CHAPTER 9

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237 Model Letter: Announcing to an Accredited Laboratory After a Sample Validation Survey or a Substantial Allegation of Noncompliance Survey That It Does Not Comply with all CLIA Conditions and That There Exists, Immediate Jeopardy to the Health and Safety of Individuals or That of the General Public

238 Model Letter: Announcing to an Accredited Laboratory After a Sample Validation Survey That the Laboratory Does Not Comply With All the CLIA Conditions- No Immediate Jeopardy

239 Clinical Laboratory Improvement Amendments (CLIA) Alternate Quality Assessment Survey, HCFA-667

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241 Model Letter: Announcing to Accredited Laboratory After a Substantial Allegation of Noncompliance Survey That the Laboratory Does Not Comply With All CLIA Conditions (Complaint)

242 Request for Validation of Accreditation Survey for Laboratories, HCFA-2802A

243 Model Letter: Announcing to a CLIA Exempt Laboratory That It Is In Compliance With the CLIA Conditions After a Sample Validation or Substantial Allegation of Noncompliance Survey

244 Model Letter: Announcing to the State Laboratory Program, That A CLIA-Exempt Laboratory is in Compliance with the CLIA Conditions After a Sample Validation or Substantial Allegation of Noncompliance Survey

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249 Model Letter: Send to the Laboratory in Conjunction With the Notice of Sanction, In Order to Officially Inform the Laboratory that the Responsibility Lies With the Laboratory to Achieve Compliance, Even if They Have Successfully Completed the Directed Plan of Correction

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280 Model Letter – Notice of Termination of Provider Agreement for CMHCs

281 Model Letter – CMHC That Has Ceased Operating

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283 Model Letter – Notice of Failure to Meet Threshold and Service Requirements, CMHCs

284 Model Denial Letter – To a Home Health Agency (HHA) That Requested a Branch Office

Exhibit IA

Model Letter Transmitting Materials to Providers

Dear _____:

This letter concerns the requirements and procedures through which your institution may be approved to participate in Medicare as a provider of services. This State agency certifies and periodically recertifies whether providers of services meet the Medicare Conditions of Participation, to assist the Health Care Financing Administration in determining whether institutions and agencies can participate in Medicare. Such approval, when required, is prerequisite to qualifying to participate in the State Medicaid program as well.

Enclosed are forms which it is necessary to complete if you desire to participate. Complete and return them promptly in order to avoid unnecessarily delaying approval, since your institution cannot claim provider reimbursement for services furnished prior to approval. If the forms are not self- explanatory, you may phone _____ for assistance. Complete and return all copies of the enclosed forms. Any questions concerning the Form HCFA-855, Medicare General Enrollment Health Care Provider/Supplier Application, should be directed to your fiscal intermediary/carrier. You may obtain information regarding the Form HCFA-855 by contacting ___(name)___ at __(phone number)__ .

On the second line of the Health Insurance Benefits Agreement, after the term, Social Security Act, enter the entrepreneurial name of the enterprise, followed by the trade name (if different from the entrepreneurial name). Ordinarily, this is the same as the business name used on all official IRS correspondence concerning payroll withholding taxes, such as the W-3 or 941 forms. For example, the ABC Corporation, owner of the community General Hospital, would enter on the agreement, "ABC Corporation d/b/a Community General Hospital." A partnership of several persons might complete the agreement to read: "Robert Johnson, Louis Miller and Paul Allen, ptr., Easy Care Home Health Services." A sole proprietorship would complete the agreement to read: "John Smith d/b/a Mercy Hospital." The person signing the Health Insurance Benefits Agreement must be someone who has the authorization of the owners of the enterprise to enter into this agreement.

Subject to availability, we are also enclosing the applicable Medicare Conditions of Participation. The Conditions are only a part of the regulations contained in Title 42, Chapter IV of the Code of Federal Regulations which Medicare providers must meet. You can purchase 42 CFR Chapter IV from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402. However, the information you need is supplied in Medicare materials provided to you without charge, and explanations are furnished either by this office or by your Medicare fiscal intermediary.

Our surveyors will inspect the institution, interview you and members of your staff, review documents, and undertake other procedures necessary to evaluate the extent to which your institution meets the Conditions of Participation. If your institution has significant deficiencies in any of the Conditions, you will be informed and given an opportunity to correct them. Following the survey, this agency will recommend to the Health Care Financing Administration whether your institution should participate.

After it is determined by the Health Care Financing Administration that all requirements are met, the Health Insurance Benefits Agreement will be countersigned. One copy will be returned to you along with the notification that your institution has been approved. If operation of the entire institution is later transferred to another owner, ownership group, or to a lessee, the agreement will usually be automatically assigned to the successor. But you are required to notify the Health Care Financing Administration at the time you are planning such a transfer.

Those institutions and agencies that are denied approval to participate in the Medicare program are sent notification giving the reasons for the denial and information about their rights to appeal the decision.

Please do not hesitate to phone this office if you have any questions.

Sincerely yours,

Enclosures

(See Exhibit 63 for list of pertinent forms to enclose.)

NOTE: When using this letter to transmit materials for Title XIX nursing facilities and intermediate care facilities for the mentally retarded omit sentences referring to the Form HCFA-855, as this form is only used for providers who participate in Medicare. These providers will complete the HCFA-1513 instead of the Form HCFA-855.

EXHIBIT 1B-1

Model Letter Transmitting CLIA Application and Form HCFA-855 to Laboratories

Dear Laboratory Director:

On February 28, 1992, the Department of Health and Human Services published regulations in the Federal Register implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of a human being to meet certain Federal requirements. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to laboratories. CLIA applies to any facility performing laboratory testing as outlined above, even if only one or a few basic tests are performed, and even if you are not charging for testing.

Prior to performing and reporting test results, you must register with the CLIA program. The enclosed CLIA application (Form HCFA-116) collects information about your laboratory's operation. This information is necessary to assess fees, to establish baseline data, and to fulfill the statutory requirements of the Public Health Service Act. This information will provide the laboratory surveyor an overview of your laboratory's operation, if it is subject to an onsite survey. When completing this form, the information submitted should be based on your laboratory's operation (i.e., hours of operation, number of personnel involved in testing). **Note: The CLIA identification number block/line should be left blank as this will be assigned when the application form is processed. Also, if you wish to apply for a Provider Performed Microscopy Procedure (PPMP) certificate, write PPMP in section II of the HCFA-116.** If you have any questions regarding completion of the Form HCFA-116, please contact your State Agency listed below:

_____
_____ (State Agency Address)
_____

Upon return of the completed Form HCFA-116 to the State Agency, a fee remittance coupon will be issued to you indicating your CLIA identification number, the amount due for the certificate and, if applicable, the compliance fee for your survey. Based on the information you provide about your laboratory, the appropriate certificate will be issued to you on receipt of full payment.

Also enclosed is the Medicare General Enrollment Health Care Provider/Supplier Application (Form HCFA-855) which must be completed and returned to the State Agency listed above. If you have any questions regarding completion of this form you should contact the appropriate contractor listed below:

_____
_____ (Contractor Address)
_____

Please return all enclosed forms to the State agency listed above to avoid any delay in processing.

Sincerely yours,

Enclosures

EXHIBIT 1B-2

Model Letter Transmitting CLIA Application and HCFA-1513 to Laboratories

Dear Laboratory Director:

On February 28, 1992, the Department of Health and Human Services published regulations in the Federal Register implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of a human being to meet certain Federal requirements. In addition, the CLIA legislation requires financing of all regulatory costs through fees assessed to laboratories. CLIA applies to any facility performing laboratory testing as outlined above, even if only one or a few basic tests are performed, and even if you are not charging for testing.

Prior to performing and reporting test results, you must register with the CLIA program. The enclosed CLIA application (Form HCFA-116) collects information about your laboratory's operation. This information is necessary to assess fees, to establish baseline data, and to fulfill the statutory requirements of the Public Health Service Act. This information will provide the laboratory surveyor an overview of your laboratory's operation, if it is subject to onsite survey. When completing this form, the information submitted should be based on your laboratory's operation (i.e., hours of operation, number of personnel involved in testing). **Note: The CLIA identification number block/line should be left blank as this will be assigned when the application form is processed. Also, if you wish to apply for a Provider Performed Microscopy Procedure (PPMP) certificate, write this in section II of the HCFA-116.**

Upon return of the completed Form HCFA-116 to the State Agency, a fee remittance coupon will be issued to you indicating your CLIA identification number, the amount due for the certificate and, if applicable, the compliance fee for your survey. Based on the information you provide about your laboratory, the appropriate certificate will be issued to you on receipt of full payment.

