 - SA Repairs and Alterations

(Rev. 1, 05-21-04)

Charges may be made for repairs and alterations in privately-owned or publicly-owned space necessary to maintain proper facilities for efficient administration of the State survey unit.

4537A - Maintenance Repairs

(Rev. 1, 05-21-04)

Maintenance repairs such as painting, repairs to plaster, patching roofs and minor repairs to doors, elevators, electrical equipment, etc., may be included in the rate for service and maintenance.

4537B - Major Repairs and Replacements

(Rev. 1, 05-21-04)

Major repairs and replacements, such as structural changes in buildings, new roofs, new heating systems, etc., may be amortized over a period of years provided the total cost for space on an annual basis does not exceed lowest comparable rental, or in the case of public owned buildings, 75 percent of lowest comparable rental for privately-owned space. If the cost is amortized, the repairs and alterations must be of a permanent nature. Repairs and alterations that remain the property of the agency can usually be classified as moveable equipment.

4537C - Alterations

(Rev. 1, 05-21-04)

Normally, quarters completely adequate to the agency should be obtained from the lessor, and the cost of necessary alterations borne by the landlord. However, where the landlord is unwilling to bear the cost of necessary alterations, CMS funds can be authorized to meet the cost of alterations provided the proposed alterations are needed for better utilization of the space, and the improvements are not obligations of the lessor under the terms of the lease. In some situations, lessors will not agree to make necessary alterations but offer space at a relatively low rental rate. In such cases, the agency may be able to negotiate an arrangement under which the lessor would make necessary alterations and the agency would amortize the cost by an increase in rent for a stipulated length of time. Before agreeing to an arrangement providing for repair or alteration, an agency should first secure approval from the RO.

4538 - SA Identifiable (Direct) Costs

(Rev. 1, 05-21-04)

An SA that is locating program personnel in extra identifiable space should charge CMS funds for the cost of such space. Where State survey program personnel share space with the agency's regular personnel, the cost of such space shall be apportioned between the programs. Apportionment is based upon a proration plan submitted by the SA and approved by CMS. The approved method applies only to rental fees paid for locations

where State survey program personnel share occupancy. Bases for prorating rental costs should be reappraised when changes in physical facilities or other conditions results in inequitable cost sharing. The SA is required to submit a rental cost apportionment plan each year as part of the budget documentation. Approval of the budget constitutes approval of the plan of apportionment.

4539 - SA Office Maintenance

(Rev. 1, 05-21-04)

A - Definition

Office maintenance includes services such as light, heat, time clock and water service, towel and janitor service, and machine repair service prorated on the same basis as rent, provided such services are not already included in rental costs.

B - Basis for Charges

If associated office maintenance cost, in whole or in part, is included in a rental contract, it need not be separated but note the inclusion. Maintenance costs that are not included in rentals may be charged on the same basis as rental costs.

4540 - SA Equipment

(Rev. 1, 05-21-04)

4540A - Definition and Quality of Office Equipment

(Rev. 1, 05-21-04)

Items that are of a non-expendable nature, that is, have a life expectancy of one year or more and a probable resale, salvage, or trade-in value, are classified as office equipment if they have a unit cost in excess of $25. However, if State law specifies a different amount, the amount so specified shall apply. The quality of items should not exceed the quality of similar office equipment in general use in other offices of the agency.

4540B - Title to and Accountability

(Rev. 1, 05-21-04)

Title to and accountability for office equipment purchased for State survey program purposes, or for shared use with other State or Federal programs, shall rest with the State. However, the purchase price(s) of individual pieces of office equipment may be shared with other State and/or Federal programs. Where the costs of equipment are prorated between Medicare and other programs, the same proration must be used in crediting

residual value to the Medicare program of all disposed equipment. Where Medicare funds are used to fully fund equipment, 100 percent of the residual value must be credited to Medicare.

4540C - Purchase of Equipment

(Rev. 1, 05-21-04)

1 - State Practice

For equipment purchased for the State survey program, follow established State law or regulations for procurement of equipment.

2 - Purchases Related to Budget Process

Funds for equipment purchases will be requested by SAs and approved by CMS as part of the budget process. The SA should anticipate the bulk of its equipment needs for the budget period during pre-budget planning, and request needed equipment in the budget submittal. To estimate equipment needs, the SA should examine the condition of equipment on hand, and consider any proposed staff increases.

The total expended for equipment during a budget period cannot exceed total funds allocated for equipment for that period without prior approval of the RO. Budget requests should, therefore, include items which were approved in the prior budget period but which will not be paid for in that period.

3 - Items Deleted by CMS

After reviewing an SA's estimate for equipment, CMS may delete an item or restrict the purchase of such an item. When CMS deletes an item, the SA may submit another request with added supporting information. However, unless the restriction is removed, the item cannot be purchased with Federal funds.

4 - Purchase of Items Not Included in Budget Submittal

Although the SA is expected to anticipate the bulk of equipment needs, occasionally a need for equipment that was not included in the budget submittal may arise. The SA must receive approval of the RO, before purchasing such items of equipment. However, if sufficient uncommitted funds are available, the SA may purchase items not included in the budget approval without prior RO approval when the unit cost of the item is $50 or less, and the item is of a kind approved in any previous budget period, e.g., tables, chairs, coat racks. Such items should be listed and identified in the equipment schedule submitted at the end of the quarter in which purchased.

5 - Reporting Equipment

The SA is required to maintain an inventory of equipment following usual State inventory practices, and make an annual physical count of equipment items for comparison against the inventory records. In the event of equipment loss and/or substantial damages due to theft, fire or weather, the SA submits a statement concerning such losses to the RO as soon as possible.

4540D - Rental of Equipment

(Rev. 1, 05-21-04)

Situations may occur where it will be advisable to rent certain office equipment instead of purchasing it. Providing rental of office equipment is not contrary to State law or regulations, expenditures for such rental are considered "necessary" if:

- The rental is for a short period of time;
- The equipment is not available for purchase (e.g., leased telephone lines, electrostatic photocopy machines); or
- Proof that renting rather than purchasing an item of equipment is advantageous in terms of cost.

The SA secures prior approval of the RO if it wishes to rent equipment for more than 90 days.

4541 - SA Retirement and Social Security

(Rev. 1, 05-21-04)

A - Retirement Contributions

Retirement contributions include the SA's cost (not employees' share) of contributions to retirement funds such as State retirement, social security, etc.

B - Prorating Costs

Where the SA prorates the personal services costs of State survey personnel, the retirement costs for these personnel are to be prorated.

4542 - Other SA Expenses

(Rev. 1, 05-21-04)

Other expenses include expenditures which can be properly charged to the State survey program, but which have not been provided for in any of the preceding classifications. Examples of such items are discussed below by category.

4542.1 - Consultants Expenses

(Rev. 1, 05-21-04)

Consultant services are generally defined as being furnished by persons who are not State employees, but who will be used on a part-time, temporary, or fee-for-service basis to provide needed skills to the State survey program. State practice will be the determining criterion in distinguishing between consultants and part-time personnel for purposes of allocating charges to the State survey program.

4542.2 - SA Expenses for Training of SA Personnel

(Rev. 1, 05-21-04)

The cost of training personnel engaged in title XVIII and title XIX survey activities is chargeable to the State survey program when the training is related to the State's responsibilities for survey and certification activities.

Training includes attendance at job-related meetings, conferences, seminars, workshops, or training courses. Training which is considered related to the SA's responsibilities includes attendance at meetings, courses, etc., where the subject matter concerns one or more areas in the certification requirements related to appraising the activities of a health facility. This may include areas such as medical records, dietary services, infection control, etc. Other training considered related to the SA's responsibilities includes attendance at professional meetings that enable individuals in the various health disciplines who are engaged in titles XVIII and XIX to stay abreast of pertinent developments affecting the inspection and approval of health facilities. Examples of professional meetings at which attendance could possibly be funded, subject to the considerations outlined here and in succeeding paragraphs, are the annual meetings of the *Association of Health Facility Survey Agencies (AHFSA),* American Hospital Association, American Public Health Association, American Dietetic Association, and similar national or regional organizations.

4542.2A - Funding

(Rev. 1, 05-21-04)

The CMS will fund the entire cost of such approved training of full-time employees and generally will pay a proportionate share for the training of part-time employees, e.g., 50 percent for employees who work one-half time on State survey activity. The State should include the cost of travel relating to training in the dollar figure requested for training. However, with specific justification, where the training meeting or course is primarily concerned with subject matter that directly relates to the SA's responsibilities in carrying out survey and certification activities, CMS will fund the entire cost of training of part-time employees. All funding for training is subject to the following considerations:

- Out-of-State attendance must be in accord with established State rules and regulations (**NOTE**: When Federal requirements mandate that the training is necessary, a State's travel policy for out-of-State travel is not an excuse for non-participation in the Federal training);

- Federal funds may not be used for attendance at any meetings, if the attendee is paid by the sponsoring organization for attending, for speaking, or for rendering other services in connection with the meeting; and

- Attendance will not significantly impair progress of certification activities.

4542.2B - Requesting Approval

(Rev. 1, 05-21-04)

Request funds for conferences and short-term training activity in the annual budget submittal. Activity of this nature that has not been provided for in the approved budget must be approved by the RO on a case-by-case basis.

At a State's request, CMS will include a dollar authorization for short-term training activity over and above the cost of attendance at CMS-sponsored meetings within the funds approved for each fiscal year. This authorization covers travel, per diem, admission fees, and any other costs related to attendance at the meetings.

Justification for the request, other than the relationship to professional staff-years, is not required provided that the total amount requested does not exceed the approved budget. (If the agency believes it necessary to exceed the allotment, see Subsection C below.) Up to the limit of funds approved in response to such a request, the SA can make expenditures for short-term training activities without consulting the RO for specific authorization provided that all of the following conditions are met:

- No single meeting will be attended more than five working days;

- The proposed attendees are professional State employees who regularly perform State survey functions;

- The training is related to SA responsibilities as defined at the beginning of §4542.2; and

- A State can not charge a higher percentage of the cost of attendance by part-time employees than the percentage of time they devote to the State survey program, as indicated by the percentage of the employee's salary reported on the State Survey Agency Budget/Expenditure Report (Form CMS-435) for the most recent complete calendar quarter.

If the employee came on duty during that quarter or later, the SA charges the percentage applicable to the employee in the budget approval. The SA ensures that there is adequate documentation of every expenditure following State practice, for subsequent audit.

Where one or more of the preceding conditions are not met with respect to any particular meeting, the SA furnishes detailed justification as explained in Subsection C below.

Authorization of funds for short-term training is in addition to the cost of attending any meetings called by CMS. The SA should consult the RO for budget information about proposed CMS meetings as part of the process of preparing the budget submittal.

4542.2C - Justification for Attendance

(Rev. 1, 05-21-04)

Where it is necessary to furnish detailed justification to the RO for attendance at short-term meetings, either in the original budget or later in the fiscal year, e.g., the criteria in Subsection B,

Above, will not be met, or the allotment has been exhausted, the SA provides the following information:

- Name and position title of each person proposed for attendance;

- A list of previous out-of-State training meetings attended by each proposed attendee during the current fiscal year (other than CMS-sponsored meetings) which were charged to Federal funds;

- Whether each proposed attendee is full-time or part-time. If part-time, the SA provides the percentage of time charged to State survey activities on the most recent Quarterly Expenditure Report (or for a new employee, the percentage approved in the budget) and the percentage of costs the SA proposes to charge to

the State survey program. If the latter percentage is higher, the SA includes justification explaining how the meeting or course directly relates to the employee's State survey activities or, where appropriate, showing how the percentage of the employee's time reflected in the most recent Quarterly Expenditure Report is not indicative of the time the employee regularly devotes to the program;

- An itemized listing of proposed expenditures for attendance, including travel, per diem, and admission fees; and

- Name, location, and dates of the meeting, the subject matter on the agenda and the name and address of the sponsoring organization. Where the description of the subject matter does not clearly establish that the subject matter relates to SA responsibilities, it includes an explanation of how the subject matter relates to the survey and certification process.

4542.2D - Fiscal and Reporting Considerations

(Rev. 1, 05-21-04)

This pertains to the amount requested for travel costs of such activity. The total amount approved and expended is shown on line 11 of Form CMS-435. The amounts reported as expended need not be broken down by specific meetings or conferences. However, the SA keeps detailed records of all expenditures for regular audit purposes.

4542.2E - Educational and Training Leave

(Rev. 1, 05-21-04)

Educational leave is leave granted for specialized professional or technical study in an accredited educational institution. Training leave is leave granted to an employee for attendance at short-term courses that will run longer than five working days, outside the agency. Approval of educational or training leave can only be granted if it is for purposes related to carrying out SA survey responsibilities. Additionally, State rules and regulations and practice must permit taking of leave for such purposes.

Approval of training or educational leave is claimed in advance from the RO. Such proposals are considered individually, based on the specific circumstances involved. Requests are to include the following:

- Employee's name, type of appointment held, position and grade, length of service with the SA, previous experience and education;

- Description of any other specialized training or courses taken by the employee within the previous 24 months;

- Name and location of training institution;
- Title and description of training in sufficient detail to demonstrate its scope, content, and how it relates to the SA's survey and certification responsibilities;
- A statement indicating how this training will benefit the employee's work and improve the agency's activity;
- The training period, showing the number of days and hours the employee will be absent from duty;
- A statement from the supervisor dealing with the ability of the unit to forego the services of the trainee during his/her absence; and
- The cost of tuition, fees, books, in detail.

4542.2F - Agreements by Employees to Continue on Job

(Rev. 1, 05-21-04)

In order to discourage resignation of an employee for whom there has been a considerable expenditure for formal training, some States require the employee to sign an agreement that he/she will remain on the job for a certain length of time (e.g., 6 months) after completion of the training. If State regulation or practice provides for such agreements, after obtaining RO approval for the activity, the SA has the selected employee sign such an agreement.

4542.3 - Miscellaneous SA Expenses

(Rev. 1, 05-21-04)

Items illustrative of this category are bonding and public liability, equipment rental, SA cost (not employee's share) of workmen's compensation, group insurance, unemployment insurance, proportionate share of merit system of civil service charges, etc.

4542.3A - Bonding

(Rev. 1, 05-21-04)

Where a new bond or an amendment to an existing bond is required in relation to receiving and handling Federal funds, the cost of such bond, when borne by the State, or the additional cost attributable to an amended bond is a proper charge.

4542.3B - Public Liability

(Rev. 1, 05-21-04)

An appropriate share of the cost to a SA for protection against financial responsibility for injury to person(s) or property is properly charged to CMS when such expenses are in the form of premiums for public liability or property damage insurance. The cost of awards, judgments, or settlements arising from injury to person(s) or property are not chargeable to CMS.

The share of public liability and property damage insurance costs properly chargeable to CMS, in the case of motor pool or personally-owned vehicles used in the discharge of a State's official business will be proportionate to that share of all agency personnel which is devoted to activities directly concerned with the State survey program.

The other items mentioned above may be prorated or charged directly, as appropriate. If prorated, the method of prorating should be appropriate and acceptable to the State and to CMS. Thus, the costs of workmen's compensation, group insurance, or unemployment insurance would usually be charged directly for employees whose salary costs are prorated in the same ratio as salary costs.

4543 - NAR/NATCEP

(Rev. 1, 05-21-04)

The allowable costs that can be charged to the Medicare State certification program for activities involving NATCEP testing are outlined in §1819(e)(1) and (2) of the Act. These costs relate to the State requirement to specify and review NATCEPs together with establishing and maintaining a NAR. The State is required to conduct these activities as part of its §1864 agreement as authorized by §1864(d) of the Act. The actual training and competency evaluation testing of nurse aides is not paid under the §1864 agreement, and therefore is not payable as part of this agreement.

All expenses incurred for title XVIII-only NATCEPs and the NAR are to be reported on Form CMS-435 as a separate line item under Miscellaneous. The Medicare survey and certification budget allows sufficient funds for this purpose.

Expenses incurred for title XIX-only facilities for NAR/NATCEP are considered administrative costs and are to be reported on the "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program," Form CMS-64. There are no provisions in the survey and certification budgets for these expenses.

Costs incurred in joint title XVIII/XIX facilities for NAR/NATCEP are to be split 50-50. Report expenses incurred for title XVIII on Form CMS-435 and expenses for title XIX on Form CMS-64.

4544 - LTC Facility Workload (SNF/NF)

(Rev. 1, 05-21-04)

The certification requirements for SNFs and NFs in the Medicare and Medicaid programs are virtually identical. The same staff must perform the survey activity relating to SNF/NFs. This ensures that interpretation of the regulations to the provider remains consistent regardless of program participation. In addition to surveying SNFs, the same staff may survey ICFs/MR for the Medicaid program in order to consolidate survey activities being performed for both programs.

The Federal share of the costs of the survey and certification activities and follow-up visits related to surveys of nursing homes participating in both titles XVIII and XIX are to be divided equally by the two programs. FFP in the costs for each program are to be in accordance with regulations pertaining to the respective program. Costs of survey and certification activities and follow-up visits related to surveys of ICFs/MR are to be chargeable entirely to title XIX in accordance with Federal regulations.

The costs of activities performed by this survey staff for purposes of the State licensure program or any other State program must be borne entirely by the State. The SA maintains records to reflect the costs of these activities. Time records having prior approval by the RO are used to support the actual charges made to either the Medicaid or Medicare program.

Since a portion of the survey and certification costs for Medicaid continues to be borne by the State, it is necessary that the budget and activity plan be submitted to the SMA for review and approval. This procedure will also assure proper coordination and scheduling of survey and certification activities by the SA with the medical review and UR responsibilities of the title XIX agency.

The Budgetary Process

4600 - SA Budget Request

(Rev. 1, 05-21-04)

The annual funding allocation cycle begins in June/July of the preceding FY when CO issues a budget call letter to the ROs and SAs, providing guidelines and program priorities to assist in the SAs annual budget request preparation and ROs with State budget negotiations.

Beginning in FY 2003, State Agencies should submit initial budget request documents and forms in accordance with instructions contained in the current State Survey and Certification Budget Call Letter. Furthermore, once a Fiscal Year budget allocation has been provided, the SA will be requested to prepare a Form CMS-435 and supporting budget forms via the State Survey and Certification and CLIA automated reporting system. The Automated Reporting System is a web-based application provided by CMS. The automated reporting system replaces the system of manually preparing and submitting reports. Supporting documentation is to be provided via e-mail, or common carrier.

In the event a congressional appropriation is not passed at the beginning of the Federal FY (October 1), Congress approves a continuing resolution that allows work to continue at the prior year funding level.

A - Expenditure Categories to Be Shown

The SA budget request should be a detailed estimate of State survey program costs for both LTC and non-LTC requirements. Such costs are to be classified according to the category of proposed expenditure. The estimate of each category must be completely explained with respect to program objectives, the State Agency's plan of operations, and the method used to compute the request. Funds provided to agencies as a result of the budget request are to be used only for necessary expenses. (See §4500.) States are free to shift funds from one expenditure category to another, except State surveyor training funds, which may only be re-designated with RO prior approval.

B - Due Date

Each SA is to prepare the budget in accordance with the due date provided by CO to ensure that CMS can complete the budget approval process in time to prevent an interruption to cash flow when one FY ends and the succeeding year begins.

C - Budget Summary

The SAs are to complete Form CMS-435 (see Exhibit 45) State Survey Agency Budget/Expenditure Report and Form CMS-434 (see Exhibit 52) State Survey Agency Workload Report for both non-LTC and LTC requirements. Form CMS-435 is a multi-purpose form (budget request and approvals, expenditures reports, supplemental funding request, etc.) used in Medicare and Medicaid applications. Its various uses are displayed at the top of the form. The SA indicates the specific use of the form by checking the appropriate box. These forms summarize requested funding levels for each category of expense and provide projected workload. The SA budget request must also include documentation as outlined in the annual budget call letter and a Form CMS-1465A (Exhibit 47) - "State Agency Budget List of Positions"; Form CMS-1466 (Exhibit 54) - "State Agency Schedule for Equipment Purchase," and any other form in accordance with instructions contained in the current State Survey and Certification Budget Call Letter.

D - Line Item Budget Justification

Explanations for specific categories of expense are essential in both budget preparation and subsequent analysis. Therefore, the budget request must contain complete rationale regarding each line item. Line item justification should consist of narrative statements providing specific rationale for budgetary needs.

4605 - Developing SA Budget Justification

(Rev. 1, 05-21-04)

The following instructions are provided to assist the SA in the development and preparation of its budget request. (§§4605-4628.)

A - Base Data

The basis for estimating line item expenditures is the State's projected workload together with historical costs. Consideration should be given to additional workload projected in the next Federal FY, such as newly established provider groups and initial inspections for facilities requesting program participation. Prior year expenditures may serve as a guide in computing expected increases or decreases in each line item for the budget year.

B - Line Item Justification - General

Projected workload together with the impact of expected program developments and emphases, the State's own plan and historical costs are to be translated into specific line item justification. The SA should develop the budget estimate using these factors as a guide.

C - RO Assistance

RO personnel are available to assist the SAs in preparing budget requests. The SA should consult with the RO on any problem or questions as early as possible in the budget preparation process.

4610 - Line Item Justification for SA Personnel Services

(Rev. 1, 05-21-04)

A - Full-Time Positions

The budget justification describes the organizational location of the staff and how it functions in relation to the workload included in the work plan. The SA lists the positions on Form CMS-1465A (see Exhibit 47) in accordance with §4612. The SA completes a separate Form CMS-1465A listing the positions requested for title XVIII non-LTC, title XVIII LTC, and title XIX LTC. The SA prepares three Forms CMS-1465A with its annual budget request.

B - Approval To Exceed Authorized Full-Time Staffing

The RO will place limitations on the number of full-time equivalents (FTEs) charged to Medicare program budgets so the SA cannot exceed the approved full-time staff without prior RO authorization. This ensures that ROs can track onboard surveyor disciplines and analyze fund requirements for support of additional staff. RO recommendations for staffing under the Medicaid program represent Federal estimates of required survey personnel.

C - Part-Time and Temporary

The SA is authorized to augment the full-time staff with the appropriate professional specialties and other positions required to perform the State survey activities and to secure the services of such persons on a part-time or temporary basis. Specific rationale for the need for such positions and skills are required in the line item justification, relating these manpower needs to activities and staff-days noted in the work plan. The SA details the basis for determining charges for part-time or temporary services in the line item justification and lists the positions requested on Form CMS-1465A in accordance with instructions stated in §4612.

4611 - Line Item Justifications for SA Direct and Indirect Costs

(Rev. 1, 05-21-04)

In making the entries for items under non-personal services (Other Direct Costs, lines 5 through 14, of Form CMS-435), the SA is required to justify the amounts approved by

providing the rationale developed for each line item separately, using base period data and format as described in §4605. Specific guides and criteria are listed below.

A. Retirement Contributions and Fringe Benefits

The SA enters the estimated total of the employer's share of social security taxes, State retirement system(s) contributions and other fringe benefits. Also, the SA indicates the percentage used to determine the level of funding for Retirement and Fringe Benefits.

B. Travel

The SA includes the estimated travel costs of its personnel, including, where appropriate, per diem or subsistence in lieu of per diem, applicable to the State survey program. The SA derives estimated costs based on provisions of State law, regulation and administrative procedures applicable to travel of State employees. The SA indicates in the budget estimate expected number, type and extent of trips, and purpose. For out-of-state travel, the SA indicates the number of trips, the purpose, and basis for charges to the State survey program. The SA includes the basis for charges for all out-of-State travel other than to meetings called by CMS.

C. Communications

In the budget estimate, the SA breaks out e-mail, telephone, telegraph, postage, and other communications separately.

D. Supplies

In the budget estimate, the SA breaks out all major items of supplies, i.e., any supplies comprising 20 percent or more of the total cost of supplies.

E. Office Space

1 - Agency In Identifiable Space

Analysis of base period expenditures and the budget estimate must contain these elements for each location: total rental costs, number of square feet of space, cost per square foot, and services included in rental. The SA identifies office space that is State-owned.

2 - Office Space - Agency In Shared Space

SA analysis of base period expenditures and the budget estimate must contain these elements:

- Total cost of space to the agency;

- Basis of proration;
- Office locations of SA staff; and
- Estimate of square feet allocated to the State survey program. The SA identifies State-owned space.

3 - Office Maintenance

In the budget estimate, the SA breaks out the major items of expense, e.g., light, heat, janitorial service, office equipment repair. If office maintenance, in whole or in part, is included in the SA rental contract, the SA notes this fact and the amount need not be separated.

F. Equipment

The SA enters costs of equipment to support specific personnel positions such as desks, chairs, typewriters, computers and computer-related equipment, file cabinets, tables, and other machines (fax machines, photocopiers, etc.) that are necessary for program operational, administrative and management needs. In addition to line item justification, the SA documents the budget estimate through use of Form CMS-1466 (Exhibit 54) for both LTC and non-LTC requirements. (See §4614.)

G. Training

The budget estimate should provide for the cost of training SA personnel. The SA includes the cost of travel and per diem associated with training sessions.

H. Consultants

The SA provides the estimated cost of consultants who are not State employees, but who are used on a part-time, temporary, or fee-for-service basis.

I. Subcontracts

The SA provides the estimated cost of subcontracts when part of its responsibilities are assigned to another State or local public agency. Subcontract costs attributable to State survey activities (e.g., State Fire Marshal) are allowable and payable at the FFP rate established for surveyors, i.e., 100 percent Federal payment for Medicare and 75 percent/25 percent FFP for Medicaid, with the exception of ICF/MRs. The Federal matching rate for ICF/MRs is 75 percent of FFP for salary, fringe benefits, travel and training. All other costs are matched at 50 percent FFP.

J. Miscellaneous

The SA provides the estimated cost of other items, which have not been reported in any of the preceding classifications. Also, the SA enters as a separate line item anticipated cost associated with the NAR and NATCEP, line 14A. (See §4543.)

K.. Total Direct Costs

Calculated sum total cost of all line items outlined here and in §4612.

L. Indirect Costs

The SA provides the rate negotiated and approved by the Director, Division of Cost Allocation and Liaison, DHHS, for use during the budget FY together with the line item base, against which it is applied.

Expenditures included in this category must not be duplicated under direct costs.

M. Total Budget Request

Calculated total of all direct and indirect costs.

4612 - Preparation of State Agency Budget List of Positions, Form CMS-1465a (Exhibit 47)

(Rev. 1, 05-21-04)

A - Usage

This form is applicable for both LTC and non-LTC budgeted positions. The SA prepares a separate Form CMS-1465A of staff years and salaries for title XVIII non-LTC, title XVIII LTC, and title XIX positions. The SA prepares three Forms CMS-1465A with its annual budget request.

B - Heading

The SA verifies the pre-filled official name of the agency and inserts the period for which funds are requested.

NOTE: The SA includes overtime needs for all categories of positions listed, and provides detail justification explanations for the estimated costs.

The SA must not enter positions on Form CMS-1465A, which represents consultants (i.e., personnel who perform services on a fee basis and are not employees of the State). The SA shows funds for such services in Other Direct Costs, line 12 of Form CMS-435.

The SA must not enter positions on Form CMS-1465A, which represents personnel related to NAR or NATCEP. The SA shows funds for such services in Other Direct Costs, as a separate line item in Miscellaneous of Form CMS-435. (See §4543 for instructions pertaining to costs incurred for NAR/NATCEP.)

C - Positions - Column Entries

1. Column (A), Position Title/Name

The SA lists each position and person's name. A full-time incumbent position:

- Will work full-time on the State survey program on a continuing basis;
- Whose time will be subject to cost allocation between State and Federal programs.

Where applicable, the SA indicates after the position title whether part-time (PT) or temporary (T) and subdivides positions into three classifications (surveyor, nonsurveyor professional and clerical) to simplify preparation of totals and for CMS review.

2. Column (B), City Where Located

The SA shows the city where the incumbent is located. If all positions are located in the same city, the SA shows the city on the first line followed by: (all).

3. Column (C), Number of Positions

The SA enters the total number of positions planned for the FY shown on the corresponding line of column (A).

4. Column (D), Staff-Years

The SA enters the total staff-years to be worked during the FY by the incumbent(s) for the position shown on corresponding line of column (C). For full-time positions whose incumbents are on duty at the beginning of the fiscal year, this is the same number as shown in column (C). The time shown in staff years for full-time positions should be the time that it is anticipated will be spent in that program for which the budget request applies. The SA determines staff-years for new full-time positions based on the quarter the incumbent is expected to enter on duty, as follows:

Entrance Quarters	Staff Years
October-December	1.00
January-March	.75
April-June	.50
July-September	.25

The staff-years shown for part-time or temporary positions are derived by multiplying the percentage of time to be applied by the number shown in column (C).

5. Column (E), Funds Required

The automated system calculates the total funds required by multiplying column (D) Staff Years and column (F) Annual Salary.

6. Column (F), Annual Salary

The SA enters the annual salary for each full-time position presented in column (A) including part-time and/or temporary positions.

D - Totals

After completion of column entries, the automated system tallies the salaries of all positions. These salaries should then be entered into the appropriate section on Form CMS-435, Salaries; line l and 2.

E - Certification: Date, Signature, and Title

The automated system dates the Form CMS-1465A. The SA certifying official enters their name and title.

4614 - Preparation of State Agency Schedule for Equipment Purchase, Form CMS-1466 (Exhibit 54)

(Rev. 1, 05-21-04)

A. Usage

This form is applicable for both LTC and non-LTC equipment requests and purchases. The SA prepares a separate equipment purchase schedule for title XVIII non-LTC, title XVIII LTC and title XIX LTC equipment and prepares three separate Form CMS-1466s with its annual budget request.

B. Heading

The SA inserts official name of the agency, indicates which program and facility type (type XVIII LTC, XVIII non-LTC, or XIX LTC) and enters the name of the State in the designated space and the period for which equipment funds are requested. When equipment is actually purchased, the SA prepares a revised Form CMS-1466 with the next quarterly expenditure report.

C. Column Entries

1. Column (A), Description of Equipment - The SA enters the items of equipment requested or reported as purchased. Note with an asterisk or other notation items previously approved by the RO, but which are being re-budgeted. On separate form, the SA explains why the purchase was not completed in the prior budget period.

2. Column (B), Number of Items on Hand - The SA lists the number of items on hand in the State survey unit as of the time the form is being prepared which are similar to the item requested. If a new and different item, enter zero ("0") or leave blank in this column.

3. Columns (C) and (D), Number of Units (Additional) or (Replacement) - The SA lists the number of units in the appropriate column, (C) or (D).

4. Column (E), Unit Cost - The SA enters the unit cost for each item listed in column (A).

5. Column (F), Gross Cost - The automated system computes and enters the gross cost for each item in column (A) by multiplying the number of units in columns (C) or (D) by the unit cost, column (E).

6. Column (G), Trade-In Value If Replacement Item - The SA enters the trade-in value for any replacement item presented in column (A).

7. Column (H), Net Cost - Calculated value by subtracting column (G) from column (F).

D. Total Net Cost of Equipment

The automated system sums all amounts shown in column (H). The SA should enter this value on Form CMS-435, line 10, in the appropriate column.

E. Certification: Date, Signature, and Title

The automated system dates the Form CMS-1466. The SA certifying official enters their name and title.

4625 - Preparation of State Survey Agency Budget Request - Non-Long-Term Care, Form CMS-435 (Exhibit 45)

(Rev. 1, 05-21-04)

A. Usage - Form CMS-435 is a multi-purpose, multi-program form. The SA can include its budget requests for title XVIII LTC and non-LTC, as well as title XIX LTC, on one Form CMS-435.

B. Heading - Automated system inserts the official name of the State agency, enters the appropriate Region and State Code. The SA enters the FY for which funds are requested.

C. Rounding To Next Higher Dollar - In preparing Form CMS-435, the automated system rounds dollar amounts of funds requested for each line item to the next higher dollar.

D. Salaries - Secure totals for professional and clerical staff-years, and money amounts from the accompanying Form CMS-1465A. Place totals in appropriate columns. Separate reporting is required for title XVIII NLTC and title XIX positions. The funds requested to support activities carried out under title XVIII, title XIX and the State are to be based on the proration of staff time determined to be supportable by Medicare, Medicaid, and the State as negotiated with the CMS-RO. (See §4514.)

E. Other Direct Costs - Enters estimates for these categories as developed in the narrative justification. (See §4611.)

F. Total Direct Costs - Automated system adds lines 3 and 15 of the appropriate column.

G. Indirect Costs - Enters the rate and the base against which the rate is charged. (See §4611.) Expenditures included in this category must not be duplicated under direct costs.

H. Total Budget Request - Automated system totals lines 16 and 17 and enters the Total Costs in Line 19.

I. Certification: Date, Signature, and Title - The automated system enters the date for budget request. In the signature space, the SA's certifying official types their name and title.

4626 - Preparation of State Survey Agency Budget Request - Long-Term Care, Form CMS-435 (Exhibit 45)

(Rev. 1, 05-21-04)

A. Usage - Form CMS-435 is a multi-purpose, multi-program form. The SA can include its budget requests for title XVIII LTC and non-LTC, as well as title XIX LTC, on one Form CMS-435.

B. Heading - Automated system inserts the official name of the State agency, enters the appropriate Region and State Code. The SA enters the FY for which funds are requested.

C. Rounding To Next Higher Dollar - In preparing Form CMS-435, the automated system rounds dollar amounts of funds requested for each line item to the next higher dollar.

D. Salaries - Secure totals for professional and clerical staff-years, and money amounts from the accompanying Form CMS-1465A. Place totals in appropriate columns. Separate reporting is required for title XVIII LTC and title XIX positions. The funds requested to support activities carried out under title XVIII, title XIX and the State are to be based on the proration of staff time determined to be supportable by Medicare, Medicaid, and the State as negotiated with the CMS-RO. (See §4514.)

E. Other Direct Costs - Enters estimates for these categories as developed in the narrative justification. (See §4611.)

F. Total Direct Costs - Automated system adds lines 3 and l5 of the appropriate column.

G. Indirect Costs - Enters the rate and the base against which the rate is charged. (See §4611.) Expenditures included in this category must not be duplicated under direct costs.

H. Total Budget Request - Automated system totals lines 16 and 17 and enters the Total Costs in Line 19.

I. Certification: Date, Signature, and Title - The automated system enters the date for budget request. In the signature space, the SA's certifying official types their name and title.

4627 - Preparation of the State Survey Agency Certification Workload Report - Form CMS-434 (Exhibit 52)

(Rev. 1, 05-21-04)

The SA is required to prepare a planned workload report to accompany its budget request for survey and certification activity. The SA:

A. Column (A), Facility Counts

Enters the projected number of facilities at the start of the FY for each facility type listed under column titled Type of Provider.

B. Column (B), Initial Visits

Enters for projected facility type, the number of visits for initial certification surveys.

C. Column (C), Resurvey Visits

Enters for projected facility type, the number of visits for recertification surveys.

D. Column (D), Follow-Up Visits

Enters for projected facility type, the number of visits that the SA makes as a result of finding deficiencies in initial, resurvey, and complaint visits to providers.

E. Column (E), Complaint Visits

Enters for each facility type, the number of visits the SA makes to investigate complaints from beneficiaries, facility staff, etc.

F. Column (F), Total Visits

The automated system totals each facility type, the cumulative number for items, columns B through E.

G. Certification

Form CMS-434 must be certified by an appropriate SA official by typing their name and title in the appropriate space.

4628 - Preparation of Budget Request

(Rev. 1, 05-21-04)

A. List of Materials and Order of Assembly

The SA assembles the budget documents in descending order, as follows:

1. Form CMS-435 and Form CMS-434;
2. State Agency Budget List of Positions, three Forms CMS-1465A;
3. State Agency Schedule for Equipment Purchases, three Forms CMS-1466;
4. The justification arranged in line item order;
5. Any bulky exhibit referred to in the line item justification; and
6. Supplemental documentation as requested in the annual budget call letter.

B. Routing

The SA certified documents are made available to RO and CO in accordance with the due date provided by CO. This will ensure that CMS can complete the budget approval process in time to prevent interruption to cash flow when one FY ends and the succeeding FY begins. The request supporting title XIX SNF/NF, NFs, and ICF/MR workload (forms and narrative justification) should have the concurrence of the SMA. All additional documentation that was requested in the annual budget call letter should be sent the CO/RO.

4629 - Developing Budget Recommendations - RO Procedures

(Rev. 1, 05-21-04)

It is the RO's responsibility to ensure that only necessary and reasonable funding is approved. In negotiations and final recommendations of the SA's budget and planned workload, it is important to ensure that the SA has a full understanding of established CMS policies. The following items are to assist the RO in the final recommendations of the SA's budget.

A. Base Data

The number of facilities the SA is required to survey and the staff-years required to accomplish the survey activity is the basis for approving the line item budget. These include any additional workload projected in the ensuing FY, e.g., newly-established

provider expenditures for the 12-month period ending March 31 may also serve as a guide in determining expected increases or decreases for each line item for the budget year. The RO will inform the State that funds provided as a result of the budget approval can only be used for the necessary expenses in carrying out the survey and certification activity.

B. Significance of Categorical Budget Recommendations

The budget recommendation is a detailed concurrence or revision to State estimated survey program costs. The RO negotiates the budgets by line item, according to the category of the proposed expenditure. The RO explains the adjustment of any category with respect to program objectives and the methods used to compute each amount.

The CMS places strong emphasis on training of State surveyors. Therefore, the budget approval must include the request that States not reprogram training funds without prior RO approval.

C. Line Item Justification

The projected workload, together with the impact of expected program developments and emphasis, the SA's own plans, and the experience of the 12-month period ending March 31 are the primary factors to consider when approving the line item budget. The RO considers these factors in its approval of the SA's budget request. The rationale for any change by the RO of the State's proposal should where possible:

- Show the revised estimate;
- Explain the rationale for the change; and
- Provide the basis for computing the revised estimate.

D. State Agency Budget List of Positions (Form 1465(A) - RO Recommendations

The RO will review and validate the list of positions to determine if the staff-years and salary costs reported on Form CMS-435 are correct. A limit on the number of full-time equivalents chargeable to the Federal program budgets will be set by the RO. The RO is responsible for monitoring all staffing and analyzing State requests and requirements for additional support staff. No costs associated with the NAR/NATCEP are to be included on this form. All costs relating to NAR/NATCEP are to be reported as Miscellaneous, line 14A. (See §4543.)

E. State Agency Schedule for Equipment Purchases (Form CMS-1466) - Recommendations

This form has a two-fold purpose: It is used when requesting budget approval of equipment purchases, and it is to be completed and notification given to the RO when an actual purchase is completed. The RO reviews the list for the necessity of items requested, comparing it to inventories of the State's existing equipment.

4630 - Notification of Approval

(Rev. 1, 05-21-04)

A. Explanation of State Survey Agency Budget Notice of Approval, Form CMS-435 (Exhibit 45)

This form is used to notify SAs of the amounts approved for the FY. It is the same form as the budget request, hence, no explanation of the entries is necessary.

B. Notification of Availability of FFP

ROs recommendation State estimated FFP Medicaid requirements on the same budget form (Form CMS-435) which the State provides to estimate State and Federal financial requirements. Since this is the same form, no explanation of the entries is necessary. The annual approval for Medicaid is for planning purposes and is non-binding. State-provided quarterly estimated requirements and actual expenditures are the final determinants for Medicaid funding. These requirements are covered under §4636.

C. Line Item Limitation on Use of Funds

To provide flexibility to the SA, line item controls are generally not placed on amounts approved for a FY, with the exception of training. However, under certain circumstances, specific controls may be imposed on expenditures through the comments attached to the budget approval documents.

D. Due Date

The CO will forward notice of budget approval to the RO who in turn will forward the original documents to the State Agency.

The RO assembles the budget documents as follows:

- Three Forms CMS-435;
- Form CMS-434;

- Form CMS-1465A. Separate forms are required for Medicare non-LTC and LTC and Medicaid LTC;

- Form CMS-1466; and

- Other documentation as required in the annual budget call letter.

4636 - RO Distribution of Approved Funds

(Rev. 1, 05-21-04)

The RO forwards the SA's recommendation funding to CO for processing. The CO is responsible for the execution and oversight of the SA's approved Medicare and Medicaid budgets for survey and certification activity.

The CO prepares an internal document quarterly for each SA with an approved Medicare title XVIII budget authorizing funds upon which the State may draw. The amount is one-fourth of the SAs approved budget. This information is forwarded to the Division of Accounting (DA) in CMS for processing. The DA enters the authorization in the Payment Management System. (See §4636.l.)

Medicaid title XIX quarterly grants are prepared and issued to States with approved plans for survey and certification activity in accordance with 42 CFR Part 430.30. The amount of a grant is based on documents provided to the CMS-RO (estimate of Federal funds required with certification of States matching funds available and prior quarter actual expenditures). The CMS-RO reviews and approves the certified documents and provides notification to CMS-CO for processing. CO prepares a computation worksheet and two-page grant award letter authorizing the release of funds to the SA. The original award is mailed to the SA and a copy is forwarded to the DA in CMS for entry into the Payment Management System.

4636.1 - Disbursement of Approved Funds

(Rev. 1, 05-21-04)

The Public Health Service (PHS), Office of Resource Management, Division of Payment Management is responsible for the disbursement and tracking of Medicare and Medicaid survey and certification funds. As CO authorizes funding levels, they are entered into the automated Payment Management System for SAs to draw upon as funds are needed. Each SA interacts directly with the Division of Payment Management in the disbursement of funds.

The SA should address any questions regarding policies and procedures to be followed regarding the disbursement of Federal funds as follows:

Health and Human Services
Program Support Center
Financial Management Services
Division of Payment Management
Post Office Box 6021
Rockville, Maryland 20852

(301) 443-1660

4640 - Need for Additional Title XVIII and Title XIX Funds

(Rev. 1, 05-21-04)

At the end of each quarter, the SA should analyze current rate of expenditures for the title XVIII non-LTC and LTC survey activities. The SA advises the CMS-RO as soon as possible if a supplemental budget may be necessary. State Agencies should take full advantage of line-item flexibility (see §4630) to stay within their approved budget before requesting additional funding.

Supplemental budget requests are not necessary for title XIX survey and certification activities. The SA will be paid at the appropriate FFP rate for the necessary and reasonable costs incurred during the FY for survey and certification activities relating to Medicaid title XIX.

4640.1 - Title XVIII Supplemental Budgets

(Rev. 1, 05-21-04)

The SA is requested at the direction of the CO or RO, to review Medicare title XVIII non-LTC and LTC survey activity requirements for the balance of the FY. If additional funds are required, the SA prepares and sends a supplemental budget request memorandum to the RO. The memorandum should include the total amount of supplemental funding required and detailed justification supporting the request. The SA should allow sufficient time for the RO to review, provide recommendation, and notify CO for processing of the supplemental budget request. Please note that CO will make all final decisions regarding supplemental budget requests. Furthermore, the limit on expenditures for a FY is the SA's approved budget. Any expenditures reported on the cumulative Form CMS-435 above the approved budget amount will be treated as a supplemental request. All supplemental funding is subject to availability of funds.

4642 - RO Monitoring of SA Fiscal Budgets

(Rev. 1, 05-21-04)

It is the responsibility of the RO to monitor the SA's performance in adhering to the policies and established guidelines. Specific instructions are provided to the SAs regarding the fiscal management of the funds provided for survey and certification activities.

A. Mid-Year Review

The RO advises the SAs to review their rate of expenditures to ensure that the Medicare title XVIII budget approval will not be exceeded. (See §4712.) Funds that exceed the SA's approved budget at the end of the FY may not be paid.

B. Supplemental Budget Requests

At the direction of the CO, the ROs should instruct the SAs to review their fiscal requirements for the balance of the FY. If it appears that additional funds will be required, the SA should prepare a supplemental budget request. The request for additional funding must be prepared in the same manner as the initial SA budget request, on Form CMS-435. The RO analyzes the State's request and provides a recommendation for approval to CO for supplemental funding subject to the availability of funds.

C. Medicare Fiscal Year Cumulative Report (Form CMS-435)

The SAs are to prepare and certify a cumulative FY title XVIII Medicare expenditure report no later than 60 days after the close of the FY and provide notification to the RO. A cumulative expenditure report for the Medicaid program is not required.

D. NAR/NATCEP

The State is required to conduct these activities as part of its §1864 Agreement as authorized by §1864 of the Act. Refer to §4543 for the allowable expenses. The Survey and Certification Program does not pay expenses incurred for the training of nurse aides.

E. State Licensure Costs

The CMS' policy is that total survey costs must be allocated to each benefiting program or activity to determine the payable costs for that program or activity. Knowledge of the State's licensure requirements is necessary in negotiating the budget to ensure that the State's share is equitable and in line with current policy. For example, if a Medicare survey covers 100 standards and the State has adopted 50 of these standards as licensing standards, Medicare would cover 100 percent of the survey costs of the 50 Medicare-only standards and the State and Medicare would equally share the survey costs of the other 50

standards. If the State has any non-Medicare standards, the State must bear 100 percent of the survey costs for those standards. For requirements common to all three programs, the State must pay two-thirds of the survey costs (representing the allocation to State licensure and Medicaid), but receives FFP in the Medicaid one-third share.

F. Cost Sharing for Title XVIII/XIX Facilities

As stated in subsection E above, it is the RO's responsibility to ensure the proper distribution of costs is made by the SA. The RO informs the States of CMS' policy concerning this issue. The SAs may not deviate from this policy. The costs of a survey for a title XVIII/XIX facility must be shared equally between Medicare and Medicaid (FFP applicable to title XIX) regardless of the number of beds assigned to each program. The requirements are the same for both Medicare and Medicaid. Consequently, both programs benefit from the survey.

Financial Accounts and Reporting

The following instructions are provided to assist the SA in the preparation of the Form CMS-435 and Form CMS-434. Please review §§4700 through 4766.

4700 - SA Accounts

(Rev. 1, 05-21-04)

It is the responsibility of the State to ensure that all estimates and reports of expenditures and other reports are prepared timely and in accordance with appropriate budgetary and accounting methods and administrative practices adopted by DHHS.

It is the desire and intent of CMS to accept State practice in the manner in which funds received from the Federal government are handled and accounted for, and in a State's choice of a depository, subject to the general accountability required under Article IX, Cost of Administration, of the §1864 Agreement. However, funds advanced to a State must be identifiable in a State's records. This is usually achieved by use of a separate account. The policies and instructions established by CMS for States' receipt of funding advances and submission of reports have been drafted with a view to following State patterns to the fullest extent possible.

4701 - Supports for SA Expenditures

(Rev. 1, 05-21-04)

The SA must provide, through its accounting and statistical records, support for all expenditures incurred in connection with survey and certification. No particular kind of accounting record, method, or procedure is required, but the State's accounting records and supporting documents must be such as will permit verification by Federal fiscal audit and CMS administrative review of all charges and of the status of advances made to the State.

If a State is receiving grants-in-aid administered by DHHS in connection with its regular program, the accounting and procurement methods and procedures described in the agency's approved plan for such grant-in-aid program are applicable with respect to the agreement to the fullest extent possible.

The State is responsible for securing necessary data from its local or district offices, and ascertaining the validity of all data for budgetary and other purposes.

4710 - SA Financial Reporting

(Rev. 1, 05-21-04)

Beginning in FY 2002, the financial reporting process requires the electronic preparation of all budget requests for State Survey and Certification and CLIA funds through the automated reporting system. The SA prepares a Form CMS-435 for budget submission, supplemental budget requests, and to report quarterly actual expenditures for both the Medicare and Medicaid survey and certification program. The SA indicates the specific use by checking the appropriate box at the top of the form. The year-end cumulative expenditure report for Medicare must also be prepared on Form CMS-435. This form is a multi-purpose, multi-program form designed to capture funds requested, approved by the RO, and expended by the SA for survey and certification activity.

4711 - Cash Basis

(Rev. 1, 05-21-04)

The method of financial reporting recommended is the "cash basis." Thus, the data will be based upon "cash accounting" which requires that charges against CMS funds be entered on the SA books when the formal vouchers (or other documents that are accepted by the State fiscal office for payment) are prepared for transmission to the State fiscal officer for payment.

4712 - SA Limit on Expenditures

(Rev. 1, 05-21-04)

The total amount approved in the State's Medicare title XVIII annual approved budget at the end of the FY shall be the limit on expenditures. The title XIX estimated annual budget is for planning purposes only. The SA is paid the FFP rate for the reasonable and necessary costs incurred for survey and certification activity.

4714 - Periodic Analysis of Accounts

(Rev. 1, 05-21-04)

Since title XVIII survey and certification total expenditures for a FY may not exceed the amount approved for that period, the SA should review the status of accounts not less frequently than once each quarter. This allows observation of expenditure trends in order to avoid over-expenditure or the unrecognized accumulation of a large amount of un-liquidated obligations, and also provide early identification of any need for supplemental funds.

4716 - Cash Balances and Expenditure Authority

(Rev. 1, 05-21-04)

Unexpended funds on hand in the agency at the end of each quarter will be available for expenditure in the succeeding quarter without formal reallotment provided it is in the same FY. Funding authority for the title XVIII Medicare survey and certification activity lapses at the end of each FY. Funds cannot be carried over into the next FY. Funding for the title XIX Medicaid survey and certification activity does not lapse at the end of a FY. Unexpended funds on hand in the agency at the end of each quarter are applied to a future grant award.

4718 - Un-Liquidated Obligations

(Rev. 1, 05-21-04)

SA fiscal controls should provide current information on un-liquidated obligations. For purposes of CMS financial reporting, un-liquidated obligations are defined as bills received, but not yet prepared for transmission to the State fiscal officer for payment, and, obligations incurred for which there is acceptable evidence of a commitment or promise to pay for goods, facilities, or services in any category of expenditure, whether or not the goods or services have been received or a bill rendered.

EXAMPLE:

Equipment that had been ordered, but not paid for (whether or not received) on a semi-annual or annual basis. For example, for an item charged on an annual basis, the un-liquidated obligation reported for the first quarter of the year would represent one-quarter of the estimated annual charge. The un-liquidated obligation reported in the second quarter would represent one-half of the estimated annual charge, etc.

In preparing the Medicare title XVIII year-end cumulative expenditure report, the SA should list un-liquidated obligations on line 20 of Form CMS-435. CO will include this amount in preparing the SA year-end closeout adjustment, providing the cumulative total does not exceed the SA annual budget authority. SAs should adjust line 20 of the cumulative year end Form CMS-435 as the obligations are liquidated.

4719 - Nothing to Report on a Given Line

(Rev. 1, 05-21-04)

The SA indicates the fact that there is nothing to report on a given line by leaving the field blank. The automated system automatically enters a zero (“0”) for blank fields.

4740 - State Survey Agency Quarterly Expenditure Report, Form CMS-435, and State Survey Agency Certification Workload Report, Form CMS-434 – Preparation and Due Date

(Rev. 1, 05-21-04)

Each SA is required to prepare quarterly a Form CMS-435 (Exhibit 45) reflecting actual expenditures incurred for survey and certification activity for both the title XVIII and title XIX programs. The purpose of Form CMS-435 is to report in a categorical listing the expenditures for each quarter and to separate costs according to funding source. (See §§4760 and 4766.) A Form CMS-434 (State Survey Agency Certification Workload Report) must accompany the quarterly expenditure report. Instructions for preparing the accomplished workload are the same as for the planned workload. (See §4627.) The Medicaid State Agency must approve the title XIX expenditures before they notify the RO. The SA is required to prepare Form CMS-435/434 and notify the RO no later than 45 days after the close of each quarter.

4760 - Preparation of State Survey Agency Non-Long-Term Care Quarterly Expenditure Report, Form CMS-435 (Exhibit 45)

(Rev. 1, 05-21-04)

The purpose of Form CMS-435 (Exhibit 45) is to report in a categorical listing the expenditures for each quarter and to separate the costs according to funding source. Because Form CMS-435 is designed to capture the costs of both non-LTC and LTC expenditures by funding source, only one form needs to be prepared quarterly.

A. Heading

The SA checks the box entitled title XVIII State Quarterly Expenditure Report. The SA selects the State agency and the automated system inserts the official name for the agency, and the appropriate Region and State Code. The SA through a drop box selects the quarter and enters the year for budget period covered by the expenditure report.

B. Rounding to Next Higher Dollar

The automated system rounds expenses incurred for each line item to the next higher dollar.

C. Salaries (Non-LTC)

The SA reports staff years and salaries of both professional and clerical personnel (full-time and part-time) on duty during the reporting quarter. Staff-years to be captured here are those that relate to non-LTC activities in the Medicare program. Instructions for reporting staff years and salaries for employees are explained below. The figures reported

in this section should not exceed the number approved by the RO, except where the SA hired in anticipation of a vacancy.

How To Report Staff-Year Totals - In each category (full-time, part-time, professional, and clerical) report the actual total of staff-years worked in the Medicare program. Thus, the SA counts each employee who worked full-time in the Medicare program on non-LTC activities during the entire quarter as having worked .25 staff-years and counts a full-time Medicare employee who started or ended work during the quarter as having worked the appropriate fraction of .25 staff-years.

Similarly, the SA counts each employee who worked part-time in the Medicare program as having worked a fraction of .25 staff-years.

EXAMPLE:

If an agency has three employees, one of whom works 1/2 time in the Medicare program and two of whom work 1/4 time in the Medicare program, report total staff-years for these part-time employees as equivalent to the time worked by one full-time employee.

EXAMPLE:

1	x	1/2 x	.25	=	.125
2	x	1/4 x	.25	=	.125
Total					.250

Line 1, Professionals.

The SA enters in columns (A) and (B) the staff-years and salary costs of those professional employees who work in the Medicare program. (See instructions below on determining staff-years.)

1a. Surveyors

1b. Non-Surveyors Professional

2. Line 2, Clerical

The SA enters in column (A) and (B) the staff-years and salary costs of those employees doing work of a general clerical nature whom work with the Medicare program. Include clerical supervisors, clerks, typists, stenographers, etc. (See instructions below on determining staff-year.)

3. Line 3, Total Employees - Non-LTC

Calculated staff-years and salary costs of all employees who worked (full-time or part-time) in the Medicare program during the reporting period. These entries are the sums of Lines la, 1b, and 2, columns (A) and (B).

4. Line 4, Rate %

The SA enters the percentage used by the State to determine the level of funding for Retirement and Fringe Benefits.

5. Line 5, Retirement Contributions and Fringe Benefits

The SA enters the total of the employer's share of social security taxes, State retirement system(s) contributions and other fringe benefits.

6. Line 6, Travel

The SA enters the costs of employee travel including per diem, or subsistence in lieu of per diem, applicable to the title XVIII State survey program and does not include costs incurred for training purposes.

7. Line 7, 8, and 9, Communications, Supplies, and Office Space

The entries should include total expenditures in each of these categories for the quarter covered by the report.

8. Line 10, Equipment Purchases

This entry should be the total amount expended for equipment during the report quarter. All equipment purchases must be supported by an accompanying "State Agency Schedule for Equipment Purchases," Form CMS-1466, (Exhibit 54). (See §4614 for instructions on completing Form CMS-1466.) The SA does not include obligations for equipment on this line, but shows them on Line 20, Un-liquidated Obligations.

9. Line 11, 12, and 13, Training, Consultants, and Subcontracts

The entries should cover total expenditures in each of these categories for the quarter covered by the report. Training expenditures should include travel costs related to training.

10. Line 14, Miscellaneous

The SA enters expenditures that have not been reported in any of the preceding classifications under. The automated system sums of all miscellaneous expenditures

itemized in rows (A) through (G) on line 14. If additional space is needed, the SA submits as supplemental data the attachment explaining these items.

11. Line 15, Total Other Direct Costs.

The automated system calculates the sum of lines 5 through 14.

12. Line 16, Total Direct Costs

The automated system calculates totals lines 3 and 15.

13. Line 17, Indirect Costs for Non-LTC Workload

This figure calculated by multiplying the approved Indirect Costs rate by the negotiated money base it is applied against. (See Line 18.)

14. Line 18, Indirect Costs Rate for Non-LTC Workload

The SA indicates the rate negotiated and approved by the Director, Division of Cost Allocation and Liaison, DHHS, for use during the FY and the money base it is applied against. This official will also negotiate the money base at the same time the rate is established.

15. Line 19, Total Expenditures for Non-LTC Workload

The automated system calculates total of lines 16, and 17, Column (B). The complete quarterly expenditure report for the title XVIII Medicare program will be the total of Line 19, column (B) and (D).

16. Line 20, Total Un-liquidated Obligations

The SA enters the total obligations remaining unpaid at the end of the reporting period and itemizes all un-liquidated obligations by category (i.e., travel, office space, equipment) and submits as supplemental data.

4766 - Preparation of State Survey Agency Quarterly Expenditure Report, Long-Term Care Facility Workload, Form CMS-435

(Rev. 1, 05-21-04)

The purpose of Form CMS-435 (Exhibit 45) is to report in a categorical listing the expenditures for each quarter and to separate the costs according to funding source. Because Form CMS-435 is designed to capture the costs of both non-LTC and LTC expenditures by funding source, only one form needs to be prepared quarterly.

A. Heading

The SA checks the boxes entitled title XVIII State Quarterly Expenditure and title XIX State Quarterly Expenditures Reports. The SA selects the State agency and the automated system inserts the official name for the agency, and the appropriate Region and State Code. The SA through a drop box selects the quarter and enters the year for budget period covered by the expenditure report.

B. Rounding to Next Higher Dollar

In preparing the Form CMS-435, the automated system rounds amounts of expenses incurred for each line item to the closest dollar.

C. Report Columns

Columns are provided for reporting staff-years and line item expenditures by funding source, i.e., Medicare, Medicaid, State matching, and totals by quarter. The SA reports all costs associated with the Medicaid program in the appropriate column, and in the State matching column, those matching costs associated with the Medicaid program. The SA does enters the State licensure costs in the State column.

D. FFP (Medicaid Only)

The Federal matching share of costs for the Medicaid nursing home survey and certification program is 75 percent.

The Federal matching rate for ICF/MR survey activity is 75 percent FFP for salaries, fringe benefits, travel, and training. All other costs are matched at 50 percent.

E. Line Entries

1. Line 1a Surveyor, 1b Non-Survey Professional

The SA enters the staff-years and total Federally supported salary costs of professional employees who worked on the LTC program during the reporting quarter. (See §4760 for instructions on determining staff-years.) For Title XVIII program, the SA enters in Columns (C) and (D) the staff-years and costs related to workload, and for Title XIX program the SA enters in Columns (E) and (F) the staff-years and costs related to workload. The State share is captured in column (G). The total costs for LTC survey activity is total by the automated system in Column (H). Survey activity relating to ICF/MRs is to be entered in Columns (E), (F), and (G).

2. Line 2, Clerical

The SA follows the same instructions as for professionals and includes clerical supervisors, clerks, typists, stenographers, etc., working during the reporting quarter.

3. Line 3, Totals, Staff-Years, and Salaries (LTC)

Calculated sums of Lines 1 and 2.

4. Line 4, Fringe Benefit Rate

The SA enters the percentage used by the State to determine the level of funding for Retirement and Fringe Benefits.

5. Lines 5, Retirement/Fringe Benefits

The SA enters the total of the employer's share of social security taxes, State retirement system(s) contributions, and other fringe benefits.

6. Line 6, Travel

The SA enters the cost of travel, including per diem or subsistence in lieu of per diem and charges all travel for the LTC program in accordance with provisions of State law, regulations, and administrative procedures applicable to travel of State employees. The SA does not include in this section travel cost incurred for training purposes.

7. Line 7, 8, and 9, Communications, Supplies, and Office Space

The entries should cover total expenditures in each of these categories for the quarter covered by the report.

8. Line 10, Equipment

This is the amount expended for equipment during the reporting quarter. All equipment purchases must be supported by an accompanying "State Agency Schedule for Equipment Purchases," Form CMS-1466. (See instructions in §4614 for completing Form CMS-1466.) The SA does not include obligations for equipment.

9. Lines 11, Training

The SA enters the cost of training SA personnel. Training expenditures should include travel costs related to training.

10. Line 12 and 13, Consultants and Subcontracts

The SA enters total expenditures in each of these categories for the quarter covered by the report.

11. Line 14, Miscellaneous

The SA enters expenditures which have not been reported in any of the preceding classifications under Miscellaneous and enters all costs incurred for maintenance of the NAR and the NATCEP in line 14A under Miscellaneous. This should include salaries, fringe benefits, indirect costs and any other expenses incurred to maintain the NAR and NATCEP. The automated system sums of all miscellaneous expenditures itemized in rows (A) through (G) on line 14. If additional space is needed, the SA submits as supplemental data the attachment explaining these items.

12. Lines 15, Total Other Direct Costs

Calculated sum of lines 5 through 14.

13. Lines 16, Total Direct Costs

Calculated total of lines 3 and l5.

14. Lines 17, Indirect Costs for LTC Workload

This figure is derived by multiplying the approved Indirect Costs rate by the negotiated money base it is applied against. (See Line 18.)

15. Line 18, Indirect Costs Rate for LTC Workload

The SA indicates the rate negotiated and approved by the Director, Division of Cost Allocation and Liaison, DHHS, for use during the FY and the money base it is applied against. This official will also negotiate the money base at the same time the rate is established.

16. Line 19, Total Expenditures for LTC Workload

Calculated total of lines 16 and 17, Column (D). The complete quarterly expenditure report for the title XVIII Medicare program will be the total of Line 19, column (B) and (D).

17. Line 20, Total Un-liquidated Obligations

The SA enters the total obligations remaining unpaid at the end of the reporting period and itemizes all un-liquidated obligations by category (i.e., travel, office space, equipment) and submits as supplemental data.

18. Certification: Signature, Title, and Date

For the Form CMS-435s, the automated system enters the date and the SA certifying official types their name and title.

4766A - Preparation of State Survey Agency Quarterly Expenditure Report, MDS, Form CMS-435

(Rev. 1, 05-21-04)

The SAs are to complete Form CMS-435 (see Exhibit 45) State Survey Agency Budget/Expenditure Report for costs associated with MDS. Form CMS-435 is a multi-purpose (budget request and approvals, reporting expenditures, supplemental funding request, etc.) form used in Medicare and Medicaid applications. Its various uses are displayed at the top of the form. The SA indicates the specific use of the form by following the same guidance provided for a standard Form CMS-435. These forms summarize requested funding levels for each category of expense.

4766B - Preparation of State Survey Agency Quarterly Expenditure Report, OASIS, Form CMS-435

(Rev. 1, 05-21-04)

The SAs are to complete Form CMS-435 (see Exhibit 45) State Survey Agency Budget/Expenditure Report for costs associated with OASIS. Form CMS-435 is a multi-purpose (budget request and approvals, reporting expenditures, supplemental funding request, etc.) form used in Medicare application. Its various uses are displayed at the top of the form. The SA indicates the specific use of the form by following the same guidance provided for a standard Form CMS-435. These forms summarize requested funding levels for each category of expense.

4767 - Initial Survey Activity Reports

(Rev. 1, 05-21-04)

The CMS CO has requested that SAs prepare and submit, on a quarterly basis, the initial survey activity being performed by the State agencies. The ROs designed the “Report on Initial Survey Activity” (Exhibit 216) and the “Aging Report on Pending Initial Survey

Activity" (Exhibit 217), to be prepared by each State agency. Instructions for completion of these two forms are as follows:

4767A - Preparation of Report on State Initial Survey Activity

(Rev. 1, 05-21-04)

Usage

The "Report on Initial Survey Activity " is used to record initial surveys requested by prospective Medicare providers in each State.

Heading

Insert the State for which the information is being reported. Enter the quarter ending date for which the activity is being reported.

Definition of a Pending Initial

A pending initial is one in which a prospective provider of care has requested and is ready for a survey. The prospective provider must also have in place the tangible assets necessary to do business, such as a facility, equipment, etc., and have submitted an application to become a Medicare provider.

Column A, # of Pending Initial Surveys at Start of the Quarter

Enter for each facility type the number of pending initial surveys that were not completed at the beginning of the report period.

Column B, # of Initials Requested for the Quarter

Enter for each facility type the number of initial surveys that have been requested by a prospective provider for the current quarter.

Column C, # of Initials Completed for the Quarter

Enter for each facility type the number of initial surveys that were completed (i.e., a survey was performed) for the current quarter being reported.

Column D, # of Initials Completed Year to Date

Enter for each facility type the number of initial surveys that were completed (i.e., a survey was performed) beginning with the current fiscal year through the current reporting period.

Column E, # of Applications Withdrawn for the Quarter

Enter for each facility type the number of initial applications that were withdrawn (i.e., prospective providers that requested an initial survey but withdrew their request before being surveyed) for the current quarter being reported.

Column F, # of Pending Initials End of Quarter

Enter for each facility type the number of initial surveys remaining at the end of the current quarter. This number must be obtained by adding Column A and Column B and subtracting Column C and Column E.

4767B - Preparation of Aging Report on Pending Initial Survey Activity

(Rev. 1, 05-21-04)

Usage

The "Aging Report on Pending Initial Survey Activity" is used to record the number of days an initial survey is pending for each State by facility type.

Reconciliation

The number of pending initials as reported in column "H" on the "Report on Initial Survey Activity" must reconcile to the aggregate number of pending initials that are aged on the "Aging Report on Pending Initial Survey Activity."

Column A, 0 - 30 days

Enter for each facility type the number of pending initials that are outstanding 0 to 30 days.

Column B, 31 - 60 days

Enter for each facility type the number of pending initials that are outstanding 31 to 60 days.

Column C, 61 - 90 days

Enter for each facility type the number of pending initials that are outstanding 61 to 90 days.

Column D, 91 - 120 days

Enter for each facility type the number of pending initials that are outstanding 91 to 120 days.

Column E, Over 120 days

Enter for each facility type the number of pending initials that are outstanding over 120 days.

Section 1864/Section 1903(a) Fiscal Audits

4780 - Scope of Audit

(Rev. 1, 05-21-04)

Occasionally, auditors for the DHHS regional OIG Office of Audit Services (OIG/OAS) audits each SA certification program to determine that:

- The SA has properly reported its accountability of Federal program funds;
- No Federal program funds were used for any purpose contrary to the §1864 agreement, applicable State and Federal laws and regulations, or CMS financial administration standards;
- The share of the Federal government in any miscellaneous receipts was properly credited on the books of the SA and reported to CMS.

4781 - Objectives of Audit

(Rev. 1, 05-21-04)

The objectives of the audit of receipts and expenditures are to determine that:

- Vouchers are mathematically correct, supported by substantiating documents, and in agreement with entries in the records;
- Expenditures for which charges are made against the certification program are properly authorized, approved, and made in accordance with Federal and State laws, rules, regulations, and the §1864 agreement;
- Expenditures are properly classified between the certification program and other programs of the SA;
- Expenditures are actually disbursed in the correct amount to the proper payees;
- Refunds or credits are properly accounted in computing the amount of the charges against Federal funds; and
- The agency properly reports its accountability for Federal funds.

The SA expenditures are audited on the basis of standards in effect at the time they were made or incurred. The State is given a full explanation of any questioned items and afforded a reasonable length of time to explain them.

4782 - Records to Be Reviewed

(Rev. 1, 05-21-04)

All records required establishing the auditors may examine the correctness of an SA's claim for Federal funds. The SA should be prepared to furnish not only those data usually considered as the formal accounting system, but also any other agency records which may contain information necessary to establish the facts. This may include the accounts and records of State fiscal officers, if they involve receipt, custody, and disbursement of Federal funds, and the records of other State agencies where necessary to substantiate claims made against Federal funds.

4784 - RO Role During Audit Process

(Rev. 1, 05-21-04)

4784A - Pre-Audit

(Rev. 1, 05-21-04)

The RO provides assistance to HHS auditors who visit the office to:

- Interview RO staff to identify specific fiscal and certification problem areas and the corrective action taken or planned, or to review certification workflow and procedures for assuring SA compliance with title XVIII/XIX certification provisions;

- Review RO records such as recent trip records, program review reports, validation survey findings, budget files, etc.;

- Examine the working relationship between the RO and the SA; and

- Analyze certification files in the RO instead of in the SA.

4784B - During Audit

(Rev. 1, 05-21-04)

The RO has only an advisory role in the performance of the audit fieldwork. It can answer program policy questions that surface during the audit, provide needed technical

advice to auditors, and interpret instructions and guidelines. The RO may be called upon by the OIG/OAS to participate in advance discussion of the audit if audit findings clearly warrant immediate corrective action, and to initiate needed action without waiting for the final audit report.

4784C - At Exit Conference

(Rev. 1, 05-21-04)

The regional OIG/OAS will notify the RO of the date of the exit conference with the SA at least 10 days in advance. RO representation at the conference is optional insofar as the OIG/OAS is concerned; however, RO attendance provides an opportunity to hear both sides and to contribute the RO viewpoint prior to the final report. An exit conference between the auditors and SA officials explains informally what the auditors' intent to report and serves to clear up misunderstandings before the audit report is drafted.

4785 - Draft and Pre-Release Audit Report to RO

(Rev. 1, 05-21-04)

Where findings are made, the auditors will issue a draft audit report and send it to the SA for comments. Like the audit exit conference, the draft report provides the SA with an opportunity to furnish comments and information that will eliminate inaccuracies and misunderstandings from the final report.

When significant findings are made, OIG/OAS will prepare a "proposed final report" or "pre-release report" which it sends to the RO with a request for written comments. The report is normally accompanied by the State's comments from the draft report. This procedure provides an opportunity for the RO to have those recommendations that are not complete, not legally enforceable, or otherwise difficult to clear removed before the final report is released. The RO uses the pre-release procedure as a means of obtaining audits with complete recommendations that are readily clearable within the required 6 months.

The RO should submit comments on the proposed final report to the audit agency within 30 days of the issuance of the report using a form called a "pre-release notification document" (PND). (See Exhibit 218.) The RA must either concur or nonconcur with each finding and recommendation in the report, providing the reason in the event of nonconcurrence. When the RA signs the PND, the RO sends it to the originating regional OIG/OAS official. Copies of the PND are sent to all parties on the report distribution schedule.

4786 - Final Audit Report and Final Determination - RO Procedures

(Rev. 1, 05-21-04)

4786A - General

(Rev. 1, 05-21-04)

The final audit report is distributed by the regional OIG/OAS in accordance with its distribution list. If the SA accepts the findings and recommendations, the SA's signed agreement must be obtained by the RO. If the SA disagrees, the RO will issue a formal written determination. (See §4792 for disallowance notifications.) The determination should be made at the point when the RA can see the unlikelihood that an agreement will be reached with the SA on the audit recommendations, in order to clear the audit within the 6-month period required by law.

4786B - Timeliness of Final Audit Resolutions

(Rev. 1, 05-21-04)

In accordance with P.L. 96-304, RAs are required to resolve (clear) audit findings within 6 months of the date of issuance of the final audit report by the OIG/OAS. For this purpose, resolution is deemed to occur when a final decision on the amount of any monetary recovery has been reached and communicated to the auditee; a satisfactory plan of corrective action, including time schedules, to correct all deficiencies has been established and communicated to the auditee; and the report has been cleared from the Department's tracking system by submission and acceptance of an audit clearance document (ACD).

To resolve difference and obtain full information upon which to base a decision or obtain a settlement, the RA may consult with the SA and the auditors either before or after the SA reply. This is a fact finding rather than a negotiating step. It does not delay public access to the final audit report, which is made available for public inspection 30 days after it is issued to the State.

4787 - RO Review of SA Response

(Rev. 1, 05-21-04)

4787A - Contacting SA

(Rev. 1, 05-21-04)

The letter transmitting the final audit report to the SA either advises the SA to respond to the RA within 30 days regarding the findings in the report or advises that CMS will

contact the SA. In either case, the RO will promptly contact the SA and, as appropriate, remind it to respond, request any needed information, and offer an opportunity for the SA to provide any further information on the report. The SA's response should provide the following information:

- Specific concurrence or nonconcurrence with each finding and recommendation;
- A description of the specific actions taken or planned (including time schedules) to correct each deficiency, if it agrees that a deficiency(ies) exists; and
- Specific reasons for each nonconcurrence.

4787B - Timely Response

(Rev. 1, 05-21-04)

The RO must maintain controls indicating the due date of the SA response, and immediately contact the SA if the date is not met. The RO should emphasize the importance of timely responses to audit reports and follow up if a response is not complete as described in subsection A. Where justified, an extension of time for the submission of the response may be granted by the RO. However, such extensions will not extend the 6-month due date set out in §4786.B.

4787C - Consideration of Supporting Arguments and Information

(Rev. 1, 05-21-04)

The RO should accord full and fair consideration to any arguments and information submitted in support of the SA's position. However, the SA should exercise caution in evaluating information that conflicts with information contained in the audit report or documentation that was not provided to the auditor. When such information is significant, the RO can discuss it with the auditor and, where necessary, refer it to the auditor for review and comments.

4787D - Agreements and Disagreements

(Rev. 1, 05-21-04)

If CMS finds that nonallowable costs have been charged to Federal awards and the State agrees with the finding, the agreement is confirmed in a letter from the RA to the State director, who signs and returns a copy of the letter to CMS. This letter constitutes the initial notification to debtors of the United States as required by the Federal Claims Collection Standards (42 CFR 102.2). Interest is charged in accordance with Federal claims collection standards.

If the SA disagrees with the CMS finding, the RA will make a unilateral final determination, notify the SA of the amount that is unallowable, and advise of the right to appeal. (See §4788.) The CMS notification also includes information on the appeal procedure.

4787E - Program Findings and Recommendations

(Rev. 1, 05-21-04)

Audit reports may fault SA management practices or fault the degree and manner in which the State carries out its responsibilities under applicable statutes and regulations. Although OIG/OAS maintains control of program findings that have significant monetary implications and require certain "safeguard" measures to be taken, implementation of recommended corrections of program findings is primarily the responsibility of CMS.

Whereas the repayment of funds may be thought of as a retrospective correction, elimination of deficient program management practices is prospective. The SA and CMS must agree upon and specify appropriate corrective actions and a time schedule for completion, which CMS follows up on in the course of subsequent management monitoring activities. Frequently, the auditor may accompany CMS representatives to meetings with the State to clarify what correction is needed. Problems may be subject to follow-up by OIG/OAS as well. In order to clear the audit, the RA must be able to advise OIG/OAS that agrees to how and when the problems will be satisfactorily corrected.

4788 - SA Disallowance Appeals

(Rev. 1, 05-21-04)

The appeals for Medicare and Medicaid disallowances are discussed in §§4788.1 and 4788.2.

4788.1 - Medicare Disallowance Appeals

(Rev. 1, 05-21-04)

To the extent that a dispute relates to the cost of the SA's activities pursuant to §1864 and the §1864 agreement, there is a right to appeal to the Armed Services Board of Contract Appeals in accordance with the Contract Disputes Act, 41 USC 607.

In the event the SA elects to appeal title XVIII issues under the Contract Disputes Act, the SA must mail or otherwise furnish written notice of appeal to the Armed Services Board of Contract Appeals within 90 days from the date of the Medicare disallowance, as instructed in the disallowance notice. Also, the SA mails a copy of such notice to the RO.

The Contract Disputes Act also affords the SA the option to bypass the appeal process entirely by bringing an action directly to the U.S. Court of Claims within 12 months of the date of the Medicare disallowance.

4788.2 - Medicaid Disallowance Appeals

(Rev. 1, 05-21-04)

When it is determined by the RO that a State claim for FFP in Medicaid expenditures for a particular item or class of items is not allowable, the RA issues a disallowance letter to the State. A Medicaid disallowance action may be initiated based upon a review of a variety of information, such as the Form CMS-435, audit report findings, or a financial review.

The SA will receive one of three letters based on the type of Medicaid disallowance determined:

- A regular disallowance letter. (See Exhibit 58.);
- A deferral disallowance letter (see Exhibit 59) and, if necessary, a subsequent disallowance letter for amounts previously deferred. (See Exhibit 60.); or
- An audit disallowance letter. (See Exhibit 61).
- After receipt of a disallowance letter, the SA has two options in order to resolve the Medicaid disallowance action:
- Concur with the Medicaid disallowance and take appropriate action to resolve it by adjusting the next quarterly expenditure report for the disallowed amount; or,
- Appeal the action to the DAB via State appeal rights outlined in each disallowance letter.

4789 - RO Documentation of Agreements on Actions to Correct Audit Deficiencies

(Rev. 1, 05-21-04)

When an agreement on the corrective actions is reached, the RO must confirm the agreement in a letter to the responsible SA official. The RA must sign this letter, and the recipient State official must sign and return a copy of the letter to the RO. If an agreement is reached on corrective actions for some but not all of the deficiencies, the letter should cover the agreed-upon actions. All agreements on corrective actions must, at a minimum, include the information described below:

- The specific actions taken or planned to correct each deficiency. Describe these actions in sufficient detail to permit a subsequent determination of the SA's compliance with the agreement;

- The date(s) the actions have been or will be implemented;

- Reference to any implementing policies, procedures, or forms, or a requirement that they be submitted by a specific date; and

- Requirements that the organization obtain the RO's advance approval of any modifications to the agreement.

4790 - General Rules on Cost Allowability - RO Procedures

(Rev. 1, 05-21-04)

4790A - Cost Allowability

(Rev. 1, 05-21-04)

Except as otherwise provided in section B, all decisions to allow or disallow costs must be based solely on whether they are allowable or unallowable under the regulatory cost principles and provisions of the budget approvals. RAs have responsibility and authority (subject to appeal) for determining whether costs are allowable or unallowable and for determining the dollar amount of any unallowable costs. In making these determinations, RAs have some discretion on matters of interpretation. However, such discretion does not include the authority to ignore applicable laws, regulations, or policies or authoritative interpretations issued by the courts, GAO, OGC, responsible policy offices, or other appropriate authorities.

- For any audit finding in which the auditor has recommended an adjustment exceeding $100,000, the CMS Administrator or Deputy Administrator must give prior written approval for any settlement which is less than 85 percent of the amount recommended by the auditor.

- In the resolution of the findings, a clear distinction must be made between the determination of whether a cost is allowable or unallowable and the actual collectability of a disallowance. If a determination is made that a cost is unallowable, the RA does not have the authority to "waive" collection of the disallowance. Disallowances constitute claims by the Government and may be waived or reduced only by CMS' claims collection officer under limited conditions prescribed in the Federal Claims Collection Act (P.L. 89-508), the Debt Collection Act of 1982 (P.L. 97-365), and implementing procedures described in the CMS Administrative Issuances System chapter on financial management.

- In determining whether a cost is allowable or unallowable, the RO cannot use factors such as the good faith of the State, its successful accomplishment of program objectives, or it's ignorance of the provisions of the budget approval process as a basis for allowing costs which are unallowable under the provisions of the budget approval.

4790B - Exceptions to Cost Allowability Rules

(Rev. 1, 05-21-04)

As stated in §3150, the decision to allow or disallow a cost must be based on whether it is allowable under the provisions of applicable regulations and the budget approval. There are two situations, however, where an exception to this rule may be permitted:

1. If a transaction requiring prior approval under the provisions of a budget letter or the SOM is questioned because the approval was not requested, the transaction may be approved retroactively, assuming that funds are available. Retroactive approvals may be granted, however, only where:

    - The transaction would have been approved had the State requested it in advance; and

    - The State agrees to institute controls to ensure that prior approval requirements are met in the future; or,

2. In exceptional cases where strict adherence to an original provision of an award would result in a clear inequity to the State, the provision may be waived.

These exceptions are to be used in extraordinary situations when adherence to cost allowability rules would result in a serious inequity. The provision to be excepted must not be one mandated by law. The RO should request OGC concurrence that the proposed exception is legal and acceptable to OGC. If OGC concurs, The RO may proceed to fix the amount of overpayment. Thoroughly check all pertinent regulations and policies in 45 CFR Part 74, in the HHS Grants Administration Manual, and in other guidelines, to assure proper handling of any deviation from standard procedures. Note that if the auditors' recommended adjustment was over $100,000, a settlement for less than 85 percent requires approval by the Administrator or Deputy Administrator.

4790.1 - Determinations of Overpayment - RO Procedures

(Rev. 1, 05-21-04)

It is essential that overpayments be determined separately for each fiscal year involved. This is true even if estimates are used as in §4790.2.

In some cases a sustained audit disallowance is not an overpayment debt to be collected by the U.S. Government. An auditor and the audit action official may determine that a particular claimed expenditure is not allowable. However, it is possible the auditee had never received cash withdrawal from the Department Federal Assistance Financing System for the disallowed expenditure. While the expenditure was "disallowed" via the audit resolution process, it would not be an overpayment since the State had never requested nor received an actual

Federal payment for the expenditure that was recorded on the debtor's records. Such a situation should be clearly explained on the audit clearance document to allow CMS to properly record the amount in the accounting records.

4790.2 - Determination and Computation of Dollar Amounts - Use of Estimates - RO Procedures

(Rev. 1, 05-21-04)

In some cases, the audit report may indicate that it was not possible or feasible to identify the precise amount of unallowable costs on each award, and that an aggregate amount of the costs for all affected awards was estimated based on an analysis of a representative sample of transactions.

These estimates may be based on a valid statistical sample of the transactions, or if the use of statistical sampling was clearly impractical under the circumstances, on other reasonable and supportable estimating techniques (such as projections based on an analysis of transactions during a representative period of time). The auditor is responsible for developing estimates of any unallowable costs.

- If the SA disagrees with the use of an estimate or with the procedures used by the auditor to develop the estimate, the SA has the option of performing an alternative analysis within a specified period of time to develop more precise results. Also, the RO should follow this procedure in situations where the auditor indicates that an estimate cannot be developed, but the SA contends that it can be developed and wishes to perform an analysis to develop the estimate. If the SA elects to perform an analysis, advance agreement on the due date for submission of the analysis and the procedures to be followed in conducting the analysis so that the audit will be cleared within 6 months should be obtained by the RO. The RO and the auditor must review the results of the analysis.

- The estimates or the analysis will cover the period prescribed in the next paragraph (or will be projected to cover this period), and this amount will be used as the basis for a dollar settlement with the SA. If the parties are unable to reach an agreement within the specified time, the RA must make a unilateral determination and notify the SA of the amount that is unallowable.

- It should be noted that estimated costs (except statistically formed estimates) and costs upon which no opinion can be offered will not be coded by the OIGAA as to dollar disallowances. They may, however, require the attention of the RO to assure correction of the deficiencies in the system responsible for the situation. In this event, a management recommendation will be coded in the audit tracking system and will require corrective action and a response.

4790.3 - Time Period for Computing Disallowances - RO Procedures

(Rev. 1, 05-21-04)

If costs are disallowed as a result of an estimate or analysis, the computation of the disallowance must cover the following periods:

- If the costs can be identified to specific awards, the computation will cover the period the SA is required to retain records under applicable record retention requirements;

- If an overall organization-wide estimate is used, the computation will cover the SA's three fiscal years immediately preceding the year in which the audit started and all subsequent periods up to the date the SA changes its procedures to discontinue the unallowable charges;

- In situations involving fraud or deliberate misrepresentation by an organization, the period will be extended as far back as necessary;

- If part of the period was covered by an earlier settlement of the same issue, the period will be appropriately reduced; and

- The period may be appropriately extended in cases where a SA has submitted a retroactive claim for reimbursement of costs incurred in an earlier period, or has failed to carry out a prior commitment to take corrective action that would have prevented the problem.

4790.4 - Inability to Determine Dollar Amounts - RO Procedures

(Rev. 1, 05-21-04)

4790.4A - Supporting Costs By Alternative Means or Developing Reasonable Estimate of Unallowable Costs

(Rev. 1, 05-21-04)

As indicated above, every effort will be made by the auditors to identify or estimate the amount of any unallowable costs. In some cases the deficiencies may be so serious that costs charged to the awards cannot be supported, and it is not possible for the auditor to develop a reasonable and supportable estimate of the amount of unallowable costs. In these situations, offer the SA the opportunity to support the costs by alternative means or to develop a reasonable estimate of any unallowable costs. The RO specifies a time limit so that the audit may be resolved within prescribed time frames. If the SA submits this information, it should be evaluated by the RO and, if necessary, by the auditor to determine whether it provides a sufficient basis for allowing the costs or for reaching a dollar settlement.

4790.4B - Costs Have Not Been Supported

(Rev. 1, 05-21-04)

If the SA does not submit the information within the time limit set or if the information is inadequate or inconclusive, the RO will formally notify the SA that the costs have not been supported as required by Federal regulations. The costs are therefore disallowed, and the organization may appeal this determination. In extreme cases, the amounts involved or other circumstances may be such that this approach is impractical or inequitable. In that event, the RO should take the following steps:

1. Notify CO that the costs have not been supported and request a programmatic evaluation to determine whether the charges to the projects or programs appear reasonable in relation to the work performed.

2. Responsible program officials will perform an evaluation to determine whether the charges appear reasonable, and if they do not appear reasonable, to determine the amount of the excessive charges. To the maximum extent possible, program officials will complete the evaluation within 30 days of the RO's request. After the evaluation is completed, the results will be transmitted to the RO.

3. If the evaluation indicates that the costs appear reasonable in relation to the work performed, the costs will be allowed. If the evaluation indicates that the costs are unreasonable, the excessive amount will be disallowed.

4791 - RO Documentation of Agreements to Effectuate Repayments

(Rev. 1, 05-21-04)

The SA may agree with the auditors' findings in its response to the audit report, or the SA and RO may reach agreement only after substantial discussion regarding the amount to be adjusted. A letter signed by the RA and countersigned by the SA director (or other designated official that the State authorizes) must document any agreement. The letter must:

- Specify the method and time of repayment;
- Stipulate the amount agreed to for each audit-questioned cost item, and clearly identify what the respective cost items are;
- Set out the amounts and times of payment under an extended payment plan if it appears that the State might be unable to make repayment by the due date. (See §4791.1);
- Advise that interest on Medicare overpayments will be charged by CMS if the amount is not paid within 30 days; and
- Instruct the SA director to countersign and return a copy of the letter to the RO. (In States where an official other than the director is the only person authorized to make the financial commitment, the RO modifies the letter accordingly.)

The RO includes two signed copies so that one can be countersigned and returned. This letter constitutes the initial notification to debtors required by the Federal claims collection standards (42 CFR 102.2).

4791.1 - Repayment Not Made Within 30 Days of Agreement Letter - RO Procedures

(Rev. 1, 05-21-04)

If the State cannot agree to make repayment within 30 days from the date the RA signs the agreement letter, and this is known beforehand, the letter should note how and when payment will be made. All debts owed to CMS are to be collected timely even though CMS may owe the State offsetting funds in a different program. Consequently, it is not permissible to defer collection of a Medicare overpayment while determining whether a Medicaid underpayment might offset it, or vice versa.