Also, enclosed is the Disclosure of Ownership and Control Interest Statement (Form HCFA-1513) which must be completed within 30 days. Please return both forms to the State agency listed below. If you have any questions regarding the completion of these forms you should contact the state agency listed below :

_____
_____ (State Agency)
_____

Sincerely yours,

Enclosures

EXHIBIT 1B-3

Initial Forms Required by Laboratories for CLIA Registration

- Laboratory requirements (if available)
- Clinical Laboratory Application (HCFA-116)
- Medicare General Enrollment Health Care Provider/Supplier Application (Form HCFA-855)

  - or -

  Disclosure of Ownership and Control Interest Statement (HCFA-1513)

NOTE: The HCFA-855 is only to be completed for laboratories that participate in Medicare. If a laboratory does not participate in Medicare, the laboratory will complete the HCFA-1513.

EXHIBIT 1C

Model Letter Transmitting Forms to Persons Furnishing
Portable X-Ray Services

Dear_____:

This is in response to your request for coverage of portable x-ray services under Medicare. The (State Agency) assists the U.S. Department of Health and Human Services in determining whether suppliers of portable x-ray services meet the Conditions for Coverage for Portable X-ray Services in order for their services to qualify for reimbursement under the Medicare program. We are enclosing a copy of the regulations which explain the specific requirements which must be met.

If you furnish portable x-ray services and desire to have such services covered under Medicare, please complete and return the enclosed HCFA-1880, Request for Approval as Supplier of Portable X-ray Services Under the Medicare Program, and the Form HCFA-855, Medicare General Enrollment Health Care Provider/Supplier Application, as soon as possible. Instructions for completing the HCFA-1880 are on the back of the form. The last copy should be kept for your records. Any questions concerning the Form HCFA-855 should be directed to your carrier. You may obtain information regarding the Form HCFA-855 by contacting (name) at (phone number).

Before you may be approved to participate your facility must be surveyed by this office. The surveyor will inspect your equipment, interview you and members of your staff, and review documents to evaluate the extent to which the Conditions for Coverage are met.

X-ray equipment made after August 1, 1974 should bear a factory label showing that it meets FDA requirements. If your equipment is not labeled you will be required to prove that it meets applicable FDA requirements.

NOTE: If you are a non-physician owner of the portable X-ray equipment, you must have a supervising physician's certification of the kind described in §405.1412(a)(2) of the enclosed "Conditions for Coverage of Portable X-ray Services." This certification must be prepared by a physician who meets one of the criteria outlined in §405.1412(b). If the certification is available before or at the time of the survey, this will expedite coverage of your services under Medicare.

Following the survey, we evaluate your qualifications and recommend to the U.S. Department of Health and Human Services whether to approve your services for coverage under Medicare. The Department of Health and Human Services notifies you whether the recommendation has been approved.

Those suppliers who are denied certification in the program are sent notification giving the reasons for the denial, and information about their rights to appeal the decision.

Please do not hesitate to communicate with this office if you have any questions.

Sincerely yours,

Enclosures

EXHIBIT 1D

Model Letter Transmitting Materials to
Rural Health Clinics

Dear _____:

This letter concerns the requirements and procedures through which you may be approved under Medicare as a Rural Health Clinic. This State agency certifies and periodically recertifies institutions and agencies to assist the Health Care Financing Administration in determining whether they meet the Medicare Conditions of Participation. Such approval is prerequisite to qualifying to participate in the State Medicaid program as well.

To be approved as a supplier of rural health clinic services, a clinic must be located in an area designated by the Bureau of the Census as nonurbanized and by the Secretary of Health and Human Services as a shortage area, where a shortage of personal health services or a shortage of primary medical care manpower exists. Under the law, the clinic also must employ either a physician's assistant or a nurse practitioner; must make arrangements with a physician for medical direction, guidance, and supervision; and must make arrangements with a Medicare certified hospital for referral and admission of patients by the clinic. Regulations of the Department of Health and Human Services specify the minimal health and safety standards rural health clinics must meet to qualify for reimbursement under this law.

In those instances where a central organization provides rural health services at more than one clinic site, each site is considered a clinic and the location of the clinic site determines its location eligibility (i.e., rural, shortage area) rather than the location of the central organization. A separate Request to Establish Eligibility is required for each clinic site.

Enclosed are forms which it is necessary to complete if you desire to be approved. Complete and return them promptly in order to avoid unnecessarily delaying approval, since your institution cannot claim provider reimbursement for services furnished prior to approval. If the forms are not self-explanatory, of if you need more Request to Establish Eligibility forms for multiple clinic locations, you may phone _____ for assistance. Complete and return all copies of the enclosed forms. Any questions concerning the Form HCFA-855 should be directed to your fiscal intermediary/carrier. You may obtain information regarding the Form HCFA-855 by contacting (name) at (phone number).

On the second line of the Health Insurance Benefits Agreement, after the term, Social Security Act, enter the entrepreneurial name of the enterprise, followed by the trade name (if different from the entrepreneurial name). Ordinarily, this is the same as the business name used on all official IRS correspondence concerning payroll withholding taxes, such as the W-3 or 94I forms. For example, the ABC Corporation, owner of the Wildwood Health Center, would enter on the agreement: "ABC Corporation d/b/a Wildwood Health Center." A partnership of several persons might complete the agreement to read: "Robert Johnson, Louis Miller and Paul Allen, ptr., Easy Care Health Services." A sole proprietorship would complete the agreement to read: "John/Smith d/b/a Wembly Walk-in-Center." The person signing the Health Insurance Benefits Agreement must be someone who has the authorization of the owners of the enterprise to enter into this agreement.

Subject to availability, we are also enclosing the Medicare Conditions for Coverage. The Conditions are only a part of the Medicare regulations contained in Title 42, Chapter IV of the Code of Federal Regulations which Rural Health Clinics must meet. You can purchase 42 CFR Chapter IV from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. However, the information you need is supplied in Medicare materials provided to you without charge, and explanations are furnished either by this office or by your Medicare carrier.

Our surveyors will inspect the clinic, interview you and members of your staff, review documents, and undertake other procedures necessary to evaluate the extent to which your institution meets the Conditions of Participation. If your institution has significant deficiencies in any of the Conditions, you will be informed and given an opportunity to correct them.

After it is determined by the Health Care Financing Administration that all requirements are met, the Health Insurance Benefits Agreement will be countersigned. One copy will be returned to you along with the notification that your institution has been approved. If operation of the entire institution is later transferred to another owner, ownership group, or to a lessee, the agreement will be automatically assigned to the successor. But you are required to notify the Health Care Financing Administration at the time you are planning such a transfer.

Those institutions and agencies that are denied Medicare approval are sent notification giving the reasons for the denial, and information about their rights to appeal the decision.

Please do not hesitate to phone this office if you have any questions.

Sincerely yours,

Enclosures

(See Exhibit 63 for list of pertinent forms to enclose.)

EXHIBIT 1E

Model Letter to Operational ESRD Facility
Requesting Initial Approval

Dear _____:

This letter explains the procedures through which you may be approved to furnish services to beneficiaries of the Medicare End-Stage Renal Disease (ESRD) Program.

Under the ESRD program, each facility desiring to furnish renal transplantation or dialysis services is required to meet all health and safety requirements, demonstrate its ability to meet minimal utilization rates, and perform a required medical review of patient care.

The regulations require such facilities to participate in network activities and pursue network goals. The Medical Review Board of each network assures review of the quality of patient care and services.

Enclosed is a copy of the ESRD facility regulations. Using these regulations, this agency surveys and certifies ESRD facilities to assist the Health Care Financing Administration in determining whether facilities meet the health and safety requirements.

Since your facility has not previously been approved as a supplier of ESRD services, you should take the actions outlined below.

Complete the Request for Approval, HCFA-3402, and return it with the documentation it requires. Your completed application must be accompanied by evidence of Certificate of Need approval, if your State law requires such approval. Any questions concerning the Form HCFA-855 should be directed to your fiscal intermediary/carrier. You may obtain information regarding the Form HCFA-855 by contacting (name) at (phone number) .

You must also submit a narrative plan of operation and state the qualifications of operating personnel. If you offer dialysis, your plan of operation must cite the type of dialysis and number of stations and shifts. For all services the plan must detail how you will meet the minimal utilization rate applicable for your service, area, and type of facility as described in the regulations. Discuss how you propose to meet patient needs. The qualifications and responsibilities of the supervisory staff (physician, registered nurse-in-charge, dietitian, social worker, etc.) must be clearly stated. Also list those ancillary services (e.g., laboratory and other tests) being provided directly, on your premises, and also the qualifications of any party with whom you have or propose to enter into an agreement for the performance of other ancillary services.

Keep a copy of the Request for Approval, and your plan and documentation, and forward the remaining copies, plan, documentation and statements to us.

Before you may be approved to participate your facility must be surveyed by this office. The surveyors will review the regulations with you and inspect your facility to determine whether the ESRD services you desire to furnish meet regulatory requirements.

If you cannot complete and return the forms within the next 30 days, please inform us as to when we may expect them. We urge that you give this matter your highest priority.

Sincerely,

Director
State Agency

Enclosures

EXHIBIT 1F

Model Letter Transmitting Title XVIII Materials
to Individual Requesting to Participate as a
Physical Therapist in Independent Practice *

Dear _____:

This letter explains the procedures through which you may qualify for reimbursement under the Medicare Program as a physical therapist in independent practice. Outpatient physical therapy services under Medicare include services of a physical therapist in independent practice if the services are furnished in the therapist's office or in the Medicare beneficiary's residence. Reimbursement can be made only for treatment on the order of a physician, and the services must be furnished under a physician's plan of care. Payment for the reasonable charges for the covered services, less coinsurance and any deductible amounts due, is made either to the beneficiary or, on assignment, directly to the physical therapist. All physical therapists desiring to participate as independent practitioners must comply with the enclosed regulations in order to qualify for reimbursement under this provision of the law.

Please complete the enclosed Request to Establish Eligibility and return all but the last copy to this agency so that an initial determination may be made on your eligibility for participation. You will be contacted regarding this determination and informed of additional procedures to be undertaken. Any questions concerning the Form HCFA-855, Medicare General Enrollment Health Care Provider/Supplier Application, should be directed to your fiscal intermediary/carrier. You may obtain information regarding the Form HCFA-855 by contacting (name) at (phone number).

The (State Agency) will certify your compliance with regulations to the Health Care Financing Administration, which will make the determination whether you qualify for participation.

Please direct any questions you may have concerning this program to this agency.

Sincerely yours,

(State Agency)

Enclosures

* This letter may also be used for an occupational therapist in independent practice by substituting "occupational" for "physical" in each place the word "physical" appears.

(Next page is 9-8.1)

Exhibit 2

ASSURANCE OF COMPLIANCE WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION UNDER TITLE VI OF THE CIVIL RIGHTS ACT OF 1964

_____(hereinafter called the "Applicant")
Name of Applicant (type or print)

HEREBY AGREES THAT it will comply with Title VI of the Civil Rights Act of 1964 (P.L. 88-352) and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 80) issued pursuant to that title, to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity for which the Applicant receives Federal financial assistance from the Department; and HEREBY GIVES ASSURANCE THAT it will immediately take any measures necessary to effectuate this agreement.

If any real property or structure thereon is provided or improved with the aid of Federal financial assistance extended to the Applicant by the Department, this Assurance shall obligate the Applicant, or in the case of any transfer of such property, any transferee, for the period during which the real property or structure is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. If any personal property is so provided, this Assurance shall obligate the applicant for the period during which it retains ownership or possession of the property. In all other cases, this Assurance shall obligate the Applicant for the period during which the Federal financial assistance is extended to it by the Department.

THIS ASSURANCE is given in consideration of and for the purpose of obtaining any and all Federal grants, loans, contracts, property, discounts or other Federal financial assistance extended after the date hereof to the Applicant by the Department, including installment payments after such date. The Applicant recognizes and agrees that such Federal financial assistance will be extended in reliance on the representations and agreements made in this assurance, and that the United States shall have the right to seek judicial enforcement of this Assurance. This Assurance is binding on the Applicant, its successors, transferees, and assignees, and the person or persons whose signatures appear below are authorized to sign this Assurance on behalf of the Applicant.

Date _____ _____
Applicant (type or print)

_____
Signature and Title of Authorized Official

_____

_____
Applicant's Mailing Address

NOTE: If this form is not returned with the application for financial assistance, return it to DHHS, Office for Civil Rights, 330 Independence Ave., SW, Washington, D.C. 20201

HAS-441 (Rev. 1 12/82)

(Next page is 9-9)

Exhibit 2 (Cont.)

Explanation of

DHHS FORM NO. 441, ASSURANCE OF COMPLIANCE WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION UNDER TITLE VI OF THE CIVIL RIGHTS ACT OF 1964

Section 80.4 of the Department of Health and Human Services' Regulation effectuating Title VI of the Civil Rights Act of 1964 requires that every application to the Department for Federal financial assistance shall contain or be accompanied by an Assurance that the program or facility to be assisted will be conducted or operated in compliance with Title VI of the Civil Rights Act and with all requirements imposed by or pursuant to the Department's Regulation.

Section 80.4 further provides that "the form of the foregoing Assurance and the extent to which like Assurances will be required of subgrantees, contractors, transferees, successors in interest and other participants "shall be specified by the responsible Department official. Under this authority, HHS Form No. 441 has been specified as the form of Assurance which shall apply to all applications for Federal financial assistance (except for continuing state programs which must meet the requirements of Section 80.4(b) and school districts availing themselves of Section 80.4(c) of the Regulation) submitted to the Department after January 3, 1965; also the circumstances have been specified under which an Applicant shall obtain comparable written Assurances of compliance from its subgrantees, contractors, and transferees. (See answers to Questions 11 and 12 below in this regard.)

HHS Form No. 441 constitutes a legally enforceable agreement to comply with Title VI of the Civil Rights Act of 1964 and with all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services issued thereunder. Applicants are urged to read the Department's Regulation before executing the Assurance.

The following explanation of the requirements of the Department's Regulation and the examples of the kinds of discriminatory practices prohibited by them are for the guidance of the Applicants.

1. ***By executing the Assurance (HHS Form No. 441), what does an Applicant agree to do?***

A. The applicant agrees to make no distinction on the ground of race, color, or national origin in providing to individuals any service, financial aid, or other benefit under any program receiving Federal financial assistance extended to the Applicant by the Department.

2. <u>What is meant by "distinction on the ground of race, color, or national origin?</u>

A. "Distinction on the ground of race, color, or national origin" includes (1) any type of segregation, separate or different treatment, or other discrimination on that ground; (2) the imposition of any admission, enrollment, quota, eligibility, or other requirement or condition which individuals must meet in order to be provided any service, financial aid or other benefit under a program or to be afforded an opportunity to participate in a program, if the race, color, or national origin of individuals is considered is considered in determining whether they meet any such requirement or condition; (3) the use of membership in a group as a basis for the selection of individuals for any purpose, if in selecting members of the group there is a discrimination on the ground of race, color, or national origin; and (4) the assignment of personnel to provide services, or the assignment of times or places for the provision of services on the basis of the race, color, or national origin of the individuals to be served. It does not, however, include distinctions on the ground of race, color, or national origin determined by the responsible Department official to be necessary to the conduct of research or experimental programs having as their primary objective the discovery of new knowledge concerning special characteristics of particular racial or other ethnic groups.

3. *What is meant by "services, financial aid, or other benefit"?*

A. "Service, financial aid or other benefit" under a program receiving Federal assistance includes any education or training, any evaluation, guidance, counseling, or placement service, any health, welfare, rehabilitation, housing, or recreational service, any referral of individuals for any of the foregoing services, any scholarship, fellowship or traineeship stipend or allowance, and any loan or other financial assistance or benefit (whether in cash or in kind), which is made available to individuals (1) with the aid of Federal financial assistance, or (2) with the aid of the Applicant's or of other non-Federal funds required to be made available for the program as a condition to the receipt of Federal financial assistance, or (3) in or through a facility provided with the aid of Federal financial assistance or the non-Federal matching funds referred to in (2).

4. *What requirements are placed on the use of facilities?*

A. The Applicant agrees to make no distinction on the ground of race, color, or national origin in making available to individuals the use of any land, building, equipment, or other facility leased, acquired, constructed, improved, or equipped with the aid of Federal financial assistance extended to the Applicant by the Department, including--

(a) The use of any room, dormitory, ward or other space in the facility;

(b) The use of any equipment in the facility;

(c) The use of any office, waiting room, restroom, eating, recreational, concession, or other accommodation or convenience provided to the facility; and

(d) The use of any facility not provided with the aid of Federal financial assistance if the availability of such facility is required as a condition to the receipt of Federal financial assistance for the Federally-assisted facility.

5. *What requirements are placed on the opportunities to participate in a program receiving Federal assistance?*

A. The Applicant agrees to make no distinction on the ground of race, color, or national origin in affording opportunities to individuals to participate (other than as employees) in any program receiving Federal financial assistance extended by the Department to the Applicant, including opportunities to participate--

(a) as providers of any service, financial aid, or other benefit to individuals under the program (e.g., as physicians, surgeons, dentists, or other professional practitioners seeking the privilege of practicing in a Federally-aided hospital or other facility);

(b) as conferees, observers, consultants, or advisors, or as members of advisory or planning groups; or

(c) as volunteers (e.g., as voluntary workers, or as patients or other subjects of study or experimentation in research, survey, demonstration, or like programs).