If the State can demonstrate to the RO's satisfaction that severe financial hardship would occur if the entire amount of debt had to be paid within 30 days, the State does have a right to elect to repay debts (or reduce them through a series of offset actions) under an

installment plan over a maximum period of three years. In such case, however, any deferred Medicare repayment is subject to interest that the RO must periodically calculate and add to the amount remaining due. Medicaid repayments are not subject to interest charges in this situation. The minimum repayment schedule, which is mandatory for Medicaid collections, is also considered the reasonable minimum for Medicare collections:

Total repayment amount as percentage of State share of annual expenditures for the specific program	**Number of quarters to make repayment**
2.5 pct. or less	1
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5	9
Greater than 47.5, but not greater than 65	10
Greater than 65, but not greater than 82.5	11
Greater than 82.5, but not greater than 100	12

The quarterly repayment amounts for each of the quarters in the repayment schedule shall not be less than the following percentages of the estimated State share of the annual expenditures for the program against which the recovery is made.

Repayment installment for each of the following quarters may not be less than these percentages:

1 to 4	2.5
5 to 8	5.0
9 to 12	17.5

If the State chooses to repay amounts representing higher percentages during the early quarters, any corresponding reduction in required minimum percentages would be applied first to the last scheduled payment, then to the next to the last payment, and so forth as necessary.

4792 - Audit Disallowance Actions - RO Notification

(Rev. 1, 05-21-04)

The following sections provide the RO with guidelines and instructions to assist in the completion of the audit process.

As soon as it is clear that agreement will not be reached expeditiously on an audit exception, the RO should make a unilateral determination of disallowance. This determination should deal only with monetary adjustments which the SA disputes. If at all possible, there should be separate earlier documents to address those financial adjustments to which the SA had agreed, remedies for audit-identified program/administrative problems, and "safeguards." The RO ensures that if there has been a prerelease notification document, there are no unreported deviations in the determination. (See §4785.)

In virtually all cases the disallowance notice must address closely intertwined Medicare and Medicaid aspects of the adjustment. However, there are slightly different notice requirements for the two programs:

- Collection and interest-charging rules are governed by Federal claim collection standards for Medicare, but are governed by §1903(d)(2) and (5) of the Act for Medicaid;

- Medicare disputes are appealed under Federal contract appeal procedures, while Medicaid disputes are appealed under grant appeal procedures; and

- If the disallowance affects Medicaid, both the SA as the auditee, and the SMA as the grantee, must be officially notified.

Consequently, it is usually necessary to prepare two separate notices. The RO should address the Medicare notice to the SA and address the Medicaid notice to both the SA and the SMA. Both should be identical up to the point where the determination is announced, but their instructions for further action differ. Exhibits 219 and 220 provide a model for the Medicaid and Medicare notices, respectively.

4792.1 - Non-Audit Medicare and/or Medicaid Disallowances - RO Procedures

(Rev. 1, 05-21-04)

When a determination is made that a State claim for Medicare survey and certification budget payment and/or FFP in expenditures for a particular item or class of items is not allowable, the RO will issue a disallowance letter to the State. A disallowance action may be initiated based upon a review of a variety of information, such as Form CMS-435

or a financial review. There must be a separate disallowance letter for the Medicare and FFP disallowances. If a Medicaid FFP disallowance is under review, the ARA consults the RO Medicaid Division for advice on regional procedures.

4792.1A - Preparation of Case File

(Rev. 1, 05-21-04)

After determining it appropriate to issue a disallowance, the RO prepares and organizes a case file, including a Disallowance Analysis Memorandum (DAM) containing necessary documentation supporting the action. (See §4793 for items comprising the records supporting disallowance actions.)

4792.1B - Assignment of File Control Number

(Rev. 1, 05-21-04)

While organizing applicable documentation, the RO assigns a unique identifying file control number to each case as follows:

- Begin the control number with a two letter State abbreviation (e.g., AL, FL, GA);
- The next series of numbers includes the current two-digit fiscal year designation (e.g., 1980 = 80, 1981 = 81); and
- The last series of numbers consists of a two-digit numerical designation (01, 02, 03, etc.), running consecutively, beginning with 01. Maintain sequential numbering series either within each State or within the region as a whole (examples: AL-80-01, FL-80-01, FL-80-02).

4792.1C - Preparation Draft Disallowance Letter

(Rev. 1, 05-21-04)

Based upon the information contained in the case record, the RO prepares a draft disallowance letter generally following the suggested format, as shown in Exhibit 219 and/or 221.

4792.1D - Circulation Draft Disallowance Action for Review

(Rev. 1, 05-21-04)

The RO circulates the draft letter and the DAM for review within the immediate responsible unit and any other necessary units and obtains clearance from the regional Counsel.

4792.1E - Signature of Disallowance Letter

(Rev. 1, 05-21-04)

Once the letter has been prepared in final format and the necessary concurrences obtained, the RO submits it through the ARA, to the RA for approval.

4792.1F - Notification of CMS

(Rev. 1, 05-21-04)

After the RA has approved the disallowance action, the RO prepares an alert to notify CO of the pending action and sends a copy of the alert, the disallowance letter, and the DAM to CO.

4792.1G - Disallowance Letter to Appropriate Recipients

(Rev. 1, 05-21-04)

After headquarters clearance has been obtained, the RO transmits the letter to the State by certified mail, return receipt requested and sends a copy of the letter to CO.

NOTE: Once an appeal has been filed, the RO does not communicate with the State concerning the disallowance. All communications must be by or with the consent of the attorney assigned to handle the case.

4793 - Establishing Records Supporting Non-Audit Medicare and/or Medicaid Disallowance Actions - RO Procedures

(Rev. 1, 05-21-04)

The RO maintains a disallowance action record containing information necessary to support the disallowance decision. The RO includes supporting documentation for items addressed in the disallowance notice. See Exhibit 221 for a model non-audit disallowance notice.

4793A - Disallowance Analysis Memorandum (DAM)

(Rev. 1, 05-21-04)

The appropriate RO/ARA must prepare a DAM for each disallowance taken. The DAM is to be a summary of pertinent facts presented in greater detail than in the disallowance

letter, so that a reader who is unfamiliar with the disallowance action is able to fully understand it. Specifically, the DAM should contain:

- A chronology of events to date;
- An explanation of why the disallowance should be taken;
- Detailed findings of fact and an analysis as to why these findings are supported;
- The disallowed amount, identified by quarter, either by proration or by specific item of cost;
- A statement and discussion of the State's position, if known, accompanied by the regional rebuttal or conclusion concerning the validity of the argument;
- If the disallowance was based on a statistically valid sample, a detailed explanation of the sampling plan to include the methodology and computations used to arrive at the disallowed amount;
- A statement as to whether a court order is in effect or litigation is in process;
- Copies of related correspondence; and
- Copies of hours, regulations, and CMS instructions.

4793B - Claim-Related Work Papers

(Rev. 1, 05-21-04)

The RO keeps as backup material copies of all summary work papers, along with copies of journal entries, ledgers, or other documents showing that the State has made a claim. These are documents that support amounts claimed on Form CMS-2824 expenditure source documents. If the amount claimed is part of a larger figure, the RO includes in the DAM an explanation with cost accumulation methodology and computation. Where appropriate, the RO includes copies of audits, contracts, pertinent parts of cost allocation plans, applicable sections of the State plan, and State cost distribution methodologies.

4793C - Citations of Authority

(Rev. 1, 05-21-04)

The RO keeps copies of the cited regulation, interpretations, policy, law, or whatever authority is used to substantiate the disallowance, a copy of the regional attorney's opinion, if any, and a copy of any material associated with litigation.

The RO provides a copy of the DAM and the proposed disallowance letter to the office of the regional counsel handling the case.

4794 - Collections - RO Procedures

(Rev. 1, 05-21-04)

4794A - Processing Collections

(Rev. 1, 05-21-04)

Audit disallowance notices include a request for full repayment within 30 days. If checks in full or partial payment of audit disallowances made out to CMS are received by the RO, the RO accepts them and forwards them to CO for processing. The RO reviews §4796 and takes appropriate updating action each time a check is received. The RO enforces interest charges if a Medicare debt is not repaid within thirty days of the repayment notice. (See subsection C.)

4794B - Appeal Will Suspend Collection Action

(Rev. 1, 05-21-04)

If the State appeals CMS' determination, collection actions will be suspended pending a final decision on the appeal, unless otherwise requested by the State. However, if the disallowance is sustained (fully or partially), interest will be charged for the full period, as described in subsection C.

4794C - Calculating Interest Charges

(Rev. 1, 05-21-04)

The RO is responsible for assessing the interest charged on the total amount of a disallowance that is unpaid as of the "due date." If the resources cited below cannot be obtained from the ARA for Financial Operations, the RO phones the CO Division of Accounting for assistance in calculating the interest due.

4794C1 - Interest on Medicare Disallowance

(Rev. 1, 05-21-04)

Interest on a Medicare disallowance accrues from the date on which the notice is sent to the SA. (Waive interest if the debt is paid in full within 30 days after the date of notice.) If the State fails to appeal a disallowance within 30 days, the RO contacts CO immediately to offset the overpayment by reducing the current award.

4794C2 - Interest on Medicaid Disallowance

(Rev. 1, 05-21-04)

Interest on a Medicaid disallowance begins to accrue on the date of disallowance, and ends on the date of final decision, if the State elects to retain the disputed funds during the appeal, and if the disallowance is upheld by the Grant Appeals Board. If the State is silent on its election to retain funds during the appeal, the RO notifies CO immediately to arrange for offset pending the appeal decision. If the State does not formally appeal the disallowance within the specified 30-day time period, no interest is assessed. Immediately notify CMSO to arrange for offset of the disallowance by issuing a negative grant award. The failure of a State to submit a revised expenditure report does not preclude offsetting against quarterly awards.

4794C3 - Interest Rates

(Rev. 1, 05-21-04)

Interest rates on delinquent Medicare disallowances are set by the U.S. Treasury rates published in their quarterly Treasury Fiscal Requirements Manual Bulletins. The rate is based on the current value of funds to the Treasury. Interest rates on delinquent Medicaid disallowances are based on the average of the bond equivalent of the weekly 90-day Treasury bill auction rates during the period in which interest is to be charged. Interest charges on extended Medicare repayment plans are based on the Treasury's monthly Schedule of Certified Interest Rates With Range of Maturities. Extended repayment plans may not contain a grace period for late payments.

4794C4 - Date of Payment

(Rev. 1, 05-21-04)

The "date of payment" is the date of offset against quarterly Medicaid grant awards or the date of reduction of Medicare annual awards.

4794D - Periodic Notices of Amounts Still Due

(Rev. 1, 05-21-04)

The RO keeps up-to-date records of balances due on all determined overpayments, reflecting reductions when made by payment or by CMS offset action taken as a result of the SA's downward adjustment of quarterly expenditure reports to offset the debt. If the quarterly expenditure report includes a specific downward adjustment to offset the debt, the RO considers the reduction to have been made at the end of the calendar quarter to which the expenditure report pertains, in order to calculate interest on the balance still due. If the State has failed to take the required offset from the quarterly expenditure

report, the RO reduces such expenditures (including calculation and reduction for interest), and forwards documentation to DA through CO for offset through the awards process. The RO notifies the SA, just before the end of each quarter in which a balance remains, of the amount still due including current interest. This notice will serve as a reminder of offset action to be taken on expenditure reports by the State.

4794.1 - Accounts Payable - RO Procedures

(Rev. 1, 05-21-04)

If it is determined as the result of an audit that funds are owed to an SA by CMS and that payment of such amounts will not exceed the approved budget for title XVIII funding, CO will ensure that the necessary funds are made available to the SA after receipt of revised State-submitted, ARA-approved expenditure reports for the audited period. In those cases where the SA chooses not to request payment, the RO notifies CO that will in turn notify DA to eliminate the account payable from the record. Similarly, if the SA does not forward revised expenditure reports after notice by the RO to do so, and the RO determines that the SA is not going to forward them, it notifies CO which will notify DA to eliminate the account payable from the record.

4795 - Audit Clearance Document - RO Procedures

(Rev. 1, 05-21-04)

Upon issuance of the final report, the audit is placed on the audit agency's list of pending audits and remains pending until that agency receives (and accepts) an audit clearance document (ACD) (Exhibit 222) showing the resolution of all recommendations. An audit clearance document provides a uniform medium by which full information is furnished to involved parties stating CMS' decision as to actions to be taken and monies to be recovered as a result of the audit report. Therefore, following agreement with the SA on implementation, the RO completes an ACD listing each recommendation, the final determination made, the action to be taken, and the agreed upon time schedule. If the final determination differs from OIGAA's position, the RO includes the rationale for the deviation.

4795.1 - RO Preparation and Processing Audit Clearance Document

(Rev. 1, 05-21-04)

4795.1A - Part I - Decisions by CMS

(Rev. 1, 05-21-04)

This part shows decisions by CMS. The RO completes as follows:

1. **Date** - Date submitted by RO.

2. **Audit Control No.** - Number assigned to audit report by OIGAA.

3. **Report Date** - Date audit report was issued.

4. **Cognizant PoC** - CMS in all cases.

5. **Program** - Program covered by audit report. In those instances where more than one program is covered, the RO indicates program with largest amount of funds (Medicare, Medicaid, Survey and Certification, or QIO.)

6. **Other Principal Operating Components** - All PoCs other than CMS involved in the audit report.

7. **Grantee/Contractor** - Name and address of the SA.

8. **Grant/Contract No** - Leave blank.

9. **Common Accounting No** - For monetary findings, the RO uses the common accounting number (CAN) for the organizational entity that made the original obligation. This information will be included in the audit reports. If not in the report, the RO obtains this information from the regional OIG/OAS.

10. **Appropriation No** - For monetary findings, the RO uses the appropriation number for the program from which the original obligation was made. This information will be included in the audit report. If not in the report, the RO obtains it from the regional OIGAA.

11. **Audit Recommendation** - The RO states the recommendation (not the finding) as it appears in the audit report. The RO shows each recommendation on a separate page. The RO uses the continuation sheet for this purpose. Amounts Recommended for Financial Adjustment

12. **Finding Code - Cost Element** - The RO shows code number and type of expense disallowed. (These are obtained from the audit report.) No more than one finding code is permitted on each line.

13. **Amount Recommended** - The amount to be shown in this column is the amount recommended for adjustment that is being addressed by the ACD. If, for some reason, only a portion of one recommended amount is being addressed, the RO shows this lesser figure in this column.

14. **Amount Sustained by PoC** - The RO shows the amount of this recommendation that is being upheld by CMS. It is the amount in this column that will determine the amount entered into CMS' accounting records for recovery from the auditee. If less than 85 percent of a recommendation of $100,000 or more is upheld, the RO obtains the concurrence of the CMS Administrator or Deputy Administrator and attaches it to the ACD.

15. **Action Taken on Recommendation** - The RO indicates briefly the actions CMS is requiring the auditee to take to implement the recommendation. If several steps need to be taken, the RO includes target dates for their accomplishment. When CMS does not concur with a recommendation, the RO includes a concise explanation of the basis for nonconcurrence. If the report was processed under prerelease procedures and CMS is deviating, or allowing an auditee to deviate, from a previously agreed upon position, the RO furnishes a concise explanation for the deviation. The RO also includes an explanation of the extent of consultation with OIG/OAS on the matter, prior to advising the auditee that the audit has been resolved. In order to more adequately describe the circumstances resulting in nonconcurrence, the RO attaches supporting documentation to the ACD. When the action taken on a recommendation cannot be fully explained within the space provided, the RO continues the explanation on bond paper. Pertinent correspondence must be attached that will aid in explaining CMS' action on this recommendation.

16. **Signature** - The signature of the RA must appear on the right hand side as "Reviewer" if the ACD consummated a settlement or decision. All ACDs should be signed by the RO originating analyst or responsible audit officer.

17. **Office of the General Counsel (OGC) Approval** - If CMS differs in it's interpretation of the law, rule, or regulation used by OIG/OAS to support its recommended disallowance and does not uphold this disallowance (management or financial), OGC's concurrence with CMS' position will be evidenced on the ACD by Counsel's signature or the attachment of the OGC opinion. CO will attach the OGC opinion.

18. **Part I - Continuation Sheet** - The RO uses this page when more than one recommendation is being addressed.

4795.1B - Part II - Recommendations Remaining Open

(Rev. 1, 05-21-04)

The RO includes this page with all ACD submissions and lists on this page any recommendations (or portions thereof) not covered by part I of the ACD; e.g., a financial recommendation that is awaiting a formal disallowance procedure before it can be cleared.

On this page the RO indicates the current date, audit control number, finding code, and recommendation(s) and amount (if any) remaining open. If the ACD clears all recommendations in the audit report, the RO shows the word "none" on this page.

4795.1C - Attachments

(Rev. 1, 05-21-04)

When applicable, the RO furnishes the following additional documentation with the ACD. (All documents listed below must bear proper signatures and approvals.)

- Disallowance letter, if one was necessary (5 copies);
- Paperwork to verify the recovery of disallowed funds (2 copies);
- Statement of concurrence of CMS Administrator if less than 85 percent of a recommendation of $100,000 or more was upheld (2 copies); and
- Agreement letter to SA director and his/her concurrence, as required in §§4789 or 4791 (2 copies).

4795.1D - Amended ACDs

(Rev. 1, 05-21-04)

In some cases, a situation may arise which would change CMS' position as stated on the ACD when an audit was cleared, such as when an appeal overturns CMS' decision or an additional amount of money is recovered as a result of the audit. In these situations, the RO prepares an "amended ACD" stating the nature of the change and how it effects the original ACD and adds the word "AMENDED" to the upper right-hand corner of each page.

4795.1E - Dispatching ACD

(Rev. 1, 05-21-04)

The RO sends the original and four copies of the ACD to CO. If Medicaid is responsible for the funds overpaid in the audit, the RO Division of Financial Operations will prepare the ACDs for the audit and will forward them to ALS. Some audits are combined with Medicaid program audits in such a way that ACDs must be coordinated by the Office of the Regional Administrator before release.

4795.1F - CO Action

(Rev. 1, 05-21-04)

CO reviews each audit report and ACD to:

- Verify that the ACD addresses all of the management recommendations;
- Verify that all recommended financial adjustments are addressed on the ACD and that the amounts are accurate; and
- Submit the required number of copies of the ACDs to Audit Liaison Staff in an acceptable and timely manner.

If CO has questions about the ACD, it will request additional information from the RO. Upon completion of its review, CO transmits the original and three copies to ALS. That office transmits the ACD to OIG/OAS.

4795.2 - Clearing Audit Clearance Document - RO Procedures

(Rev. 1, 05-21-04)

An audit may be cleared when:

- The RA has rendered a decision as to what action CMS will require of the State to resolve each management recommendation in the report, and that decision has been transmitted to the State; and
- A decision has been reached as to the amount of the financial recommendation to be upheld by CMS and to be repaid by the State, and that decision has been transmitted to the State.
- It is not necessary that corrective action be completed before an ACD can be processed. Even though a determination may be appealed, the ACD should be

prepared by this point. The RO should make every effort to include the entire audit in a single ACD issuance in order to expedite the clearance process.

On occasion, clearance of an item occurs when the RO rejects an OIGOA recommendation in whole or in part. Where the basis for disagreement is a difference in interpretation of the law, rule, or regulation used by the OIG/OAS to support its recommended action, the ACD must be cleared through the Office of the General Counsel before being sent to the Audit Agency. (CMSO will request General Counsel reaction.) The RO transmits the ACD to CO and, in a covering memorandum, points out that a disagreement of this nature exists and gives the rationale for the RO position.

4795.3 - Closure Versus Clearance - RO Procedures

(Rev. 1, 05-21-04)

A finding is cleared when there is conclusive agreement on a PoC or, in a financial audit, on the amount overpaid. RO completion of an ACD showing that a final determination has been made on each OIG/OAS recommendation will clear an audit from the OIG/OAS's pending list of audits or Stewardship Report and from CMS' status report.

A finding is closed when the RO reports it has been satisfied, by evidence or observation, that correction has been achieved, or when the overpayment has been offset or repaid. An audit is not considered closed until the SA has implemented all the final decisions and the implementation verified. The RO furnishes documents verifying recovery of funds by check or by offset to the Audit Liaison Staff.

4796 - Audit Findings and Recommendations Remaining Open at End of Four Months - RO Procedures

(Rev. 1, 05-21-04)

If the SA and the RO fail to reach agreement on all audit recommendations (as contained in the final report) and their implementation by the end of 4 months following the date of the final report, the RO completes the ACD within 10 working days. The RO shows those recommendations that have been cleared up to that time in the space provided together with implementation plans and expected implementation schedule. The RO lists those not cleared in the page headed "Findings Remaining Open," together with the reason not yet cleared and the expected date of resolution. The RO prepares an ACD even when it is certain that a disallowance will be appealed.

It is the responsibility of the RO to follow up on cleared audit reports until it has been determined that the State has taken action necessary to fully implement all audit recommendations. When this has been done, the audit will be closed. In order that central office components and ALS may be kept abreast of actions taken by the auditee and regional personnel to close audit recommendations, the RO submits a status report

quarterly on all cleared audits not previously closed. The RO sends one copy to ALS and one copy to CO 15 days after the end of the quarter.

When audits have been cleared from the OIG/OAS Stewardship Report but are not entirely closed, ALS, not OIG/OAS, will maintain follow-up control. The RO sends a memo to CO to report how and when final closure has been verified. CO will then advise ALS to discontinue the control.

Disposition of Medicare and Medicaid Records

4800 - Retention and Destruction of Medicare and Medicaid Records

(Rev. 1, 05-21-04)

The SA's copies of records produced in the administration of the State survey program become Federal records when the original documents are transmitted to CMS. The provisions of the Federal Records Disposition Act, therefore, govern retention and destruction of these records.

The following sections list the various types of title XVIII and XIX records to be retained in the SA and the applicable periods of retention. However, where State law or practices require longer retention periods than those shown, State law or practice is controlling.

4801 - Provider Certification Records

(Rev. 1, 05-21-04)

(See http://cmsnet.cms.hhs.gov/hpages/iocs/records/admin4.htm)

PROVIDER RECORDS

4801A. Provider Certification Files (N1-440-95-1, Item 9)

(Rev. 1, 05-21-04)

Documents relating to the survey and certification of suppliers and providers of service. Included are official certification and transmittal forms, survey report forms, utilization review plans, provider agreements, transfer agreements, plans of correction, civil rights compliance forms, intermediary designation and tie-in notices, certification letters, and various forms and correspondence used in the certification process with respect to individual facilities. Excluded from this definition are surveyor's notes, rough copy survey report forms, and other work papers which are merged into and superseded by a final product.

DISPOSITION:

1. CMS Regional Office

    a. Non-participating Facilities

    Cutoff file after termination or denial. Destroy 6 years after cutoff.

b. Participating Facilities

(1) Maintain the Form CMS-1561--(Health Insurance Benefits Agreement) the two most recent certifications and background/support materials - Maintain in an active file for as long as the facility is participating.

(2) Survey report forms and related documents - Cutoff file after completion of survey. Destroy 6 years after cutoff.

(3) Survey report forms and related documents pertaining to access hospitals, nursing homes and home health agencies-Cutoff file after removal from the access category and completion of the survey. Destroy 4 years after cutoff.

(4) Mammography Facilities Files - Cutoff file upon approval of schedule and transfer to the FRC. Destroy 3 years after cutoff.

2. State Agencies

a. Non-Participating Facilities- Cutoff file after termination, closure, withdrawal, or denial. Destroy 4 years after cutoff.

(1) Non-Certified Facilities - Cutoff file after termination, closure, withdrawal, or denial. Destroy 1 year after cutoff.

b. Participating Facilities

(1) Retain a facility's (hospitals and skilled nursing facilities (SNFs)) current utilization review plan, transfer agreements and floor plan or physical plant layout. Destroy when superseded, obsolete or when facility becomes non-participating.

(2) Maintain the two most recent certification actions at all times. Destroy all other records when 4 years old.

4802 - Budget and Financial Report Files- Records to Be Retained

(Rev. 1, 05-21-04)

These files are used to estimate, justify, and approve SA program costs, and to account for funds received and expended by the SAs.

The files include: Form CMS-1465A, "State Agency Budget List of Positions"; Form CMS-1466, "State Agency Schedule for Equipment Purchases"; Form CMS-435, "Quarterly Expenditure Report(s)"; Form CMS-434, "Certification Workload Report(s)"; and indirect cost forms.

4802A. Provider Statistical and Reimbursement Reports (BHI.g:40-2, Item BB)

EDP printouts or microfilms showing summaries of payments to hospitals, skilled nursing facilities, home health agencies, and other providers of service. They are used to effect cost settlements between the intermediaries and the providers for program validation purposes, and to determine accuracy of cost reports. These reports contain Part A and Part B inpatient and outpatient information, inpatient statistics, total bills, covered costs, and other related data.

DISPOSITION:

1. CMS Headquarters - Destroy printouts after a total retention of 3 years after the date issued. Destroy microfilm upon receipt and verification of subsequent film.

2. Intermediaries - Destroy after a total retention of 5 years after completion of audit and/or settlement process for provider cost report for corresponding fiscal year.

4802B. Medical Facilities Directory Files (BHI.g:40-2, Item CC)

Listing of providers of service showing provider identification and intermediary numbers, effective date, and city where located. Also included are alphabetical listing of facilities by State, cities within the State, and facility name within the city. These lists contain mailing addresses, provider numbers, intermediary numbers, effective dates, termination codes, billing elections, radiological and laboratory services, total beds, nursing beds, and accreditation by Joint Commission on Accreditation of Hospitals and the American Osteopathic Association.

DISPOSITION: Destroy when superseded or obsolete.

4802C. State Agency Budget and Financial Report Files (NC1-440-79-1, Item 50, description revised 11/2000)

Files used to estimate, justify, and approve State agency health insurance program costs, and to account for funds received and expended by the State agencies. Included are Forms CMS-435 (used by the State agencies to request funding by CMS regional offices to approve budgets, by the State agencies to request supplemental funding, and by the State agencies to report quarterly expenditures)--State Survey Agency Budget/Expenditure Report; CMS-1465A--State Agency Budget List of Positions; CMS-1466--State Agency Schedule for Equipment Purchases; and indirect cost forms. (Form CMS-435 replaces Forms CMS-1465, CMS-1467, CMS-1468 and CMS-1469A.)

DISPOSITION:

1. CMS Headquarters and Regional Offices - Destroy after a total retention of 6 years following the close of the budget year.

2. State Agencies - Destroy after a total retention of 3 years after HHS audit or after a total retention of 5 years after the close of the budget year, whichever is earlier.

4802D. State Agency Agreements (BHI.g:40-2, Item EE)

Agreements entered into with the State agencies by the Secretary of Health and Human Services under the provisions of Section 1864 of the Social Security Act, by which the State agency assists CMS in determining whether health care providers and suppliers met and continue to meet the requirements for coverage or participation. Also included are “sub-agreements” by which State agencies subcontract some Medicare functions to other governmental or private organizations.

DISPOSITION:

1. CMS Headquarters - PERMANENT. Transfer to the FRC at the close of the calendar year in which terminated. Transfer to the National Archives 20 years thereafter.

2. Regional Offices - Destroy after a total retention of 5 years after the close of the calendar year in which terminated.

3. State Agencies - Dispose of according to State practice.

4802E. State Agency Review Files (BHI.g:40-2, Item FF)

Documents relating to administrative review of State agency operations and certification procedures. Included are reports of visits, communications concerning improvements in operations, and other papers pertaining to reviews of State agency practices.

DISPOSITION:

1. CMS Headquarters - Destroy after a total retention of 5 years after the close of the calendar year in which dated.

2. State Agencies - Dispose of according to State practice.

4802F. State Buy-In Agreements (BHI.g:40-2, Item GG)

Agreements entered into with the State agencies by the Secretary of Health and Human Services under the provisions of section 1843 of the Social Security Act. The agreements provide coverage under the Supplementary Medical Insurance Program for certain individuals receiving money payments under State approved public assistance plans. Buy-In Agreements allow coverage for individuals not normally eligible for coverage.

DISPOSITION:

1. CMS Headquarters - PERMANENT. Transfer to the FRC at the close of the calendar year in which terminated. Transfer to the National Archives 20 years thereafter.

2. Regional Offices - Destroy after a total retention of 5 years after the close of the calendar year in which terminated.

3. State Agencies - Dispose of according to State practice.

4802G. Program Validation Reviews (BHI.g:40-2, Item HH)

Documents relating to program validation reviews conducted to identify the degree to which program provisions are being properly applied by the providers of health care services. Included are planned validation reviews, notice of visits, and other papers directly related to the program validation review process.

DISPOSITION: Place in inactive file after 2 years or upon receipt of subsequent review, whichever is earlier. Destroy after a total retention of 5 years.

4802H. Detailed Printouts (Depots) (BHI.g:40-2, Item II)

EDP printouts showing individual bill and payment information for hospitals skilled nursing facilities, home health agencies, and other providers of service. These reports are used by intermediaries and providers to reconcile the Provider Statistical and Reimbursement Reports to their own records by itemizing which bills have been processed by CMS and are included in the PS&R report.

DISPOSITION:

1. CMS Headquarters - Destroy printouts after a total retention of 3 years after the date issued.

2. Intermediaries - Destroy after a total retention of 5 years after the completion of the audit and/or settlement process for provider cost report for the corresponding fiscal year.

4802I. Interim Rate Listings (BHI.g:40-2, Item JJ)

Listings of interim rates in use by intermediaries in making interim payments to hospitals, skilled nursing facilities, home health agencies, and other providers of services. These listing are used as a source of information and for studies.

DISPOSITION: Destroy after a total retention of 5 years.

4802J. Provider Hearing Files (BHI.g:40-2, Item MM)

These files accumulate when a provider of services is dissatisfied with CMS' determination that it does not meet the conditions for participation in the Medicare program and requests an administrative hearing on the matter. The documents are used by CMS to support its initial determination at the hearing. Included are copies of provider inspection reports, correspondence, and similar records relating to provider operations. After the hearing, the files must be retained in the event that the provider seeks court review.

DISPOSITION: Transfer to the CMS Records Holding Area at the close of the calendar year in which hearing is held. Hold for 2 years and then transfer to the FRC. Destroy after a total retention of 7 years.

4802K. Supplementary Medical Insurance (SMI) General Enrollment Period (GEP) Records (N1-440-95-1, Item 10)

Records consisting of source documents, (the CMS-L40D) for all individuals who responded in the direct mail solicitation for SMI enrollment. The records contain

such information as beneficiary name, claim number, address, premium amount, and a check mark reflecting individual's election or refusal of enrollment.

DISPOSITION:

1. Source Document - Cutoff at the close of the General Enrollment Period. Destroy 1 year after cutoff.

2. Timely Filed Yes Reply List - Cutoff at the end of the calendar year. Destroy 3 years after cutoff.

4802L. Claims Processing File (Previously, Quality Assurance File--NC1-440-76-29, Item II)

The Medicare Part B Carrier Quality Assurance System was designed as a program for measuring the quality of carrier claims processing operations and to provide management tools for identifying and monitoring actions needed to derive improvements in claims processing. Claims processing files are transmitted electronically to CMS' Data Center (HDC) by all Part B carriers.

DISPOSITION: Retained at the HDC for a total retention of 3 years.

4802M. Correction Payment Action Summary Report (NC1-440-76-29, Item III)

Documents relating to corrective payment action taken on Part B claims selected for end-of-line or quality assurance sample review. Included are summary report forms and transmittal letters.

DISPOSITION: Destroy after a total retention of 1 year.

4802N. **Civil Litigation Case Files** (NC1-440-79-1, Item 3HH)

Case files documenting central office involvement in Medicare civil litigation. Civil Litigation cases usually have no fraud involvement. They relate to any aspect of the Medicare program, such as overpayment or underpayment of monies by CMS to contractors or providers of services, coverage and entitlement questions, provider terminations, and regulation promulgation and enforcement. Unless settled beforehand, civil litigation cases are heard in Federal (and rarely State) courts. Documentation in the case files may include but not be limited to, complaints and answers, court orders, transcripts, briefs, evidentiary material (cost reports, accounting data, affidavits, etc.), correspondence and related background information. The Department of Justice maintains the record copy of cases reaching the court level. The Civil Litigation and Hearings Branch maintains record copies of central office involvement in these cases.

DISPOSITION: Place in an inactive file after final action on the case. Cut off inactive file at the close of the calendar year in which final action was taken, hold 2 additional years, and then transfer to the FRC. Destroy when inactive for a total retention of 5 years.

4802O. **Professional Qualifications File** (NC1-440-79-1, Item IV.A.)

Records of certain individuals who are employed in hospitals and clinical laboratories, or who are self-employed providing therapy and medical services who have taken HHS proficiency examinations. The records contain professional qualification information on the academic and experience qualifications of the individuals and identify information such as social security number, name, address license number and eligibility, and results of HHS proficiency examination. Records are maintained by State agencies and regional Medicare offices, and are used to determine whether individuals rendering health care services meet qualification requirements.

DISPOSITION: Transfer to an inactive file upon termination of individual's participation. Destroy after a total retention of 5 years.

4802P. Teaching Hospital Medical Records Audit Files (NC1-440-78-1, Item A)

Documents created from audits of teaching facilities' medical records, conducted nationwide by carriers. These audits, conducted annually or semi-annually, are intended to verify, through medical records, the degree of participation of supervising physicians in the care and treatment of beneficiaries for which payment is requested under Part B Medicare. Documents in these files include copies of Part B claims records, letters of inquiry and responses from facilities or physicians, copies of documentation supplied to carriers, and related correspondence.

DISPOSITION: Transfer to the FRC after completion of the audit. Destroy after a total retention of 4 years after completion of audit.

4802Q. Teaching Hospital Medical Record Recoupment Audit Files (NC1-440-78-1, Item B)

Documents relating to periodic audits of teaching facilities nationwide by carriers to recover overpayment. These audits are similar to the teaching hospital medical record audits. Findings adverse to the facility may be appealed through the fair hearing process. Documents in the files include copies of Part B claims records; correspondence or documentation supplied by the facility or physician; and documents relating to the fair hearing (transcripts, decisions, etc.).

DISPOSITION: Transfer to the FRC after completion and settlement of the audit. Destroy 4 years after completion of audit.

4802R. Utilization Review Files (NC1-440-80-1)

Records documenting postpayment utilization review of physicians, conducted by State and local medical societies. These files are maintained by carriers nationwide and contain copies of Part B claim forms, medical documentation, determination documentation, correspondence and related background documents. No original claims records are included in these files. Physician overpayment may be collected based on the results of the reviews.

DISPOSITION: Transfer to an inactive file upon completion of review. Close out inactive file at the end of each calendar year, and transfer to Federal Records Center (FRC). Destroy after a total retention of 7 years.

4802S. Provider/Supplier and Durable Medical Equipment Supplier Application (N1-440-01-1)

Document relating to the enrollment of providers and suppliers into the Medicare program. These include but are not limited to Form CMS-855 enrollment forms (OMB Approval No. 0938-0685) and all supporting documents. Also included are attachments that would be submitted with the application. These include but are not limited to copy(s) of: Federal, State and/or local (city/county) professional licenses, certifications and/or registrations; Federal, State, and/or local (city/county) business licenses, certification and/or registrations; professional school degrees or certificates or evidence of qualifying course work; curriculum vitae/resumes; CLIA certificates and FDA mammography certificates; controlled substances registrations from the Drug Enforcement Agency; Central Office letter issuing an indirect billing number to a managed care organization or plan.

1. Provider/Supplier and Durable Medical Equipment Supplier Application

    a. Unprocessed applications as a result of provider/supplier failing to provide additional information

    DISPOSITION: Destroy when 7 years old.

    b. Approved applications of provider/supplier

    DISPOSITION: Destroy 15 years after the provider/supplier's enrollment has ended.

c. Denied applications of provider/supplier.

DISPOSITION: Destroy 15 years after the date of denial.

d. Approved application of provider/supplier, but subsequently, the billing number has been revoked

DISPOSITION: Destroy 15 years after the billing number is revoked.

e. Voluntary deactivation of billing number

DISPOSITION: Destroy 15 years after deactivation.

f. Provider/Supplier dies

DISPOSITION: Destroy 7 years after date of death.

2. Electronic Mail and Word Processing System Copies

a. Copies that have no further administrative value after the recordkeeping copy is made. Includes copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives, and copies on shared network drives that are used only to produce the recordkeeping copy.

DISPOSITION: DELETE within 180 days after the recordkeeping copy has been produced.

b. Copies used for dissemination, revision or updating that are maintained in addition to the recordkeeping copy

DISPOSITION: DELETE when dissemination, revision, or updating is complete.

4803 - Title XVIII State Agreements

(Rev. 1, 05-21-04)

The SA retains §1864 agreements (see §4002) and interagency subagreements (see §4006) during the life of the agreements, after which they may be disposed of according to State practice.

4804 - Title XIX State Plans

(Rev. 1, 05-21-04)

The SA retains State plans, required by §1903 of the Act, during the life of the plan, after which they may be disposed of according to State practice.

4805 - SA Review Files

(Rev. 1, 05-21-04)

Documents relating to administrative review of SA operations and certification procedures, such as reports of visits, communications concerning improvements in operations, and other papers pertaining to reviews of SA practices, are to be destroyed 3 years after the year in which the document was prepared or when no longer needed for reference, whichever is later.

4806 - Destruction of Records

(Rev. 1, 05-21-04)

When records no longer need to be retained, the SA may destroy them. To ensure confidentiality, the SA destroys records by shredding, mutilation, or other protective measures.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R39SOM	12/19/2008	Revisions to Chapter 4-Program Administration and Fiscal Management	12/19/2008	N/A
R23SOM	01/19/2007	Federal Minimum Qualifications Standards	02/20/2007	N/A
R01SOM	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A

F161

(Rev.)

483.10(c)(7) Assurance of Financial Security

The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

Definitions §483.10(c)(7)

A "surety bond" is an agreement between the principal (the facility), the surety (the insurance company), and the obligee (depending on State law, either the resident or the State acting on behalf of the resident), wherein the facility and the insurance company agree to compensate the resident (or the State on behalf of the resident) for any loss of residents' funds that the facility holds, safeguards, manages, and accounts for.

Interpretive Guidelines §483.10(c)(7)

The purpose of the surety bond is to guarantee that the facility will pay the resident (or the State on behalf of the resident) for losses occurring from any failure by the facility to hold, safeguard, manage, and account for the residents' funds, i.e., losses occurring as a result of acts or errors of negligence, incompetence or dishonesty.

Unlike other types of insurance, the surety bond protects the obligee (the resident or the State), not the principal (the facility), from loss. The surety bond differs from a fidelity bond, which covers no acts or errors of negligence, incompetence or dishonesty.

The surety bond is the commitment of the facility in an objective manner to meet the standard of conduct specified in §483.10(c)(2), that the facility will hold, safeguard, manage and account for the funds residents have entrusted to the facility. The facility assumes the responsibility to compensate the obligee for the amount of the loss up to the entire amount of the surety bond.

NOTE: *The surety bond is not limited to personal needs allowance funds. Any resident funds that are entrusted to the facility for a resident must be covered by the surety bond, including refundable deposit fees.*

Reasonable alternatives to a surety bond must:

- Designate the obligee (depending on State law, the resident individually or in aggregate, or the State on behalf of each resident) who can collect in case of a loss;
- Specify that the obligee may collect due to any failure by the facility, whether by commission, bankruptcy, or omission, to hold, safeguard, manage, and account for the residents' funds; and

- Be managed by a third party unrelated in any way to the facility or its management.

The facility cannot be named as a beneficiary.

Self-insurance is not an acceptable alternative to a surety bond. Likewise, funds deposited in bank accounts protected by the Federal Deposit Insurance Corporation, or similar entity, also are not acceptable alternatives.

Procedures §483.10(c)(7)

As part of Phase 2 *for the Traditional Survey Process*, if your team has any concerns about residents' funds, check the amount of the surety bond to make sure it is at least equal to the total amount of residents' funds, as of the most recent quarter.

If the State survey agency determines that individual circumstances associated with a facility's surety bond or its alternative are such that the survey agency cannot determine whether or not the facility is in compliance with the requirements at §483.10(c)(7), then it would be appropriate to make the referral to the State's fiscal department.

If a corporation has a surety bond that covers all of its facilities, there should be a separate review of the corporation's surety bond by the appropriate State agency, such as the State's fiscal department, to ensure that all the residents in the corporation's facilities within the State are covered against any losses due to acts or errors by the corporation or any of its facilities. The focus of the review should be to ensure that if the corporation were to go bankrupt or otherwise cease to operate, the funds of the residents in the corporation's facilities would be protected.

F202

(Rev.)

§483.12(a)(3) Documentation

When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by--

(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

Interpretive Guidelines:§483.12(a)(2) and (3)

If transfer is due to a significant change in the resident's condition, but not an emergency requiring an immediate transfer, then prior to any action, the facility must conduct the appropriate assessment to determine if a new care plan would allow the facility to meet the resident's needs. (See §483.20(b)(4)(iv), F274, for information concerning assessment upon significant change.)

Conversion from a private pay rate to payment at the Medicaid rate does not constitute non-payment.

Refusal of treatment would not constitute grounds for transfer, unless the facility is unable to meet the needs of the resident or protect the health and safety of others.

Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy.

If a nursing home discharges a resident or retaliates due to an existing resident's failure to sign or comply with a binding arbitration agreement, the State and Region may initiate an enforcement action based on a violation of the rules governing resident discharge and transfer. A current resident is not obligated to sign a new admission agreement that contains binding arbitration.

Procedures:§483.12(a)(2) and (3)

During closed record review, determine the reasons for transfer/discharge.

If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's physician justify why the facility could not meet the needs of this resident.

Probes: §483.12(a)(2) and (3)

Do records document accurate assessments and attempts through care planning to address resident's needs through multi-disciplinary interventions, accommodation of individual needs and attention to the resident's customary routines?

Did the resident's physician document the record if:

- The resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization)? or

- The resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility.

Did a physician document the record if residents were transferred because the health of individuals in the facility is endangered?

Do the records of residents transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary? Did the survey team observe residents with similar safety concerns in the facility? If so, determine differences between these residents and those who were transferred or discharged.

Look for changes in source of payment coinciding with transfer. If you find such transfer, determine if the transfers were triggered by one of the criteria specified in §483.12(a)(2).

Ask the ombudsman if there were any complaints regarding transfer and/or discharge. If there were, what was the result of the ombudsman's investigation?

F208

(Rev.)

§483.12(d) Admissions Policy

(1) The facility must--

(i) Not require residents or potential residents to waive their rights to Medicare or Medicaid; and

(ii) Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

Interpretive Guidelines §483.12(d)(1)

This provision prohibits both direct and indirect request for waiver of rights to Medicare or Medicaid. A direct request for waiver, for example, requires residents to sign admissions documents explicitly promising or agreeing not to apply for Medicare or Medicaid. An indirect request for waiver includes requiring the resident to pay private rates for a specified period of time, such as two years ("private pay duration of stay contract") before Medicaid will be accepted as a payment source for the resident. Facilities must not seek or receive any kind of assurances that residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

Procedures §483.12(d)(1)

If concerns regarding admissions procedures arise during interviews, review admissions packages and contracts to determine if they contain prohibited requirements (e.g., "side agreements" for the resident to be private pay or to supplement the Medicaid rate).