6. ***Does that mean that an Applicant who signs the Department's Assurance may nevertheless make distinctions among his employees on the basis of race, color, or national origin?***

A. Title VI of the Civil Rights Act does not concern itself with employment practices except where a primary objective of the Federal financial assistance is to provide employment. Thus, where a basis objective of the program is to provide employment, the Applicant's employment practices are subject to the Department's Regulation. However, even where this is not the case, an Applicant may be precluded from engaging in any discriminatory employment practices under the provisions of Title VII of the Civil Rights Act, Executive Orders 10925 and 11114, and the Merit System Regulations.

7. ***When an Applicant's employment practices are covered by the Department's Regulation, what requirements must be met?***

A. The applicant agrees to make no distinction on the ground of race, color, or national origin in its employment practices (including recruitment or recruitment advertising, hiring, layoff or termination, upgrading, demotion, or transfer, rates of pay or other forms of compensation, and use of facilities) with respect to individuals seeking employment or employed under any program receiving Federal financial assistance extended to the Applicant by the Department, in those programs where a primary objective of the Federal financial assistance is to provide employment to such individuals. This includes programs under which the employment is provided--

(a) as a means of extending financial assistance to students or to needy persons,

(b) to students, fellows, interns, residents, or others in training for related employment (including research associates or assistants in training for research work), or

(c) to reduce unemployment or to provide remunerative activity to individuals who because of severe handicaps cannot be readily absorbed in the competitive labor market.

8. ***What effect will the Regulation have on a college or university's admission practices or other problems related to the treatment of students?***

A. An institution of higher education which applies for any Federal financial assistance of any kind must agree that it will make no distinction on the ground of race, color, or national origin in the admission practices or any other practices of the institution relating to the treatment of students.

(a) "Student" includes any undergraduate, graduate, professional or postgraduate student, fellow, intern, student, or other trainee receiving education or training from the institution.

(b) "Admission practices" include recruiting and promotional activities, application requirements, eligibility conditions, qualifications, preferences, or quotes used in selecting individuals for admission to the institution, or any program of the institution, as students.

(c) "Other practice relating to the treatment of students" include the affording to students of opportunities to participate in any educational, research, cultural, athletic, recreational, social, or other program activity; the performance evaluation, discipline, counseling of students; making available to students any housing, eating, health, or
recreational services; affording work opportunities or scholarship, loan or other financial assistance to students; and making available for the use of students any building, room, space, materials, equipment, or other facility or property.

9. ***Does the Assurance of nondiscrimination apply to the entire operation or an institution?***

A. Insofar as the Assurance given by the Applicant relates to the admission or other treatment of individuals as students, patients, or clients of an institution of higher education, a school, hospital, nursing home, center, or other institution owned or operated by the Applicant, or to the opportunity to participate in the provision of services, financial aid, or other benefits to such individuals, the Assurance applies to the entire institution. In the case of a public school system the Assurance would be applicable to all of the elementary or secondary schools operated by the Applicant.

10. ***What about a university which operates several campuses?***

A. Section 80.4(d)(2) of the Regulation provides for a more limited Assurance only where an institution can demonstrate that the practices in part of its operation in no way affect its practice in the program for which it seeks Federal funds. This would be a rare case.

11. ***If an Applicant intends to make use of other individuals to help carry out the Federally-assisted program, does the requirement not to discriminate apply to such a subgroup or contractor?***

A. It does. The Applicant must require any individual, organization, or other entity which it utilizes, to which it subgrants, or with which it contracts or otherwise arranges to provide services, financial aid, or other benefits under, or to assist it in the conduct of, any program receiving Federal financial assistance extended to the Applicant by the Department, or with which it contracts or otherwise arranges for the use of any facility provided with the aid of Federal financial assistance for a purpose for which the Federal financial assistance was extended, to comply fully with Title VI of the Civil Rights Act of 1964 and the Regulation of the Department of Health and Human Services issued thereunder.

12. ***Must this Assurance of nondiscrimination by the subgroup, etc., be in writing?***

A. In the case (1) of any contractual or other arrangement with another such individual or entity which will continue for an indefinite period or for a period of more than three months, (2) of any subgrant, or (3) of any conveyance, lease, or other transfer of any real property or structure thereon provided with the aid of Federal financial assistance extended to the Applicant by the Department, the Applicant shall obtain from such other person, subgrantee, or transferee, an agreement, in writing, enforceable by the Applicant and by the United States, that such other individual or entity, subgrantee, or transferee will carry out its functions under subgrant, or contractual or other arrangement, or will use the transferred property, as the case may be, in accordance with Title VI of the Act and the Regulation will otherwise comply herewith.

13. ***What obligations does the Applicant have to inform beneficiaries, participants, and others of the provisions of the Regulation?***

    A. The Applicant must make available to beneficiaries, participants, and other interested persons information regarding the provisions of the Regulation and protections against discrimination provided under Title VI of the Civil Rights Act. The Department will issue shortly more detailed instructions on carrying out this phase of the Regulation.

14. ***What obligations does the Applicant have to keep records and to make them available to the Department?***

    A. From time to time, Applicants may be required to submit reports to the Department, and the Regulation provides that the facilities of the Applicant and all records, books, accounts, and other sources of information pertinent to the Applicant's compliance with the Regulation be made available for inspection during normal business hours on request of an officer or employee of the Department specifically authorized to make such inspections. More detailed instructions in this regard will also be forthcoming from the Department in the near future.

15. ***Must separate Assurance forms be filed with such application?***

    A. As a general rule, once a valid Assurance is given, it will apply to any further application as long as there is no indication of a failure to comply.

Exhibit 3

Expression of Intermediary Preferences

RE: (Name and Address of Facility Here)

_____

_____

_____

Dear: _____:

In order to assure that the Health Care Financing Administration has your intermediary preference on record, would you please identify the organization you have selected as intermediary for your facility.

Please write your selection in the space provided at the bottom of this page. Be sure to sign this form and return it as soon as possible.

Sincerely yours,

State Agency

_____
(Intermediary Choice)

_____
(Signature)

PAGES 9-15 - 9-19

ARE RESERVED FOR EXHIBITS

4B - Health Insurance Benefits Agreement

5 - Statement of Financial Solvency

6 - Instructions for Completing Disclosure of Ownership and Control Interest Statement (HCFA-1515)

Exhibit 6

Errata Sheet

Disclosure of Ownership and Control Interest Statement, HCFA-1513

General Instructions

All items requiring the continuation of additional information are to be listed under the Remarks section on page 2 and should be followed by item number to be continued.

The following items are to be disregarded in completing the HCFA-1513 form.

Item II. - Disregard (PE). This is a printing error.

Item III. (c) - Disregard listing vendor and MMACS numbers for Title XIX providers.

- Substitute ownership interest in other disclosing entities for Medicare/Medicaid facilities.

The following wording should be substituted in Item III. (d):

Item III. (d) - Delete "owners of other Medicare/Medicaid facilities" and substitute "have ownership interest in other disclosing entities."

PAGES 9-21 - 9-29

ARE RESERVED FOR EXHIBITS

7 - Statement of Deficiencies and Plan of Correction

8 - Post-Certification Revist Report

9 - Medicare Medicaid Certification Transmittal

10 - Certification and Transmittal Spell of Illness Determination 1861 (j)(l)

Exhibit 14 A

HOSPITAL SURVEY REPORT CRUCIAL DATA EXTRACT

(To be used with 4/86 revision of HCFA 1537 A, C)

_____
Provider No. Facility Name Survey Date

Hospital Survey Report
Survey Team Composition (A2, A500, B2)

SF 42: Indicate the number of surveyors according to discipline.

A. _____ Administrator
B. _____ Nurse
C. _____ Dietitian
D. _____ Pharmacist
E. _____ Records Administrator
F. _____ Social Worker
G. _____ Qualified Mental Retardation Prof.
H. _____ Life Safety Code Spec.
I. _____ Laboratorian
J. _____ Sanitarian
K. _____ Therapist
L. _____ Physician
M. _____ Psychologist
N. _____ Other

NOTE: More than one discipline may be marked for surveyors qualified in multiple disciplines.

SF7 (A3, A501, B3): Indicate the Total Number of Surveyors Onsite:

SF44: Is this a Hospital-SNF Swing-Bed Facility? (1) Yes (2) No

If yes, check the appropriate bed-count category. (See the bed-count block on the Swing-Bed Request for Approval form.)

SF28: (1) 49 or fewer beds (2) 50-99 beds

Indicate the CLIA identification number of the laboratory providing laboratory services for the hospital._____
CLIA Identification Number

NOTE: Attach a copy of page 12 of Form HCFA-1537

Form HCFA-1537E (08/92)

Exhibit 14 B

CRUCIAL DATA EXTRACT

FIRE SAFETY SURVEY REPORT

(TO BE USED WITH HCFA-2786 FORMS)

PROVIDER NUMBER	FACILITY NAME	SURVEY DATE * K4

COMPLETE FOR EACH LSC SURVEY (IF APPROPRIATE)

* K3 MULTIPLE CONSTRUCTION

TOTAL NUMBER OF BUILDINGS

NUMBER OF THIS BUILDING

A BUILDING
B WING
C FLOOR
D APARTMENT UNIT

LSC FORM INDICATOR

1 2786A-67 EXISTING
2 A-67 NEW
3 B-73 EXISTING
4 B-73 NEW
5 F-81 EXISTING
6 F-81 NEW
7 C-SHORT
8 H-ASC
9 J, K, L -85-CHAPTER 21 (ICFs/MR ONLY)

*** K7** SELECT NUMBER OF FORM USED FROM ABOVE

(CHECK IF NOT APPLICABLE)

K29: **K56:**

COMPLETE IF ICF/MR IS SURVEYED UNDER CHAPTER 21

SMALL (16 BEDS OR LESS)

K8: 1 PROMPT
2 SLOW
3 IMPRACTICAL

LARGE

K8: 4 PROMPT
5 SLOW
6 IMPRACTICAL

APARTMENT HOUSE

K8: 7 PROMPT
8 SLOW
9 IMPRACTICAL

ENTER E-SCORE HERE

K5:

e.g. 2.5

*** K9:** FACILITY MEETS LSC BASED ON: (CHECK ALL THAT APPLY)

A1:	A2:	A3:	A4:
(COMP. WITH ALL PROVISIONS)	(ACCEPTABLE POC)	(WAIVERS)	(FSES)

FACILITY DOES NOT MEET LSC: B: .

* MANDATORY

Form HCFA-2786E (6-86) * U.S. GOVERNMENT PRINTING OFFICE : 1986 0 - 165-650

*PAGES 9-32 - 9-38

ARE RESERVED FOR EXHIBITS

14C - Skilled Nursing Facility & Intermediate Care Facility

14D - Home Health Agency Survey and Deficiencies Report

Exhibit 14 H

OUTPATIENT PHYSICAL THERAPY SURVEY REPORT
CRUCIAL DATA EXTRACT

(To be used with 3/78 revision of HCFA-1893)

_____ _____
Provider No. Facility Name Survey Date

SURVEY TEAM COMPOSITION

Indicate the number of Surveyors according to discipline:

SF42:

A.____ Administrator
B.____ Nurse
C.____ Dietitian
D.____ Pharmacist
E.____ Records Administrator
F.____ Social Worker
G.____ Qualified Mental Retardation Professional
H.____ Life Safety Code Specialist
I.____ Laboratorian
J.____ Sanitarian
K.____ Therapist
L.____ Physician
M.____ National Inst. of Mental Health
N.____ Other

N/A N/A

I8: [___] I72: [___]

I11: [___] I79: [___]

I172: Does the facility provide outpatient occupational therapy services?

(1) Yes [___] (2) No [___]

If yes, indicate the total number of qualified occupational therapists.
(Express full-time equivalents to the nearest quarter decimal, e.g., 3.25.)

I173 _____

Form HCFA-1893E (12/87)

Exhibit 14 I

ESRD Facility Survey Report
Crucial Data Extract

(To be used with Part II of the HCFA-3427)

_____	_____	*V33:
Provider No.	Facility Name	Survey Date

SURVEY TEAM COMPOSITION (V34)

Indicate the number of Surveyors according to discipline:

SF42:

A.____ Administrator
B.____ Nurse
C.____ Dietitian
D.____ Pharmacist
E.____ Records Administrator
F.____ Social Worker
G.____ Qualified Mental Retardation Professional
H.____ Life Safety Code Specialist
I.____ Laboratorian
J.____ Sanitarian
K.____ Therapist
L.____ Physician
M.___ National Inst. of Mental Health
N.____ Other

Note: More than one discipline may be marked for surveyors qualified in multiple disciplines.

SF7: Indicate the total number of surveyors onsite: _____.

*Mandatory Field

Form HCFA-3427

PAGES 9-41 - 9-47

ARE RESERVED FOR EXHIBITS

14J - Rural Health Clinic Survey Report Crucial Data Extract

14K - Intermediate Care Facility and the Mentally Retarded Crucial Date Extract

14L - Ambulatory Surgical Center Survey Report Crucial Data Extract

14M - Physical Therapist in Independent Practice Crucial Data Extract

14O - Hospice Survey Report Crucial Data Extract

15 - Regional Office Request for Additional Information or Other Action

PAGES

9-50 - 9-53

ARE RESERVED FOR EXHIBITS

21 - Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services

22 - Physical Therapist in Independent Practice Request for Certification in the Medicare Program

Exhibit 23

Model Letter Notifying Physical Therapists of
Scheduled Survey of Their Office(s) After Eligibility Determined

Dear _____:

Medicare coverage of your services as a physical therapist in independent practice requires a finding that you comply with Medicare health and safety requirements. A survey of your office(s) has been scheduled for ___(date)_ at __(a.m. or p.m.)__.

This agency has the responsibility for certifying your compliance with regulations to the U.S. Health Care Financing Administration. An opportunity to correct deficiencies will be afforded you if deficiencies are found.

Please make available for review at the time of the survey, the following material: names and evidence of appropriate licensure (where applicable) for all personnel; active and closed clinical records; your policies relating to confidentiality of records; and procedures governing equipment maintenance.

Please direct any questions you may have concerning the scheduled survey to this agency.

Sincerely yours,

Exhibit 24

Model Letter to Ineligible Physical Therapist Requesting to Participate as a Physical Therapist in Independent Practice

Dear _____:

This is to inform you that, on the basis of information submitted to us, you were found to be ineligible to participate as a physical therapist in independent practice under the Medicare program.

The decision is based on the following:

1. Medicare qualifications for physical therapists are not met.

2. You do not have independent practice status because:

   a. You do not render physical therapy services on your own responsibility and are not free of administrative and professional control of an employer.

   b. The individuals treated are not your own patients.

   c. You do not have the right to collect the fee or other compensation for the services rendered.

   d. You do not maintain, at your own expense, an office or office space and equipment.

If you disagree with this finding, and you request a review of your eligibility, enclose any additional information you deem pertinent.

Sincerely yours,

Exhibit 25

Model Letter to Rural Health Clinic
Regarding Scheduling a Survey

Dear _____:

Based on the information submitted in your Request to Establish Eligibility, the (name of clinic) meets the Medicare location requirements of a rural health clinic. The purpose of this letter is to advise you that the clinic will be surveyed on _____.

Please make available for review at the time of survey the following material:

- o names, and evidence of appropriate licensure for all clinic personnel, where applicable;
- o evidence of professional qualification of the physician's assistant and/or nurse practitioner clinic staff member;
- o evidence that the responsible physician formally agrees to provide medical direction, supervision, and guidance to the clinic;
- o a copy of the clinic's written policies and procedures;
- o evidence that the clinic has an agreement with one or more Medicare/Medicaid-approved hospitals for referral and admission of the clinic's patients;
- o a list of the services the clinic furnishes directly through its own staff.

As a part of the survey, we will be reviewing a random sample of the clinic's patients records to determine if the requirements of the regulations are met.

Should you need additional information about the survey, do not hesitate to call us. In the event it is not possible for the clinic to participate in a survey on the date scheduled, please call (name and telephone number) at (State agency location).

Sincerely,

Enclosures: Conditions for Coverage
Ownership and Control Interest Disclosure Statement
Health Insurance Benefits Agreement, HCFA-l56lA (2 copies)

Exhibit 26

Model Letter to Rural Health Clinic
Ineligible to Participate

Dear _____:

This is to inform you that, on the basis of information submitted to us, the (name of health clinic) at (site) has been tentatively identified as not meeting eligibility requirements for Medicare/Medicaid coverage of rural health clinic services.

The decision is based on the following:

A. The clinic is not located in an area that is designated as a non-urbanized area.

B. The clinic is not located in an area designated either as a primary medical shortage area or an area with a shortage of personal health services.

C. The clinic does not employ either a nurse practitioner or a physician assistant.

D. Other:

If you feel this finding is not correct, please advise us and forward any relevant material that would assist in reconsidering it.

Sincerely,

Exhibit 27

Model Letter to Previously Approved Facility
Requesting Approval to Expand or Add a New End Stage Renal Disease
(ESRD) Service

Dear _____:

You have indicated that your facility desires to be approved to (expand existing dialysis capacity)(add a new dialysis service)(add transplantation service) for beneficiaries of the ESRD program.