Ask staff what factors lead to decisions to place residents in different wings or floors. Note if factors other than medical and nursing needs affect these decisions. Do staff know the source of payment for the residents they take care of?

Ask the ombudsman if the facility treats residents differently in transfer, discharge and covered services based on source of payment.

With respect to transfer and discharge, if the facility appears to be sending residents to hospitals at the time (or shortly before) their payment source changes from private-pay or Medicare to Medicaid, call the hospitals and ask their discharge planners if they have detected any pattern of dumping. Also, ask discharge planners if the facility readmits Medicaid recipients who are ready to return to the facility. During the tour, observe possible differences in services

- Observe if there are separate dining rooms. If so, are different foods served in these dining rooms? For what reasons? Are residents excluded from some dining rooms because of source of payment?

- Observe the placement of residents in rooms in the facility. If residents are segregated on floors or wings by source of payment, determine if the facility is providing different services based on source of payment. Be particularly alert to differences in treatment and services. For example, determine whether less experienced aides and nursing staff are assigned to Medicaid portions of the facility. Notice the condition of the rooms (e.g., carpeted in private-pay wings, tile in Medicaid wings, proximity to the nurses' station, quality of food served as evening snacks).

As part of closed record review, determine if residents have been treated differently in transfers or discharges because of payment status. For example, determine if the facility is sending residents to acute care hospitals shortly before they become eligible for Medicaid as a way of getting rid of Medicaid recipients.

Ask social services staff to describe the facility's policy and practice on providing services, such as rehabilitative services. Determine if services are provided based on source of payment, rather than on need for services to attain or maintain functioning.

§483.12(d)(2) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

Interpretive Guidelines §483.12(d)(2)

The facility may not require a third person to accept personal responsibility for paying the facility bill out of his or her own funds. However, he or she may use the resident's money to pay for care. A third party guarantee is not the same as a third party payor, e.g., an insurance company; and this provision does not preclude the facility from obtaining information about Medicare or Medicaid eligibility or the availability of private insurance. The prohibition against third-party guarantees applies to all residents and prospective residents in all certified long term care facilities, regardless of payment source.

§483.12(d)(3) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,--

(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term "nursing facility services" so long as the facility gives

proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and

(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

Interpretive Guidelines §483.12(d)(3)

This requirement applies only to Medicaid certified nursing facilities.

Facilities may not charge for any service that is included in the definition of "nursing facility services" and, therefore, required to be provided as part of the daily rate. Facilities may not accept additional payment from residents or their families as a prerequisite to admission or to continued stay in the facility. Additional payment includes deposits from Medicaid-eligible residents or their families, or any promise to pay private rates for a specified period of time.

NOTE: *This regulation does not preclude a facility from charging a deposit fee to, or requiring a promissory note from, an individual whose stay is not covered by Medicaid. In instances where the deposit fee is refundable and remains as funds of the resident, the facility must have a surety bond that covers the deposit amount (§483.10(c)(7)).*

Permitted Charges for Medicaid Eligible Residents §483.12(d)(3)

A nursing facility is permitted to charge an applicant or resident whose Medicaid eligibility is pending, typically in the form of a deposit prior to admission and/or payment for services after admission. Medicaid eligibility will be made retroactive up to 3 months before the month of application if the applicant would have been eligible had he or she applied in any of the retroactive months.

In addition, the nursing facility must accept as payment in full the amounts determined by the state for all dates the resident was both Medicaid eligible and a nursing facility resident. Therefore, a nursing facility that charged a recipient for services between the first month of eligibility established by the state and the date notice of eligibility was received is obligated to refund any payments received for that period less the state's determination of any resident's share of the nursing facility's costs for that same period. A nursing facility must prominently display written information in the facility and provide oral and written explanation to applicants or residents about applying for Medicaid, including how to use Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

Under the post-eligibility process, if the Medicaid-eligible resident has income and is required to make a monthly payment to the nursing facility (which is a portion of the Medicaid payment

amount), then the nursing facility is permitted to retain the amount it is legally owed. However, the nursing facility must not charge any administrative fees.

A nursing facility may charge a Medicaid beneficiary for a service the beneficiary has requested and received, only if:

- That service is not defined in the State plan as a "nursing facility" service;
- The facility informs the resident and the resident's representative in advance that this is not a covered service to allow them to make an informed choice regarding the fee; and
- The resident's admission or continued stay is not conditioned on the resident's requesting and receiving that service.

Procedures §483.12(d)(3)

Review State covered services. Compare with the list of items for which the facility charges to determine if the facility is charging for covered services.

Determine if the facility requires deposits from residents. If you identify potential problems with discrimination, review the files of one or more residents selected for a focused or comprehensive review to determine if the facility requires residents to submit deposits as a precondition of admission besides what may be paid under the State plan.

If interviews with residents suggest that the facility may have required deposits from Medicaid recipients at admission, except those admitted when Medicaid eligibility is pending, corroborate by, for example, reviewing the facility's admissions documents or interviewing family members.

§483.12(d)(4) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

F221

Use Tag F221 for deficiencies concerning **physical** restraints.

USE GUIDANCE UNDER TAG F222

F222

(Rev.)

Use Tag F222 for deficiencies concerning **chemical** restraints.

§483.13(a) Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

Intent §483.13(a)

The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

Definitions

"Chemical Restraints" is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms.

"Convenience" is defined as any action taken by the facility to control a resident's behavior or manage a resident's behavior with a lesser amount of effort by the facility and not in the resident's best interest.

"Discipline" is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

"Freedom of movement" means any change in place or position for the body or any part of the body that the person is physically able to control.

"Medical Symptom" is defined as an indication or characteristic of a physical or psychological condition.

"Physical Restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body (e.g. leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions, and lap trays the resident cannot remove easily).

"Removes easily" means that the manual method, device, material, or equipment can be removed intentionally by the resident in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the resident's physical condition and ability to accomplish objective (e.g., transfer to a chair, get to the bathroom in time).

Overview

Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident's unanticipated violent or aggressive behavior places him/her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The facility may not use restraints in violation of the regulation solely based on a legal surrogate or representative's request or approval.

Finally, residents who are restrained may face a loss of autonomy, dignity and self-respect, and may show symptoms of withdrawal, depression, or reduced social contact.

Facility practices that meet the definition of a restraint include, but are not limited to:

- Using side rails that keep a resident from voluntarily getting out of bed;
- Tucking in or using velcro to hold a sheet, fabric, or clothing tightly so that a resident's movement is restricted;
- Using devices in conjunction with a chair, such as trays, tables, bars or belts, that the resident cannot remove easily, that prevent the resident from rising;
- Placing a resident in a chair that prevents a resident from rising; and

- Placing a chair or bed so close to a wall that the wall prevents the resident from rising out of the chair or voluntarily getting out of bed.

NOTE: An enclosed framed wheeled walker, with or without a posterior seat, would not meet the definition of a restraint if the resident could easily open the front gate and exit the device. If the resident cannot open the front gate (due to cognitive or physical limitations that prevent him or her from exiting the device or because the device has been altered to prevent the resident from exiting the device), the enclosed framed wheeled walker would meet the definition of a restraint since the device would restrict the resident's freedom of movement (e.g. transferring to another chair, to the commode, or into the bed). The decision on whether framed wheeled walkers are a restraint must be made on an individual basis.

Side Rails

Side rails sometimes restrain residents. The use of side rails as restraints is prohibited unless they are necessary to treat a resident's medical symptoms *or assist with physical functioning*. Residents who attempt to exit a bed through, between, over or around side rails are at risk of injury or death. The potential for serious injury is more likely from a fall from a bed with raised side rails than from a fall from a bed where side rails are not used. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from the bed.

As with other restraints, for residents who are restrained by side rails, it is expected that the process facilities employ to reduce the use of side rails as restraints is systematic and gradual to ensure the resident's safety while treating the resident's medical symptom.

The same device may have the effect of restraining one individual but not another, depending on the individual resident's condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another.

Medical Symptom and Restraint Use

Objective findings derived from clinical evaluation and the resident's subjective symptoms should be considered to determine the presence of a medical symptom. The resident's subjective symptoms may not be used as the sole basis for using a restraint. In addition, the resident's medical symptoms should not be viewed in isolation; rather, the symptoms should be viewed in the context of the resident's condition, circumstances, and environment. Before a resident is restrained, the facility must determine the presence of a specific medical symptom that would require the use of restraints, and how *their use* would treat the medical symptom, protect the resident's safety, and assist the resident in attaining or maintaining his or her highest practicable level of physical and psychosocial well-being. This includes the facility's discussion with the resident, (and/or if indicated) their legal surrogate or representative of potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use.

Medical symptoms that warrant the use of restraints must be documented in the resident's medical record, ongoing assessments, and care plans. Surveyors should be aware that physical restraints as an intervention do not treat the underlying causes of medical symptoms and that they should be used temporarily and not be used without also seeking to identify and address the physical or psychosocial condition causing the medical symptom. While there must be a physician's order reflecting the presence of a medical symptom, CMS will hold the facility ultimately accountable for the appropriateness of that determination. The physician's order alone is not sufficient to warrant the use of the restraint. It is further expected, for those residents whose care plans indicate the need for restraints, that the facility engages in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities). This systematic process would also apply to recently admitted residents for whom restraints were used in the previous setting.

***NOTE**: Falls do not constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint. Although restraints have been traditionally used as a falls prevention approach, they have major, serious drawbacks and can contribute to serious injuries. There is no evidence that the use of physical restraints, including but not limited to side rails, will prevent or reduce falls. Additionally, falls that occur while a person is physically restrained often result in more severe injuries (e.g., strangulation, entrapment).*[i]

Orthotic Body Devices

Orthotic body devices may be used solely for therapeutic purposes to improve the overall functional capacity of the resident.

Assessment and Care Planning for Restraint Use

There are instances where, after assessment and care planning, a least restrictive restraint may be deemed appropriate for an individual resident to attain or maintain his or her highest practicable physical and psychosocial well-being. This does not alter the facility's responsibility to assess and care plan restraint use on an ongoing basis.

Before using a device for mobility or transfer, assessment should include a review of the resident's:

- Bed mobility (e.g., would the use of a device assist the resident to turn from side to side? Is the resident totally immobile and unable to change position without assistance?); and

- Ability to transfer between positions, to and from bed or chair, to stand and toilet (e.g., does the raised side rail add risk to the resident's ability to transfer?).

The facility must design its interventions not only to minimize or eliminate the medical symptom, but also to identify and address any underlying problems causing the medical symptom.

- Interventions that the facility might incorporate in care planning include:
    - Providing restorative care to enhance abilities to stand, transfer, and walk safely;
    - Providing a device such as a trapeze to increase a resident's mobility in bed;
    - Placing the bed lower to the floor and surrounding the bed with a soft mat;
    - Equipping the resident with a device that monitors his/her attempts to arise;
    - Providing frequent monitoring by staff with periodic assisted toileting for residents who attempt to arise to use the bathroom;
    - Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information and are able to use the call bell device; and/or
    - Providing exercise and therapeutic interventions, based on individual assessment and care planning, that may assist the resident in achieving proper body position, balance and alignment, without the potential negative effects associated with restraint use.

Procedures: §483.13(a)

Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. Since continued restraint use is associated with a potential for a decline in functioning if the risk is not addressed, determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated and that the care plan reflected measures to minimize a decline. Also determine if the plan of care was consistently implemented. Determine whether the decline can be attributed to a disease progression or inappropriate use of restraints.

For sampled residents observed as physically restrained during the survey or whose clinical records show the use of physical restraints within 30 days of the survey, determine whether the facility used the restraint for convenience or discipline, or a therapeutic intervention for specific periods to attain and maintain the resident's highest practicable physical, mental, or psychosocial well-being.

Probes: §483.13(a)

This systematic approach should answer these questions:

1. What are the medical symptoms that led to the consideration of the use of restraints?
2. Are these symptoms caused by failure to:
    a. Meet individual needs in accordance with the resident assessments?
    b. Use rehabilitative/restorative care?
    c. Provide meaningful activities?
    d. Manipulate the resident's environment, including seating?
3. Can the cause(s) of the medical symptoms be eliminated or reduced?
4. If the cause(s) cannot be eliminated or reduced, then has the facility attempted to use alternatives in order to avoid a decline in physical functioning associated with restraint use?
5. If alternatives have been tried and deemed unsuccessful, does the facility use the least restrictive restraint for the least amount of time? Does the facility monitor and adjust care to reduce the potential for negative outcomes while continually trying to find and use less restrictive alternatives?
6. Did the resident or legal surrogate make an informed choice about the use of restraints? Were risks, benefits, and alternatives explained?
7. Does the facility use the Care Area Assessments (CAAs) to evaluate the appropriateness of restraint use?
8. Has the facility re-evaluated the need for the restraint, made efforts to eliminate its use and maintained residents' strength and mobility?

Endnotes

[i] *American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. Journal of the American Geriatrics Society. 49(5):664-72, 2001 May.*

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F278

(Rev.)

§483.20(g) Accuracy of Assessment

The assessment must accurately reflect the resident's status.

Intent §483.20(g)

To assure that each resident receives an accurate assessment by staff that are qualified to assess relevant care areas and knowledgeable about the resident's status, needs, strengths, and areas of decline.

Interpretive Guidelines §483.20(g)

"The accuracy of the assessment" means that the appropriate, qualified health professional correctly documents the resident's medical, functional, and psychosocial problems and identifies resident strengths to maintain or improve medical status, functional abilities, and psychosocial status. The initial comprehensive assessment provides baseline data for ongoing assessment of resident progress.

Probes §483.20(g)

Based on your total review of the resident, is each portion of the assessment accurate?

§483.20(h) Coordination

A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

Intent §483.20(h)

The registered nurse will conduct and/or coordinate the assessment, as appropriate. Whether conducted or coordinated by the registered nurse, he or she is responsible for certifying that the assessment has been completed.

Interpretive Guidelines §483.20(h)

According to the Utilization Guidelines for each State's RAI, the physical, mental and psychosocial condition of the resident determines the appropriate level of involvement of physicians, nurses, rehabilitation therapists, activities professionals, medical social workers, dietitians, and other professionals, such as developmental disabilities specialists, in assessing the resident, and in correcting resident assessments. Involvement of other disciplines is dependent upon resident status and needs.

Probes §483.20(h)

Have appropriate health professionals assessed the resident? For example, has the resident's nutritional status been assessed by someone who is knowledgeable in nutrition and capable of correctly assessing a resident?

If the resident's medical status, functional abilities, or psychosocial status declined and the decline was not clinically unavoidable, were the appropriate health professionals involved in assessing the resident?

§483.20(i) Certification

(1) A registered nurse must sign and certify that the assessment is completed.

(2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

Interpretive Guidelines §483.20(i)

Whether the MDS assessments are manually completed, or computer generated following data entry, each individual assessor is responsible for certifying the accuracy of responses relative to the resident's condition and discharge or entry status. Manually completed forms are signed and dated by each individual assessor the day they complete their portion(s) of the MDS record.

Electronic Signatures

When MDS forms are completed directly on the facility's computer (e.g., no paper form has been manually completed), then each individual assessor signs and dates a computer generated hard copy, or provides an electronic signature, after they review it for accuracy of the portion(s) they completed.

Facilities may use electronic signatures on the MDS when permitted to do so by state and local law and when this is authorized by the long-term care facility's policy. Additionally, they must have written policies in place to ensure that they have proper security measures to protect use of an electronic signature by anyone other than to which the electronic signature belongs. The policy must also ensure that access to a hard copy of clinical records is made available to surveyors and others who are authorized access to clinical records by law.

Facilities that are not capable of maintaining the MDS signatures electronically must adhere to the current requirements addressing the need for either a hand-written copy or a computer-generated form. All state licensure and state practice regulations continue to apply to certified facilities.

NOTE: *Where state law is more restrictive than federal requirements, the provider needs to apply the state law standard.*

Backdating Completion Dates

Backdating completion dates is not acceptable – note that recording the actual date of completion is not considered backdating. For example, if an MDS was completed electronically and a hard copy was printed two days later, writing the date the MDS was completed on the hard copy is not considered backdating.

Probes §483.20(i)

Are the appropriate certifications in place, including the RN Coordinator's certification of completion of an assessment or Correction Request, and the certification of individual assessors of the accuracy and completion of the portion(s) of the assessment or tracking record completed or corrected?

§483.20(j) Penalty for Falsification

(1) Under Medicare and Medicaid, an individual who willfully and knowingly--

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty or not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

Interpretive Guidelines §483.20(j)

MDS information serves as the clinical basis for care planning and delivery. With the introduction of additional uses of MDS information such as for payment rate setting and quality monitoring, MDS information as it is reported impacts a nursing home's payment rate and standing in terms of the quality monitoring process. A pattern within a nursing home of clinical documentation or of MDS assessment or reporting practices that result in higher RUG scores, untriggering *CAA*(s), or unflagging QI(s), where the information does not accurately reflect the resident's status, may be indicative of payment fraud or avoidance of the quality monitoring process. Such practices may include but are not limited to a pattern or high prevalence of the following:

- Submitting MDS Assessments (including any reason(s) for assessment, routine or non-routine) or tracking *record*s, where the information does not accurately reflect the resident's status as of the ARD, or the Discharge or *Entry* date, as applicable;

- Submitting correction(s) to information in the *QIES ASAP system* where the corrected information does not accurately reflect the resident's status as of the original ARD, or

the original Discharge or Entry date, as applicable, or where the record it claims to correct does not appear to have been in error;

- Submitting Significant Correction Assessments where the assessment it claims to correct does not appear to have been in error;

- Submitting Significant Change in Status Assessments where the criteria for significant change in the resident's status do not appear to be met;

- Delaying or withholding MDS Assessments (including any reason(s) for assessment, routine or non-routine), Discharge or Entry Tracking information, or correction(s) to information in the *QIES ASAP system*.

When such patterns or practices are noticed, they should be reported by the State Agency to the proper authority.

F281

§483.20(k)(3)

(3) The services provided or arranged by the facility must--

(i) Meet professional standards of quality and;

Intent §483.20(k)(3)(i):

The intent of this regulation is to assure that services being provided meet professional standards of quality (in accordance with the definition provided below) and are provided by appropriate qualified persons (e.g., licensed, certified).

Interpretive Guidelines §483.20(k)(3)(i):

"Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include:

- Current manuals or textbooks on nursing, social work, physical therapy, etc.
- Standards published by professional organizations such as the American Dietetic Association, American Medical Association, American Medical Directors Association, American Nurses Association, National Association of Activity Professionals, National Association of Social Work, etc.
- Clinical practice guidelines published by the Agency of Health Care Policy and Research.
- Current professional journal articles.

If a negative resident outcome is determined to be related to the facility's failure to meet professional standards, and the team determines a deficiency has occurred, it should be cited under the appropriate quality of care or other relevant requirement.

Probes §483.20(k)(3):

Question only those practices which have a negative outcome or have a potential negative outcome. Ask the facility to produce references upon which the practice is based.

- Do nurses notify physicians, as appropriate, and show evidence of discussions of acute medical problems?

- Are residents with acute conditions who require intensive monitoring and hospital-level treatments that the facility is unable to provide, promptly hospitalized?

- Are there errors in the techniques of medication administration? (Cite actual medication errors at §483.25(m).)

- *Does the staff follow facility policies for assuring each resident has a sufficient supply of medications to meet the needs of residents and does the staff adhere to the facility's system for reordering medications?*

- Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and comprehensive care plan?

- Are physicians' orders carried out, unless otherwise indicated by an advanced directive?

F286

(Rev.)

§483.20(d) Use

A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record.

Intent: §483.20(d)

Facilities are required to maintain 15 months of assessment data in the resident's active clinical record.

Interpretive Guidelines §483.20(d)

The requirement to maintain 15 months of data in the resident's active clinical record applies regardless of form of storage to all MDS records, including the CAA Summary, Quarterly Assessment records, Identification Information and Entry, Discharge and Reentry Tracking Records and MDS Correction Requests (including signed attestation). MDS assessments must be kept in the resident's active clinical record for 15 months following the final completion date for all assessments and correction requests. Other assessment types require maintaining them in the resident's active clinical record for 15 months following:

- The entry date for tracking records including re-entry; and
- The date of discharge or death for discharge and death in facility records.

Facilities may maintain MDS data electronically regardless of whether the entire clinical record is maintained electronically and regardless of whether the facility has an electronic signature process in place. *This is in accordance with state and local law, and when this is authorized by the long-term care facility's policy.*

Facilities that maintain their MDS data electronically and do not utilize an electronic signature process must ensure that hard copies of the MDS assessment signature pages are maintained for every MDS assessment conducted in the resident's active clinical record for 15 months. (This includes enough information to identify the resident and type and date of assessment linked with the particular assessment's signature pages),

The information, regardless of form of storage (i.e., hard copy or electronic), must be kept in a centralized location and must be readily and easily accessible. This information must be available to all professional staff members (including consultants) who need to review the information in order to provide care to the resident. (This information must also be made readily and easily accessible for review by the State Survey agency and CMS.)

After the 15-month period, RAI information may be thinned from the clinical record and stored in the medical records department, provided that it is easily retrievable if requested by clinical staff, the State agency, or CMS.

F332 and F333

(Rev.)

§483.25(m) Medication Errors

The facility must ensure that--

[F332] §483.25(m)(1) It is free of medication error rates of 5 percent or greater; and

[F333] §483.25(m)(2) Residents are free of any significant medication errors.

Interpretive Guidelines §483.25(m) ***(1) and (2)***

Definitions §483.25(m)(1) and (2)

"Medication Error" the observed preparation or administration of *medications* or biologicals which is not in accordance with:

1. *The prescriber's order*;

2. Manufacturer's specifications (not recommendations) regarding the preparation and administration of the *medication* or biological;

3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

"**Significant medication error**" means one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided under significant and non-significant medication errors. Discomfort may be a subjective or relative term used in different ways depending on the individual situation. (Constipation that is unrelieved by an ordered laxative that results in a *medication* error that is omitted for one day may be slightly uncomfortable or perhaps not uncomfortable at all. When the constipation persists for greater than three days, the constipation may be more significant. Constipation causing obstruction or fecal impaction can jeopardize the resident's health and safety.)

"**Medication error rate**" is determined by calculating the percentage of medication errors observed during a medication administration observation. The numerator in the ratio is the total number of errors that the survey team observes, both significant and non-significant. The denominator consists of the total number of observations or "opportunities for errors" and includes all the doses the survey team observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

The error rate must be 5% or greater in order to cite F332. Rounding up of a lower rate (e.g., 4.6%) to a 5% rate is not permitted. *A medication error rate of 5% or greater may indicate that the facility has systemic problems with its medication distribution system.*

NOTE: *Significant and non-significant medication errors observed at 5% or greater during the Medication Administration Observation task should continue to be cited at F332. However, any* ***significant*** *medication error included in the F332 (5% or greater) citation should also be cited at F333. If concerns are identified related to the administration of medications at F332-Medication Errors,, then additional requirements may also be considered and investigated such as F425 - Pharmacy Services.*

Significant and Non-significant Medication Errors

Determining Significance

The relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not:

- Resident Condition - The resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.

- Drug Category - If the *medication* is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a *medication* that has a Narrow Therapeutic Index (NTI) (i.e., a *medication* in which the therapeutic dose is very close to the toxic dose). Examples of *medications* with NTI are as follows: Anticonvulsant: phenytoin (Dilantin), carbamazepine (Tegretol), Anticoagulants: warfarin (Coumadin) Antiarrhythmic (digoxin) Lanoxin) Antiasthmatics: theophylline (TheoDur) Antimanic Drigs: lithium salts (Eskalith, Lithobid).

- Frequency of Error - If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's *medication* was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be more in order. This conclusion should be considered in concert with the resident's condition and the *medication* category.

Significant medication errors are cited in the following circumstances:

- *When observed during the medication administration observation. A significant medication error observed during a medication administration observation should be cited, regardless of whether the facility error rate is 5% or greater;*

- *When identified during the course of a resident record review, including a revisit survey or a complaint investigation. A surveyor may cite a deficiency at F333 based upon either a resident record review and/or an observation of a medication preparation or administration. Surveyors must conduct any follow up investigation to obtain corroborating information regarding the error, such as interviews with the nurse, Director of Nursing, or the pharmacist, and document that information and facts as required by the Principles of Documentation. Also, it may be necessary to apply the past non-compliance protocol when determining a deficient practice or citation.*

Examples of Significant and Non-Significant Medication Errors

Some of these errors are identified as significant. This designation is based on expert opinion without regard to the status of the resident. Most experts concluded that the significance of these errors, in and of themselves, have a high potential for creating problems for the typical long term care facility resident. Those errors identified as non-significant have also been designated primarily on the basis of the nature of the *medication*. Resident status and frequency of error could classify these errors as significant.

Examples of Medication Errors
In the following tables, S=Significant; NS=Not Significant.
Omissions Examples (*Medication* ordered but not administered at least once):

***Medication* Order**	**Significance**
Quinidine 200mg TID	S
Nitrol Oint. one inch	S
Haldol 1mg BID	NS
Motrin 400mg TID	NS
Tearisol Drops 2 both eyes TID	NS
Metamucil one packet BID	NS
Multivitamin one daily	NS
Mylanta Susp. one oz., TID AC	NS

Unauthorized *Medication* Examples (*Medications* administered without a physician's order):

***Medication* Order**	**Significance**
Coumadin 4mg	S
Feosol	NS
Zyloprim 100mg	NS
Tylenol 5 gr	NS

Medication **Order**	**Significance**
Motrin 400mg	NS

Wrong Dose Examples:

Medication **Order**	**Administered**	**Significance**
Digoxin 0.125mg everyday	0.25mg	S
Dilantin 125 SUSP 12ml	2ml	S
Timoptic 0.25% one drop in the left eye TID	Three drops in each eye	NS
Amphojel 30ml QID	15ml	NS

Wrong Route of Administration Examples:

Medication **Order**	**Administered**	**Significance**
Cortisporin Ear Drops 4 to 5 left ear QID	Left Eye	S

Wrong Dosage Form Examples:

Medication **Order**	**Administered**	**Significance**
Dilantin Kapseals 100 mg three Kapseals p.o. HS	Prompt Phenytoin 100 mg three capsules p.o. HS	S*
Colace Liquid 100mg BID	Capsule	NS
Mellaril Tab 10mg	Liquid Concentrate	NS (if correct dose was given)

* Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.

Wrong *Medication* Examples:

Medication **Order**	**Administered**	**Significance**
Vibramycin	Vancomycin	S
Tums	Oscal	NS

Wrong Time Examples:

Medication **Order**	**Administered**	**Significance**
Percocet 2 Tabs 20 min. before painful treatment	2 Tabs given after treatment	S
Digoxin 0.25mg daily at 8 a.m.	At 9:30 am	NS

Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards

Failure to "Shake Well"

The failure to "shake" a medication that is labeled "shake well" may lead to an under dose or over dose depending on the product and the elapsed time since the last "shake." The surveyor should use common sense in determining the adequacy of the shaking of the medication. Some *medications*, for example *phenytoin*, are more critical to achieve correct dosage delivery than others.

- Insulin Suspensions: Also included under this category is the failure to "mix" the suspension without creating air bubbles. Some individuals "roll" the insulin suspension to mix it without creating air bubbles. Any motion used is acceptable so long as the suspension is mixed and does not have air bubbles in it prior to the administration.

Crushed Medications

The crushing of tablets or capsules for which the manufacturer instructs to "do not crush" requires further investigation. Some exceptions to the "Do Not Crush" instruction include:

- If the prescriber orders a *medication* to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects.

- If the facility can provide literature from the *medication* manufacturer or from a reviewed health journal to justify why modification of the dosage form will not compromise resident care.

Giving Adequate Fluids with Medications

Administering medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication requires further investigation. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. Surveyors should also be aware if a resident is on a fluid restriction, and not apply this standard to residents who are fluid restricted. For example, the surveyor should count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes).

Medications that are recommended to be given with adequate fluid include, but are not limited to:

- Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel);
- Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) should be administered with adequate fluid. Adequate fluid is not defined by the manufacturer but is usually four to eight ounces; and
- Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted.

Medications that must be taken with food or antacids

The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a medication error. The most commonly used *medications* that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There is evidence that elderly, debilitated persons are at greater risk of gastritis and GI bleeds, including silent GI bleeds. Determine if the time of administration was selected to take into account the need to give the medication with food.

Examples of commonly used NSAIDs are as follows:

Generic Name	**Brand Name**
Diclofenac	Voltaren, Cataflam
Diflunisal	Dolobid
Etodolac	Lodine

Generic Name	Brand Name
Fenoprofen	Nalfon
Ibuprofen	Motrin, Advil
Indomethacin	Indocin
Ketoprofen	Orudis, Oruvail
Mefenamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Naprosyn, Aleve
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin

Medications Administered Via Enteral Feeding Tubes

The placement of the feeding tube should be confirmed in accordance with the facility's policy.

NOTE: *If the placement of the tube is not checked, it is not a medication error, but should be evaluated under F322, §483.25(g)(1) and (2) – Nasogastric Tubes.*

Determine if the staff member administers each medication separately and flushes the tubing between each medication. An exception would be if there is a physician's order that specifies a different flush schedule because of a fluid restriction. For a resident who requires fluid regulation, the physician's order should include the amount of water to be used for the flushing and administration of medications.

NOTE: *Failure to flush before and in between each medication administration is considered a single medication error and would be included in the facility's medication error rate calculation.*

The administration of enteral nutrition formula and administration of phenytoin (Dilantin) should be separated to minimize interaction. The surveyor should look for appropriate documentation and monitoring if the two are administered simultaneously. If the facility is not aware that there is a potential for an interaction between the two when given together, and is not monitoring for outcome of seizures or unwanted side effects of phenytoin, then the surveyor should consider simultaneous administration a medication error.

Nutritional and Dietary Supplements

Nutritional Supplements are medical foods that are used to complement a resident's dietary needs. Examples of these are total parenteral products, enteral products, and meal replacement products (e.g., Ensure, Glucerna and Promote.)

Herbal and alternative products are considered to be dietary supplements. They are not regulated by the Food and Drug Administration (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). If a dietary supplement that is given to a resident between meals and has a vitamin(s) as one or more of its ingredients, it should be documented and evaluated as a dietary supplement, rather than a medication. For clinical purposes, it is important to document a resident's intake of such substances elsewhere in the clinical record and to monitor their potential effects, as they can interact with other medications.

NOTE: *Because nutritional and dietary supplements are not considered to be medications for purposes of the medication administration observation, noncompliance with the administration of these products should not be included in the calculation of the facility's medication error rate at F332 or as a significant medication error at F333. Medication errors involving vitamins and/or minerals <u>should</u> be documented at F332 and counted towards the error rate calculation. Medication errors involving vitamins and minerals <u>would not</u> be considered to be a significant medication error unless the criteria at F333 were met.*

It is expected that the facility staff, along with the prescriber and consulting pharmacist, are aware of, review for, and document any potential adverse consequences between medications, nutritional supplements, and dietary supplements that a resident is receiving.

Medications Instilled into the Eye

When observing the administration of eye drops, confirm that the medication makes full contact with the conjunctival sac, so that the medication is washed over the eye when the resident closes eyelid. The eye drop must contact the eye for a sufficient period of time before the next eye drop is instilled. The time for optimal eye drop absorption is approximately 3 to 5 minutes. (It should be encouraged that when the procedures are possible, systemic effects of eye medications be reduced by pressing the tear duct for one minute after eye drop administration or by gentle eye closing for approximately three minutes after the administration.)

Sublingual Medications

If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative dosage form for this *medication*.

Metered Dose Inhalers (MDI)

Ensuring that a device is administered correctly is vital to optimizing inhalation therapy. The surveyor would observe the administration of MDIs for the following:

- Shake the container well;

- Position the inhaler in front of or in the resident's mouth. Alternatively a spacer *or valved holding chamber* may be used;

- For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication into the lungs, when this method can be used.

- *If more than one puff is required (whether the same medication or a different medication), follow the manufacturer's product information for administration instructions including the acceptable wait time between inhalations.*

NOTE: If the person administering the *medication* follows all the procedures outlined above, and there is a failure to administer the medication because the resident can't cooperate (for example, a resident with dementia may not understand the procedure), this should not be counted as a medication error. The surveyor should evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers.

Determining Medication Errors

Timing Errors

If a *medication* is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a *medication* is ordered PC and is given AC, count as a medication error. Count a wrong time error if the *medication* is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY. Counting a *medication* with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this *medication* has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).

To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

Prescriber's Orders

The latest recapitulation of *medication* orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the *medication*.

Omitted Dose

One of the most frequent types of errors is an omitted dose*, i.e. a dose of medication that is ordered but not given*. If a surveyor detects an omitted dose, investigate the omission further:

- Ask the person administering *medications*, if possible, to describe the system for administering the *medications* given. Occasionally, a respiratory therapist may administer inhalers, a designated treatment person may only administer topical treatments, a hospice nurse may administer hospice medications, another person may administer eye drops or as needed *medications*, etc.

- Sometimes people may share medication carts. Under these circumstances, these individuals should be interviewed about the omitted dose, if they were involved, if possible.

- When persons that were actually responsible for administering the *medications* are not available, ask their supervisor for clarification.

Procedures §483.25(m) ***(1) and (2)***

Medication ***Administration Observation*** **Methodology**

The survey team should observe the administration of *medications*, on several different *medication* "passes," when necessary. Record what is observed; and reconcile the record of observation with the prescriber's *medication* orders to determine whether or not medication errors have occurred.

Do not rely solely on a paper review to determine medication errors. Detection of blank spaces on a medication administration record does not constitute the detection of actual medication errors. Paper review only identifies possible errors in most cases. In some cases paper review can help identify actual errors but research has shown that the procedure is time consuming for the number of actual errors detected.

Observation Technique

The survey team must know without doubt, what *medications*, in what strength, and dosage forms, are being administered. This is accomplished prior to *medication* administration and may be done in a number of ways depending on the *medication* distribution system used (e.g. unit dose, vial system, punch card). *Refer to Medication Administration Observation and Pharmacy Services in Appendix P for additional information related to the Medication Administration Observation.*

1. Identify the *medication*. There are two principal ways to do this. In most cases, they are used in combination:

- Identify the *medication* by its size, shape, and color. Many *medications* are identifiable by their distinctive size, shape, or color. This technique is problematic because not all *medications* have distinctive sizes, shapes, or color.

- Identify the *medication* by observing the label. When the punch card or the unit dose system is used, the survey team can usually observe the label and adequately identify the *medication*. When the vial system is used, observing the label is sometimes more difficult. Ask the nurse to identify the medication being administered.

2. Observe and record the administration of *medications* ("pass"). Follow the person administering *medications* and observe residents receiving *medications* (e.g., actually swallowing oral dosage forms). Be neutral and as unobtrusive as possible during this process.

    - Make every effort to observe residents during several different *medication* "passes," if possible, so the survey team will have an assessment of the entire facility rather than one staff member on one *medication* pass.

    - Identifying residents can present a problem. The surveyor should ask appropriate staff to explain the facility policy or system for the identification of residents.

    - *Multiple tablets or capsules required to deliver a dose of medication count as one observation;*

    - *Observe infection prevention practices by staff administering medications, including the procedures used for insulin pens and single dose vial use. If the caregiver fails to observe appropriate infection control and prevention standards of practice, it should also be evaluated under F441, Preventing the Spread of Infection/Indirect Transmission.*

3. Reconcile the surveyor's record of observation with physician's orders. Compare the record of observation with the most current orders for *medications*. This comparison involves two distinct activities:

    - For each *medication* on the surveyor's list: Was it administered according to the prescriber's orders? For example, in the correct strength, by the correct route? Was there a valid order for the *medication*? Was the *medication* the correct one?

    - For *medications* not on the surveyor's list: Are there orders for *medications* that should have been administered, but were not? Examine the record for *medication* orders that were not administered and should have been. Such circumstances may represent omitted doses, one of the most frequent types of errors.

Do not rely solely on a paper review of the *Medication Administration Record (MAR)* to determine medication errors. Detection of blank spaces on a *MAR* does not constitute the detection of actual medication errors. Paper review only identifies possible errors in most cases.

The surveyor should now have a complete record of what was observed and what should have occurred according to the prescribers' orders. Determine the number of errors by adding the errors on each resident. Before concluding for certain that an error has occurred, discuss the apparent error with the person who administered the *medications* if possible. There may be a logical explanation for an apparent error. For example, the surveyor observed that a resident had received Lasix 20 mg, but the order was for 40 mg. This was an apparent error in dosage. But the nurse showed the surveyor another more recent order which discontinued the 40 mg order and replaced it with a 20 mg order.

4. Reporting Errors -- Describe to the facility each error that the survey team detects (e.g., Mary Jones received digoxin in 0.125 instead of 0.25 mg). The survey team is not required to analyze the errors and come to any conclusions on how the facility can correct them. Do not attempt to categorize errors into various classifications (e.g., wrong dose, wrong resident). Stress that an error occurred and that future errors must be avoided.

5. Observe Many Individuals Administering Medications. Strive to observe as many individuals administering medications as possible. This provides a better picture of accuracy of the facility's entire *medication* distribution system.

Dose Reconciliation Technique Supplement to the Observation Technique -- When an omission error has been detected through the observation technique, the dose reconciliation technique can sometimes enable the survey team to learn how frequently an error has occurred in the past. Learning about the frequency of an error can assist in judging the significance of the error. (See Significant and Non-Significant Medication Errors above.) The dose reconciliation technique requires a comparison of the number of doses remaining in a supply of *medications* with the number of days the *medication* has been in use and the directions for use. For example, if a *medication* were in use for 5 days with direction to administer the *medication* 4 times a day, then 20 doses should have been used. If a count of the supply of that *medication* shows that only 18 doses were used (i.e., two extra doses exist) and no explanation for the discrepancy exists (e.g., resident refused the dose, or resident was hospitalized), then two omission errors may have occurred.

Use the dose reconciliation technique in facilities that indicate the number of *medications* received, and the date and the specific "pass" when that particular *medication* was started. Unless this information is available, do not use this technique. If this information is not available, there is no Federal authority under which the survey team may require it, except for controlled drugs.

F371

(*Rev.*)

§483.35(i) - Sanitary Conditions

The facility must –

§483.35(i)(1) - Procure food from sources approved or considered satisfactory by Federal, State or local authorities; and

§483.35(i)(2) - Store, prepare, distribute and serve food under sanitary conditions

INTENT: (Tag F371) 42 CFR 483.35(i) Sanitary Conditions

The intent of this requirement is to ensure that the facility:

- Obtains food for resident consumption from sources approved or considered satisfactory by Federal, State or local authorities; and
- Follows proper sanitation and food handling practices to prevent the outbreak of foodborne illness. Safe food handling for the prevention of foodborne illnesses begins when food is received from the vendor and continues throughout the facility's food handling processes.

DEFINITIONS

Definitions are provided to clarify terms related to sanitary conditions and the prevention of foodborne illness.

- **"Cross-contamination"** refers to the transfer of harmful substances or disease-causing microorganisms to food by hands, food contact surfaces, sponges, cloth towels, or utensils which are not cleaned after touching raw food, and then touch ready-to-eat foods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.[1]
- **"Danger Zone"** refers to temperatures above 41 degrees Fahrenheit (F) and below 135 degrees F that allow the rapid growth of pathogenic microorganisms that can cause foodborne illness. Potentially Hazardous Foods (PHF) or Time/Temperature Control for Safety (TCS) Foods held in the danger zone for more than 4 hours (if being prepared from ingredients at ambient temperature) or 6 hours (if cooked and cooled) may cause a foodborne illness outbreak if consumed.
- **"Dry Storage"** refers to storing/maintaining dry foods (canned goods, flour, sugar, etc.) and supplies (disposable dishware, napkins, and kitchen cleaning supplies).

- **"Food Contamination"** refers to the unintended presence of potentially harmful substances, including, but not limited to microorganisms, chemicals or physical objects in food.[2]
- **"Food Preparation"** refers to the series of operational processes involved in getting foods ready for serving, such as: washing, thawing, mixing ingredients, cutting, slicing, diluting concentrates, cooking, pureeing, blending, cooling, and reheating.
- **"Food Service/Distribution"** refers to the processes involved in getting food to the resident. This may include holding foods hot on the steam table or under refrigeration for cold temperature control, dispensing food portions for individual residents, family style and dining room service, or delivering trays to residents' rooms or units, etc.
- **"Foodborne Illness"** refers to illness caused by the ingestion of contaminated food or beverages.
- **"Highly Susceptible Population"** refers to persons who are more likely than the general population to experience foodborne illness because of their susceptibility to becoming ill if they ingest microorganisms or toxins. Increased susceptibility may be associated with immuno-compromised health status, chronic disease and advanced age. *The Food and Drug Administration's Food Code (Section 3-801.11) includes nursing facilities in its definition of a "highly susceptible population."*
- **"Pathogen"** refers to an organism capable of causing a disease (e.g., pathogenic bacteria or viruses).
- **"Potentially Hazardous Food (PHF)"** or "Time/Temperature Control for Safety (TCS) Food" refers to food that requires time/temperature control for safety to limit the growth of pathogens or toxin formation.
- "**Ready-to-Eat Food"** refers to food that is edible with little or no preparation to achieve food safety. It includes foods requiring minimal preparation for palatability or culinary purposes, such as mixing with other ingredients (e.g., meat type salads such as tuna, chicken, or egg salad).
- **"Storage"** refers to the retention of food (before and after preparation) and associated dry goods.
- **"Toxins"** refer to poisonous substances that are produced by living cells or organisms (e.g., pathogenic bacteria) that cause foodborne illness when ingested.

OVERVIEW

Nursing home residents risk serious complications from foodborne illness as a result of their compromised health status. Unsafe food handling practices represent a potential source of pathogen exposure for residents. Sanitary conditions must be present in health care food service settings to promote safe food handling. *CMS recognizes the U.S. Food and Drug Administration's (FDA) Food Code and the Centers for Disease Control and Prevention's (CDC) food safety guidance as national standards to procure, store, prepare, distribute and serve food in long term care facilities in a safe and sanitary manner.*

Effective food safety systems involve identifying hazards at specific points during food handling and preparation, and identifying how the hazards can be prevented, reduced or eliminated. It is important to focus attention on the risks that are associated with foodborne illness by identifying critical control points (CCPs) in the food preparation processes that, if not controlled, might result in food safety hazards. Some operational steps that are critical to control in facilities to prevent or eliminate food safety hazards are thawing, cooking, cooling, holding, reheating of foods, and employee hygienic practices.

Web sites for additional information regarding safe food handling to minimize the potential for foodborne illness include:

- National Food Safety Information Network's Gateway to Government Food Safety Information at www.FoodSafety.gov;
- United States Food & Drug Administration Food Code Web site at http://www.cfsan.fda.gov/~dms/primecon.html;
- United States Food & Drug Administration Hazard Analysis Critical Control Point http://www.cfsan.fda.gov/~dms/hret2toc.html, (Operator's Manual) and http://www.cfsan.fda.gov/~dms/hret3toc.html (Regulator's manual).

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. The uniform resource locator addresses were current as of the date of this publication.

TYPES OF FOOD CONTAMINATION

Food contaminants fall into 3 categories: biological, chemical, and physical.

Biological Contamination

Biological contaminants are pathogenic bacteria, viruses, toxins, and spores that contaminate food. The two most common types of disease producing organisms are bacteria and viruses. Parasites may also contaminate food, but are less common.

- **Pathogenic Bacteria -** Not all bacteria in food cause illness in humans. For example, live cultures of Lactobacillus bacteria are added to yogurt to enhance digestion. However, some bacteria can be pathogenic and thus may cause illness or death (e.g., some strains of Escherichia Coli). It is vital to control the growth of bacteria during food storage and preparation because raw or uncooked food may naturally contain pathogenic organisms (e.g., Salmonella in poultry).

  Several factors which may influence the growth of bacteria include:

  - Hazardous nature of the food. Although almost any food can be contaminated, certain foods are considered more hazardous than others and are called "potentially

hazardous foods (PHF) or Time/Temperature Controlled for Safety (TCS)" food. Examples of PHF/TCS foods include ground beef, poultry, chicken, seafood (fish or shellfish), cut melon, unpasteurized eggs, milk, yogurt and cottage cheese;

- Acidity (pH) of the food. More acidic food (i.e., pH < 5), such as pineapple, vinegar, and lemon juice, inhibits bacterial growth;

- Water percentage of the food. Foods that have a high level of water (e.g., fruits and vegetables) encourage bacterial growth; and

- Time and temperature control of the food. Time in conjunction with temperature controls is critical. The longer food remains in the danger zone, the greater the risks for growth of harmful pathogens. Bacteria multiply rapidly in a moist environment in the danger zone. Freezing does not kill bacteria. Rapid death of most bacteria occurs at 165 degrees F or above.

  NOTE: Some foods may be considered a TCS food needing time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. Examples include foods held for later service (e.g., cooked rice, refried beans, grilled sautéed onions, or baked potatoes).

- **Viruses -** Viruses cannot reproduce without a living host (animal or human). While they cannot reproduce in or on food, viruses may survive long enough in or on a food to be transmitted to a new host. Two viruses that are well known for being spread by poor food handling practices are Hepatitis A and Norovirus (formerly known as Norwalk virus).
- **Toxins -** Toxins are poisonous substances that come from a variety of sources. Some pathogens (e.g., Staphylococcus aureus and Clostridium botulinum) produce toxins as a byproduct of their growth. Most toxins are not destroyed by high temperatures. A PHF/TCS food that is allowed to remain in the danger zone long enough for the bacteria to produce toxins will become unsafe to eat.
- **Spores -** A spore is an inactive form of an organism that is highly resistant to extreme temperatures, acidity, and dehydration. The organism is reactivated once conditions become favorable for its growth. Two common spore-forming pathogens are Bacillus cereus and Clostridium botulinum. Temperature control is the way to minimize the danger associated with spore-forming organisms.

Chemical Contamination

The most common chemicals that can be found in a food system are cleaning agents (such as glass cleaners, soaps, and oven cleaners) and insecticides. Chemicals used by the facility staff, in the course of their duties, may contaminate food (e.g., if a spray cleaner is used on a worktable surface while food is being prepared it becomes exposed to a chemical). An inadequately identified chemical may be mistaken for an ingredient used in food preparation. For example, incorrectly stored (e.g., dishwashing liquid stored in a syrup bottle) or unlabeled (e.g., white

granulated cleaner that looks like salt) cleaning products may be inadvertently added to food and cause illness. It is recommended that chemical products including, but not limited to cleaning supplies, be stored separately from food items.

Physical Contamination

Physical contaminants are foreign objects that may inadvertently enter the food. Examples include but are not limited to staples, fingernails, jewelry, hair, glass, metal shavings from can openers, and pieces of bones.

FACTORS IMPLICATED IN FOODBORNE ILLNESSES

Many pathogens contribute to foodborne outbreaks in facilities. Several factors that cause pathogen growth include, but are not limited to:

- Poor Personal Hygiene - Employee health and hygiene are significant factors in preventing foodborne illness. This has been demonstrated in the population at large[3], commercial food service establishments[4], and in nursing facilities[5]. Foodborne illness in nursing homes has been associated with Norovirus. Because "infectious" individuals (persons capable of transmitting an infection or communicable disease whether they be colonized or infected) are a source of Norovirus, proper hand washing techniques and exclusion of infectious workers from handling food are critical for prevention of foodborne illness.

- Inadequate Cooking and Improper Holding Temperatures - Poorly cooked food promotes the growth of pathogens that may cause foodborne illness. The PHF/TCS foods require adequate cooking and proper holding temperatures to reduce the rapid and progressive growth of illness producing microorganisms, such as Salmonellae and Clostridium botulinum.

- Contaminated Equipment - Equipment can become contaminated in various ways including, but not limited to:

    - Poor personal hygiene;
    - Improper sanitation; and
    - Contact with raw food (e.g., poultry, eggs, seafood, and meat).

- Unsafe Food Sources - Unsafe food sources are sources not approved or considered satisfactory by Federal, State, or local authorities. Nursing homes are not permitted to use home-prepared or home-preserved (e.g., canned, pickled) foods for service to residents[3].

    NOTE: The food procurement requirements for facilities are not intended to restrict resident choice. All residents have the right to accept food brought to the facility by any visitor(s) for any resident.

Pathogenic Microorganisms and Strategies for their Control

The table below illustrates the more commonly identified ingestible items which have been associated with the listed illness-producing organisms. The primary agents are the organisms that have been associated with the ingestible food source[7]. Further, the primary control strategies list the preventive actions to inhibit the growth of these organisms.

Source of Contamination	Primary Agents of Concern	Primary Control Strategies
A. Hazards that are likely to occur - strategies that must be in place to prevent foodborne illness.		
Eggs, raw or unpasteurized	• Salmonella	• PHF/TCS • Cook *until all parts of the egg are completely firm* • Prevention of cross-contamination to ready-to-eat foods
Poultry, raw	• Campylobacter • Salmonella	• PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to ready-to-eat foods
	• Clostridium perfringens	• PHF/TCS • Cook to proper temperature
Meat, raw	• E. coli 0157:H7 • Salmonella • Campylobacter	• PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to ready-to-eat foods
	• Clostridium perfringens	• PHF/TCS • Cook to proper temperature
Infectious food workers	• Norovirus • Hepatitis A virus • Shigella • Salmonella	• Exclusion of infectious food workers • Proper hand-washing procedures • Avoid bare-hand contact with ready-to-eat foods
	• Staphylococcus aureus	• PHF/TCS • Proper hand-washing procedures • Avoid bare-hand contact with ready-to-eat foods
B. Hazards that may occur as a result of adulteration of food products, and for which good food handling practices are needed to minimize the potential for foodborne illness transmission.		
Fruits and vegetables, fresh	• E. coli O157:H7 • Salmonella • Norovirus • Hepatitis A virus • Shigella	• Wash prior to use (unless pre-washed) • Keep cut and raw fruits and vegetables refrigerated
Ready-to-eat meat and poultry products	• Listeria monocytogenes	• Proper refrigeration during storage
Pasteurized dairy products	• Listeria monocytogenes	• Proper refrigeration during storage
Ice	• Norovirus	• Cleaning and sanitizing the internal

		components of the ice machine according to manufacturers' guidelines

PREVENTION OF FOODBORNE ILLNESS

Food Handling and Preparation

Proper food preparation, storage, and handling practices are essential in preventing foodborne illness. Education, training, and monitoring of all staff and volunteers involved in food service, as well as establishing effective infection control and quality assurance programs help maintain safe food handling practices.

Approaches to create a homelike environment or to provide accessible nourishments may include a variety of unconventional and non-institutional food services. Meals or snacks may be served at times other than scheduled meal times and convenience foods, ready-to-eat foods, and pre-packaged foods may be stored and microwave heated on the nursing units. Whatever the approach, it is important that staff follow safe food handling practices.

Employee Health

Employees who handle food must be free of communicable diseases and infected skin lesions. (See the requirement at 42 CFR 483.65(b) (2) regarding preventing the spread of infection.) Bare hand contact with foods is prohibited.

Hand Washing, Gloves, and Antimicrobial Gel

Since the skin carries microorganisms, it is critical that staff involved in food preparation consistently utilize good hygienic practices and techniques. Staff should have access to proper hand washing facilities with available soap (regular or anti-microbial), hot water, and disposable towels and/or heat/air drying methods. Antimicrobial gel (hand hygiene agent that does not require water) cannot be used in place of proper hand washing techniques in a food service setting[8].

The appropriate use of utensils such as gloves, tongs, deli paper and spatulas is essential in preventing foodborne illness. Gloved hands are considered a food contact surface that can get contaminated or soiled. Failure to change gloves between tasks can contribute to cross-contamination. Disposable gloves are a single use item and should be discarded after each use.

NOTE: The use of disposable gloves is not a substitute for proper hand washing with soap and water.

Hair Restraints/Jewelry/Nail Polish

Dietary staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent their hair from contacting exposed food. Dietary staff maintaining nails that are clean and neat, and wearing intact disposable gloves in good condition, and that are changed appropriately will also help reduce the spread of microorganisms. Since jewelry can harbor microorganisms, it is recommended that dietary staff keep jewelry to a minimum and cover hand jewelry with gloves when handling food[9].

Food Receiving and Storage

When food is brought into the nursing home, inspection for safe transport and quality upon receipt and proper storage helps ensure its safety. Keeping track of when to discard perishable foods and covering, labeling, and dating all foods stored in the refrigerator or freezer is indicated.

When food is brought into the facility from an off-site kitchen (any kitchen that is not operated by the facility) and the food preparation entity is approved or considered satisfactory by and is inspected by other federal, State, or local authorities, verify the last approved inspection of the supplier and continue to inspect the facility for safe food handling and storage and food quality.

- **Dry Food Storage -** Dry storage may be in a room or area designated for the storage of dry goods, such as single service items, canned goods, and packaged or containerized bulk food that is not PHF/TCS. The focus of protection for dry storage is to keep non-refrigerated foods, disposable dishware, and napkins in a clean, dry area, which is free from contaminants. Controlling temperature, humidity, rodent and insect infestation helps prevent deterioration or contamination of the food. Dry foods and goods should be handled and stored to maintain the integrity of the packaging until they are ready to use. It is recommended that foods stored in bins (e.g., flour or sugar) be removed from their original packaging.

  Keeping food off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents can also help maintain food quality and prevent contamination. Desirable practices include managing the receipt and storage of dry food, removing foods not safe for consumption, keeping dry food products in closed containers, and rotating supplies.

- **Refrigerated Storage -** PHF/TCS foods must be maintained at or below 41 degrees F, unless otherwise specified by law. Frozen foods must be maintained at a temperature to keep the food frozen solid.

  Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microorganisms. Inadequate temperature control during refrigeration can promote bacterial growth. Adequate circulation of air around refrigerated products is essential to maintain appropriate food temperatures. Foods in a walk-in unit should be stored off the floor.

Practices to maintain safe refrigerated storage include:

- Monitoring food temperatures and functioning of the refrigeration equipment daily and at routine intervals during all hours of operation;
- Placing hot food in containers (e.g., shallow pans) that permit the food to cool rapidly;
- Separating raw animal foods (e.g., beef, fish, lamb, pork, and poultry) from each other and storing raw meats on shelves below fruits, vegetables or other ready-to-eat foods so that meat juices do not drip onto these foods; and
- Labeling, dating, and monitoring refrigerated food, including, but not limited to leftovers, so it is used by its use-by date, or frozen (where applicable) or discarded.

NOTE: Chemical products, including, but not limited to cleaning supplies, should be stored away from food items.

Safe Food Preparation

Many steps in safe food preparation must be controlled or monitored to prevent foodborne illness. Identification of potential hazards in the food preparation process and adhering to critical control points can reduce the risk of food contamination and thereby prevent foodborne illness.

Commercially pre-washed, pre-cut, and pre-packaged lettuce and other fruits and vegetables are considered edible without further preparation.

- **Cross-Contamination -** Cross-contamination can occur when harmful substances or disease-causing microorganisms are transferred to food by hands, food contact surfaces, sponges, cloth towels, or utensils that are not cleaned after touching raw food and then touch ready-to-eat goods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods. Examples of ways to reduce cross-contamination include, but are not limited to:
  - Store raw meat (e.g., beef, pork, lamb, poultry, and seafood) separately and in drip-proof containers and in a manner that prevents cross-contamination of other food in the refrigerator;
  - Between uses, store towels/cloths used for wiping surfaces during the kitchen's daily operation in containers filled with sanitizing solution at the appropriate concentration per manufacturer's specifications (see Manual Washing and Sanitizing section). Periodically testing the sanitizing solution helps assure that it maintains the correct concentration[10].

    Wash and sanitize cutting boards made of acceptable materials (e.g., hardwood, acrylic) between uses, consistent with applicable code[11], and
  - Clean and sanitize work surfaces and food-contact equipment (e.g., food processors, blenders, preparation tables, knife blades, can openers, and slicers) between uses.

- **Thawing -** Thawing frozen foods is often the first step in food preparation. Thawing food at room temperature is not acceptable because the food is within the danger zone for rapid bacterial proliferation. Recommended methods to safely thaw frozen foods include:
    - Thawing in the refrigerator, in a drip-proof container, and in a manner that prevents cross-contamination;
    - Completely submerging the item under cold water (at a temperature of 70 degrees F or below) that is running fast enough to agitate and float off loose ice particles;
    - Thawing the item in a microwave oven, then cooking and serving it immediately afterward; or
    - Thawing as part of a continuous cooking process**.**
- **Final Cooking Temperatures -** Cooking is a critical control point in preventing foodborne illness. Cooking to heat all parts of food to the temperature and for the time specified below will either kill dangerous organisms or inactivate them sufficiently so that there is little risk to the resident if the food is eaten promptly after cooking. Monitoring the food's internal temperature for 15 seconds determines when microorganisms can no longer survive and food is safe for consumption.
- Foods should reach the following internal temperatures:
    - Poultry and stuffed foods - 165 degrees F;
    - Ground meat (e.g., ground beef, ground pork), ground fish, and eggs held for service - at least 155 degrees F;
    - Fish and other meats - 145 degrees F for 15 seconds;
    - *Unpasteurized eggs when cooked to order in response to resident request and to be eaten promptly after cooking must be cooked until all parts of the egg are completely firm;*
    - When cooking raw animal foods in the microwave, foods should be rotated and stirred during the cooking process so that all parts of the food are heated to a temperature of at least 165 degrees F, and allowed to stand covered for at least 2 minutes after cooking to obtain temperature equilibrium.

  NOTE: Fresh, frozen, or canned fruits and vegetables that are cooked do not require the same level of microorganism destruction as raw animal foods. Cooking to a hot holding temperature (135 degrees F) prevents the growth of pathogenic bacteria that may be present in or on these foods.
- **Reheating Foods -** Reheated cooked foods present a risk because they have passed through the danger zone multiple times during cooking, cooling, and reheating. The PHF/TCS food that is cooked and cooled must be reheated so that all parts of the food reach an internal temperature of 165 degrees F for at least 15 seconds before holding for hot service. Ready-to-eat foods that require heating before consumption are best taken directly from a sealed container (secured against the entry of microorganisms) or an intact package from an approved food processing source and heated to at least 135 degrees F for holding for hot service.

Although proper reheating will kill most organisms of concern, some toxins, such as that produced by Staphylococcus aureus, cannot be inactivated by reheating food.

NOTE: Using the steam table to reheat food is unacceptable since it does not bring the food to the proper temperature within acceptable timeframes.

- **Cooling -** Improper cooling is a major factor in causing foodborne illness. Taking too long to chill PHF/TCS foods has been consistently identified as one factor contributing to foodborne illness. Foods that have been cooked and held at improper temperatures promote the growth of disease-causing microorganisms that may have survived the cooking process (e.g., spore-formers). Cooled food items can be re-contaminated by unsanitary handling practices or cross-contaminated from other food products, utensils, and equipment.

  Large or dense food items, such as roasts, turkeys, soups, stews, legumes, and chili may require interventions (e.g., placing foods in shallow pans, cutting roasts into smaller portions, utilizing ice water baths, and stirring periodically)in order to be chilled safely within an allowed time period. These foods take a long time to cool because of their volume and density. If the hot food container is tightly covered, the cooling rate may be slowed further, leading to longer cooling times during which the food remains in the danger zone. Cooked potentially hazardous foods that are subject to time and temperature control for safety are best cooled rapidly within 2 hours, from 135 to 70 degrees F, and within 4 more hours to the temperature of approximately 41 degrees F. The total time for cooling from 135 to 41 degrees F should not exceed 6 hours.

- **Modified Consistency -** Residents who require a modified consistency diet may be at risk for developing foodborne illness because of the increased number of food handling steps required when preparing pureed and other modified consistency foods. When hot pureed, ground, or diced food drop into the danger zone (below 135 degrees F), the mechanically altered food must be reheated to 165 degrees F for 15 seconds**.**

- **Pooled Eggs -** Pooled eggs are raw eggs that have been cracked and combined together. The facility should crack only enough eggs for immediate service in response to a resident's requests or as an ingredient immediately before baking. *Salmonella infections associated with unpasteurized eggs can be prevented by using pasteurized shell eggs or be substituted for raw eggs in the preparation of foods that will not be thoroughly cooked, such as but not limited to Caesar dressing, Hollandaise or Béarnaise sauce, egg fortified beverages, ice cream and French toast*[13].

The U.S. Department of Agriculture, Food Safety and Inspection Service, Salmonella Enteritidis (SE) Risk Assessment states "A partial list of persons with increased susceptibility to infectious agents includes persons with chronic diseases, and nursing home residents. The elderly are particularly susceptible to infectious agents such as SE for a number of reasons. The disproportionate impact of severe complications and death from Salmonellosis in the elderly is illustrated by epidemiologic evidence." Waivers to allow undercooked unpasteurized eggs for resident preference are not acceptable. Pasteurized shell eggs are available and allow for safe consumption of undercooked eggs.

NOTE: Raw eggs with damaged shells are also unsafe because of the potential for contamination.

Food Service and Distribution

Various systems are available for serving and distributing food items to residents. These include but are not limited to tray lines, portable steam tables transported to a unit or dining area, open shelved food transport carts with covered trays, or enclosed carts that have hot and cold compartments. Some systems incorporate a heating element (pellet) under each plate of hot food. The purpose of these systems is to provide safe holding and transport of the food to the resident's location. Food safety requires consistent temperature control from the tray line to transport and distribution to prevent contamination (e.g., covering food items). The length of time needed to transport trays is more critical when the food is simply covered and transported in open or closed carts without a heated and cooled environment.

- **Tray line and Alternative Meal Preparation and Service Area -** The tray line may include, but is not limited to the steam table where hot prepared foods are held and served, and the chilled area where cold foods are held and served. A resident's meal tray may consist of a combination of foods that require different temperatures. Food preparation or service area problems/risks to avoid include, but are not limited to:

    - Holding foods in danger zone temperatures which are between 41 degrees F and 135 degrees F;
    - Using the steam table to heat food;
    - Serving meals on soiled dishware and with soiled utensils; and
    - Handling food with bare hands or improperly handling equipment and utensils.

  The maximum length of time that foods can be held on a steam table is a total of 4 hours. Monitoring of the temperature by food service workers while food is on the steam table is essential. Foods may be reheated (only once) to 165 degrees F. Reheated foods are best discarded if not eaten within two hours after reheating[12].

Food Distribution - Dining locations include any area where one or more residents eat their meals. These can be located adjacent to the kitchen or a distance from the kitchen, such as residents' rooms and dining rooms in nursing units on other floors or wings of the building. Potential food handling problems/risks associated with food distribution include:

- Staff distributing trays without first properly washing their hands; and
- Serving food to residents after collecting soiled plates and food waste, without proper hand washing.

Snacks - Snacks refer to those foods that are served between meals or at bed time. Temperature control and freedom from contamination are also important when ready-to-eat or prepared food items for snacks are sent to the unit and are held for delivery; or stored at the nursing station, in a unit refrigerator or unit cupboards. Food handling risks associated with food stored on the units may include but are not limited to:

- Food left on trays or countertops beyond safe time and/or temperature requirements;

- Food left in refrigerators beyond safe "use by" dates (including, but not limited to foods that have been opened but were not labeled, etc.);
- Food stored in a manner (open containers, without covers, spillage from one food item onto another, etc.) that allows cross-contamination; and
- Failure to maintain refrigerated food temperatures at safe levels;

Special Events - Facility-sponsored special events, such as cookouts and picnics where food may not be prepared in the facility's kitchen and is served outdoors or in other locations, require the same food safety considerations.

Nursing Home Gardens *– Nursing homes with gardens are compliant with the food procurement requirements as long as the facility has and follows policies and procedures for maintaining the gardens. The facility should immediately report any outbreaks of food borne illnesses, for any cause, to their local health department.*

> ***NOTE:*** *If there are local or State requirements related to food grown on the facility grounds for resident consumption, facilities are to be in compliance with the specific State requirement.*

Transported Foods - If residents take prepared foods with them out of the facility (e.g., bag lunches for residents attending dialysis, clinics, sporting events, or day treatment programs), the foods must be handled and prepared for them with the same safe and sanitary approaches used during primary food preparation in the facility. Appropriate food transport equipment or another approach to maintaining safe temperatures for food at special events can help prevent foodborne illness.

Ice - Appropriate ice and water handling practices prevent contamination and the potential for waterborne illness. Ice must be made from potable water. Ice that is used to cool food items (e.g., ice in a pan used to cool milk cartons) is not to be used for consumption. Keeping the ice machine clean and sanitary will help prevent contamination of the ice. Contamination risks associated with ice and water handling practices may include, but are not limited to:

- Staff who use poor hygiene, fail to wash hands adequately, or handle ice with their bare hands are not following appropriate infection control practices when dispensing water and ice; and
- Unclean equipment, including the internal components of ice machines that are not drained, cleaned, and sanitized as needed and according to manufacturer's specifications.

Refrigeration - A potential cause of foodborne illness is improper storage of PHF/TCS food. The refrigerator must be in good repair and keep foods at or below 41 degrees F. The freezer must keep frozen foods frozen solid. The following are methods to determine the proper working order of the refrigerators and freezers:

- Document the temperature of external and internal refrigerator gauges as well as the temperature inside the refrigerator. Measure whether the temperature of a PHF/TCS food that has been inside for at least 24 hours is 41 degrees or less;

- To make sure the cooling process is effective, measure the temperature of a PHF/TCS that has a prolonged cooling time (e.g., one in a large, deep, tightly covered container). Determine if it is in the danger zone;
- Check for situations where potential for cross-contamination is high (e.g., raw meat stored over ready-to-eat items);
- Check the firmness of frozen food and inspect the wrapper to determine if it is intact enough to protect the food; and
- Interview food service personnel regarding the operation of the refrigerator and the freezer.

EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION

A potential cause of foodborne outbreaks is improper cleaning (washing and sanitizing) of contaminated equipment. Protecting equipment from contamination via splash, dust, grease, etc. is indicated. Dishwashing machines, operated according to the manufacturer specifications, wash, rinse, and sanitize dishes and utensils using either heat or chemical sanitization. Manual dishwashing is often used for pots and pans, or when the dishwashing machine is not operational.

Machine Washing and Sanitizing

Dishwashing machines use either heat or chemical sanitization methods. The following are specifications according to the U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration Food Code (or according to manufacturer's directions) for each method.

- High Temperature Dishwasher (heat sanitization):
    - Wash 150-165 degrees F wash; and
    - Final Rinse 180 degrees F final rinse
      (160 degrees F at the rack level/dish surface reflects 180 degrees F at the manifold, which is the area just before the final rinse nozzle where the temperature of the dish machine is measured); or
    - 165 degrees F for a stationary rack, single temperature machine.
- Low Temperature Dishwasher (chemical sanitization):
    - Wash 120 degrees F wash; and
    - Final Rinse 50 ppm (parts per million) hypochlorite (chlorine) on dish surface in final rinse.

Manual Washing and Sanitizing

A 3-step process is used to manually wash, rinse, and sanitize dishware correctly. The first step is thorough washing using hot water and detergent after food particles have been scraped. The second is rinsing with hot water to remove all soap residues. The third step is sanitizing with

either hot water or a chemical solution maintained at the correct concentration, based on periodic testing, and for the effective contact time according to manufacturer's guidelines.

After washing and rinsing, dishes and utensils are sanitized by immersion in either:

- Hot water (at least 171 degrees F) for 30 seconds; or
- A chemical sanitizing solution used according to manufacturer's instructions. Chemical sanitization requires greater controls than hot water sanitization. If explicit instructions are not provided by the manufacturer, the recommended sanitization concentrations are as follows:
    - Chlorine — 50-100 ppm minimum 10 second contact time
    - Iodine — 12.5 ppm minimum 30 second contact time
    - QAC space (Quaternary) — 150-200 ppm concentration and contact time per Manufacturer's instructions (Ammonium Compound)

A high concentration of sanitation solutions may be potentially hazardous (see manufacturer's instructions). Improper test strips yield inaccurate results when testing for chemical sanitation.

Drying food preparation equipment and utensils with a towel or cloth may increase risks for cross contamination.

Cleaning Fixed Equipment

When cleaning fixed equipment (e.g., mixers, slicers, and other equipment that cannot readily be immersed in water), the removable parts are washed and sanitized and non-removable parts are cleaned with detergent and hot water, rinsed, air-dried and sprayed with a sanitizing solution (at the effective concentration). Finally, the equipment is reassembled and any food contact surfaces that may have been contaminated during the process are re-sanitized (according to the manufacturer's instructions). Service area wiping cloths are cleaned and dried or placed in a chemical sanitizing solution of appropriate concentration.

Endnotes

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[11] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (pp. 103-104; 123).

[12] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 114).

[13] U.S. Food and Drug Administration Food Code http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm. Section 3-801.11(B).

INVESTIGATIVE PROTOCOL

SANITARY CONDITIONS

Objectives

- To determine if the facility obtained food safe for consumption from approved sources;
- To determine if the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness;
- To determine if the facility has systems (e.g., policies, procedures, training, and monitoring) in place to prevent the spread of foodborne illness and minimize food storage, preparation and handling practices that could cause food contamination and could compromise food safety; and
- To determine if the facility utilizes safe food handling from the time the food is received from the vendor and throughout the food handling processes in the facility.

Use

Use this protocol to investigate compliance at F371 (§483.35(i) (1) and (2)).

Procedures

Adhere to sanitary requirements (e.g., proper washing hands when entering the kitchen and between tasks, use of hair restraints) when assessing the kitchen and meal service throughout the survey process. During the initial tour of the facility and throughout the survey, observe the kitchen(s) and food service area(s) and review planned menus to determine when to assess food preparation processes. Observe subsequent kitchen/food services during times when food is being stored, prepared, cooked, plated, transported, and distributed to determine if safe food handling practices are being followed. Corroborate observations through interview, record review, and other appropriate documentation.

NOTE: When a facility receives food from an off-site kitchen (any kitchen not operated by the facility), determine whether the food was obtained from an approved source.

1. Observation

Conduct the following observations:

- Food procurement procedures:
    - Determine whether food meets safe and sanitary conditions related to when, where, and how the food was received for residents consumption.
    - Check invoices from food vendors when necessary to verify the source of food acquisition and the date of delivery.
- Food preparation procedures:
    - Observe staff food handling practices, such as proper hand washing, the appropriate use of utensils, glove, and hairnets;

- Observe food labeling and dates (e.g., used by dates);
- Observe food handling practices that have potential for cross-contamination (e.g., use of food contact surfaces and equipment to prepare various uncooked and ready-to-eat foods);
- If the facility is cooking a PHF/TCS food, evaluate if the food reached the acceptable final cooking temperatures, by inserting the stem of a calibrated thermometer into the middle or thickest part of the food;
- If a PHF/TCS food is prepared from ingredients at room temperature, determine if it was cooled to 41 degrees F within 4 hours. For example, when observing tuna or chicken salad preparation, determine when the salad was prepared, then measure the current temperature; and
- Observe staff preparing modified consistency (e.g., pureed, mechanical soft) PHF/TCS foods to determine whether food safety was compromised.
- *Observe the facility's egg products to determine if the facility is using pasteurized shell eggs, liquid pasteurized eggs or unpasteurized shell eggs. If the staff is preparing resident requests for soft cooked and undercooked eggs (i.e. sunny side up, soft scrambled, soft boiled), determine if pasteurized shell eggs, liquid pasteurized eggs or unpasteurized shell eggs were used.*

Service of food during meal times -

- Observe the staff measuring the temperature of all hot and cold menu items. Cold foods should be at or below 41 degrees F when served. Hot foods should be at 135 degrees F or above when served.

Service after meal times:

- Observe whether facility personnel are operating the dish washing machine according to the manufacturer's specifications. Evaluate sanitization with a calibrated thermometer (for a high temperature machine), chlorine test tape (for a low temperature machine), or other manufacturer recommended method;
- Check whether the facility has the appropriate equipment and supplies to evaluate the safe operation of the dish machine and the washing of pots and pans (e.g., maximum registering thermometer, appropriate chemical test strips, and paper thermometers);
- Evaluate sanitization during manual pot and pan washing (3-step process). Test the final rinse water temperature if using hot water for sanitization or the concentration of chemical sanitizer being used. Determine if the appropriate test strip for that chemical is being utilized;

- Observe stored dishes, utensils, pots/pans, and equipment for evidence of soiling. These items should be stored in a clean dry location and not exposed to splash, dust or other contamination; and
- Evaluate whether proper hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes.

Storage of food:

- Observe for evidence of pests, rodents and droppings and other sources of contamination in food storage areas;
- Observe food labeling and dates (e.g., used by dates);
- Observe that foods are stored off of the floor, and clear of ceiling sprinklers, sewer/waste disposal pipes and cleaning chemicals;
- Observe whether the facility has canned goods that have a compromised seal (e.g., punctures); and
- Observe whether staff access bulk foods without touching the food.

2. Interview

During the course of the survey, interview the staff who performs the task about the procedures they follow to procure, store, prepare, distribute, and serve food to residents. Request clarification from the dietary supervisor/manager or qualified dietitian concerning the following:

- What is the facility's practice for dealing with employees who come to work with symptoms of contagious illness (e.g., coughing, sneezing, diarrhea, vomiting) or open wounds;
- How does the facility identify problems with time and temperature control of PHF/TCS foods and what are the processes to address those problems;
- Whether the facility has, and follows, a cleaning schedule for the kitchen and food service equipment; and
- If there is a problem with equipment, how staff informs maintenance and follows up to see if the problem is corrected.

- *Is the facility aware of current CDC and FDA nursing home egg handling and preparation polices and does the facility have written egg storage and preparation policies that honor resident preferences safely.*

3. Record Review

In order to investigate identified food safety concerns, review supporting data, as necessary, including but not limited to:

- Any facility documentation, such as dietary policies and procedures, related to compliance with food sanitation and safety. Determine if the food service employees have received training related to such compliance;
- Food temperature records from the tray line, refrigerator/freezer temperature records, and dishwasher records;
- Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food; and
- Facility infection control records regarding surveillance for foodborne illness and actions related to suspected or confirmed outbreaks of gastrointestinal illnesses.
- *The policies and procedures for maintaining nursing home gardens should be reviewed, if there is an outbreak of food borne illness and the facility's primary food service has been ruled out as the cause of the outbreak.*

4. Review of Facility Practices

Review of facility practices may include, but is not limited to, review of policies and procedures for sufficient staffing, staff training, and following manufacturer's recommendations as indicated. In order to establish if the facility has a process in place to prevent the spread of foodborne illness, interview the staff to determine how they:

- Monitor whether the facility appropriately procures, stores, prepares, distributes, and serves food;
- Identify and analyze pertinent issues and underlying causes of a food safety concern (e.g., refrigerator or dishwasher malfunction);
- Implement interventions that are pertinent and timely in relation to the urgency and severity of a concern; and
- Monitor the implementation of interventions and determine if additional modification is needed.
- Identify if negative outcomes are the result of system failure by interviewing dietary managers and staff to ascertain egg storage and preparation knowledge.

DETERMINATION OF COMPLIANCE (TASK 6, APPENDIX P)

Synopsis of Regulation (F371)

The sanitary conditions requirement has two aspects. The first aspect requires that the facility procures food from sources approved or considered satisfactory by Federal, State, or local

authorities. The second aspect requires that the facility stores, prepares, distributes, and serves food under sanitary conditions to prevent foodborne illness.

Criteria for Compliance

The facility is in compliance with 42 CFR 483.35(i) (1)(2), Sanitary Conditions, if staff:

- Procures, stores, handles, prepares, distributes, and serve food to minimize the risk of foodborne illness;
- Maintains PHF/TCS foods at safe temperatures, cools food rapidly, and prevents contamination during storage;
- Cooks food to the appropriate temperature and holds PHF/TCS food at or below 41 degrees F or at or above 135 degrees F;
- Utilizes proper hand washing and personal hygiene practices to prevent food contamination; and
- Maintains equipment and food contact surfaces to prevent food contamination.

If not, cite at Tag F371.

Noncompliance for F371

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for Tag F371 may include, but is not limited to, failure to do one or more of the following:

- Procure, store, handle, prepare, distribute, and serve food in accordance with the standards summarized in this guidance;
- Maintain PHF/TCS foods at safe temperatures, at or below 41 degrees F (for cold foods) or at or above 135 degrees F (for hot foods) except during preparation, cooking, or cooling, and ensure that PHF/TCS food plated for transport was not out of temperature control for more than four hours from the time it is plated;
- Store raw foods (e.g., meats, fish) in a manner to reduce the risk of contamination of cooked or ready-to-eat foods;
- Cook food to the appropriate temperature to kill pathogenic microorganisms that may cause foodborne illness;
- Cool food in a manner that prevents the growth of pathogenic microorganisms;
- Utilize proper personal hygiene practices (e.g., proper hand washing and the appropriate use of gloves) to prevent contamination of food; and
- Use and maintain equipment and food contact surfaces (e.g., cutting boards, dishes, and utensils) to prevent cross-contamination.
- *Failure to report a food borne illness outbreak to the local health department.*

Potential Tags for Additional Investigation

During the investigation of 42 CFR §483.35(i)(1)(2), the surveyor may have identified concerns related to these requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are related outcome, process, and structure requirements that may be considered:

- 42 CFR 483.25(g)(2), F322, Nasogastric Tubes
    - Determine if residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms as a result of the failure to store, handle, administer, or remove and discard tube feeding solutions in a safe and sanitary manner.
- 42 CFR 483.25(i), F325, Nutrition
    - Determine if multiple residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms related to foodborne illness, which may impact their nutritional status.
- 42 CFR 483.30(a)(b), F353 Sufficient Staffing
    - Determine if the facility has sufficient staffing to meet the needs of the resident.
- 42 CFR 483.35(a)(1)(2), F361, Dietary Services - Staffing
    - Determine if the facility employs or consults with a qualified dietitian. If not employed full-time, determine if the director of food service receives scheduled consultation from the dietitian concerning storage, preparation, distribution and service of food under sanitary conditions.
- 42 CFR 483.35(b), F362, Standard Sufficient Staff
    - Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.
- 42 CFR 483.35(h) Paid Feeding Assistant
    - Determine if the Feeding Assistant has successfully completed a State-approved training course that meets Federal requirements and that the Feeding Assistant is utilizing proper techniques to prevent foodborne illness.
- 42 CFR 483.65(a), F441, Infection Control
    - Determine if the facility's infection control program included investigation, control, and prevention of foodborne illness.
- 42 CFR 483.65(b)(3), F444, Handwashing Techniques
    - Determine if the facility has practices in place to prevent the spread of infection, including proper hand washing techniques.

- 42 CFR 483.70(c)(2), F456, Maintain All Essential Equipment
    - Determine if the equipment in the kitchen, such as refrigerators, food carts, tray line equipment, freezers, dishwashers, ovens, stoves, and ranges etc. is maintained in safe operating condition and according to manufacturers' specifications.
- 42 CFR 483.70(h), F465, Other Environmental Conditions
    - Determine if the kitchen physical environment, such as, floors, walls, ceilings, and vent hoods are safe, clean, and sanitary.
- 42 CFR 483.70(h)(4), F469, Effective Pest Control Program
    - Determine if the facility has maintained an effective pest control program so that it remains free of pests and rodents. Determine whether there is evidence of roaches, ants, flies, mice, etc. in food storage, preparation and service areas.
- 42 CFR 483.70(o) (2) (i) (ii), F520, Quality Assessment and Assurance
    - Determine whether the quality assessment and assurance committee seeks and reviews concerns related to foodborne illness, and food safety and sanitation to develop and implement appropriate actions to correct identified quality deficiencies when indicated.

IV. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for Tag F371 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of the presence of unsanitary conditions. Actual or potential harm/negative outcome for Tag F371 may include, but is not limited to:

- Foodborne illness; or
- Ingestion or potential ingestion of food that was not procured from approved sources, and stored, prepared, distributed or served under sanitary conditions.

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility's noncompliance caused, resulted in, allowed or contributed to the actual or potential for harm.

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or

- If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F371. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed/caused/resulted in or is likely to allow/cause/result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventive or corrective measures.

  NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance, which allowed or caused the immediate jeopardy.

Examples of negative outcomes that occurred or have the potential to occur at Severity Level 4 as a result of the facility's deficient practices may include:

- A roast (raw meat) thawing on a plate in the refrigerator had bloody juices overflowing and dripping onto uncovered salad greens on the shelf below. The contaminated salad greens were not discarded and were used to make salad for the noon meal;
- The facility had a recent outbreak of Norovirus after the facility allowed a food worker who was experiencing vomiting and diarrhea to continue preparing food. Observations and interviews indicate that other food service staff with gastrointestinal illnesses are also permitted to prepare food.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Severity Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of

well-being. Therefore, a Level 3 deficiency is indicated when unsafe food handling and inadequate sanitary conditions result in actual harm to residents.
Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- Outbreak of nausea and vomiting occurs in the facility related to the inadequate sanitizing of dishes and utensils; and

- Episode of food poisoning occurs because facility had an event in which tuna, chicken, and potato salads served in bulk were not kept adequately chilled and were still left out for eating after 5 hours.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

As a result of the facility's noncompliance, the potential for food contamination and/or growth of pathogenic microorganisms exists. Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 2 may include, but are not limited to:

- Food service workers sliced roast pork on the meat slicer. The meat slicer was not washed, rinsed, and sanitized after usage. The facility failed to educate and train staff on how to clean and sanitize all kitchen equipment;
- During the initial tour of the kitchen, two food service workers were observed on the loading dock. One was smoking and the other employee was emptying trash. Upon returning to the kitchen, they proceeded to prepare food without washing their hands; and
- Upon inquiry by the surveyor, the food service workers tested the sanitizer of the dish machine, the chemical rinse of the pot-and-pan sink, and a stationary bucket used for wiping cloths. The facility used chlorine as the sanitizer. The sanitizer tested less than 50 ppm in all three locations. Staff interviewed stated they were unaware of the amount of sanitizer to use and the manufacturer's recommendations to maintain the appropriate ppm of available sanitizer.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

The failure of the facility to procure, prepare, store, distribute and handle food under sanitary conditions places this highly susceptible population at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F387

§483.40(c) Frequency of Physician Visits

(1) The residents must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 thereafter.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

F388

(Rev.)

§483.40(c)(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

§483.40(c) (4) At the option of the physician, required visits in SNFs, after the initial visit, may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner or clinical nurse specialist in accordance with paragraph (e) of this section.

Definitions **§483.40(c)**

"**Must be seen**" means that the physician must make actual face-to-face contact with the resident. There is no requirement for this type of contact at the time of admission, since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission.

Definitions

"**Nurse practitioner**" is a registered professional nurse now licensed to practice in the State and who meets the State's requirements governing the qualification of nurse practitioners.

"**Clinical nurse specialist**" is a registered professional nurse currently in practice in the State and who meets the State's requirements governing the qualifications of clinical nurse specialists.

"**Physician assistant**" is a person who meets the applicable State requirements governing the qualifications for assistants to physician.

For the purposes of this guidance, "non-physician practitioner (NPP)" means a nurse practitioner (NP), clinical nurse specialist (CNS) or physician assistant (PA) as defined above.

Interpretive Guidelines §483.40(c)

The timing of physician visits is based on the admission date of the resident. *In a SNF, the first physician visit (this includes the initial comprehensive visit) must be conducted* within the first 30 days, and then at 30 day intervals up until 90 days after the admission date. *After the first 90 days, visits must be conducted at least once every 60 days thereafter.*

Permitting up to 10 days slippage of a due date will not affect the next due date. However, do not specifically look at the timetables for physician visits unless there is indication of inadequate medical care. The regulation states that the physician (or his/her delegate) must visit the resident **at least** every 30 or 60 days. There is no provision for physicians to use discretion in visiting at intervals longer than those specified at §483.40(c). *Although the physician may not delegate the responsibility for conducting the initial visit in a SNF, NPP's may perform other medically necessary visits prior to and after the physician's initial visit, as allowed by State law.*

After the initial physician visit in SNFs, where States allow their use, a qualified NP, CNS or PA may make every other required visit. (See §483.40(e) Physician delegation of tasks in SNFs.) These alternate visits, as well as medically necessary visits, may be performed and signed by the NPP. (Physician co-signature is not required).

In a NF, the physician visit requirement may be satisfied in accordance with State law by NP, CNS, or PA who is not an employee of the facility but who is working in collaboration with a physician and who is licensed by the State and performing within the state's scope of practice. (See F390-§483.40(f).)

Facility policy that allows an NP, *CNS*, or PA to make every other required visit, and that allows a 10 day slippage in the time of the visit, does not relieve the physician of the obligation to visit a resident when the resident's medical condition makes that visit necessary.

Table 1: Authority for NPP to Perform Visits and Sign Orders when Permitted by the State

	Initial Comprehensive Visit/Orders	*Other Required Visits*	*Other Medically Necessary Visits &Orders*
SNF's			
PA, NP & CNS employed by the facility	*May not perform/ May not sign*	*May perform alternate visits*	*May perform and sign**

PA, NP & CNS not a facility employee	*May not perform/ May not sign*	*May perform alternate visits*	*May perform and sign**
NF's			
PA, NP, & CNS employed by the facility	*May not perform/ May not sign*	*May not perform*	*May perform and sign*
PA, NP, & CNS not a facility employee	*May perform/ May sign*	*May perform*	*May perform and sign*

**Except radiology and other diagnostic services as stated at §483.75(k)(2).*

In a facility where beds are dually-certified under Medicare and Medicaid, the facility must determine how the particular resident stay is being paid in order to identify whether physician delegation of tasks is applicable and if a NPP may perform the tasks. For example:

- *For a resident receiving Part A Medicare benefits for the nursing home stay in a Medicare certified bed, the NPP must follow the requirements for physician services in a SNF. This includes, at the option of a physician, required physician visits alternated between personal visits by the physician and visits by a NPP after the physician makes the initial first visit; and*

- *For a resident receiving Medicaid benefits, the NPP must follow the requirements for physician services in a NF. The NPP may perform required physician task for a Medicaid beneficiary in a Medicaid stay certified bed, at the option of the State. This NPP may not be an employee of the facility and must be working in collaboration with a physician*

It is expected that visits will occur at the facility rather than the doctor's office unless office equipment is needed or a resident specifically requests an office visit. If the facility has established policy that residents leave the grounds for medical care, the resident does not object, and this policy does not infringe on his/her rights, there is no prohibition to this practice. The facility should inform the resident of this practice, in accordance with §483.10(b).

Probes: §483.40(c)

- How does the scheduling and frequency of physician visits relate to any identified quality of care problems?