Each facility desiring to (expand)(add new) services for ESRD beneficiaries is required to meet all health and safety requirements.

Complete Part I of the attached ESRD Application and Survey and Certification Report, Form HCFA-3427, and return it with the documentation described on the instruction page. Your completed application must be accompanied by evidence of Certification of Need approval, if your State law requires such approval.

Also, you must furnish:

1. A Plan of Operation. If you offer dialysis, your plan of operation must cite the type of dialysis and number of stations and shifts.

2. The qualifications and responsibilities of the supervisory staff (physician, registered nurse in charge, dietitian, social worker, etc.) must be stated. If you plan to hire additional staff to service the (expanded capacity)(new activity), list the numbers of additional staff by job category. List the laboratory services being performed on premise.

   Keep a copy of the Part I of Form HCFA-3427 and forward the remaining copies with the supporting statements, plan, and documentation to us. Meanwhile, we will schedule a mutually convenient date for a site visit to be made by our surveyors after we receive the materials. The surveyors will review the regulations with you and inspect your facility to determine whether the ESRD services you desire to furnish meet regulatory requirements.

If you cannot complete and return the forms within the next 30 days, please inform us as to when we may expect them. We urge that you give this matter your highest priority.

Sincerely yours,

Director, State Agency

Enclosures (3):
End Stage Renal Disease Application and
Survey and Certification Report,
Form HCFA-3427
ESRD Program Regulations

Exhibit 30

Model Letter to Facility Returning Application
Not Accompanied by Required Certificate
of Need (Where Applicable)

Dear _____:

To constitute a valid application for (initial approval) (expansion) as a supplier of End-Stage Renal Disease (ESRD) services, the Request for Approval, HCFA-3402, must be accompanied by evidence of (name of State) Certificate of Need approval.

Since your application is not accompanied by the required documentation, we have no alternative but to return it to you. You may reapply at any time, submitting the documentation with your Request for Approval.

If you desire further information, we will be glad to assist you.

Sincerely yours,

Director
State Agency

Enclosure

Copies to:
HCFA RO

PAGES 9-60 - 9-64

ARE RESERVED FOR EXHIBIT

31 - End Stage Renal Disease Application\Notification and Survey and Certification Report

31 (Cont.) - Instructions for Form HCFA-3427

31 (Cont.) - End Stage Renal Disease Survey and Deficiencies Report

Exhibit 32

Model Letter Explaining to Provider that
One-Story Protected Wood Frame Facility
Does Not Meet Sprinkler Equivalency Standard

Dear _____:

The Department of Health and Human Services has established sprinkler equivalency criteria for one-story protected wood frame facilities. The criteria are:

A. All hazardous areas must be sprinklered;

B. Automatic fire detection devices must be installed in all areas required by the Life Safety Code to be protected by an automatic sprinkler system. The detection equipment shall be listed in U.L.'s Fire Protection Equipment List. The system shall be arranged to close all fire doors in barrier partitions and where possible shall be hooked into the local fire department or central control. At a minimum, the detection system shall activate an alarm system inside and outside the building;

C. Patient rooms are separated from each other and all other areas by construction having at least a l-hour fire resistance rating; and

D. The response time and capability of the local fire department shall, in the judgment of the State fire authority, be adequate to provide an acceptable level of protection for the unsprinklered facility.

(Your facility does not meet requirement(s) _____) (The State fire authority has advised us that criterion D is not met) and it will be necessary for you to either install a sprinkler system or take action to achieve equivalency, in order to meet the fire safety requirements.

We would appreciate your advising us by (l5 days) what action you intend to take.

If you disagree with our records as to your facility's type of construction or fire safety deficiencies, or have any further questions, you should get in touch with us immediately.

Sincerely yours,

Director
State Agency

PAGE 9-66 IS RESERVED FOR EXHIBIT

33 - Request for Validation of Accreditation Survey

Exhibit 35

SURVEY MATERIAL

1. Bylaws of the hospital's governing body.
2. Most recent minutes of the governing body and its committees.
3. Current contracts or plans for building modifications.
4. Most recent fire inspection reports.
5. Record of fire drills.
6. Current fire, evacuation and disaster plans.
7. Employee health examination reports.
8. Diet manual.
9. Records of menus served over the last 30-day period.
10. Most recent food service and/or sanitation inspection reports.
11. If food service is contracted for, the current contract governing such arrangements.
12. If a consultant pharmacist is used, his written consultative reports.
13. Drug requisition records.
14. Formulary or list of drugs approved for use in the hospital by the medical staff.
15. Nursing department duty roster and time records for the most recent 6-week period.
16. List of current nurses' license numbers.
17. CLIA Certificate.
18. Incident and accident reports.
19. Medical staff bylaws, rules, and regulations.
20. Minutes of recent meetings of the medical staff and its committees.
21. Minutes of recent departmental meetings, if applicable.
22. Inservice training program records, schedules, reports, etc.
23. Current and discharged patient medical records.

24. Applications of physicians and surgeons appointed to the medical staff.
25. Current roster of medical staff members.
26. Current roster of physicians with surgical privileges.
27. Qualifications of chief in-house laboratory and radiologic personnel.
28. Any available, currently effective policy and procedural manuals.
29. Incident and accident reports.

PAGES 9-69 - 9-71

ARE RESERVED FOR EXHIBIT

36 - Instructions for Completing Hospital Request for Certification in the Medicare\Medicaid Program

Exhibit 37
Model Letter Announcing Sample Validation
Survey to Accredited Hospital

Hospital Name PROVIDER NUMBER:

Address

Dear _____, Administrator

Section 1865 of the Social Security Act provides that a hospital accredited by the Joint Commission on Accreditation of Hospitals will be deemed to meet all the Medicare Conditions of Participation, with the exception of those relating to utilization review. (For psychiatric hospitals add: "and special psychiatric hospital medical staffing and medical records requirements.") Through Federal regulations, deemed status is extended to hospitals accredited by the American Osteopathic Association, as well. Section 1864 of the Act authorizes the Secretary of Health and Human Services to conduct, on a selective basis, surveys of JCAH accredited hospitals participating in Medicare, as a means of validating the JCAH survey process. Section 1865 of the Act extends this provision to AOA hospitals as well. In (Name of State), Medicare sample validation surveys of accredited hospitals are conducted by the (State agency). This is the agency which inspects unaccredited hospitals and other providers of Medicare/Medicaid services to assist the Health Care Financing Administration in determining whether they meet the Medicare Conditions of Participation.

We have scheduled a Medicare sample validation survey of your hospital on (date). Section 1865 of the Act requires a hospital selected for a sample validation survey to authorize the accrediting body to release to the Secretary (or to a State agency designated by him), upon his request, a copy of the most current accreditation survey of such institution. We are enclosing a Hospital Request for Certification form for signature by an authorized official of your hospital. This form is requested to obtain authorization from the accrediting body to release to HCFA the hospital's most recent survey findings. Please complete and sign this form. Mail the original copy (pink) and yellow copy to this office as soon as possible. The green copy is to be mailed to your accrediting body at the same time. You may retain the white copy for your files.

A copy of the Medicare sample validation survey findings will be subject to public disclosure after you have been given an opportunity to review the findings, present your comments to us, and submit a plan for correction of deficiencies. The current accreditation survey report, however, is not disclosable to the public.

Medicare survey procedures are very similar to accreditation survey procedures, so that you already have a good idea of what our survey will cover. To save time at the survey, please have the material on the enclosed list available for inspection.

If you have any questions or problems concerning either the authorization form or the scheduled date of our suvey, please call _____.

Sincerely yours,

Director

Enclosures:
HCFA-2674
Survey Material List

cc:
Accrediting Body
HSQ-RO

EXHIBIT 38

Model Form For Certification of Chiropractors
Where Requirements Prior to July 1, l974 Apply

I certify that the persons listed below meet the following Medicare qualifications as Chiropractors:

1. Preliminary education equal to the requirements for graduation from an accredited high school or other secondary school; and

2. Licensed, or commenced studies in a chiropractic school, before July/l, l974; and

3. Graduation from a college of chiropractic approved by the State chiropractic examiners with completion of a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance covering adequate courses of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing and adjusting; and

4. Passage of an examination prescribed by the State's chiropractic examiners covering the subjects listed in 3 above.

Name	Address	Social Security Number

Name and Title of Certifying Officer Date

(Continuation sheets can be used.)