- When a PA, clinical nurse specialist, or NP performs a delegate physician visit, and determines that the resident's condition warrants direct contact between the physician and the resident, does the physician follow-up promptly with a personal visit?

F390

(Rev.)

§483.40(e) Physician Delegation of Tasks in SNFs

(1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who--

(i) Meets the applicable definition in §491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State;

(ii) Is acting within the scope of practice as defined by State law; and

(iii) Is under the supervision of the physician.

(2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

Definitions

"**Nurse practitioner**" is a registered professional nurse now licensed to practice in the State and who meets the State's requirements governing the qualification of nurse practitioners.

"**Clinical nurse specialist**" is a registered professional nurse currently in practice in the State and who meets the State's requirements governing the qualifications of clinical nurse specialists.

"**Physician assistant**" is a person who meets the applicable State requirements governing the qualifications for assistants to physician.

Interpretive Guidelines §483.40(e)

When **personal** performance of a particular task by a physician is specified in the regulations, performance of that task cannot be delegated to anyone else. The tasks of examining the resident, reviewing the resident's total program of care, writing progress notes, and signing orders may be delegated according to State law. The extent to which physician services are delegated to physician extenders in SNFs will continue to be determined by the provisions of §483.40(e), while the extent to which these services are performed by physician extenders in NFs will be determined by the individual States under §483.40(f). *(Refer to table in F388.)*

Probes: §483.40(e)

- Do the facility's attending physicians delegate to NPs, clinical nurse specialists, or PAs?

- Do NP/clinical nurse specialist/PA progress notes and orders follow the scope of practice allowed by State law?

- What evidence is there of physician supervision of NPs or PAs? For example, do physicians countersign NP/PA orders, if required by State law?

§483.40(f) Performance of Physician Tasks in NFs

At the option of State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

Interpretive Guidelines §483.40(f)

The performance of physician tasks in a NF includes NPP's (as defined in F388) performing required visits at the option of the State. The resident must be seen every 30 days for the first 90 days and every 60 days thereafter. NPPs that have a direct relationship with a physician and who are not employed by the facility may perform the initial visit, any other required physician visit and other medically necessary visit, and verify and sign orders for a resident of a NF as the State allows. NPPs may also perform other medically necessary visits prior to and after the initial visit. Where the NPP is permitted to perform a medically necessary visit, the NPP is likewise permitted to write applicable orders during that visit and may do so without a countersignature unless State law requires it.

The initial visit must take place no later than 30 days after admission.

According to F386, the physician or NPP (at the option of the State) must review the resident's total program of care, including medications and treatments, at each visit required under §483.40(c); write, sign, and date progress notes at each visit; and sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

*The timing of physician visits is based on the admission date of the resident. In a NF, the first physician visit must be conducted within the first 30 days, and then at 30 day intervals up until 90 days after the admission date. After the first 90 days, visits must be at least once every 60 days thereafter. Permitting up to 10 days slippage of a due date will not affect the next due date. However, do not specifically look at the timetables for visits unless there is indication of inadequate medical care. The regulation states that the physician (or his/her delegate) must visit the resident **at least** every 30 or 60 days. There is no provision for physicians to use discretion in visiting at intervals longer than those specified at §483.40(c). (See also F388)*

Facility policy that allows an NPP to make required visits, and that allows a 10 day slippage in the time of the visit, does not relieve the physician of the obligation to visit a resident when the resident's medical condition makes that visit necessary.

NOTE: *If the facility is not in compliance with timeliness of physician visits, cite at F387 – §483.40(c) Frequency of Physician Visits.*

Orders written by an NPP who is employed by the NF and are written during visits that are not required visits, and are therefore "other medically necessary visits," do not require physician co-signature except as mandated by State law.

If delegation of physician tasks is permitted in your State and the physician extender does not meet the qualifications listed here, cite F388.

Procedures §483.40(f)

If a nurse practitioner, clinical nurse specialist, or physician assistant is performing required physician tasks in a NF, is this allowed by the State? Is this person an employee of the facility? (Facility employees are prohibited from serving in this capacity.)

Probes: §483.40(f)

Is this person working in collaboration with the physician?

F425

(Rev.)

§483.60 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who--

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

INTENT (F425) 42 CFR 483.60, 483.60(a) & (b)(1)

The intent of this requirement is that:

- In order to meet the needs of each resident, the facility accurately and safely provides or obtains pharmaceutical services, including the provision of routine and emergency medications and biologicals, and the services of a licensed pharmacist;

- The licensed pharmacist collaborates with facility leadership and staff to coordinate pharmaceutical services within the facility, and to guide development and evaluation of the implementation of pharmaceutical services procedures;

- The licensed pharmacist helps the facility identify, evaluate, and address/resolve pharmaceutical concerns and issues that affect resident care, medical care or quality of life such as the:

    - Provision of consultative services by a licensed pharmacist between the pharmacist's visits, as necessary; and

    - Coordination of the pharmaceutical services if multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP]); and

- The facility utilizes only persons authorized under state requirements to administer medications.

NOTE: Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, adverse drug reaction or consequence).

For purposes of this guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

DEFINITIONS

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety.

- **"Acquiring medication"** is the process by which a facility requests and obtains a medication.

- **"Administering medication"** is the process of giving medication(s) to a resident.

- **"Biologicals"** are products isolated from a variety of natural sources—human, animal, or microorganism—or produced by biotechnology methods and other cutting-edge technologies. They may include a wide range of products such as vaccine, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

- **"Current standards of practice"** refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.

- **"Dispensing"** is a process that includes the interpretation of a prescription; selection, measurement, and packaging or repackaging of the product (as necessary); and labeling of the medication or device pursuant to a prescription/order.

- **"Disposition"** is the process of returning, releasing and/or destroying discontinued or expired medications.

- **"Pharmaceutical Services"** refers to:

    - The process (including documentation, as applicable) of receiving and interpreting prescriber's orders; acquiring, receiving, storing, controlling, reconciling, compounding (e.g., intravenous antibiotics), dispensing, packaging, labeling, distributing, administering, monitoring responses to, using and/or

disposing of all medications, biologicals, chemicals (e.g., povidone iodine, hydrogen peroxide);

- The provision of medication-related information to health care professionals and residents;

- The process of identifying, evaluating and addressing medication-related issues including the prevention and reporting of medication errors; and

- The provision, monitoring and/or the use of medication-related devices.

- **"Pharmacy assistant or technician"** refers to the ancillary personnel who work under the supervision and delegation of the pharmacist, consistent with state requirements.

- **"Receiving medication"**—for the purpose of this guidance—is the process of accepting a medication from the facility's pharmacy or an outside source (e.g., vending pharmacy delivery agent, Veterans Administration, family member).

OVERVIEW

The provision of pharmaceutical services is an integral part of the care provided to nursing home residents. The management of complex medication regimens is challenging and requires diverse pharmaceutical services to minimize medication-related adverse consequences or events. The overall goal of the pharmaceutical services system within a facility is to ensure the safe and effective use of medications.

Preventable medication-related adverse consequences and events are a serious concern in nursing homes. Gurwitz and colleagues evaluated the incidence and preventability of adverse drug events in 18 nursing homes in Massachusetts noting that 51% of the adverse drug events were judged to be preventable including 171 (72%) of the 238 fatal, life threatening or serious events and 105 (34%) of the 308 significant events. If these findings are extrapolated to all US nursing homes, approximately 350,000 adverse drug events may occur annually among this patient population, including 20,000 fatal or life threatening events.[i,ii]

Factors that increase the risk of adverse consequences associated with medication use in the nursing home setting include complex medication regimens, numbers and types of medication used, physiological changes accompanying the aging process, as well as multiple comorbidities.

The consultative services of a pharmacist can promote safe and effective medication use. A pharmacist evaluates and coordinates all aspects of pharmaceutical services provided to all residents within a facility by all providers (e.g., pharmacy, prescription drug plan, prescribers). A pharmacist can also help in the development of medication-related documentation procedures, such as identification of abbreviations approved for use in the facility and can help guide the selection and use of medications in accordance with the authorized prescriber's orders, applicable state and federal requirements, manufacturers' specifications, characteristics of the resident population, and individual resident conditions.

Providing pharmaceutical consultation is an ongoing, interactive process with prospective, concurrent, and retrospective components. To accomplish some of these consultative responsibilities, pharmacists can use various methods and resources, such as technology, additional personnel (e.g., dispensing pharmacists, pharmacy technicians), and related policies and procedures.

Numerous recognized resources address different aspects of pharmaceutical services and medication utilization, such as:

- The American Society of Consultant Pharmacists (ASCP) www.ascp.com;
- The American Society of Health System Pharmacists (ASHP) www.ashp.com;
- The American Medical Directors Association (AMDA) www.amda.com;
- The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) www.nccmerp.org;
- US Department of Health and Human Services (DHHS), Food and Drug Administration (FDA) www.fda.gov/cder; and
- *American Society for Parenteral and Enteral Nutrition,* https://www.nutritioncare.org/.

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

PROVISION OF ROUTINE AND/OR EMERGENCY MEDICATIONS

The regulation at 42 CFR 483.60 (F425) requires that the facility provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident. Facility procedures and applicable state laws may allow the facility to maintain a limited supply of medications in the facility for use during emergency or after-hours situations. Whether prescribed on a routine, emergency, or as needed basis, medications should be administered in a timely manner. Delayed acquisition of a medication may impede timely administration and adversely affect a resident's condition. Factors that may help determine timeliness and guide acquisition procedures include:

- Availability of medications to enable continuity of care for an anticipated admission or transfer of a resident from acute care or other institutional settings;

- Condition of the resident including the severity or instability of his/her condition, a significant change in condition, discomfort, risk factors, current signs and symptoms, and the potential impact of any delay in acquiring the medications;

- Category of medication, such as antibiotics or analgesics;

- Availability of medications in emergency supply, if applicable; and

- Ordered start time for a medication.

Procedures should identify how staff, who are responsible for medication administration:

- *Ensure each resident has a sufficient supply of his or her prescribed medications (for example, a resident who is on pain management has an adequate supply of medication available to meet his or her needs). At a minimum, the system is expected to include a process for the timely ordering and reordering of a medication;*

- *Monitor the delivery of medications when they are ordered; and*

- *Determine the appropriate action, e.g., contact the prescriber or pharmacist, when a resident's medication(s) is not available for administration.*

Foreign Acquired Medications

It has been reported that some residents and/or facilities may be obtaining medications from foreign sources. Medications obtained from foreign sources may present safety issues since they have been manufactured or held outside of the jurisdiction of the United States(U.S.) regulatory system. These medications may not be safe and effective for their intended uses. The Federal Food, Drug, and Cosmetic Act (FFDCA) strictly limits the types of drugs that may be imported into the U.S. Medications imported into the U.S. may violate the FFDCA if they are unapproved by the FDA, labeled incorrectly, or dispensed without a valid prescription. The facility should, in collaboration with the pharmacist, assure that medications are provided or obtained from approved sources and do not violate the FFDCA.

If a surveyor becomes aware that a resident has in his or her possession imported prescription medications that are not FDA-approved, the surveyor should determine whether the facility is aware of the presence of the imported medications.

If the facility is unaware of the imported medications, the surveyor should determine whether the medications are delivered to the resident via the facility staff or are self-administered.

- *If the medications are administered by facility staff, the surveyor should cite the facility for this unsafe practice under §483.60(a) Pharmacy Services; or*

- *If the resident self-administers the medications without the facility's knowledge, the surveyor should notify the facility of the unsafe practice.*

In addition, if it is determined that the facility is providing/obtaining foreign medications for use by the residents that are not FDA approved, the State Agency must make referrals to appropriate agencies, such as the FDA; depending on the medication classification, the Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; and the State Licensure Board for Nursing Home Administrators.

SERVICES OF A LICENSED PHARMACIST

The facility is responsible for employing or contracting for the services of a pharmacist to provide consultation on all aspects of pharmaceutical services. The facility may provide for this service through any of several methods (in accordance with state requirements) such as direct employment or contractual agreement with a pharmacist. Whatever the arrangement or method employed, the facility and the pharmacist identify how they will collaborate for effective consultation regarding pharmaceutical services. The pharmacist reviews and evaluates the pharmaceutical services by helping the facility identify, evaluate, and address medication issues that may affect resident care, medical care, and quality of life.

The pharmacist is responsible for helping the facility obtain and maintain timely and appropriate pharmaceutical services that support residents' healthcare needs, that are consistent with current standards of practice, and that meet state and federal requirements. This includes, but is not limited to, collaborating with the facility and medical director to:

- Develop, implement, evaluate, and revise (as necessary) the procedures for the provision of all aspects of pharmaceutical services;

- Coordinate pharmaceutical services if and when multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP])

- Develop intravenous (IV) therapy procedures if used within the facility (consistent with state requirements) *which* may include: determining competency of staff *and* facility-based IV admixture procedures that address sterile compounding, dosage calculations, IV pump use, and flushing procedures;

- Determine (in accordance with or as permitted by state law) the contents of the emergency supply of medications and monitor the use, replacement, and disposition of the supply;

- Develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services;

- Strive to assure that medications are requested, received, and administered in a timely manner as ordered by the authorized prescriber (in accordance with state requirements), including physicians, advanced practice nurses, pharmacists, and physician assistants;

- Provide feedback about performance and practices related to medication administration and medication errors;

- Participate on the interdisciplinary team to address and resolve medication-related needs or problems;

- Establish procedures for:
    - conducting the monthly medication regimen review (MRR) for each resident in the facility,
    - addressing the expected time frames for conducting the review and reporting the findings,
    - addressing the irregularities,
    - documenting and reporting the results of the review (See F428 for provision of the review.); and

- Establish procedures that address medication regimen reviews for residents who are anticipated to stay less than 30 days or when the resident experiences an acute change of condition as identified by facility staff.

    NOTE: Facility procedures should address how and when the need for a consultation will be communicated, how the medication review will be handled if the pharmacist is off-site, how the results or report of their findings will be communicated to the physician, expectations for the physician's response and follow up, and how and where this information will be documented.

In addition, the pharmacist may collaborate with the facility and medical director on other aspects of pharmaceutical services including, but not limited to:

- Developing procedures and guidance regarding when to contact a prescriber about a medication issue and/or adverse effects, including what information to gather before contacting the prescriber;

- Developing the process for receiving, transcribing, and recapitulating medication orders;

- Recommending the type(s) of medication delivery system(s) to standardize packaging, such as bottles, bubble packs, tear strips, in an effort to minimize medication errors;

- Developing and implementing procedures regarding automated medication delivery devices or cabinets, if automated devices or cabinets are used, including: the types or categories of medications, amounts stored, location of supply, personnel authorized to access the supply, record keeping, monitoring for expiration dates, method to ensure

accurate removal of medications and the steps for replacing the supply when dosages are used, and monitoring the availability of medications within the system;

- Interacting with the quality assessment and assurance committee to develop procedures and evaluate pharmaceutical services including delivery and storage systems within the various locations of the facility in order to prevent, to the degree possible, loss or tampering with the medication supplies, and to define and monitor corrective actions for problems related to pharmaceutical services and medications, including medication errors;

- Recommending current resources to help staff identify medications and information on contraindications, side effects and/or adverse effects, dosage levels, and other pertinent information; and

- Identifying facility educational and informational needs about medications and providing information from sources such as nationally recognized organizations to the facility staff, practitioners, residents, and families.

  NOTE: This does not imply that the pharmacist must personally present educational programs.

PHARMACEUTICAL SERVICES PROCEDURES

The pharmacist, in collaboration with the facility and medical director, helps develop and evaluate the implementation of pharmaceutical services procedures that address the needs of the residents, are consistent with state and federal requirements, and reflect current standards of practice. These procedures address, but are not limited to, acquiring; receiving; dispensing; administering; disposing; labeling and storage of medications; and personnel authorized to access or administer medications.

Acquisition of Medications

Examples of procedures addressing acquisition of medications include:

- Availability of an emergency supply of medications, if allowed by state law, including the types or categories of medications; amounts, dosages/strengths to be provided; location of the supply; personnel authorized to access the supply; record keeping; monitoring for expiration dates; and the steps for replacing the supply when medications are used;

- When, how to, and who may contact the pharmacy regarding acquisition of medications and the steps to follow for contacting the pharmacy for an original routine medication order, emergency medication order, and refills;

- The availability of medications when needed, that is, the medication is either in the facility (in the emergency supply) or obtained from a pharmacy that can be reached 24 hours a day, seven days a week;

- The receipt, labeling, storage, and administration of medications dispensed by the *prescriber*, if allowed by state requirements;

- Verification or clarification of an order to facilitate accurate acquisition of a medication when necessary (e.g., clarification when the resident has allergies to, or there are contraindications to the medication being ordered);

- Procedure when delivery of a medication will be delayed or the medication is not or will not be available; and

- Transportation of medications from the dispensing pharmacy or vendor to the facility consistent with manufacturer's specifications, state and federal requirements, and standards of professional practice to prevent contamination, degradation, and diversion of medications.

Receiving Medication(s)

Examples of procedures addressing receipt of medications include:

- How the receipt of medications from dispensing pharmacies (and family members or others, where permitted by state requirements) will occur and how it will be reconciled with the prescriber's order and the requisition for the medication;

- How staff will be identified and authorized in accordance with applicable laws and requirements to receive the medications and how access to the medications will be controlled until the medications are delivered to the secured storage area; and

- Which staff will be responsible for assuring that medications are incorporated into the resident's specific allocation/storage area.

Dispensing Medication(s)

Examples of procedures to assure compatible and safe medication delivery, to minimize medication administration errors, and to address the facility's expectations of the in-house pharmacy and/or outside dispensing pharmacies include:

- Delivery and receipt;

- Labeling; and

- The types of medication packaging (e.g., unit dose, multi-dose vial, blister cards).

Administering Medications

Examples of procedures addressing administration of medications include:

- Providing continuity of staff to ensure that medications are administered without unnecessary interruptions;

- Reporting medication administration errors, including how and to whom to report;

- Authorizing personnel, consistent with state requirements, to administer the medications, including medications needing intravenous administration (see Authorized Personnel and Staff Qualifications section within this document);

- Assuring that the correct medication is administered in the correct dose, in accordance with manufacturer's specifications and with standards of practice, to the correct person via the correct route in the correct dosage form and at the correct time;

- Defining the schedules for administering medications to:

    - Maximize the effectiveness (optimal therapeutic effect) of the medication (for example, antibiotics, antihypertensives, insulins, pain medications*, proton pump inhibitors, metered dose inhalers, and medications via enteral feeding tubes*);

    - *Not administering medications with known incompatibilities at the same time;*

    - Avoid potential significant medication interactions such as medication-food or medication-medication interactions; and

    - Recognize resident choices and activities, to the degree possible, consistent with the medical plan of care;

- Defining general guidelines for specific monitoring related to medications, when ordered or indicated, including specific item(s) to monitor (e.g., blood pressure, pulse, blood sugar, weight), frequency (e.g., weekly, daily), timing (e.g., before or after administering the medication), and parameters for notifying the prescriber;

- Defining pertinent techniques and precautions *that meet current standards of practice* for administering medications through alternate routes such as eye, ear, buccal, injection, intravenous, atomizer/aerosol/ inhalation therapy, or enteral tubes. *For example, for enteral feeding tubes, define procedures including but not limited to:*

    - *Types of medications that may be safely administered via enteral feeding tube;*

    - *Appropriate dosage forms;*

- *Techniques to monitor and verify that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) before administering medications;*

- *Preparing drugs for enteral administration, administering drugs separately, diluting drugs as appropriate, and flushing the feeding tube before, between, and after drug administration, including the amount of water to be used for the flushing and administration of medications (and obtaining physician/practitioners order to address a resident with fluid restrictions);*[1] *and*

1. *http://www.ismp.org/newsletters/acutecare/articles/20100506.asp 5/06/10.*

- Documenting the administration of medications, including:

    - The administration of routine medication(s), and if not administered, an explanation of why not;

    - The administration of "as-needed" medications including the justification and response;

    - The route, if other than oral (intended route may be preprinted on MAR); and

    - Location of administration sites such as transdermal patches and injections;

- Providing accessible current information about medications (e.g., medication information references) and medication-related devices and equipment (e.g., user's manual);

- Clarifying any order that is incomplete, illegible, or presents any other concerns, prior to administering the medication; and

- Reconciling medication orders including telephone orders, monthly or other periodic recapitulations, medication orders to the pharmacy, and medication administration record (MAR), including who may transcribe prescriber's orders and enter the orders onto the MAR.

Disposition of Medications

Examples of procedures addressing the disposition of medications include:

- Timely identification and removal (from current medication supply) of medications for disposition;

- Identification of storage method for medications awaiting final disposition;

- Control and accountability of medications awaiting final disposition consistent with standards of practice;

- Documentation of actual disposition of medications to include: resident name, medication name, strength, prescription number (as applicable), quantity, date of disposition, and involved facility staff, consultant(s) or other applicable individuals; *and*

- Method of disposition *(including controlled medications) should prevent diversion and/or accidental exposure and is* consistent with applicable state and federal requirements, local ordinances, and standards of practice;

Labeling and Storage of Medications, including Controlled Substances

Examples of procedures addressing accurate labeling of the medications (including appropriate accessory and cautionary instructions) include:

- Labeling medications prepared by facility staff, such as IV solutions prepared in the facility;

- Requirements for labeling medications not labeled by a pharmacy, such as bulk supplies/bottles of over-the counter (OTC) medications (as permitted);

- Modifying labels due to changes in the medication orders or directions, in accordance with state and federal requirements; and

- Labeling multi-dose vials to assure product integrity, considering the manufacturer's specifications (e.g., modified expiration dates upon opening the multi-dose vial).

Examples of procedures addressing the safe storage of medications include:

- Location, security (locking), and authorized access to the medication rooms, carts and other storage areas;

- Temperatures and other environmental considerations of medication storage area(s) such as the medication room(s) and refrigerators; and

- Location, access, and security for discontinued medications awaiting disposal.

Examples of procedures addressing controlled medications include:

- Location, access, and security for controlled medications, including the separately locked permanently affixed compartment for those Schedule II medications or preparations with Schedule II medications needing refrigeration;

- A system of records of receipt and disposition of all controlled medications that accounts for all controlled medications; and

- Periodic reconciliation of controlled medications including the frequency, method, administration by whom, and pertinent documentation.

Authorized Personnel

The facility may permit unlicensed personnel to administer medications if state law permits, but only under the general supervision of a licensed nurse.

The facility assures that all persons administering medications are authorized according to state and federal requirements, oriented to the facility's procedures, and have access to current information regarding medications being used within the facility, including side effects of medications, contraindications, doses, etc.

Examples of procedures addressing authorized personnel include:

- How the facility assures ongoing competency of all staff (including temporary, agency, or on-call staff) authorized to administer medications and biologicals;

- Training regarding the operation, limitations, monitoring, and precautions associated with medication administration devices or other equipment, if used, such as:

    - IV pumps or other IV delivery systems including calculating dosage, infusion rates, and compatibility of medications to be added to the IV;

    - Blood glucose meters, including calibration and cleaning between individual residents; and

    - Using, maintaining, cleaning, and disposing of the various types of devices for administration including nebulizers, inhalers, syringes, medication cups, spoons, and pill crushers;

- Identifying pharmacy personnel in addition to the pharmacist (e.g., pharmacy technicians, pharmacist assistants) who are authorized under state and federal requirements to access medications and biologicals.

INVESTIGATIVE PROTOCOL

For investigating compliance with the requirements at 42 CFR 483.60 and 483.60(a) & (b), see State Operations Manual, Appendix P, II.B., The Traditional Standard Survey, Task 5, Sub-Task 5E Investigative Protocol: Medication Pass and Pharmacy Services.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F425)

The Pharmaceutical Services, Procedures and Consultation requirement has four aspects. First, the facility must provide routine and/or emergency medications and biologicals or obtain them under an agreement described in 42 CFR 483.75(h). Second, the facility must have procedures for pharmaceutical services to meet the resident's needs. The procedures must assure accurate acquisition, receipt, dispensing, and administration of all medications and biologicals. Third, the facility must have a licensed pharmacist who provides consultation and oversees all aspects of the pharmaceutical services. Fourth, the facility must follow applicable laws and regulations about who may administer medications.

Criteria for Compliance

Compliance with 42 CFR 483.60, F425, Pharmaceutical Services

The facility is in compliance with this requirement, if they provide or arrange for:

- Each resident to receive medications and/or biologicals as ordered by the prescriber;
- The development and implementation of procedures for the pharmaceutical services;
- The services of a pharmacist who provides consultation regarding all aspects of pharmaceutical services; and
- Personnel to administer medications, consistent with applicable state law and regulations.

If not, cite F425.

Noncompliance for F425

After completing the Investigative Protocol, analyze the data and review the regulatory requirement in order to determine whether or not compliance with F425 exists. As the requirements for F425 include both process and structural components, a determination of noncompliance with F425 does not require a finding of harm to the resident. If the survey team identifies noncompliance at other tags which may be related to the roles and responsibilities of the pharmacist or the provision of pharmaceutical services, the team must also decide whether there is noncompliance with this requirement. Noncompliance for F425 may include (but is not limited to) the facility failure to:

- Utilize the services of a pharmacist;
- Ensure that only appropriate personnel administer medications;
- Provide medications and/or biologicals to meet the needs of the resident; and

- Develop or implement procedures for any of the following: acquiring, receiving, dispensing or accurately administering medications.

Potential Tags for Additional Investigation

If noncompliance with 42 CFR 483.60 and 483.60(a) & (b) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present. Examples of some of the related requirements that should be considered when noncompliance has been identified include the following:

- 42 CFR 483.30(a), F353, Sufficient Staff
    - Determine if the facility had qualified staff in sufficient numbers to provide medications on a 24-hour basis to meet the needs of the residents, based upon the comprehensive assessment and care plan.
- 42 CFR 483.75(i)(2), F501, Medical Director
    - Determine whether the medical director, in collaboration with the facility and the pharmacist, and based on current standards of practice, helped the facility develop procedures for the safe and accurate provision of medications to meet the needs of the residents.
- 42 CFR 483.75 (o), F520, Quality Assessment and Assurance
    - Determine whether the quality assessment and assurance committee, if concerns regarding pharmaceutical services have been identified, has identified those concerns, responded to the concerns and, as appropriate, has developed, implemented, and monitored appropriate plans of action to correct identified quality deficiencies.
- 42 CFR 483.75(l)(1), F514, Clinical Records
    - Determine whether the facility has maintained clinical records, including medication administration, in accordance with accepted professional standards and practices that are complete, accurately documented, and readily accessible.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the survey team has completed its investigation, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The key elements for severity determination for F425 are as follows:

1. **Presence of potential or actual harm/negative outcome(s) due to a facility failure related to pharmaceutical services.**

   Identify actual or potential harm/negative outcomes for F425 which may include, but are not limited to:

   - The facility's failure to involve a pharmacist in developing, implementing, and evaluating pharmaceutical procedures including procedures for accurately acquiring, receiving, storing, controlling, dispensing, and administering routine and emergency medications and biologicals resulted in the lack of specific procedures or in procedures that were not consistent with current standards of practice, for example:

     - Absent or inadequate IV infusion procedures led to a resident developing congestive heart failure as a result of an IV infusing too quickly.

   - The facility's failure to provide medications needed by a resident in a timely manner resulted in continued pain or worsening symptoms.

   - The use of unauthorized personnel to administer medications created the potential for harm.

2. **Degree of potential or actual harm/negative outcome(s) due to a facility failure related to pharmaceutical services.**

   Identify how the facility's practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

   - If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort.

   - If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. **The immediacy of correction required.**

   Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F425. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

- Severity Level 4 (Immediate Jeopardy) deficiency at another tag (e.g., F309, F329, F332, F333, F428) and the noncompliance is related to a failure of the facility to provide or obtain the service of a pharmacist or to collaborate with the pharmacist to establish and implement procedures for using medications, resulting in the potential for significant adverse consequences.

- The facility, in collaboration with the pharmacist, failed to establish effective procedures to meet the needs of the residents, such as:

    - Assuring that pain medications were available to meet the needs of the resident. For example, failure to assure availability of pain medication for a recently admitted resident resulting in the resident complaining of excruciating pain (e.g., a pain score of 9 on a 10-point scale).

    - Assuring that devices used to administer medications (such as IV pumps) were working properly, leading to an adverse consequence at the immediate jeopardy level.

    - Identifying medication errors, for example, medications were being dispensed without a valid prescriber's order, resulting in a resident incorrectly receiving three medications over two consecutive months.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- Severity Level 3 deficiency at another tag (e.g., F309, F329, F332, F333, F428) and the noncompliance is related to a failure of the facility to provide or obtain the services of a pharmacist or to collaborate with the pharmacist to develop and implement procedures for monitoring medication therapy, resulting in a failure to monitor treatment and the resident experiencing actual harm.

- The facility in collaboration with the pharmacist failed to assure that procedures were developed and implemented, such as:

    - An effective procedure/mechanism to assure that all medication orders were processed consistently and accurately through the stages of ordering, receiving, and administering medications (including transfer orders, admission orders, telephone orders, order renewals, and the MAR). For example, a transcription error led to an incorrect dose of a medication being administered and the resident experiencing spontaneous bruising and epistaxis requiring medical intervention.

    - Provisions to assure that staff were trained or competent to use new medication-related devices (e.g., intravenous pump). This resulted in a resident receiving an excessive dose of medication requiring subsequent hospitalization or receiving a sub-therapeutic dose of medication with consequential exacerbation of a condition (e.g., infection), continuation of treatment beyond the expected time frame, and subsequent functional decline.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- A Severity Level 2 deficiency at another tag (e.g., F309, F329, F332, F333, F428) and the noncompliance is related to a failure of the facility to implement established medication administration procedures. For example, as a result of failure of licensed staff to supervise medication administration by authorized unlicensed personnel, errors occurred in providing timely oral antibiotic therapy.

- The facility failed to obtain or provide the services of a pharmacist or to collaborate with the pharmacist to assure that effective policies and procedures were established and implemented including, for example:

    - As a result of not reordering medications often enough to maintain an adequate supply, a resident did not receive medication for heartburn for seven days and had difficulty sleeping due to nocturnal heartburn. The level of discomfort did not interfere with the resident's participating in activities or performing activities of daily living.

    - As a result of failure to identify medications that should not be crushed for administration, a resident received a medication that was crushed, contrary to the manufacturer's specifications (e.g., an enteric coated aspirin). While the resident did not experience any harm, the potential for harm was present.

NOTE: If Severity Level 2 (no actual harm with potential for more than minimal harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 1 (no actual harm with the potential for minimal harm) exists.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

In order to cite no actual harm with potential for minimal harm at this tag, the surveyor must verify that no resident harm or potential for more than minimal harm identified at other requirements was related to lack of pharmaceutical services, absence of or failure to implement pharmaceutical procedures, or absence of oversight by the pharmacist.

Examples of noncompliance for Severity Level 1 may include:

- The facility and the pharmacist failed to collaborate to:

    - Implement pharmaceutical procedures, but there were no negative resident outcomes or potential for more than minimal negative outcomes as a result of that deficient practice.

- There is no pharmacist; and

    - There were no negative resident outcomes or potential for more than minimal negative outcomes related to pharmaceutical services; and

    - Pharmaceutical procedures were in place; and

    - The facility was actively seeking a new pharmacist.

NOTE: If there is no pharmacist and there were negative outcomes, or procedures were not in place or if the facility was not looking for a replacement, cite at a Severity Level 2 or higher severity.

- There was a short term failure to provide medications that posed minimal risk to the resident, such as a routine order for a daily multivitamin.

F428

(Rev.)

§483.60(c) Drug Regimen Review

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon.

INTENT (F428) 42 CFR 483.60(c)(1)(2) Medication Regimen Review

The intent of this requirement is that the facility maintains the resident's highest practicable level of functioning and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing:

- A licensed pharmacist's review of each resident's regimen of medications at least monthly; or
- A more frequent review of the regimen depending upon the resident's condition and the risks or adverse consequences related to current medication(s);
- The identification and reporting of irregularities to the attending physician and the director of nursing; and
- Action taken in response to the irregularities identified.

NOTE: Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

For purposes of this guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

DEFINITIONS

Definitions are provided to clarify terminology related to pharmaceutical services and the management of each resident's medication regimen for effectiveness and safety.

- **"Adverse consequence"** refers to an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of

adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).

NOTE: Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic and helpful effects of the medication or any response to a medication that is noxious and unintended and occurs in doses used for prophylaxis, diagnosis, or therapy. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories. The others are hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not rise to the level of being an adverse consequence.

- **"Clinically significant"** means effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

- **"Dose"** is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

- **"Excessive dose"** (including duplicate therapy) means the total amount of any medication given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, or current standards of practice for a resident's age and condition; without evidence of a review for the continued necessity of the dose or of attempts at, or consideration of the possibility of, tapering a medication; and there is no documented clinical rationale for the benefit of, or necessity for the dose or for the use of multiple medications from the same class.

- **"Duration"** is the total length of time the medication is being received.

- **"Excessive Duration"** means the medication is administered beyond the manufacturer's recommended time frames or facility-established stop order policies, beyond the length of time advised by current standards of practice, and/or without either evidence of additional therapeutic benefit for the resident or clear clinical factors that would warrant the continued use of the medication.

- **"Irregularity"** refers to any event that is inconsistent with usual, proper, accepted, or right approaches to providing pharmaceutical services (see definition in F425), or that impedes or interferes with achieving the intended outcomes of those services.

- **"Medication Interaction"** is the impact of another substance (such as another medication, herbal product, food or substances used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

- **"Medication Regimen Review"** (MRR) is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team.[i]

- **"Monitoring"** is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data in order to:

    - Ascertain the individual's response to treatment and care, including progress or lack of progress toward a therapeutic goal;

    - Detect any complications or adverse consequences of the condition or of the treatments; and

    - Support decisions about modifying, discontinuing, or continuing any interventions.

- **"Pharmacy Assistant or Technician"** refers to ancillary personnel who work under the supervision and delegation of the pharmacist as consistent with state requirements.

OVERVIEW

Many nursing home residents require multiple medications to address their conditions, leading to complex medication regimens. Medications are used for their therapeutic benefits in diagnosing, managing, and treating acute and/or chronic conditions, for maintaining and/or improving a resident's functional status, and for improving or sustaining the resident's quality of life. The nursing home population may be quite diverse and may include geriatric residents as well as individuals of any age with special needs, such as those who are immunocompromised or who have end stage renal disease or spinal cord or closed head injuries. Regardless, this population has been identified as being at high risk for adverse consequences related to medications. Some adverse consequences may mimic symptoms of chronic conditions, the aging process, or a newly emerging condition.

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increase the risk of medication-related issues. Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues include:

- The physician providing and reviewing the orders and total program of care on admission and the prescriber reviewing at each visit;

- The nurse reviewing medications when transmitting the orders to the pharmacy and/or prior to administering medications;

- The interdisciplinary team reviewing the medications as part of the comprehensive assessment for the Resident Assessment Instrument (RAI) and/or care plan;

- The pharmacist reviewing the prescriptions prior to dispensing; and

- The pharmacist performing the medication regimen review at least monthly.

During the MRR, the pharmacist applies his/her understanding of medications and related cautions, actions and interactions as well as current medication advisories and information. The pharmacist provides consultation to the facility and the attending physician(s) regarding the medication regimen and is an important member of the interdisciplinary team. Regulations prohibit the pharmacist from delegating the medication regimen reviews to ancillary staff.

Some resources are available to facilitate evaluating medication concerns related to the performance of the MRR, such as:

- American Society of Consultant Pharmacists (ASCP) www.ascp.com;

- American Medical Directors Association (AMDA) www.amda.com;

- National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) www.nccmerp.org;

- American Geriatrics Society (AGS) www.americangeriatrics.org;

- U.S. Department of Health and Human Services, Food and Drug Administration (FDA) http://www.fda.gov/medwatch/safety.htm; and

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

This guidance is not intended to imply that all adverse consequences related to medications are preventable, but rather to specify that a system exists to assure that medication usage is evaluated on an ongoing basis, that risks and problems are identified and acted upon, and that medication-related problems are considered when the resident has a change in condition. This guidance will discuss the following aspects of the facility's MRR component of the pharmaceutical services systems:

- A pharmacist's review of the resident's medication regimen to identify and report irregularities; and

- Acting upon identified irregularities in order to minimize or prevent adverse consequences, to the extent possible.

NOTE: The surveyor's review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

MEDICATION REGIMEN REVIEW (MRR)

The MRR is an important component of the overall management and monitoring of a resident's medication regimen. The pharmacist must review each resident's medication regimen at least once a month in order to identify irregularities; and to identify clinically significant risks and/or adverse consequences resulting from or associated with medications. It may be necessary for the pharmacist to conduct the MRR more frequently, for example weekly, depending on the resident's condition and the risks for adverse consequences related to current medications.

The requirement for the MRR applies to each resident, including residents who:

- *Are receiving respite care;*
- *Are at the end of life or have elected the hospice benefit and are receiving respite care;*
- *Have an anticipated stay of less than 30 days; or*
- *Have experienced a change in condition.*

A complex resident generally benefits from a pharmacist's review during the transition from hospital to skilled nursing facility.[1] Medication review upon transition of care may prevent errors due to drug-drug interactions, omissions, duplication of therapy, or miscommunication during the transition from one team of care providers to another.

Generally, MRRs are conducted in the facility because important information about indications for use, potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and observing and speaking with the resident. However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review outside the facility.

Important aspects of the MRR include identification of irregularities, including medication-related errors and adverse consequences, location and notification of MRR findings, and response to identified irregularities. This guidance discusses these aspects and also provides some examples of clinically significant medication interactions.

Identification of Irregularities

An objective of the MRR is to try to minimize or prevent adverse consequences by identifying irregularities including, for example: syndromes potentially related to medication therapy, emerging or existing adverse medication consequences, as well as the potential for adverse drug reactions and medication errors. The resident's record may contain information regarding possible and/or actual medication irregularities. Possible sources to obtain this information include: the medication administration records (MAR); prescribers' orders; progress, nursing and consultants' notes; the Resident Assessment Instrument (RAI); laboratory and diagnostic test results, and other sources of information about behavior monitoring and/or changes in condition. The pharmacist may also obtain information from the Quality Measures/Quality Indicator reports, the attending physician, facility staff, and (as appropriate) from interviewing, assessing, and/or observing the resident.

The pharmacist's review considers factors such as:

- Whether the physician and staff have documented objective findings, diagnoses and/or symptom(s) to support indications for use;

- Whether the physician and staff have identified and acted upon, or should be notified about, the resident's allergies and/or potential side effects and significant medication interactions (such as medication-medication, medication-food, medication-disease, medication-herbal interactions);

- Whether the medication dose, frequency, route of administration, and duration are consistent with the resident's condition, manufacturer's recommendations, and applicable standards of practice;

- Whether the physician and staff have documented progress towards, or maintenance of, the goal(s) for the medication therapy;

- Whether the physician and staff have obtained and acted upon laboratory results, diagnostic studies, or other measurements (such as bowel function, intake and output) as applicable;

- Whether medication errors exist or circumstances exist that make them likely to occur; and

- Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms. The following are examples of changes potentially related to medication use that could occur at any age, however, some of the changes are more common in the geriatric population and may be unrelated to medications:

    - Anorexia and/or unplanned weight loss, or weight gain;

- Behavioral changes, unusual behavior patterns (including increased distressed behavior);
- Bowel function changes including constipation, ileus, impaction;
- Confusion, cognitive decline, worsening of dementia (including delirium) of recent onset;
- Dehydration, fluid/electrolyte imbalance;
- Depression, mood disturbance;
- Dysphagia, swallowing difficulty;
- Excessive sedation, insomnia, or sleep disturbance;
- Falls, dizziness, or evidence of impaired coordination;
- Gastrointestinal bleeding;
- Headaches, muscle pain, generalized aching or pain;
- Rash, pruritus;
- Seizure activity;
- Spontaneous or unexplained bleeding, bruising;
- Unexplained decline in functional status (e.g., ADLs, vision); and
- Urinary retention or incontinence.

Upon conducting the MRR, the pharmacist may identify and report concerns in one or more of the following categories:[ii] (See F329 for additional discussion of irregularities relating to dose, duration, indications for use, monitoring, and adverse consequences.)

- The use of a medication without identifiable evidence of adequate indications for use;
- The use of a medication to treat a clinical condition without identifiable evidence that safer alternatives or more clinically appropriate medications have been considered;
- The use of an appropriate medication that is not helping attain the intended treatment goals because of timing of administration, dosing intervals, sufficiency of dose, techniques of administration, or other reasons;

- The use of a medication in an excessive dose (including duplicate therapy) or for excessive duration, thereby placing the resident at greater risk for adverse consequences or causing existing adverse consequences;

- The presence of an adverse consequence associated with the resident's current medication regimen;

- The use of a medication without evidence of adequate monitoring; i.e., either inadequate monitoring of the response to a medication or an inadequate response to the findings;

- Presence of medication errors or the risk for such errors;

- Presence of a clinical condition that might warrant initiation of medication therapy; and

  NOTE: The presence of a diagnosis or symptom does not necessarily warrant medication, but often depends on the consideration of many factors simultaneously.

- A medication interaction associated with the current medication regimen.

The following table provides examples of some problematic medication interactions in the long-term care population. These examples represent common interactions but are not meant to be all inclusive.

NOTE: Concomitant use of these medication combinations is not necessarily inappropriate and these examples are not intended to imply that the medications cannot be used simultaneously. Often, several medications with documented interactions can be given together safely. However, concomitant use of such medications warrants careful consideration of potential alternatives, possible need to modify doses, and diligent monitoring.

Common Medication-Medication Interactions in Long Term Care[iii]

Medication 1	Medication 2	Impact
warfarin	NSAIDs such as ibuprofen, naproxen, COX-2 inhibitors	Potential for serious gastrointestinal bleeding
warfarin	sulfonamides such as trimethoprim/ sulfamethoxazole	Increased effects of warfarin, with potential for bleeding
warfarin	macrolides such as clarithromycin, erythromycin	Increased effects of warfarin, with potential for bleeding
warfarin	fluoroquinolones such as ciprofloxacin, levofloxacin, ofloxacin	Increased effects of warfarin, with potential for bleeding
warfarin	phenytoin	Increased effects of warfarin and/or phenytoin
ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril	potassium supplements	Elevated serum potassium levels
ACE Inhibitors such as benazepril, captopril, enalapril, and lisinopril	spironolactone	Elevated serum potassium levels
digoxin	amiodarone	digoxin toxicity
digoxin	verapamil	digoxin toxicity
theophylline	fluoroquinolones such as ciprofloxacin, levofloxacin, ofloxacin	theophylline toxicity

Location and Notification of Medication Regimen Review Findings

The pharmacist is expected to document either that no irregularity was identified or the nature of any identified irregularities. The pharmacist is responsible for reporting any identified irregularities to the attending physician and director of nursing. The timeliness of notification of irregularities depends on factors including the potential for or presence of serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a resident who is receiving anticoagulants or in cases of possible allergic reactions to antibiotic therapy. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect. The facility and the pharmacist may collaborate to identify the most effective means for assuring appropriate notification. This notification may be done electronically.

The pharmacist does not need to document a continuing irregularity in the report each month if the pharmacist has deemed the irregularity to be clinically insignificant or evidence of a valid

clinical reason for rejecting the pharmacist's recommendation was provided. In this situation, the pharmacist need only reconsider annually whether to report the irregularity again or make a new recommendation.

The pharmacist's findings are considered part of each resident's clinical record. If documentation of the findings is not in the active record, it is maintained within the facility and is readily available for review. The interdisciplinary team is encouraged to review the reports and to get the pharmacist's input on resident problems and issues. Establishing a consistent location for the pharmacist's findings and recommendations can facilitate communication with the attending physician, the director of nursing, the remainder of the interdisciplinary team, the medical director, the resident and his or her legal representative (in accord with 42 CFR 483.10(b)(2),(d)(2)), ombudsman (with permission of the resident in accord with 42 CFR 483.10(j)(3)), and surveyors.

Response to Irregularities Identified in the MRR

Throughout this guidance, a response from a physician regarding a medication problem implies appropriate communication, review, and resident management, but does not imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician determines that those are medically valid and indicated.

For those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects all or some of the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable for a physician to document only that he/she disagrees with the report, without providing some basis for disagreeing.

If there is the potential for serious harm and the attending physician does not concur with or take action on the report, the facility and the pharmacist should contact the facility's medical director for guidance and possible intervention to resolve the issue. The facility should have a procedure to resolve the situation when the attending physician is also the medical director. For those recommendations that do not require a physician intervention, such as one to monitor vital signs or weights, the director of nursing or designated licensed nurse addresses and documents action(s) taken.

ENDNOTES

[1]Boockvar KS, Carlson LaCorte H, Giambanco V, Fridman B, Siu A. Medication reconciliation for reducing drug discrepancy adverse effects. Am J Geriatr Pharmacother. 2006 Sep; 4(3): 236-43.

INVESTIGATIVE PROTOCOL

Refer to the Investigative Protocol at F329 for evaluation of medication regimen review.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F428)

This requirement has four aspects relating to the safety of the resident's medication regimen, including:

- A review by the pharmacist of each resident's medication regimen at least once a month or more frequently depending upon the resident's condition and the risks or adverse consequences related to current medication(s);
- The identification of any irregularities;
- Reporting irregularities to the attending physician and the director of nursing; and
- Action in response to irregularities reported.

Criteria for compliance

Compliance with 42 CFR 483.60(c)(1) and (2), F428, Medication Regimen Review

The facility is in compliance with this requirement if:

- The pharmacist has performed a medication regimen review on each resident at least once a month or more frequently depending upon the resident's condition and/or risks or adverse consequence associated with the medication regimen;
- The pharmacist has identified any existing irregularities;
- The pharmacist has reported any identified irregularities to the director of nursing and attending physician; and
- The report of any irregularities has been acted upon.

If not, cite F428.

Noncompliance for F428

After completing the Investigative Protocol, analyze the data in order to determine whether or not compliance with F428 exists. A determination of noncompliance with F428 does not require a finding of harm to the resident. Noncompliance may include (but is not limited to) one or more of the following:

- The pharmacist failed to conduct an MRR at least monthly (or more frequently, as indicated *by the resident's condition*).

- The pharmacist failed to identify or report the absence of or inadequate indications for use of a medication, or a medication or medication combination with significant potential for adverse consequences or medication interactions.

- The pharmacist failed to identify or report medications in a resident's regimen that could (as of the review date) be causing or associated with new, worsening, or progressive signs and symptoms.

- The pharmacist failed to identify and report the absence of any explanation as to why or how the benefit of a medication(s) with potential for clinically significant adverse consequences outweighs the risk.

- The pharmacist failed to identify and report the lack of evidence or documentation regarding progress toward treatment goals.

- The facility failed to act upon a report of clinically significant risks or existing adverse consequences or other irregularities.

Potential Tags for Additional Investigation

If noncompliance with 483.60(c)(1) and (2) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present. Examples of some of the related requirements that should be considered when noncompliance has been identified include the following:

- 42 CFR 483.10(b)(11), F157, Notification of Changes

    - Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a different form of treatment).

- 42 CFR 483.25(l), F329, Unnecessary Medications

    - Review whether the resident is receiving any medications without an indication

for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.

- 42 CFR 483.40(a), F385, Physician Supervision

    - Review whether the attending physician supervised the resident's medical treatment, including assessing the resident's condition, identifying the need for and continuing use of medication to address the resident's needs, and identifying and addressing adverse consequences related to medications.

- 42 CFR 483.40(b), F386, Physician Visits

    - Review whether the attending physician or another designated practitioner reviewed the resident's total program of care including the beneficial and adverse effects of medications and treatment, and provided a relevant progress note at each visit.

- 42 CFR 483.60(a)(b)(1), F425, Pharmacy Services

    - Review whether the licensed pharmacist has provided consultation regarding all aspects of pharmaceutical services.

- 42 CFR 483.75(i), F501, Medical Director

    - Review whether the medical director, when requested by the facility, interacted with the attending physician regarding an inadequate response to identified or reported potential medication irregularities and adverse consequences.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident. The survey team must identify whether noncompliance cited at other tags (e.g., F329, F332/333) was the direct result of or related to inadequate or absent MRR or response to notification regarding irregularities.

The key elements for severity determination for F428 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a facility failure related to the MRR.

Identify actual or potential harm/negative outcomes which for F428 may include, but are not limited to:

- The resident experienced a clinically significant adverse consequence associated with a medication.

- Irregularities within the medication regimen or inaccuracy of medication-related documents created the potential for adverse consequences such as overdose, respiratory depression, rash, or anorexia.

2. Degree of potential or actual harm/negative outcome(s) due to a facility failure related to the MRR.

Identify to what degree the facility practices caused, resulted in, allowed, or contributed to the actual or potential harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or

- If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F428. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

- Despite identifying irregularities with the potential for serious harm or death, the pharmacist did not report the irregularities to the attending physician or no action was taken on the irregularities reported.

- Findings of noncompliance at Severity Level 4 at Tag(s) F309, F329, F332, or F333 that show evidence of process failures for conducting the MRR.

- Repeated or cumulative failures in multiple areas of the medication regimen review process (e.g., failure to identify, report, or act upon) that resulted in the resident(s) experiencing actual or potential harm.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- The pharmacist's MRR failed to identify the indication for continued use for opioid analgesics that had been prescribed for a resident's acute pain which had resolved. As a result of prolonged duration of use, the resident became more lethargic, withdrawn, and anorectic.

- The pharmacist's MRR identified that the staff were crushing medications that should not be crushed, based on inappropriate standing orders to crush all medications. As a result of facility failure to act upon the notification, the resident experienced clinically significant adverse consequences such as hypoglycemia or hypotension that required medical intervention.

- The pharmacist's MRR identified that medications were not being given as ordered (such as antiparkinsons or pain medications not given prior to physical therapy), which may have contributed to impaired function. The facility failed to take any action to adhere to the orders.

- The physician and/or director of nursing failed to act in response to the pharmacist's MRR which identified the indefinite continuation of an antidepressant in a resident who had no history of depression, who had been placed on the antidepressant without an evaluation to confirm presence of depression, and whose function and mood were not monitored while getting the medication for months. The resident experienced clinically significant adverse consequences such as falls, constipation, or change in weight.

- The pharmacist's MRR failed to identify and report the medication regimen as a possible cause of recurrent falling in a resident who was given increasing doses of anticonvulsants to treat behavioral symptoms related to dementia, resulting in serious injury.

- The pharmacist's MRR failed to identify and report clinically significant medication interactions in a resident who was started on warfarin, and who had also been receiving one or more of the following: digoxin, phenytoin, antibiotics, amiodarone, or an oral antifungal, resulting in a marked elevation in the INR with significant gastrointestinal bleeding or hematuria.

- Findings of noncompliance at Severity Level 3 at tag(s) F309, F329, F332, F333 that show evidence of process failures for conducting the MRR.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples include, but are not limited to:

- The facility failed to respond to the pharmacist's notification that the resident was not receiving all the medications ordered; however, there was no change in the resident condition.

- The pharmacist's MRR failed to identify and report a resident who is receiving multiple antihypertensive medications, but is not being monitored for postural hypotension, and who complains of lightheadedness especially while upright.

- The pharmacist's MRR failed to identify and report risks of hyperkalemia in a resident who has impaired renal function and is receiving an ACE inhibitor and potassium supplements.

- The pharmacist's MRR failed to evaluate and report on the potential adverse consequences of a medication known to cause anorexia for a resident with a recently decreased appetite, who had not yet experienced a significant unplanned weight loss.

- Findings of noncompliance at Severity Level 2 at tag(s) F309, F329, or F332, F333 that show evidence of process failures for conducting the MRR.

NOTE: If Severity Level 2 (no actual harm with potential for more than minimal harm that is not immediate jeopardy) has been ruled out based upon the evidence, then

evaluate as to whether Severity Level 1 (no actual harm with the potential for minimal harm) exists.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

Level 1 indicates noncompliance that resulted in no harm to the resident, and the potential for no more than minimal harm. Examples may include, but are not limited to:

- The pharmacist conducted the medication review, identified an irregularity that has not resulted in a negative outcome and is of minimal consequence (such as a multi-vitamin not being given as ordered) and reported to the director of nursing and attending physician, but neither of them acted upon the report.

F431

(Rev.)

§483.60(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who--

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

§483.60(d) Labeling of Drugs and Biologicals

Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(e) Storage of Drugs and Biologicals

(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

INTENT (F431) 42 CFR 483.60(b)(2)(3)(d) Labeling of Drugs and Biologicals & (e) Storage of Drugs and Biologicals

The intent of this requirement is that the facility, in coordination with the licensed pharmacist, provides for:

- Safe and secure storage (including proper temperature controls, limited access, and mechanisms to minimize loss or diversion) and safe handling (including disposition) of all medication;

- Accurate labeling to facilitate consideration of precautions and safe administration of medications;

- A system of medication records that enables periodic accurate reconciliation and accounting of all controlled medications; and

- Identification of loss or diversion of controlled medications so as to minimize the time between actual loss or diversion and the detection and determination of the extent of loss or diversion.

NOTE: For purposes of this guidance, references to "the pharmacist" mean the licensed pharmacist, whether employed directly by the facility or through arrangement.

DEFINITIONS (refer to F425 and F428 for additional definitions)

- "Adverse consequence" refers to an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).

- "Clinically significant" refers to effects, results, or consequences that materially affect or are likely to affect an individual's physical, mental, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

OVERVIEW

Due to the number and types of medications that may be used and the vulnerable populations being served, the regulations require a long term care facility to have formal mechanisms to safely handle and control medications, and to maintain accurate and timely medication records. These regulations also require the facility to use a pharmacist to help establish and evaluate these mechanisms or systems. This guidance addresses those portions of the facility's pharmaceutical services related to medication access and storage, appropriate security and safeguarding of controlled medications, and labeling of medications to assure that they are stored safely and are provided to the residents accurately and in accordance with the prescriber's instructions.

MEDICATION ACCESS AND STORAGE

A facility is required to secure all medications in a locked storage area and to limit access to authorized personnel (for example, pharmacy technicians or assistants who have been delegated access to medications by the facility's pharmacist as a function of their jobs) consistent with state or federal requirements and professional standards of practice.

Storage areas may include, but are not limited to, drawers, cabinets, medication rooms, refrigerators, and carts. Depending on how the facility locks and stores medications, access to a medication room may not necessarily provide access to the medications (for example, medications stored in a locked cart, locked cabinets, a locked refrigerator, or locked drawers

within the medication room). When medications are not stored in separately locked compartments within a storage area, only appropriately authorized staff may have access to the storage area.

Access to medications can be controlled by keys, security codes or cards, or other technology such as fingerprints. Schedule II medications must be maintained in separately locked, permanently affixed compartments. The access system (e.g. key, security codes) used to lock Schedule II medications and other medications subject to abuse, cannot be the same access system used to obtain the non-scheduled medications. The facility must have a system to limit who has security access and when access is used. Exception: Controlled medications and those subject to abuse may be stored with non-controlled medications as part of a single unit package medication distribution system, if the supply of the medication(s) is minimal and a shortage is readily detectable.

During a medication pass, medications must be under the direct observation of the person administering the medications or locked in the medication storage area/cart. In addition, the facility should have procedures for the control and safe storage of medications for those residents who can self-administer medications.

Safe medication storage includes the provision of appropriate environmental controls. Because many medications can be altered by exposure to improper temperature, light, or humidity, it is important that the facility implement procedures that address and monitor the safe storage and handling of medications in accordance with manufacturers' specifications, State requirements and standards of practice (e.g., United States Pharmacopeia (USP) standards).

CONTROLLED MEDICATIONS

Regulations require that the facility have a system to account for the receipt, usage, disposition, and reconciliation of all controlled medications. This system includes, but is not limited to:

- Record of receipt of all controlled medications with sufficient detail to allow reconciliation (e.g., specifying the name and strength of the medication, the quantity and date received, and the resident's name). However, in some delivery systems (e.g., single unit package medication delivery system or automated dispensing systems utilizing single-unit packages of medications that are not dispensed pursuant to a specific order), the resident's name may not be applicable;

  NOTE: The facility may store some controlled medications in an emergency medication supply in accordance with state requirements. The facility's policies and procedures must address the reconciliation and monitoring of this supply.

- Records of usage and disposition of all controlled medications with sufficient detail to allow reconciliation (e.g., the medication administration record [MAR], proof-of-use sheets, or declining inventory sheets), including destruction, wastage, return to the pharmacy/manufacturer, or disposal in accordance with applicable State requirements;

- Periodic reconciliation of records of receipt, disposition and inventory for all controlled medications (monthly or more frequently as defined by facility procedures or when loss is identified). The reconciliation identifies loss or diversion of controlled medications so as to minimize the time between the actual loss or diversion and the time of detection and follow-up to determine the extent of loss. Because diversion can occur at any time, the reconciliation should be done often enough to identify problems. Some State or other federal requirements may specify the frequency of reconciliation.

    - If discrepancies are identified during the reconciliation, the pharmacist and the facility develop and implement recommendations for resolving them.

    - If the systems have not been effective in preventing or identifying diversion or loss, it is important that the pharmacist and the facility review and revise related controls and procedures, as necessary, such as increasing the frequency of monitoring or the amount of detail used to document controlled substances.

    NOTE: The pharmacist is not required by these regulations to perform the reconciliation, but rather to evaluate and determine that the facility maintains an account of all controlled medications and completes the reconciliation according to its procedures, consistent with State and federal requirements.

If during a survey, a concern is identified regarding a controlled medication and the resulting investigation identifies diversion of a resident's medication, the surveyor must review for F224 - Misappropriation of Resident's Property. If it is determined that a resident's medications were diverted for staff use, the State Agency must make referrals to appropriate agencies, such as local law enforcement; Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; and possibly the State licensure Board for Nursing Home Administrators.

LABELING OF MEDICATIONS AND BIOLOGICALS

This section requires facility compliance with currently accepted labeling requirements, even though the pharmacies are responsible for the actual labeling. Labeling of medications and biologicals dispensed by the pharmacy must be consistent with applicable federal and State requirements and currently accepted pharmaceutical principles and practices. Although medication delivery systems may vary, the medication label at a minimum includes the medication name (generic and/or brand) and strength, the expiration date when applicable, and typically includes the resident's name, route of administration, appropriate instructions and precautions (such as shake well, with meals, do not crush, special storage instructions).

For medications designed for multiple administrations (e.g., inhalers, eye drops), the label is affixed in a manner to promote administration to the resident for whom it was prescribed.

When medications are prepared or compounded for intravenous infusion, the label contains the name and volume of the solution, resident's name, infusion rate, name and quantity of each additive, date of preparation, initials of compounder, date and time of administration, initials of

person administering medication if different than compounder, ancillary precautions as applicable, and date after which the mixture must not be used.

For over-the-counter (OTC) medications in bulk containers (e.g., in states that permit bulk OTC medications to be stocked in the facility), the label contains the original manufacturer's or pharmacy-applied label indicating the medication name, strength, quantity, accessory instructions, lot number, and expiration date when applicable. If supplies of bulk OTC medications are used for a specific resident, the container identifies that resident by name and must contain the original manufacturer's or pharmacy-applied label.

The facility ensures that medication labeling in response to order changes is accurate and consistent with applicable state requirements.

INVESTIGATIVE PROTOCOL

For investigating compliance with the requirement at 483.60(d) & (e), see State Operations Manual, Appendix P, II.B. The Traditional Standard Survey, Task 5, Sub- Task 5E Investigative Protocol: Medication Pass and Pharmacy Services.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F431)

This requirement has several aspects. The pharmaceutical services must:

- Provide for the safe and secure storage of medications, i.e., medications must be stored at proper temperatures and locked at all times (except when under direct staff observation);
- Limit access to medications only to authorized staff;
- Label medications in accordance with Federal and State labeling requirements and accepted standards of practice; and
- Have safeguards and systems in place to control, account for, and periodically reconcile controlled medications *in order to prevent loss, diversion, or accidental exposure.*

Criteria for Compliance

Compliance with 42 CFR 483.60(b)(2)(3)(d)(e), F431, Labeling, Storage, and Controlled Medications

The facility is in compliance if:

- The facility safeguards medications by locking the medications, limiting access, and disposing of medications appropriately;

- Medications are stored under proper temperature controls and in accordance with manufacturers' specifications;

- Medication labeling identifies, at a minimum, the medication's name, strength, expiration date when applicable, and lot number, and provides instructions as necessary for safe administration;

- Schedule II medications are stored in separately locked, permanently affixed compartments, except when the facility uses single unit medication distribution systems in which the quantity stored is minimal and a missing dose can be readily detected; and

- Controlled medications are reconciled accurately.

If not, cite F431.

Noncompliance for F431

After completing the investigation, determine whether compliance with the regulation exists. Noncompliance for F431 may include (but is not limited to) facility failure to:

- Store medications to preserve their integrity, for example allowing medications that should be stored between 40 and 86 degrees Fahrenheit to either reach temperatures below 32 degrees or above 100 degrees;

- Provide accurate labeling with appropriate accessory and cautionary instructions, thereby creating a potential for the wrong medication to be administered or for the correct medications to be given by the wrong route; and

- Accurately reconcile controlled medications.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The key elements for severity determination for F431 are as follows:

1. **Presence of actual or potential harm/negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.**

   Identify actual or potential harm/negative outcomes for F431 which may include, but are not limited to:

- Accidental ingestion of medication(s) by a resident(s) as a result of failure to lock medications;

  One or more residents received (or had the potential to receive) the wrong medication or dose or the correct medication by the wrong route as a result of inaccurate or incomplete labeling;

- Potential for a resident(s) to receive potentially ineffective medication(s) as a result of storing medications or vaccines at wrong temperatures, resulting in their potential inactivation; *or*

- *Potential for a resident or other individual to abuse or overdose as a result of improper disposal of used controlled medications, e.g. used Fentanyl transdermal patches or remaining controlled medication in a syringe.*

2. **Degree of actual or potential harm/negative outcome(s) due to a facility failure related to storage, labeling, or reconciliation of controlled medications.**

   Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

   - If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or

   - If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. **The immediacy of correction required.**

   Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F431. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Guidelines for Determining Immediate Jeopardy.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

- The facility failed to restrict access to medications resulting in serious injury or harm or death from ingestion of the medications (e.g., warfarin, digoxin, antibiotics, opioids, anticonvulsants, antipsychotics) or posed a significant risk to the health of the residents resulting in the potential for clinically significant adverse consequences such as kidney or liver failure, anaphylaxis, cardiac arrest, or death; or

- As a result of an incorrect label on the package, staff administered the wrong medication or wrong dose(s) of a medication (e.g., anticonvulsant, antihyperglycemic, benzodiazepine) with a potential for clinically significant adverse consequences, which resulted in or had the potential for serious harm or death (e.g., toxic levels of the medication, unresponsiveness, uncontrolled seizures).

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and can include but may not be limited to compromise, decline, or interference with the resident's ability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

- Medication labeling was incomplete and lacked instructions that the medication was not to be given with specific foods (e.g., milk or milk-based products) resulting in altered effectiveness of the medication and worsening of the residents' symptoms, requiring medical intervention; or

- The facility failed to implement a system to reconcile controlled medications. As a result, medications were unavailable for residents for whom the medications were prescribed. Residents experienced moderate pain that compromised their ability to perform ADLs.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:

- The facility's medication cart was not kept locked or under direct observation of authorized staff and a wandering resident with dementia ingested a medication that he/she had taken off the cart but did not suffer any adverse consequences; or

- As a result of inaccurate labeling, the resident received the wrong medication or dose or the correct medication by the wrong route and experienced discomfort but did not require any interventions.

NOTE: If Severity Level 2 (no actual harm with potential for more than minimal harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 1 (no actual harm with the potential for minimal harm) exists.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

Level 1 indicates noncompliance that resulted in no harm to the resident, and the potential for no more than minimal harm. Examples may include, but are not limited to:

- The facility failed to reconcile controlled medications but there was no negative resident outcome and no potential for more than minimal harm.

F441

(Rev.)

§483.65 Infection Control

The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an Infection Control Program under which it –

(1) Investigates, controls, and prevents infections in the facility;
(2) Decides what procedures, such as isolation, should be applied to an individual resident; and
(3) Maintains a record of incidents and corrective actions related to infections.

§483.65(b) Preventing Spread of Infection

(1) When the Infection Control Program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.
(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.
(3) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.

§483.65(c) Linens

Personnel must handle, store, process and transport linens so as to prevent the spread of infection.

INTENT: (F441) 42CFR 483.65 Infection Control

The intent of this regulation is to assure that the facility develops, implements, and maintains an Infection Prevention and Control Program in order to prevent, recognize, and control, to the extent possible, the onset and spread of infection within the facility. The program will:

- Perform surveillance and investigation to prevent, to the extent possible, the onset and the spread of infection;

- Prevent and control outbreaks and cross-contamination using transmission-based precautions in addition to standard precautions;

- Use records of infection incidents to improve its infection control processes and outcomes by taking corrective actions, as indicated;

- Implement hand hygiene (hand washing) practices consistent with accepted standards of practice, to reduce the spread of infections and prevent cross-contamination; and

- Properly store, handle, process, and transport linens to minimize contamination.

DEFINITIONS

Definitions are provided to clarify terminology or terms related to infection control practices in nursing homes.

- **"Airborne precautions"** refers to actions taken to prevent or minimize the transmission of infectious agents/organisms that remain infectious over long distances when suspended in the air. These particles can remain suspended in the air for prolonged periods of time and can be carried on normal air currents in a room or beyond, to adjacent spaces or areas receiving exhaust air.[i]

- **"Alcohol-based hand rub"** (ABHR) refers to a 60-95 percent ethanol or isopropyl-containing preparation base designed for application to the hands to reduce the number of viable microorganisms.

- **"Antifungal"** refers to a medication used to treat a fungal infection such as athlete's foot, ringworm or candidiasis.

- **"Anti-infective"** refers to a group of medications used to treat infections.

- **"Antiseptic hand wash"** is "washing hands with water and soap or other detergents containing an antiseptic agent."[ii]

- **"Cohorting"** refers to the practice of grouping residents infected or colonized with the same infectious agent together to confine their care to one area and prevent contact with susceptible residents (cohorting residents). During outbreaks, healthcare personnel may be assigned to a cohort of residents to further limit opportunities for transmission (cohorting staff).

- **"Colonization"** refers to the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression.

- **“Communicable disease”** (also known as [a.k.a.] “Contagious disease”) refers to an infection transmissible (as from person-to-person) by direct contact with an affected individual or the individual's body fluids or by indirect means (as by a vector).

- **“Community associated infections”** (formerly “Community Acquired Infections”) refers to infections that are present or incubating at the time of admission, or generally develop within 72 hours of admission.

- **“Contact precautions”** are measures that are “intended to prevent transmission of infectious agents, including epidemiologically important microorganisms, which are spread by direct or indirect contact with the resident or the resident’s environment.”[iii]

- **“Droplet precautions”** refers to actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.[iv]

- **“Hand hygiene”** is a general term that applies to washing hands with water and either plain soap or soap/detergent containing an antiseptic agent; or thoroughly applying an alcohol-based hand rub (ABHR).

- **“Hand washing”** refers to washing hands with plain (i.e., nonantimicrobial) soap and water.

- **“Health care associated infection [HAI]”** (a.k.a. “nosocomial” and “facility-acquired” infection) refers to an infection that generally occurs after 72 hours from the time of admission to a health care facility.

- *"**Hygienically Clean**" means being free of pathogens in sufficient numbers to cause human illness.”*[v]

- **“Infection”** refers the establishment of an infective agent in or on a suitable host, producing clinical signs and symptoms (e.g., fever, redness, heat, purulent exudates, etc).

- **“Infection prevention and control program”** refers to a program (including surveillance, investigation, prevention, control, and reporting) that provides a safe, sanitary and comfortable environment to help prevent the development and transmission of infection.

- **“Infection preventionist (IP)”** (a.k.a. infection control professional) refers to a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired additional training in infection control.

- **“Isolation”** refers to the practices employed to reduce the spread of an infectious agent and/or minimize the transmission of infection.

- **“Isolation precautions”** see “Transmission-Based Precautions”

- **“Medical waste”** refers to any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining to, or in the production or testing of biologicals (e.g., blood-soaked bandages, sharps).

- **“Methicillin resistant staphylococcus aureus (MRSA)"** refers to Staphylococcus aureus bacteria that are resistant to treatment with semi-synthetic penicillins (e.g., Oxacillin/Nafcillin/Methicillin).

- **“Multi-Drug resistant organisms (MDROs)”** refers to microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents. Although the names of certain MDROs describe resistance to only one agent, these pathogens are frequently resistant to most available antimicrobial agents.[vi]

- **“Outbreak”** is the occurrence of more cases of a particular infection than is normally expected, the occurrence of an unusual organism, or the occurrence of unusual antibiotic resistance patterns.[vii]

- **“Personal protective equipment” (PPE)** refers to protective items or garments worn to protect the body or clothing from hazards that can cause injury.

- **“Standard precautions”** (formerly “Universal Precautions”) refers to infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. Standard Precautions is a combination and expansion of Universal Precautions and Body Substance Isolation (a practice of isolating all body substances such as blood, urine, and feces).[viii]

- **“Surveillance”** refers to the ongoing, systematic collection, analysis, interpretation, and dissemination of data to identify infections and infection risks, to try to reduce morbidity and mortality and to improve resident health status.

- **“Transmission-based precautions”** (a.k.a. “Isolation Precautions”) refers to the actions (precautions) implemented, in addition to standard precautions, that are based upon the means of transmission (airborne, contact, and droplet) in order to prevent or control infections.

- **“Vancomycin resistant enterococcus (VRE)”** refers to enterococcus that has developed resistance to vancomycin.

OVERVIEW

Infections are a significant source of morbidity and mortality for nursing home residents and account for up to half of all nursing home resident transfers to hospitals. Infections result in an estimated 150,000 to 200,000 hospital admissions per year at an estimated cost of $673 million to $2 billion annually. When a nursing home resident is hospitalized with a primary diagnosis of infection, the death rate can reach as high as 40 percent.

It is estimated that an average of 1.6 to 3.8 infections per resident occur annually in nursing homes. Urinary tract, respiratory (e.g., pneumonia and bronchitis), and skin and soft tissue infections (e.g., pressure ulcers) represent the most common endemic infections in residents of nursing homes.[ix] Other common infections include conjunctivitis, gastroenteritis, and influenza.[x]

Confirming and managing an infectious outbreak can be costly and time consuming. An effective facility-wide infection prevention and control program can help to contain costs and reduce adverse consequences. An effective program relies upon the involvement, support, and knowledge of the facility's administration, the entire interdisciplinary team, residents, and visitors.

Critical aspects of the infection prevention and control program include recognizing and managing infections at the time of a resident's admission to the facility and throughout their stay, as well as following recognized infection control practices while providing care (e.g., hand hygiene, handling and processing of linens, use of standard precautions, and appropriate use of transmission-based precautions and cohorting or separating residents). It is important that residents' conditions be reassessed because older adults may have coexisting diseases that complicate the diagnosis of an infection (e.g., joint degeneration vs. infectious arthritis, COPD versus pneumonia), and they may also have atypical or non-specific signs and symptoms related to infections, such as altered mental status, function or behavior, and impaired fever response.

Because of the potential negative impact that a resident may experience as a result of the implementation of special precautions, the facility is challenged to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections.

NOTE: It is important that all infection prevention and control practices reflect current Centers for Disease Control (CDC) guidelines.

INFECTION PREVENTION AND CONTROL PROGRAM

An effective infection prevention and control program is necessary to control the spread of infections and/or outbreaks.

Program Development and Oversight

Program development and oversight emphasize the prevention and management of infections. Program oversight involves establishing goals and priorities for the program, planning, and implementing strategies to achieve the goals, monitoring the implementation of the program

(including the interdisciplinary team's infection control practices), and responding to errors, problems, or other identified issues. Additional activities involved in program development and oversight may include but are not limited to:

- Identifying the staff's roles and responsibilities for the routine implementation of the program as well as in case of an outbreak of a communicable disease, an episode of infection, or the threat of a bio-hazard attack;

- Developing and implementing appropriate infection control policies and procedures, and training staff on them;

- Monitoring and documenting infections, including tracking and analyzing outbreaks of infection as well as implementing and documenting actions to resolve related problems;

- Defining and managing appropriate resident health initiatives, such as:

    - The immunization program (influenza, pneumonia, etc); and

    - Tuberculosis screening on admission and following the discovery of a new case, and managing active cases consistent with State requirements;

- Providing a nursing home liaison to work with local and State health agencies; and

- Managing food safety, including employee health and hygiene, pest control, investigating potential food-borne illnesses, and waste disposal.

The facility identifies personnel responsible for overall program oversight, which may involve collaboration of the administrator, the medical director or his/her designee, the director of nursing, and other appropriate facility staff as needed. This group may define how and when the program is to be routinely monitored and situations that may trigger a focused review of the program. The group communicates the findings from collecting and analyzing data to the facility's staff and management, and directs changes in practice based on identified trends, government infection control advisories, and other factors.

Components of an Infection Prevention and Control Program

An effective infection prevention and control program incorporates, but is not limited to, the following components:

- Policies, procedures, and practices which promote consistent adherence to evidence-based infection control practices;

- Program oversight including planning, organizing, implementing, operating, monitoring, and maintaining all of the elements of the program and ensuring that the facility's interdisciplinary team is involved in infection prevention and control;

- Infection preventionist, a person designated to serve as coordinator of the infection prevention and control program;

- Surveillance, including process and outcome surveillance, monitoring, data analysis, documentation and communicable diseases reporting (as required by State and Federal law and regulation);

- Education, including training in infection prevention and control practices, to ensure compliance with facility requirements as well as State and Federal regulation; and

- Antibiotic review including reviewing data to monitor the appropriate use of antibiotics in the resident population.

Examples of activities related to the Infection Prevention and Control Program may include but are not limited to:

- Undertaking process and/or outcome surveillance activities to identify infections that are causing, or have the potential to cause an outbreak;

- Conducting data analysis to help detect unusual or unexpected outcomes and to determine the effectiveness of infection prevention and control practices;

- Documenting observations related to the causes of infection and/or infection trends; and

- Implementing measures to prevent the transmission of infectious agents and to reduce risks for device and procedure-related infections.

Policies and Procedures

Policies and procedures are the foundation of the facility's infection prevention and control program. Policies and procedures are reviewed periodically and revised as needed to conform to current standards of practice or to address specific facility concerns.

Written policies establish the program's expectations and parameters. For example, policies may specify the use of standard precautions facility-wide and use of transmission-based precautions when indicated, define the frequency and nature of surveillance activities, require that staff use accepted hand hygiene after each direct resident contact for which hand hygiene is indicated, or prohibit direct resident contact by an employee who has an infected skin lesion or communicable disease.

Procedures guide the implementation of the policies and performance of specific tasks. Procedures may include, for example, how to identify and communicate information about residents with potentially transmissible infectious agents, how to obtain vital signs for a resident on contact precautions and what to do with the equipment after its use, and essential steps and considerations (including choosing agents) for performing hand hygiene.

Infection Preventionist (IP)

A facility may designate an IP to serve as the coordinator of an Infection Prevention and Control Program. Responsibilities may include collecting, analyzing, and providing infection data and trends to nursing staff and health care practitioners; consulting on infection risk assessment, prevention, and control strategies; providing education and training; and implementing evidence-based infection control practices, including those mandated by regulatory and licensing agencies, and guidelines from the Centers for Disease Control and Prevention.

Surveillance

Essential elements of a surveillance system include use of standardized definitions and listings of the symptoms of infections, use of surveillance tools such as infection surveys and data collection templates, walking rounds throughout the facility,[xi] identification of segments of the resident populations at risk for infection, identification of the processes or outcomes selected for surveillance, statistical analysis of data that can uncover an outbreak, and feedback of results to the primary caregivers so that they can assess the residents for signs of infection.

Two types of surveillance (process and outcome) can be implemented in facilities.

Process Surveillance

Process surveillance reviews practices directly related to resident carexi in order to identify whether the practices comply with established prevention and control procedures and policies based on recognized guidelines. Examples of this type of surveillance include monitoring of compliance with transmission based precautions, proper hand hygiene,[xii] and the use and disposal of gloves. Process surveillance determines, for example, whether the facility:

- Minimizes exposure to a potential source of infection;
- Uses appropriate hand hygiene prior to and after all procedures;[xiii]
- Ensures that appropriate sterile techniques are followed; for example, that staff:
    - Use sterile gloves, fluids, and materials, when indicated,[xiv] depending on the site and the procedure;[xv]
    - Avoid contaminating sterile procedures;[xvi] and
    - Ensure that contaminated/non-sterile items are not placed in a sterile field.
- Uses Personal Protective Equipment (PPE) when indicated;[xvii]
- Ensures that reusable equipment is appropriately cleaned, disinfected, or reprocessed; and
- Uses single-use medication vials and other single use items appropriately (proper disposal after every single use). [xviii]

Outcome Surveillance

In contrast to process surveillance, outcome surveillance is designed to identify and report evidence of an infection. The outcome surveillance process consists of collecting/documenting data on individual cases and comparing the collected data to standard written definitions (criteria) of infections. The IP or other designated staff reviews data (including residents with fever or purulent drainage, and cultures or other diagnostic test results consistent with potential infections) to detect clusters and trends. Other sources of relevant data may include antibiotic orders, laboratory antibiograms (antibiotic susceptibility profiles), medication regimen review reports, and medical record documentation such as physician progress notes and transfer summaries accompanying newly admitted residents.[xix] The facility's program should choose to either track the prevalence of infections (existing/current cases both old and new) at a specific point, or focus on regularly identifying new cases during defined time periods. When conducting outcome surveillance, the facility may choose to use one or more of the automated systems and authoritative resources that are available, and include definitions.

Documentation

Facilities may use various approaches to gathering, documenting, and listing surveillance data. The facility's infection control reports describe the types of infections and are used to identify trends and patterns. Descriptive documentation provides the facility with summaries of the observations of staff practices and/or the investigation of the causes of an infection and/or identification of underlying cause(s) of infection trends.

It is important that the infection prevention and control program define how often and by what means surveillance data will be collected, regardless of whether the facility creates its own forms, purchases preprinted forms, or uses automated systems.

Monitoring

Monitoring of the implementation of the program, its effectiveness, the condition of any resident with an infection, and the resolution of the infection and/or an outbreak is considered an integral part of nursing home infection surveillance. The facility monitors practices (e.g., dressing changes and transmission-based precaution procedures) to ensure consistent implementation of established infection prevention and control policies and procedures based on current standards of practice. All residents are monitored for current infections and infection risks.

Data Analysis

Determining the origin of infections helps the facility identify the number of residents who developed infections within the nursing home. Comparing current infection control surveillance data (including the incidence or prevalence of infections and staff practices) to past data enables detection of unusual or unexpected outcomes, trends, effective practices, and performance issues. The facility can then evaluate whether it needs to change processes or practices to enhance infection prevention and minimize the potential for transmission of infections.

It is important that surveillance reports be shared with appropriate individuals including, but not limited to, the director of nursing and medical director. In addition, it is important that the staff and practitioners receive reports that are relevant to their practices to help them recognize the impact of their care on infection rates and outcome.

Communicable Disease Reporting

It is important for each facility to have processes that enable them to consistently comply with State and local health department requirements for reporting communicable diseases.

Education

Both initial and ongoing infection control education help staff comply with infection control practices. Updated education and training are appropriate when policies and procedures are revised or when there is a special circumstance, such as an outbreak, that requires modification or replacement of current practices.[xx] In addition to education regarding general infection control principles, some infection control training is discipline and task specific (e.g., insertion of urinary catheters, suctioning, intravenous care or blood glucose monitoring). Follow-up competency evaluations identify staff compliance.

Essential topics of infection control training include, but are not limited to routes of disease transmission, hand hygiene, sanitation procedures, MDROs, transmission-based precaution techniques, and the federally required OSHA education.

Antibiotic Review

Because of increases in MDROs, review of the use of antibiotics (including comparing prescribed antibiotics with available susceptibility reports) is a vital aspect of the infection prevention and control program. It is the physician's (or other appropriate authorized practitioner's) responsibility to prescribe appropriate antibiotics and to establish the indication for use of specific medications. As part of the medication regimen review, the consultant pharmacist can assist with the oversight by identifying antibiotics prescribed for resistant organisms or for situations with questionable indications, and reporting such findings to the director of nursing and the attending physician. See the Guidance at §483.65, Tag F329 regarding use of a medication without adequate indication for use and at §483.65, Tag F428 regarding medication regimen review.

PREVENTING THE SPREAD OF INFECTION

Factors Associated with the Spread of Infection in Nursing Homes

Many factors contribute to a substantial severity and frequency of infections and infectious diseases in nursing homes. These infections can arise from individual or institutional factors, or both. Modes of transmission of infection include, but are not limited to:

- Contact;
- Droplet; and
- Airborne.

Individual Factors

Examples of individual factors contributing to infections and the severity of the infection outcomes in facility residents include, but are not limited to the following:

- Medications affecting resistance to infection such as corticosteroids and chemotherapy;
- Limited physiologic reserve (e.g., decreased function of the heart, lungs, and kidneys);
- Compromised host defenses (e.g., decreased or absent cough reflex predisposing to aspiration pneumonia, thinning skin associated with pressure ulcers, decreased tear production predisposing to conjunctivitis, vascular insufficiency, and impaired immune function);
- Coexisting chronic diseases (e.g., diabetes, arthritis, cancer, COPD, anemia);
- Complications from invasive diagnostic procedures such as skin or bloodstream infections;
- Impaired responses to infection (e.g., cell mediated responses); and
- Increased frequency of therapeutic toxicity (e.g., declining kidney and liver function).

Institutional Factors

In addition to individual factors, institutional factors may also facilitate transmission of infections among residents, including but not limited to:

- Pathogen exposure in shared communal living space (e.g., handrails and equipment);
- Common air circulation;
- Direct/indirect contact with health care personnel/visitors/other residents;
- Direct/indirect contact with equipment used to provide care; and
- Transfer of residents to and from hospitals or other settings.

Residents can be exposed to potentially pathogenic organisms in several ways, including but not limited to the following:

- Improper hand hygiene;

- Improper glove use (e.g., utilizing a single pair of gloves for multiple tasks or multiple residents); and

- Improper food handling.

Direct Transmission (Person to Person)

Direct transmission occurs when microorganisms are transferred from an infected/colonized person to another person. Contaminated hands of healthcare personnel are often implicated in direct contact transmission. Agents that can be transmitted by direct contact include, but are not limited to MRSA, VRE, and Influenza.

Indirect Transmission

Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object. The following are examples of opportunities for indirect contact.

- Resident-care devices (e.g., electronic thermometers or glucose monitoring devices) may transmit pathogens if devices contaminated with blood or body fluids are shared without cleaning and disinfecting between uses for different residents; and

- Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and Clostridium difficile). Indirect contact may occur through toilets and bedpans. Examples of illnesses spread via a fecal-oral route include salmonella, shigella, and pathogenic strains of E. coli, norovirus, and symptomatic Clostridium difficile.

Reducing and/or preventing infections through indirect contact requires the decontamination (i.e., cleaning, sanitizing, or disinfecting an object to render it safe for handling) of resident equipment, medical devices, and the environment. Alternatively, the facility may also consider using single-use disposable devices. The choice of decontamination method depends on the risk of infection to the resident coming into contact with equipment or medical devices.

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical and noncritical.[xxi] This includes:

- Critical items (e.g., needles, intravenous catheters, indwelling urinary catheters) are defined as those items which normally enter sterile tissue, or the vascular system, or through which blood flows. The equipment must be sterile when used, based on one of several accepted sterilization procedures;[xxi]

- Semi-critical items (e.g., thermometers, podiatry equipment, electric razors) are defined

as those objects that touch mucous membranes or skin that is not intact. Such items require meticulous cleaning followed by high-level disinfection treatment using an FDA-approved chemo sterilizer agent, or they may be sterilized; and

- Non-critical items (e.g., stethoscopes, blood pressure cuffs, over-bed tables) are defined as those that come into contact with intact skin or do not contact the resident. They require low level disinfection by cleaning periodically and after visible soiling, with an EPA disinfectant detergent or germicide that is approved for health care settings.

- *Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Single-use devices must be discarded after use and are never used for more than one resident. Nursing homes may purchase reprocessed single-use devices when these devices are reprocessed by an entity or a third party reprocessor that is registered with the FDA. The nursing home must have documentation from the third party reprocessor that indicates that it has been cleared by the FDA to reprocess the specific device in question.*

Single Dose/Single Use Medications

The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, Pharmaceutical Compounding - Sterile Preparations ("USP <797>").

Medications labeled as single-dose vials or single use vials, collectively referred to as SDVs in this guidance, must not be used for multiple patients due to the risk of spreading infectious diseases. Medications labeled as single-use or single dose by manufacturers typically lack antimicrobial preservatives, and once a SDV is entered, the contents can support the growth of microorganisms. The risk of infection transmission associated with using SDVs for multiple patients is well documented, with evidence accumulated from the investigation of multiple outbreaks.

*However, when **previously unopened** SDVs are repackaged consistent with aseptic conditions under the requirements of United States Pharmacopeia <797>, and subsequently stored consistent with USP <797> and the manufacturer's package insert, it is permissible for healthcare personnel to administer repackaged doses derived from SDVs to multiple patients, provided that each repackaged dose is used for a single patient in accordance with applicable storage and handling requirements.*

Among other things, these standards currently require that:

- *The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.*

- *All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process*

Administering drugs from one SDV to multiple residents without adhering to USP <797> standards is not acceptable.

Insulin Pens

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use, using a new needle for each injection. Insulin pens are designed to be used multiple times by a single resident ***only*** *and must never be shared. Regurgitation of blood into the insulin cartridge after injection will create a risk of bloodborne pathogen transmission if the pen is used for more than one patient/resident, even when the needle is changed.*[xxii] *The Food and Drug Administration (FDA) makes the following recommendations to prevent transmission of blood-borne infections in residents who require insulin pens:*

- *Insulin pens containing multiple doses of insulin are meant for single-resident use only, and must never be used for more than one person, even when the needle is changed.*

- *Insulin pens must be clearly labeled with the resident's name or other identifiers to verify that the correct pen is used on the correct resident.*

- *Facilities should review their policies and procedures and educate their staff regarding safe use of insulin pens.*

NOTE: *Sharing insulin pens between residents is similar to reusing needles or syringes for more than one resident, and such a finding may warrant a further investigation of the overall infection control practices within the facility. If it is discovered that insulin pens are shared between residents, the facility's plan of correction should include notification of the local health department or state epidemiologist for determination of the need for post-exposure follow up of patients and residents.*

Facilities who fail to observe appropriate infection control and prevention standards of practice during medication administration may also require evaluation under F332 and F333, Medication Errors.