EXHIBIT 39

Model Form for Certification of Chiropractors
Where Requirements After June 30, 1974 Apply

I certify that the persons listed below meet the following Medicare qualifications as Chiropractors:

1. Preliminary education equal to the requirements for graduation from an accredited high school or other secondary school, and satisfactory completion of 2 years of pre-chiropractic study at the college level; and

2. Graduation from a college of chiropractic approved by the State chiropractic examiners with completion of a course of study covering a period of not less than 4 school years of 8 months each year in actual continuous attendance. The course of study included not less than 4,000 hours in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing and adjusting, plus courses in the use and effect of X-ray and chiropractic analysis; and

3. Passage of an examination prescribed by the State's chiropractic examiners covering the subjects listed in 2 above; and

4. The practitioners are over 21 years of age.

Name	Address	Social Security Number

Name and Title of Certifying Officer Date

(Continuation sheets can be used.)

Exhibit 41

State Agency's Letter to Medicare Entity Seeking Readmission
After Involuntary Termination

Dear _____:

This is in response to your expression of interest in again becoming a provider of services under the Medicare program.

Under the provisions of section l866(c) of the Social Security Act, a provider of services previously terminated for cause may not obtain a new agreement to participate until it is found that the reasons for termination of the previous provider agreement no longer exist and also that there is reasonable assurance that the deficiencies will not recur. In order to have reasonable assurance, the Health Care Financing Administration requires that you demonstrate __* consecutive days of compliance with program eligibility requirements.

Our records show that (name of facility) previously participated in the program as a (type of facility) and that its agreement was terminated effective (date). (Name of facility) was found--(cover reasons for termination of the prior agreement as stated in the notice of termination to the facility).

In view of this, you are requested to forward to this office a written statement, signed by an authorized official, describing the steps taken to correct those deficiencies that led to the termination of your prior agreement, and the precautions that have been taken to assure that these deficiencies will not recur.

In addition to this statement please complete and return to this office the following forms:

(1) Two copies of Request to Establish Eligibility in the Health Insurance for the Aged Program;

(2) Two copies of the Health Insurance Benefits Agreement;

(3) One copy of the Expression of Intermediary Preference; and

(4) Two copies of the Assurance of Compliance.

Following a survey, this agency will recommend to the Health Care Financing Administration whether your facility should again be approved for participation.

When it is determined that the deficiencies upon which the prior termination was based have been corrected and you have maintained compliance for ___* consecutive days, the agreement will be countersigned effective with the date that these and all other requirements for participation are met.

In addition to being in substantial compliance with the Conditions of Participation, to receive payments under Medicare you must meet the requirements of Title VI of the Civil Rights Act of l964. Title VI prohibits discrimination on grounds of race, color, or national origin in any program or activity receiving Federal financial assistance. The Office for Civil Rights is responsible for

*number of days

determining whether a health facility meets the requirements of Title VI. If you are denied participation in the program, notification will be forwarded to that effect together with the reasons for the denial and information about your right to appeal the decision.

Please do not hesitate to communicate with this office if you have any questions.

Sincerely yours,

Enclosures

Exhibit 42

Orientation Program for the Newly
Employed Health Facility Surveyor

A. Primary Objective

The primary objective of the orientation program for the newly employed health facility surveyor is to prepare the new employee to assume the responsibilities of a health facility surveyor.

B. Broad Objective

At the completion of this orientation program the newly employed surveyor will be able to demonstrate acquired knowledge and skills by:

(l) Performing effectively, efficiently, and independently in areas of observation, decision making, documentation and evaluation of the performance of providers and suppliers.

(2) Uniformly imparting the HHS philosophy and intent of Federal regulations in face-to-face contact with providers and suppliers.

This orientation is designed to provide meaningful learning opportunities for health care professionals to gain additional technical knowledge, knowledge of Medicare/Medicaid health and safety regulations, and skills required to perform their duties more effectively. Participants study the survey and certification processes, read Federal regulations, review slides, listen to cassette tapes, and practice survey skills under supervision.

C. Introduction

The orientation program is divided into four parts and may be customized to fit the individual strengths and weaknesses of each new surveyor. The orientation should cover a four month period, after which the surveyor is presented with a certificate for program completion.

D. Program Content

Part I General Principles

Outlines the surveyor's role and responsibilities, indoctrination to standards and the survey/certification process, confidentiality, patient rights, technique of oral communication, basic data-collecting skills, and documentation of findings.

Part II Survey Methods

Outlines techniques and approaches to surveying standards for administration, medical direction, nursing, patient management, patient care planning, dietary service, pharmacy, medical records, restorative service, patient activities, physical therapy, occupational therapy, fire safety and disaster planning. Other selected conditions of participation and standards for specific suppliers of service, e.g., HHA, ESRD, are outlined.

Part III Field Experience

Emphasizes the process of surveying and the practice application of Part I and Part II. The surveyor participates as a team member under supervision in assessing a variety of areas, e.g., patient rights, nursing, medical records, until all areas have been covered.

Part IV Regional Office

Provides an overview of the Federal-State relationship in Title XVIII and XIX programs, requirements for common Medicare/Medicaid standards and procedures, organization and role of DHHS in survey and certification programs, the role and relation of the RO to the SA, and other selected topics identified by the RO.

Recommended time spans for the four parts are:

Part I 2 weeks

Part II 9 weeks

Part III 3 weeks

Part IV 1 week

E. Administration

The orientation program is designed to be a cooperative responsibility of the SA and RO. Most of the orientation is conducted at the SA. As necessary, the surveyor may travel to the RO and make site visits to implement certain aspects of the program.

F. State Agency

The SA has the overall responsibility for planning, coordinating, and supervising the orientation program for each new surveyor. However in the evaluation of the new surveyor the SA should have input from the RO when appropriate, e.g., observation and discussion with surveyor during direct surveys and RO orientation. The SA is also responsible for appointing a preceptor and/or coordinator for the orientation program.

(1) Preceptor

The preceptor should be a person who has successfully completed an orientation and a basic surveyor training program and has been responsible for successfully completing a number of surveys. This person must work closely with the new surveyors to set up time-tables for completion of program, hold conferences, and evaluate each new surveyor's progress throughout the orientation period. In States that have ROs if new surveyors need to receive their training out in the region, there will need to be a preceptor in each region.

(2) Coordinator

Each SA must identify a training coordinator. The coordinator is the person responsible for communicating with the HCFA regional training administration and for making the arrangement for the regional training administrator to meet individually or with a group of persons enrolled at any one time in the orientation training program. The SA training coordinator is also responsible for the design and expediting of training programs for surveyors who have completed the orientation program.

G. Regional Office

The HCFA RO and the SA are equally responsible for the orientation of the new surveyor. The RO is responsible for assisting States in developing an orientation program utilizing the "HHS Core" curriculum, reviewing and approving the plans for the program providing the RO's technical and field experiences, and monitoring the implementation of the program. The contact person in the RO should be the regional training administrator. The regional training administrator has the responsibility for assuring that an effective and meaningful orientation is defined for each new surveyor.

PAGES 9-81 - 9-85

ARE RESERVED FOR EXHIBITS

45 - State Survey Agency Budget\Expenditure Report

47 - State Agency Budget List of Positions

52 - State Survey Agency Certification Workload Report

54 - State Agency Schedule for Equipment Purchases

56 - Identification of Extension Units of OPT\OSP Providers

j Exhibit 57

Model Letter Requesting Identification of Extension Units

Dear (Administrator):

Our records indicate that your facility is approved in the Medicare program as a provider of outpatient physical therapy/speech pathology (OPT/OSP) services. In addition to furnishing services on their already approved premises OPT/OSP providers at time render services on the premises of other institutions (e.g., skilled nursing facilities). If the OPT/OSP bills the Medicare program for these services and renders these services in an area within the institution set aside for rehabilitation care, those premises are considered extension units of the OPT/OSP. In addition, premises owned or rented by the OPT/OSP and from which services are provided are also considered extension units of the OPT/OSP.

Extension units are considered part of the OPT/OSP regardless of proprietorship. The extension units are subject to the same approval as is applicable to the OPT/OSP provider overall. These extension units fall under the OPT/OSP provider agreement and are identified under the OPT/OSP provider number.

Enclosed is a questionnaire for the purpose of identifying the extension units of your OPT/OSP. In the event you list more than one extension unit in section A of the questionnaire, do not complete section B. Instead, in the spaces where you have listed each location (including the primary site) note whether at that location you provide "OPT", "OSP", or "Both." Please complete this form and return it to this office within 30 days. If at any time following completion of this form you plan to delete or add a service or close or add an extension unit, please notify this office immediately. If you have any questions or problems, please contact us.

Sincerely yours,

Exhibit 58

EXAMPLE OF REGULAR DISALLOWANCE LETTER

Certified Mail--Return Receipt Requested

FILE ID: RE: File No.

ADDRESSEE: Dear (Medicaid State Agency Director):

INTRODUCTION: The Quarterly Statement of Expenditures, HCFA 2824, for the State provider certification program submitted by your Department for the quarter ending _____has been reviewed by this office. The statement contains a claim totaling $_____ in Federal financial participation (FFP) of which $_____ is being disallowed.