Prevention and Control of Transmission of Infection

Infectious organisms (e.g., bacteria, viruses, or parasites) may be transmitted by direct contact (e.g., skin to skin) or indirect contact (e.g., via air, water, inanimate objects). Healthcare personnel and resident care equipment often move from resident to resident and therefore may serve as a vehicle for transferring infectious organisms. Another potential challenge is that the transmission of infectious organisms within the facility may be facilitated by inadequate hand

hygiene facilities, rinsing bed pans in inappropriate places (e.g., resident's sink), or inappropriate placement of colonized or infected residents (e.g., sharing a bathroom with a non- infected resident).

Airborne transmission can occur by inhaling pathogenic droplet nuclei (e.g., M Tuberculosis). Contaminated environmental surfaces are also potential reservoirs for infections. Infections caused by bacteria and viruses are especially common. Clostridium difficile can live on inanimate surfaces for up to 5 months[xxiii] while the hepatitis B virus can last up to a week[xxiv] and the influenza virus can survive on fomites (e.g., any inanimate object or substance capable of carrying infectious organisms and transferring them from one individual to another) for up to 8 hours. [xxv]

The appropriate disposal of waste helps minimize the potential transmission of infections. It is important for the facility to monitor safe handling of blood and body fluids and the disposal of contaminated waste.

General Approaches to Prevention and Control

A facility's infection control practices are important to preventing the transmission of infections. Infection control precautions used by the facility include two primary tiers: "Standard Precautions" and "Transmission-Based Precautions."

Standard Precautions

Standard precautions are based upon the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents. Standard precautions are intended to be applied to the care of all persons in all healthcare settings, regardless of the suspected or confirmed presence of an infectious agent. Implementation of standard precautions constitutes the primary strategy for preventing healthcare-associated transmission of infectious agents among residents and healthcare personnel. Appropriate infection control measures should be used in each resident interaction.

Standard precautions include but are not limited to hand hygiene, safe injection practices, the proper use of PPE (e.g., gloves, gowns, and masks), resident placement, and care of the environment, textiles, and laundry. Also, equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g., wear gloves for handling soiled equipment, and properly clean and disinfect or sterilize reusable equipment before use on another resident).[xxvi] In addition to proper hand hygiene, it is important for staff to use appropriate protective equipment as a barrier to exposure to any body fluids (whether known to be infected or not). For example, in situations identified as appropriate, gloves and other equipment such as gowns and masks are to be used as necessary to control the spread of infections. Standard precautions are also intended to protect residents by ensuring that healthcare personnel do not carry infectious agents to residents on their hands or via equipment used during resident care.

Disposal of waste is also handled as though all body fluids are infectious. Potentially contaminated articles are stored and disposed of in appropriate containers (e.g., sharps containers, biohazard bags, etc.), and the environment is cleaned using germicidal agents to reduce the risk of transmission of infection.

Hand Hygiene

Hand hygiene continues to be the primary means of preventing the transmission of infection. The following is a list of some situations that require hand hygiene:

- When coming on duty;
- When hands are visibly soiled (hand washing with soap and water);Before and after direct resident contact (for which hand hygiene is indicated by acceptable professional practice);
- Before and after performing any invasive procedure (e.g., fingerstick blood sampling);
- Before and after entering isolation precaution settings;
- Before and after eating or handling food (hand washing with soap and water);
- Before and after assisting a resident with meals;
- Before and after assisting a resident with personal care (e.g., oral care, bathing);
- Before and after handling peripheral vascular catheters and other invasive devices;
- Before and after inserting indwelling catheters;
- Before and after changing a dressing;
- Upon and after coming in contact with a resident's intact skin, (e.g., when taking a pulse or blood pressure, and lifting a resident);
- After personal use of the toilet (hand washing with soap and water);
- Before and after assisting a resident with toileting;
- After contact with a resident with infectious diarrhea including, but not limited to infections caused by norovirus, salmonella, shigella, and C. difficile (hand washing with soap and water);
- After blowing or wiping nose;

- After contact with a resident's mucous membranes and body fluids or excretions;
- After handling soiled or used linens, dressings, bedpans, catheters and urinals;
- After handling soiled equipment or utensils;
- After performing your personal hygiene (hand washing with soap and water);
- After removing gloves or aprons; and
- After completing duty.

Consistent use by staff of proper hygienic practices and techniques is critical to preventing the spread of infections. It is necessary for staff to have access to proper hand washing facilities with available soap (regular or anti-microbial), warm water, and disposable towels and/or heat/air drying methods. Alcohol based hand rubs (ABHR) cannot be used in place of proper hand washing techniques in a food service setting.[xxvii]

Recommended techniques for washing hands with soap and water include wetting hands first with clean, running warm water, applying the amount of product recommended by the manufacturer to hands, and rubbing hands together vigorously for at least 15 seconds covering all surfaces of the hands and fingers; then rinsing hands with water and drying thoroughly with a disposable towel; and turning off the faucet on the hand sink with the disposable paper towel.

Except for situations where hand washing is specifically required, antimicrobial agents such as ABHR are also appropriate for cleaning hands and can be used for direct resident care. Recommended techniques for performing hand hygiene with an ABHR include applying product to the palm of one hand and rubbing hands together, covering all surfaces of hands and fingers, until the hands are dry. In addition, gloves or the use of baby wipes are not a substitute for hand hygiene.

Other Staff-Related Preventive Measures

Facility staff who have direct contact with residents or who handle food must be free of communicable diseases and open skin lesions, if direct contact will transmit the disease. It is important that the facility maintain documentation of how they handle staff with communicable infections or open skin lesions.

It is important that all staff involved in direct resident contact maintain fingernails that are clean, neat, and trimmed. Wearing intact disposable gloves in good condition and that are changed after each use helps reduce the spread of microorganisms. It is important for dietary staff to wear hair restraints (e.g., hairnet, hat, and/or beard restraint) while in the kitchen areas to prevent their hair from contacting exposed food. Since jewelry can harbor microorganisms, it is recommended by the FDA that dietary staff keep jewelry to a minimum and remove or cover hand jewelry when handling food.[xxviii]

Transmission-based Precautions

Transmission-based precautions are used for residents who are known to be, or suspected of being infected or colonized with infectious agents, including pathogens that require additional control measures to prevent transmission. In nursing homes, it is appropriate to individualize decisions regarding resident placement (shared or private), balancing infection risks with the need for more than one occupant in a room, the presence of risk factors that increase the likelihood of transmission, and the potential for adverse psychological impact on the infected or colonized resident.[xxix]

It is essential both to communicate transmission-based precautions to all health care personnel, and for personnel to comply with requirements. Pertinent signage (i.e., isolation precautions) and verbal reporting between staff can enhance compliance with transmission-based precautions to help minimize the transmission of infections within the facility.

It is important to use the standard approaches, as defined by the CDC for transmission-based precautions: airborne, contact, and droplet precautions.[xxx] The category of transmission-based precaution determines the type of PPE to be used. Communication (e.g., verbal reports, signage) regarding the particular type of precaution to be utilized is important. When transmission-based precautions are in place, PPE should be readily available. Proper hand washing remains a key preventive measure, regardless of the type of transmission-based precaution employed.

Transmission-based precautions are maintained for as long as necessary to prevent the transmission of infection. It is appropriate to use the least restrictive approach possible that adequately protects the resident and others. Maintaining isolation longer than necessary may adversely affect psychosocial well-being. The facility should document in the medical record the rationale for the selected transmission-based precautions.

Airborne Precautions

Airborne precautions prevent the transmission of organisms that remain infectious when suspended in the air (e.g., varicella zoster (shingles) and M. tuberculosis). Resident health activities related to infection control include tuberculosis (TB) screening and management of active cases, consistent with State requirements. Management of some airborne infections such as active TB requires a single-resident airborne infection isolation room (AIIR) that is equipped with special air handling and ventilation capacity. Although not all residents with airborne infections will require an AIIR, residents with infections requiring an AIIR may need to be transported to an acute care setting unless the facility can place the resident in a private AIIR room with the door closed. In cases when AIIR is required it is important for the facility to have a plan in place to effectively manage a situation involving a resident with suspected or active TB while awaiting the resident's transfer to an acute care setting.

Personnel caring for residents on airborne precautions should wear a mask or respirator that is donned prior to room entry, depending on the disease-specific recommendations.[xxxi] Depending

on the condition, staff can use N95 or higher level respirators or wear masks if respirators are not available.

Contact Precautions

Contact transmission risk requires the use of contact precautions to prevent infections that are spread by person-to-person contact. Contact precautions require the use of appropriate PPE, including a gown and gloves upon entering the contact precaution room. Prior to leaving the contact precaution room the PPE is removed and hand hygiene is performed.

Depending on the situation, options for residents on contact precautions may include the following: a private room, cohorting, or sharing a room with a roommate with limited risk factors (e.g., without indwelling devices, without pressure ulcers and not immunocompromised).

Droplet Precautions

In contrast to contact transmission, respiratory droplets transmit infections directly from the respiratory tract of an infected individual to susceptible mucosal surfaces of the recipient. Since this generally occurs at close proximity, facial protection is necessary. Respiratory droplets are generated when an infected person coughs, sneezes, or talks; or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation. Studies have shown that respiratory viruses can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth.[xxxii] Examples of droplet-borne organisms that may cause infections include, but are not limited to influenza and mycoplasma.

The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.[xxxiii] In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances. Masks are to be used within approximately 6 to 10 feet of a resident or upon entry into a resident's room with respiratory droplet precautions. Residents with droplet precautions are placed in either a private room, cohorted, or share a room with a roommate with limited risk factors.

Implementation of Transmission-Based Precautions

It is important that facility staff clearly identify the type of precautions and the appropriate PPE to be used in the care of the resident. The PPE should be readily available near the entrance to the resident's room. Signage can be posted on the resident's door instructing visitors to see the nurse before entering.

It is not always possible to identify prospectively residents needing transmission-based precautions. The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation. However, since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, transmission-based precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.[xxxiv] The use of appropriate transmission-based

precautions when a resident develops symptoms or signs of a transmissible infection or arrives at a nursing home with symptoms of an infection (pending laboratory confirmation) reduces transmission opportunities. However, once it is confirmed that the resident is no longer a risk for transmitting the infection, removing transmission-based precautions avoids unnecessary social isolation.

Safe Water Precautions

Safe drinking water is also critical to controlling the spread of infections. The facility is responsible for maintaining a safe and sanitary water supply, by meeting nationally recognized standards set by the FDA for drinking water (<500 CFU/mL per heterotrophic plate count).

HANDLING LINENS TO PREVENT AND CONTROL INFECTION TRANSMISSION

It is important that all potentially contaminated linen be handled with appropriate measures to prevent cross-transmission. If the facility handles all used linen as potentially contaminated (i.e., using standard precautions), no additional separating or special labeling of the linen is recommended. No special precautions (i.e., double bagging) or categorizing is recommended for linen originating in isolation rooms. Double bagging of linen is only recommended if the outside of the bag is visibly contaminated or is observed to be wet through to the outside of the bag. Alternatively, leak-resistant bags are recommended for linens contaminated with blood or body substances. If standard precautions for contaminated linens are not used, then some identification with labels, color coding or other alternatives means of communication is important.

For the routine handling of contaminated laundry, minimum agitation is recommended, to avoid the contamination of air, surfaces, and persons. The risk of environmental contamination may be reduced by having personnel bag or contain contaminated linen at the point of use, and not sorting or pre-rinsing in resident care areas.

It is important that laundry areas have hand washing facilities and products, as well as appropriate PPE (i.e., gloves and gowns) available for workers to wear while sorting linens. Laundry equipment should be used and maintained according to the manufacturer's instructions to prevent microbial contamination of the system. It is recommended that damp linen is not left in machines overnight. *The CDC recommends leaving washing machines open to air when not in use to allow the machine to dry completely and to prevent growth of microorganisms in wet, potentially warm environments.*

Detergent and water physically remove many microorganisms from the linen through dilution during the wash cycle. *Advances in technology allow modern-day detergents to be much more effective in removing soil and reducing the presence of microbes than those used in the past when much of the research on laundry processing was first conducted. Facilities may use any detergent designated for laundry in laundry processing. Further, laundry detergents used within facilities are not required to have stated anti-microbial claims. Facilities should closely follow manufacturer's instructions for laundry detergents used. The CMS, in collaboration with the*

CDC, has determined that ozone cleaning systems are acceptable methods of processing laundry. Ozone cleaning systems also should be used per manufacturer's instructions.

An effective way to destroy microorganisms in laundry items is through hot water washing at temperatures above 160ºF (71ºC) for 25 minutes.[xxxv] Alternatively, low temperature washing at 71 to 77 degrees F (22-25 degrees C) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles.[xxxvi] *Laundry washing within facilities typically occurs in a low water temperature environment. Many laundry items are composed of materials that cannot withstand a chlorine bleach rinse and remain intact. A chlorine bleach rinse is not required for all laundry items processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach. However, a chlorine bleach rinse may still be used for laundry items composed of materials such as cottons. Hot water washing at temperatures greater than 160 degrees F for 25 minutes and low temperature washing at 71 to 77 degrees F (22-25 degrees C) with a 125-part-per-million (ppm) chlorine bleach rinse continue to be effective ways to wash laundry. If a facility chooses to process laundry using a hot water temperature environment, the temperature maintained for 25 minutes should be at or above 160 degrees Fahrenheit (71ºC).*

Facilities are not required to maintain a record of water temperatures during laundry processing cycles. Facilities are required to follow manufacturer's instructions for all materials involved in laundry processing (e.g., washing machines; dryers; any laundry detergents, rinse aids, or other additives employed during the laundry process). Facilities should also follow manufacturer's instructions for clothing, linens, and other laundry items to determine the appropriate methods to use to produce a hygienically clean product. Facilities should also consider a resident's individual needs (e.g., allergies) when selecting methods for processing laundry.

If laundry chutes are used, it is recommended that they are properly designed and maintained so as to minimize dispersion of aerosols from contaminated laundry (e.g., no loose items in the chute and bags are closed before tossing into the chute).

If linen is sent off to a professional laundry, the facility should obtain an initial agreement between the laundry service and facility that stipulates the laundry will be hygienically clean and handled to prevent recontamination from dust and dirt during loading and transport. *For example, an ozone laundry cleaning system is a method which may require a professional laundry service. The facility will need to obtain such an agreement in this instance. Whether laundry processing is completed within the facility or outside the facility, facilities should have written policies & procedures which should include training for staff who will handle linens and laundry.*

Standard mattresses and pillows can become contaminated with body substances during resident care if the integrity of the covers of these items is compromised. A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an

impermeable surface over the mattress. Therefore it is recommended that mattress covers with tears or holes be replaced. It is recommended that moisture resistant mattress covers be cleansed and disinfected between residents with an EPA approved germicidal detergent to help prevent the spread of infections, and fabric mattress covers should be laundered between residents. Pillow covers and washable pillows should be laundered in a hot water laundry cycle between residents or when they become contaminated with body substances. Discarding mattresses if fluids have penetrated into the mattress fabric and washing pillows and pillow covers in a hot-water laundry cycle will also reduce the risk of indirect contact with infectious agents.[xxxvii]

RECOGNIZING AND CONTAINING OUTBREAKS

It is important that facilities know how to recognize and contain infectious outbreaks. An outbreak is typically one or more of the following:[xxxviii]

One case of an infection that is highly communicable;

Trends that are 10 percent higher than the historical rate of infection for the facility that may reflect an outbreak or seasonal variation and therefore warrant further investigation; or

- Occurrence of three or more cases of the same infection over a specified length of time on the same unit or other defined areas.

Once an outbreak has been identified, it is important that the facility take the appropriate steps to contain it. State health departments offer guidance and regulations regarding responding to and reporting outbreaks. This information is often received in advance of an outbreak and included in the infection prevention and control program. Plans for containing outbreaks usually include efforts to prevent further transmission of the infection while considering the needs of all residents and staff.**XXXVIII**

PREVENTING SPREAD OF ILLNESS RELATED TO MDROs

The MDROs found in facilities include, but are not limited to MRSA, VRE, and clostridium difficile (C. difficile). Transmission-based precautions are employed for residents who are actively infected with multi-drug resistant organisms. Aggressive infection control measures and strict compliance by healthcare personnel can help minimize the spread of MDROs to other susceptible individuals.[xxxix]

Staphylococcus is a common cause of infections in hospitals and nursing homes, and increasingly in the community. Common sites of MRSA colonization include the rectum, perineum, skin and nares.[xl] Colonization may precede or endure beyond an acute infection. MRSA is transmitted person-to-person (most common), and on inanimate objects.

The MRSA infection is commonly treated with vancomycin, which in turn can lead to increased enterococcus antibiotic resistance. Therefore, preventing infection with MRSA and the limited use of antibiotics for individuals who are only colonized can also help prevent the development of VRE. Enterococcus is an organism that normally occurs in the colorectal tract. VRE infections have been associated with prior antibiotic use.

C. difficile is a bacterial species of the genus clostridium, which are gram-positive, anaerobic, spore-forming rods (bacilli). The organism normally lives benignly in the colon in spore form. When antibiotic use eradicates normal intestinal flora, the organism may become active and produce a toxin that causes symptoms such as diarrhea, abdominal pain, and fever. More severe cases can lead to additional complications such as intestinal damage and severe fluid loss. Treatment options include stopping antibiotics and starting specific anticlostridial antibiotics, e.g., metronidazole or oral vancomycin. If a resident has diarrhea due to C. difficile, large numbers of C. difficile organisms will be released from the intestine into the environment and may be transferred to other individuals, causing additional infections.

Contact precautions are instituted for residents with symptomatic C. difficile infection. Thorough hand washing with soap and water after caring for the resident reduces the risk of cross-transmission. Another control measure is to give the resident his or her own toilet facilities that will not be shared by other residents.

The C. difficile can survive in the environment (e.g., on floors, bed rails or around toilet seats) in its spore form for up to 6 months. Rigorously cleaning the environment removes C. difficile spores, and can help prevent transmission of the organism.[xli] Cleaning equipment used for residents with C. difficile with a 1:10 dilution of sodium hypochlorite (nine parts water to one part bleach) will also reduce the spread of the organism. Once mixed, the solution is effective for 24 hours.

PREVENTING INFECTIONS RELATED TO THE USE OF SPECIFIC DEVICES

Intravascular catheters are used widely to provide vascular access, and are increasingly seen in nursing homes. While providing such access, they may increase the risk for local and systemic infections and additional complications such as septic thrombophlebitis.

Central venous catheters (CVCs) have also been associated with infectious complications. Other intravascular catheters such as dialysis catheters and implanted ports may be accessed multiple times per day, such as for hemodynamic measurements, or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection. Limiting access to central venous catheters for only the primary purpose may help reduce the risk of infection.

Consistent use of appropriate infection control measures when caring for residents with vascular access catheters reduces the risk for catheter-related infections.[xlii] Surveillance consistently includes all residents with vascular access, including those with venous access and implanted ports such as peripherally inserted central catheter lines, and midline access catheters. Activities

to reduce infection risk includes surveillance such as observation of insertion sites, routine dressing changes, use of appropriate PPE and hand hygiene during the care and treatment of residents with venous catheters, and review of the resident for clinical evidence of infection.**XLII** It is important that practices reflect the most current CDC guidelines.

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[vi] *Siegel, J.D., Rhinehart, E., Jackson, M., and Chiarello, L. (2006). Management of multidrug-resistant organisms in healthcare settings, 2006. Pp. 5. Accessed December 8, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf*

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INVESTIGATIVE PROTOCOL FOR INFECTION CONTROL

Objectives

- To determine if the facility has an infection prevention and control program that prevents, investigates, and controls infections in the facility, and determines appropriate procedures to be applied to a resident with an infection;
- To determine if the facility has a program that collects information regarding infections acquired in the facility, analyzes the information and develops a plan of action to prevent further infections;
- To determine if staff practices are consistent with current infection control principles and prevent cross-contamination (e.g., laundry and hand hygiene practices); and
- To determine whether staff with communicable disease or open lesions are prohibited, as appropriate, from direct contact with the resident.

Use

Use this protocol to investigate compliance at F441 for every initial certification and recertification survey. In addition, use this protocol on revisit or abbreviated surveys (complaint investigations) when indicated.

Procedures

The surveyor(s), throughout the survey, should conduct the following observations, interviews and record reviews. In addition, the surveyor(s) should also review the facility's infection control policies, procedures, as well as documentation of staff training, and as necessary, interview facility staff with responsibility for oversight of the infection prevention and control program.

Observations

Observe various disciplines (nursing, dietary, and housekeeping) to determine if they follow appropriate infection control practices and transmission based precaution procedures. Observe, for example, whether:

- Linens are handled, processed, transported, and stored to prevent contamination and the transmission of infection;
- Employees exhibit overt signs of illness or communicable disease that have the potential to transmit disease (e.g., cold symptoms, infected, open lesions on hands) and if present, whether they are prohibited from contact with the resident or the resident's food;
- Staff and visitors adhere to precautions and related processes, including the use of PPE;

- Precautions/accommodations are in place and followed (as recommended, e.g., gowns, singles rooms or adequate space between residents, exclusion from group activities, etc.) for residents with potentially transmissible infections;

- *Insulin Pens containing multiple doses of insulin are used for the resident prescribed only, even when the needle is changed, and clearly labeled with the resident's name or other identifiers to verify correct use.*

- Staff utilize appropriate precautions when residents on special precautions are permitted out of their rooms,(e.g., mask on resident with TB in the halls, wound drainage contained); and

- Staff involved in the care and management of residents with special needs, e.g., urinary catheters (also note characteristics of urine, which may indicate potential infection), wound care, respiratory treatments, and residents on ventilators, receiving IVs, or with tracheotomies follow current accepted infection control standards of practice.

Also, observe residents for signs and symptoms of potential infection, such as:

- Elevated respiratory rate or labored breathing, coughing, congestion;

- Vomiting or loss of appetite, diarrhea;

- Skin rash, reddened or draining eyes, wound drainage; and

- Frequency/urgency of urination, malodorous urine.

Observe for cleaning and disinfecting to determine whether:

- Equipment in transmission based precaution rooms is either dedicated to that resident and appropriately cleaned or is thoroughly cleaned and disinfected between residents using appropriate agents and procedures;

- High touch surfaces in the environment are visibly soiled (i.e., contaminated) or have been cleaned and disinfected;

- Small non-disposable equipment such as glucose meters, scissors, and thermometers are cleaned and appropriately disinfected after each use for individual resident care;

- Single-use items (e.g., blood glucose lancet, other sharps) are properly disposed of after one use;

- Single resident use items (e.g., basins, bed pans) are maintained to be visibly clean for use, and are disposed of after use by a single resident;

- Resident dressings and supplies are properly stored to maintain their integrity, and soiled dressings and supplies are appropriately discarded; and
- Multiple use items (e.g., shower chairs, bedside scales, resident lifts, commodes, tubs) are properly cleaned/disinfected between each resident use.

Observe whether hand hygiene and use of gloves (when indicated) is in accordance with current standards. Hand hygiene should occur before and after putting on sterile gloves and after taking off all gloves during all resident care that requires the use of gloves. This includes:

- Medication administration (e.g., eye drops, sublinguals, and injections);
- Dressing changes that require the use of gloves (e.g., anticipated contact with body fluid, excretions, tissue and specimens);
- Insertion or removal of a catheter; and
- Any invasive procedure.

Note the availability of gloves and the equipment and products to perform hand hygiene.

Interview

During the resident review, interview the resident, family or responsible party to the extent possible to identify, as appropriate, whether they have received education and information about infection control practices, such as appropriate hand hygiene and any special precautions applicable to the resident.

Interview direct care staff to determine:

- Whether they are aware of and have reported any signs or symptoms exhibited by the resident that may be associated with an infection;
- Whether they are aware of and have been instructed on any special precautions that are applicable to any resident on transmission based precautions;
- Whether they are familiar with the indications for washing hands and/or using alcohol based products and understand the basis for the use of gloves and when they are to be removed;
- How staff know which residents are covered by transmission-based precautions; and
- Whether staff is aware of what specific actions are required for each type of transmission-based precautions.

Record Review

Review the resident's record to determine, for example:

- Whether the resident's record included an evaluation of the factors which may increase a resident's risk of infection (e.g., indwelling urinary catheters, intravenous catheters, and tracheostomy tubes), and if an infection is present, whether the resident's record reflects the identification of the infection, potential causes and contributing factors; and

- Whether the resident's plan of care identifies interventions (device management and isolation precaution measures) to prevent the transmission of infection.

Review the facility's record of incidents of infection and related corrective actions to help determine whether the facility is identifying, recording, and analyzing infections.

In order to investigate identified infection control concerns, review, as applicable, the facility's:

- Infection control policies to determine if they are consistent with current professional standards of practice and if the infection control policies are defined by department (e.g., dietary, nursing, laundry);

Documentation of whether and how the infection prevention and control program collects, analyzes, and uses data and implements a program to guide all disciplines to prevent the spread of infections and identify infections in a standardized and systematic way;

- Policies regarding handling and processing soiled linens as well as handling, transporting, and storing clean linens;

- Applied preventive components of the infection prevention and control program in the care of individual residents;

- Policies, procedures, and documentation regarding identifying and prohibiting contact with residents or food by employees with open lesions or communicable diseases and addressing occupational communicable disease exposure and post-exposure follow up;

- Employee records to determine if employees receive initial and ongoing employee infection control training regarding critical elements of the infection control plan; and

- Documentation related to their review of the appropriateness and effectiveness of antibiotics for residents that are identified as receiving antibiotics.

Interview the Designated Infection Control Representative

If concerns are identified, (e.g., practices are not consistent with accepted principles of infection control or residents are exhibiting symptoms of infections, but have not been assessed or surveillance data are not available or being utilized) interview the facility staff members who are responsible for implementing and overseeing the infection prevention and control program. Investigate as appropriate, for example, whether:

- The facility identifies where infections are acquired (e.g., nursing home, hospital, or community);

- The infection prevention and control program includes any review, in addition to the medication regimen review, of whether antibiotic use in the nursing home is appropriate and effective;

- Staff training includes critical areas of infection control such as hand hygiene, areas for improvement from surveillance data, and appropriate use of protective equipment and isolation precautions; how staff are apprised of changes in policies and procedures;

- The facility collects, analyzes, and uses data related to infections, to identify and prevent the spread of infections and to adjust its infection prevention and control program,(e.g., policies and procedures) as appropriate;

- The program implements processes to identify and address infection control issues and to monitor staff hand hygiene and sterile technique, and the implementation and discontinuation of transmission-based or other isolation precautions and cohorting or separating, as applicable;

- The facility appropriately implements and discontinues transmission based precaution procedures, and communicates initiation and discontinuation of these transmission-based precaution policies across departments;

- The facility has in place effective means to identify individuals (residents, staff, visitors, volunteers, practitioners) with infections;

- The facility has policies and procedures addressing linen handling and how it monitors how linens are stored, transported, and processed to prevent the spread of infection;

- The infection prevention and control program identifies and addresses infection control issues, for example whether the facility's infection control practices are consistent with CDC recommendations; and

- The facility effectively identifies and prevents employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

DETERMINATION OF COMPLIANCE CRITERIA FOR COMPLIANCE

Synopsis of Regulation (F441)

Criteria for Compliance

The facility is in compliance with 42 CFR 483.65 Infection Control if:

- The infection prevention and control program demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection, to the extent possible;

- The facility demonstrates practices to reduce the spread of infection and control outbreaks through transmission-based precautions (e.g., isolation precautions);

- The facility demonstrates practices and processes (e.g., intravenous catheter care, hand hygiene) consistent with infection prevention and prevention of cross-contamination;

- The facility demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;

- The facility has processes and procedures to identify and prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease;

- The facility consistently demonstrates appropriate hand hygiene (e.g., hand washing) practices, after each direct resident contact as indicated by professional practice; and

- The facility demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.

- *The facility demonstrates appropriate use of SDVs (including appropriate repackaging).*

If not, cite at Tag F441.

Noncompliance for F441

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for Tag F441 may include, but is not limited to, failure to do one or more of the following:

- Develop an infection prevention and control program;

- Utilize infection precautions to minimize the transmission of infection;

- Identify and prohibit employees with a communicable disease from direct contact with a resident;

- *Use fingerstick devices (e.g. pen like devices) for only one resident in accordance with appropriate infection control practices and processes;*

- *Appropriately use of or repackage of SVDs (e.g., adherence to USP <797>);*

- *Using a blood glucose meter (or other point-of-care device) for more than one resident, cleaning and disinfecting it after each use;*

- Demonstrate proper hand hygiene;

- Properly dispose of soiled linens;

- Demonstrate the use of surveillance; or

- Adjust facility processes as needed to address a known infection risk.

Potential Tags for Additional Investigation

During the investigation of F441, the surveyor may have identified concerns with additional outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Examples of some related requirements that may be considered when non-compliance at F441 has been identified include the following:

- 42 CFR §483.20(b), F272, Comprehensive Assessments

  If the infection or risks were present at the time of the required comprehensive assessment, determine whether the facility comprehensively assessed the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's condition and the impact upon the resident's function, mood, and cognition.

- 42 CFR §483.20(b), F274, Significant Change Assessments

  If there was a significant change in the infection or risk to the resident's condition, determine whether the facility did a significant change comprehensive assessment within 14 days.

- 42 CFR §483.20(k)(1)(i), F279, Comprehensive Care Plan

Determine if the facility developed a care plan consistent with the resident's specific infection status, risks, needs, behaviors, and current standards of practice and included measurable objectives and timetables, and specific interventions/services to prevent the onset and/or transmission of infection.

- 42 CFR §483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision

  Determine whether staff reassessed the effectiveness of the interventions and review and revised the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident.

- 42 CFR §483.25(l), F329, Unnecessary Drugs

  Determine if the facility has reviewed with the prescriber the rationale for placing the resident on an antibiotic to which the organism seems to be resistant or when the resident remains on antibiotic therapy without adequate monitoring or appropriate indications, or for an excessive duration.

- 42 CFR §483.25(l)(2)(n), F334, Influenza and Pneumococcal Immunizations

  Determine if the facility has systems in place to immunize residents against influenza and pneumococcal infections.

- 42 CFR §483.35(i)(2), F371, Sanitary Conditions

  Determine if the facility has implemented processes to prevent infection transmission via food handling, storing and delivery systems.

- 42 CFR 483.75(f) (F498) Proficiency of Nurse Aides

  Determine whether the nurse aides demonstrate the knowledge and skills regarding use of accepted infection control principles, e.g., hand hygiene, transmission barriers, signs and symptoms of infection to report to the nurse, etc.

V. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for Tag F441 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services. Actual or potential harm/negative outcomes for F441 may include but are not limited to facility failure to:

    - Properly implement transmission based precautions when indicated resulting in an increase (or potential) of infections or communicable diseases;

    - Develop and implement corrective actions despite recording an increase in infections in the facility;

    - Recognize and act on an increase or trend in infections within the facility;

    - Prohibit employees with symptoms of active communicable infections from continuing to provide resident care or have direct contact with food;

    - Properly perform hand hygiene when entering and exiting the room of a resident on special precautions; and

    - Recognize and investigate a resident's complaints of rash and pruritis resulting in additional resident's requiring treatment for scabies.

2. Degree of harm (actual or potential) related to the noncompliance**.** Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

    - If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and

    - If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

3. The immediacy of correction required**.** Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for this tag. First, the team must rule out whether Severity Level 4, immediate jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate jeopardy to resident health or safety

Immediate jeopardy is a situation in which the facility's noncompliance:

- With one or more requirements of participation has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

  NOTE: The death or transfer of a resident who was harmed as a result of facility practices, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.

Examples of negative outcomes that occurred or have the potential to occur at Severity Level 4 as a result of the facility's deficient practices may include:

- *The facility failed to follow Standard Precautions during the performance of routine testing of blood glucose. The facility reused fingerstick devices for more than one resident. This practice of re-using fingerstick devices for more than one resident created an Immediate Jeopardy to resident health by potentially exposing residents who required blood glucose testing to the spread of bloodborne infections in the facility.*

- The facility failed to restrict a staff member with a documented open, draining and infected skin lesion that was colonized with MRSA from working without adequately covering the area, resulting in MSRA transmission and infection of one or more residents under that staff person's care.

- The facility failed to investigate, document surveillance of and try to contain an outbreak of gastrointestinal illness among residents; as a result, additional residents became ill with diarrheal illnesses.

  NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3 or the potential for more than minimal harm at Level 2 exists.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include, but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- The facility routinely sent urine cultures of asymptomatic residents with indwelling catheters, putting residents with positive cultures on antibiotics, resulting in two residents acquiring antibiotic-related colitis and significant weight loss.

- The facility failed to institute internal surveillance for adherence to hand washing procedures or pertinent reminders to staff regarding appropriate respiratory precautions

during an influenza outbreak, resulting in additional cases of influenza in residents on another, previously unaffected unit or section of the facility.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

For Level 2 severity, the resident was at risk for, or has experienced the presence of one or more outcome(s). Examples of avoidable outcomes include, but are not limited to:

- The facility failed to ensure that their staff demonstrates proper hand hygiene between residents to prevent the spread of infections. The staff administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The staff did not remove the used gloves and wash or sanitize their hands between residents.
- The facility failed to implement a surveillance program including the investigation of infections or attempt to distinguish facility-acquired infections from community-acquired infections.
- The facility identified issues related to staff infection control practices, as part of its infection prevention and control program, but did not follow up to identify the cause, and institute measures to correct the problems.

Severity Level 1: No actual harm with potential for minimal harm

The failure of the facility to provide appropriate care and services for infection control practices places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F492

(Rev.)

§483.75(b) Compliance With Federal, State, and Local Laws and Professional Standards

The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

Intent: §483.75(b)

The intent of this regulation is to ensure that a facility is in compliance with Federal, State, and local laws, regulations, and codes relating to health, safety, and sanitation *and with accepted professional standards and principles that apply to professionals providing services in facilities*.

Definitions: §483.75(b)

"Accepted professional standards and principles" *means the individual State professional licensure practice acts and scope of practice regulations and/or standards. This may include the various practice acts and scope of practice regulations in each State, and current, commonly accepted health standards established by national organizations, boards and councils as well as various licensed professionals (i.e., Physicians, Nurses, Therapists, etc.) as specifically defined under individual State law and regulations.*

An ***authority having jurisdiction*** *is a Federal, State, local, or other regional department or individual, such as a fire chief; fire marshal; chief of a fire prevention bureau, labor department, or health department; building official; electrical inspector; professional licensure boards; or others having statutory authority. A Federal, State or the local authority having jurisdiction is responsible for making decisions about whether there are violations of the applicable Federal, State or local laws, regulations, codes and/or standards for which they have statutory and oversight authority.*

"Final adverse action" *means an adverse action imposed by the authority having jurisdiction that is more than a corrective action plan or the imposition of a civil money penalty, such as a ban on admissions, suspension or loss of a facility or professional license, etc., and is NOT under appeal or litigation by the facility or the professional providing services in the facility. The authority having jurisdiction is the public agency or official(s) having the authority to make a determination of noncompliance, and is responsible for providing and signing official correspondence notifying the facility or professional of the final adverse action.*

Interpretive Guidelines: §483.75(b)

The State is responsible for making decisions about whether there are violations of State laws and regulations. Licenses, permits and approvals of the facility must be available to you upon request. Current reports of inspections by State and/or local health authorities are on file, and notations are made of action taken by the facility to correct deficiencies.

*Failure of the facility to meet a Federal, State or local law, regulation, code, or accepted professional standards and principles that apply to professionals providing services in facilities **may only be cited** when the Federal, State or local authority having jurisdiction has both made a determination of non-compliance AND has taken a final adverse action.*

*Do **not** cite Tag F492:*

- *When a determination is made by the authority having jurisdiction that a facility is not in compliance with Federal, State, or local requirements, regulations, codes and /or standards and final adverse action has not been taken by the authority having jurisdiction;*

- *To simply cite non-compliance with State or local licensure requirements; or*

- *As past non-compliance if at the time of the standard, complaint or follow-up survey, the facility or professional within the facility is in compliance with the Federal, State or local law, regulation, code and /or standard but was found not to be in compliance with those requirements during a time before the on-site survey. If there is a question, the SA may confirm the facility's current compliance status with the authority having jurisdiction for State and local authorities or the Regional Office (RO) for other Federal agencies.*

§483.75(c) Relationship to Other HHS Regulations

In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

Procedures 42 CFR §§483.75(b) and (c)

If resident/family interviews reveal possible problems with admission contracts, review these contracts for violations of requirements at §§483.10 and 483.12. As appropriate, refer problems to an ombudsman or other agencies, e.g., Office for Civil Rights.

If interviews with residents suggest that the facility may have required deposits from Medicare residents at admission, review the facility's admissions documents.

Some State or local laws and regulations are more stringent that the Federal requirement on the same issue. If you believe you have identified a situation indicating that the facility or professional providing services in the facility may not be in compliance with a State or local law, regulation, code and/or standard, refer that information to the authority having jurisdiction for their follow-up action. If you have determined ***and*** *received written confirmation from the authority having jurisdiction that a final adverse action has been taken, then the facility could be found to not meet the requirements at 42 CFR §§483.75(b) and (c) and a deficiency may be cited at Tag F492.*

If during the survey you identify and suspect that you have observed noncompliance with a law, regulation, code and/or standard which is under the purview of another Federal agency other than CMS, notify the RO. The RO may assist you to contact the appropriate Federal agency to refer your observation and/or concern.

Do not prolong or delay a survey waiting for confirmation from an authority having jurisdiction to determine compliance with this requirement.

F514

(Rev)

§483.75(l) Clinical Records

(1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are--

(i) Complete;

(ii) Accurately documented;

(iii) Readily accessible; and

(iv) Systematically organized.

Intent §483.75(l)(1)

To assure that the facility maintains accurate, complete and organized clinical information about each resident that is readily accessible for resident care.

Interpretive Guidelines §483.75(l)(1)

A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided. Documentation should provide a picture of the resident's progress, including response to treatment, change in condition, and changes in treatment.

The facility determines how frequently documentation of an individual's progress takes place apart from the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments. Good practice indicates that for functional and behavioral objectives, the clinical record should document change toward achieving care plan goals. Thus, while there is no "right" frequency or format for "reporting" progress, there is a unique reporting schedule to chart each resident's progress in maintaining or improving functional abilities and mental and psychosocial status. Be more concerned with whether the staff has sufficient progress information to work with the resident and less with how often that information is gathered.

Electronic Health Records and Use of Electronic Signatures

In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable *whether or not the record is entirely electronic, and when permitted to do so by state and local law and when this is*

authorized by the facility's policies. If a facility implements the use of electronic signatures, they must have policies in place and implemented that identify those who are authorized to sign electronically and describe the security safeguards to prevent unauthorized use of electronic signatures. Such security safeguards (policies) include, but are not limited to, the following:

- *Built-in safeguards to minimize the possibility of fraud;*
- *That each staff responsible for an attestation has an individualized identifier;*
- The date and time is recorded from the computer's internal clock at the time of entry;
- An entry is not to be changed after it has been recorded, *and;*
- The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore his/her level of professional qualifications).

NOTE: *As there are no regulatory requirements delineating the use of a specific Electronic Health Records (EHR) system, a facility may utilize the EHR system that meets their specific needs. The facility must grant access to any medical record, including EHRs, when requested by the survey team. If access to an EHR is requested by the surveyor, the facility will (a) provide the surveyor with a tutorial on how to use its particular electronic system and (b) designate an individual who will, when requested by the surveyor, access the system, respond to any questions or assist the surveyor as needed in accessing electronic information in a timely fashion.* Each surveyor will determine the EHR access method that best meets the need for that survey.

If the facility is unable to provide direct print capability to the survey team, the provider must make available a printout of any record or part of a record upon request in a timeframe that does not impede the survey process. Impeding the survey process by unnecessarily delaying or restricting access to the medical records may lead to determinations of noncompliance and enforcement actions. The facility should ensure that data are backed up and secure, and access does not impede the survey process or the provision of care and services to the resident.

Probes **§483.75(l)(1)**

In reviewing sampled residents' clinical records:

- Is there enough record documentation for staff to conduct care programs and to revise the program, as necessary, to respond to the changing status of the resident as a result of interventions?

- How is the clinical record used in managing the resident's progress in maintaining or improving functional abilities and mental and psychosocial status?

§483.75(l)(5) the clinical record must contain--

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) the plan of care and services provided;

(iv) The results of any preadmission screening conducted by the State; and

(v) progress notes.

F516

(Rev.)

§483.20(f)(5)

(5) Resident-identifiable information.

(i) A facility may not release information that is resident-identifiable to the public.

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

Interpretive Guidelines §483.20(f)(5):

Automated RAI data are part of a resident's clinical record and as such are protected from improper disclosure by facilities under current law. Facilities are required by §§1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act and 42 CFR Part 483.75(l)(3) and (l)(4), to keep confidential all information contained in the resident's record and to maintain safeguards against the unauthorized use of a resident's clinical record information, regardless of the storage method of the records.

§483.75(l) (3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

Intent §483.75(l)(3)

To maintain the safety and confidentiality of the resident's record.

Interpretive Guidelines §483.75(1)(3)

Determine through observations and interviews with staff, the policy and implementation of that policy, for maintaining confidentiality of residents' records.

Electronic Health Records (EHR)

All providers and suppliers that conduct standard transactions (electronic claims filing, etc.) are "covered entities" and, as such, they must comply with the HIPAA Privacy Rule and the HIPAA Security Rule. These rules are found at 45 CFR Parts 160 and 164. Surveyors are not responsible for assessing compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules. The Department of Health and Human Services Office of Civil Rights has the primary responsibility for enforcing the HIPAA Privacy Rule. The Office of eHealth Standards and Services within CMS is responsible for enforcing the HIPAA Security Rule. The surveyors' responsibility is to assess compliance with the provider or supplier-specific requirements for maintaining the content and confidentiality of the medical record.

A facility that utilizes EHRs is responsible for ensuring the necessary backing up of data and security of information in the resident's medical record. In situations where a facility EHR system is shared with other facilities because of the same ownership, the facility must not be cited strictly due to their participation in an EHR system that includes multiple facilities. CMS actively encourages the development of systems that permit appropriate sharing of clinical information across providers, if the development of such systems is fully consistent with the requirement for protecting the confidentiality of the medical record.

There is no expectation that the State Agency evaluate the overall features of the EHR system for compliance with HIPAA Security and Privacy Rules. Surveyors instead are to focus on how the EHR system is being used in the facility, and whether that use is consistent with the Medicare CoPs or CfCs. If a survey team has a concern that the facility's practice may constitute significant violations of the HIPAA Privacy Rule, the SA has the discretion to file a complaint with the Office of Civil Rights and/or the CMS Office of eHealth Standards and Services.

Probes: §483.75(1)(3)

- How does the facility ensure confidentiality of resident records*?*
- If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person's use of records, e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons?
- *Are computer screens showing clinical record information left unattended and readily observable or accessible by other residents or visitors?*
- *Are there documents publicly posting passwords, which would be evidence of noncompliance with confidentiality?*

NOTE: *Use F-287, §483.20(f)(5) if breach of confidentiality is related to the RAI.*