BACKGROUND FACTS: (Description of the issues involved and the findings of fact)

DISALLOWANCE DETERMINATION: (Citation of statute and/or regulations, an explanation of how the statute or regulation has been violated, and the decision)

HCFA regulation _____ CFR _____ provides that:

(Provide explanation here.)

Therefore, in accordance with the regulation(s) cited above, this letter constitutes your notice of disallowance in the amount of $ FFP. Please resubmit the Quarterly Statement of Expenditures for which this disallowance action was taken, making the applicable decreasing adjustment and referencing disallowance number .

NOTICE OF ADJUSTMENT: As this disallowance includes FFP previously paid the State for expenditures for services furnished on or after October 1, 1980, it is subject to the provisions of section 961(a) of the Omnibus Reconciliation Act of 1980 (Public Law 96-499) as amended by section 2163 of the Omnibus Reconciliation Act of 1981 (Public Law 97-35). If you appeal this disallowance as provided below, Public Law 96-499 provides you the option of retaining the funds disallowed by this notice pending a final administrative decision. If the final decision upholds the disallowance and you elected to retain the funds during the appeal process, the proper amount of the disallowance, plus interest computed pursuant to Public Laws 96-499 and 97-35, will be offset in a subsequent grant award. You may exercise your option to retain the disputed funds by notifying the Regional Administrator in writing no later than 30 days after the postmarked date of this letter. In the absence of your notification that you elect to retain the funds, the Secretary will recover the disputed funds pending the final decision of the Grant Appeals Board.

APPEAL RIGHTS: Under section 1116(d) of the Social Security Act, you have the right to request reconsideration of this disallowance. Your reconsideration request must be submitted to the Executive Secretary, Departmental Grant Appeals Board, U.S. Department of Health and Human Services, Washington, DC 20201, no later than 30 days after your receipt of this letter. Your request must include a copy of this decision, a brief statement of the amount in dispute in your appeal, and a brief statement as to why you believe this decision is incorrect. Please send one copy of your request to me and one copy to the Associate Regional Administrator, Division of Health Standards and Quality. Your request will be processed pursuant to the rules and regulations of the Departmental Grant Appeals Board which are currently found at 45 CFR part 16. (See Federal Register, Vol. 46, No. 168, published August 31, l981.)

RO/DHSQ PROGRAM CONTACT: Should you require further details regarding this matter, please contact the Associate Regional Administrator, Division of Health Standards and Quality at (area code and telephone number).

Sincerely,

(Regional Administrator)

Enclosure (if any)

cc:
Central Office

Exhibit 59

EXAMPLE OF DEFERRAL LETTER

(NOTE: This letter is to be sent prior to the disallowance letter with regard to amounts deferred.)

Dear (Addressee):

We have reviewed your Quarterly Statement of Expenditures, HCFA-2824, for title XIX survey and certification activities for the quarter ending ___ __. Our review disclosed that consultant claims on section I of the Statement of Expenditures were claimed by the State at 75 percent Federal financial participation (FFP).

In accordance with section 1903(a)(2) of the Social Security Act and 42 CFR 432.50, Code of Federal Regulations, 75 percent FFP is available in expenditures for salaries or other compensation, fringe benefits, travel, per diem, and training for personnel of the State agency responsible for inspection of providers which participate in the Medicaid program.

No evidence was found during our review to indicate that the services provided by consultants are allowable at 75 percent FFP. Therefore, I am deferring your claim for FFP by $____ in accordance with the requirement of 45 CFR 201.15.

Please make available for review, within 60 days from the date of this letter, documentation that shows the type of work performed by consultants. If you find that you require additional time to make the requested documentation available for review, you may request in writing (in accordance with 45 CFR 201.15) an extension of up to an additional 60 days. If documentation reflects that services provided were directly related to the inspection of facilities, the deferred amount of $ will be reinstated on your next grant award.

Inquiries regarding this matter may be directed to my office, or you may contact me at (area code and telephone).

Sincerely yours,

(Regional Administrator)

Exhibit 60

EXAMPLE OF DISALLOWANCE LETTER FOR AMOUNTS PREVIOUSLY DEFERRED

Certified Mail--Return Receipt Requested

FILE ID: RE: File No.

ADDRESSEE: Dear (Medicaid State Agency Director):

INTRODUCTION: Your department was notified by our letter dated ___(copy enclosed) of our decision to defer, in accordance with 45 CFR 201.15, a claim totaling $_____ in Federal financial participation (FFP) for _____. This claim was made on line(s) _____ of the Quarterly Statement of Expenditures,HCFA-2824, for the State provider certification program submitted by your Department for the quarter ending _____.

This deferral action was taken because we questioned whether.

_____ In accordance with 45 CFR 201.15, you were requested to make available all related documents and materials necessary to determine the allowability of the claim.* This letter is to inform you of our decision after review of the documentation, regarding your claim for FFP.

BACKGROUND FACT: (Description of the issues involved and the findings of fact.)

DISALLOWANCE DETERMINATION: (Citation of statute and/or regulations, an explanation of how the statute or regulation has been violated, and the decision)

* If the deferral time requirements are not met you should also add the following:

Since we were unable to meet the time requirements of 45 CFR 201.15, your claim was paid on your grant award for the _____ quarter of fiscal year ___dated _____.

HCFA regulation ___ CFR ____ provides that:

(Provide explanation here.)

Therefore, in accordance with the regulation(s) cited above, this letter constitutes your notice of disallowance in the amount of $ FFP. Please resubmit the Quarterly Statement of Expenditures for which this disallowance action was taken, making the applicable decreasing adjustment and referencing disallowance number .

NOTICE/
ADJUSTMENT: As this disallowance includes FFP previously paid the State for expenditures for services furnished on or after October 1, 1980, it is subject to the provisions of section 961(a) of the Omnibus Reconciliation Act of 1980 (Public Law 96-499) as amended by section 2163 of the Omnibus Reconciliation Act of 1981 (Public Law 97-35). If you appeal this disallowance as provided below, Public Law 96-499 provides you the option of retaining the funds disallowed by this notice pending a final administrative decision. If the final decision upholds the disallowance and you elected to retain the funds during the appeal process, the proper amount of the disallowance, plus interest computed pursuant to Public Laws 96-499 and 97-35, will be offset in a subsequent grant award. You may exercise your option to retain the disputed funds by notifying the Regional Administrator in writing no later than 30 days after the postmarked date of this letter. In the absence of your notification that you elect to retain the funds, the Secretary will recover the disputed funds pending the final decision of the Grant Appeals Board.

APPEAL RIGHTS: Under section 1116(d) of the Social Security Act, you have the right to request reconsideration of this disallowance. Your reconsideration request must be submitted to the Executive Secretary, Departmental Grant Appeals Board, U.S. Department of Health and Human Services, Washington, DC 20201, no later than 30 days after your receipt of this letter. Your request must include a copy of this decision, a brief statement of the amount in dispute in your appeal, and a brief statement as to why you believe this decision is incorrect. Please send one copy of your request to me and one copy to the Associate Regional Administrator, Division of Health Standards and Quality. Your request will be processed pursuant to the rules and regulations of the Departmental Grant Appeals Board which are currently found at 45 CFR part 16. (See Federal Register, Vol. 46, No. 168, published August 31, l981.)

RO/DHSQ
PROGRAM
CONTACT: Should you require further details regarding this matter, please contact the Associate Regional Administrator, Division of Health Standards and Quality at (area code and telephone).

Sincerely,

(Regional Administrator)

Enclosure (if any)

cc:
Central Office

Exhibit 61

EXAMPLE OF AUDIT DISALLOWANCE LETTER

Certified Mail--Return Receipt Requested

FILE ID: RE: File No.

ADDRESSEE: Dear (Medicaid State Agency Director):

INTRODUCTION: Your department was notified on _____ of the results of an HHS Office of Inspector General Audit Agency (OIGAA) report entitled " " (ACN). The audit covered the period _____ through _____.

The auditors identified unallowable costs totaling $_____ in Federal financial participation (FFP) which had been reported for Title XIX reimbursement during the period reviewed. Your Department's response to the audit findings was noted in the final report. This letter is to convey to you our final determination on the audit findings as discussed below and summarized on the enclosed schedule (if any).

RECOMMENDED FACTS AND DISALLOWANCE DETERMINATION: (There should be a discussion of each of the financial findings: the issues involved, the regulations/statutes violated, the State agency position, and our determination. Relevant pages of the audit report may be referenced. When relying upon audit results, especially the results of State audits, there must be an independent determination by HCFA that the factual record supports a disallowance.)

SUMMATION: In summary, based on the findings of the OIGAA report, ACN_____, and the law and regulations discussed above, it is necessary to disallow $_____ in FFP. A detailed schedule of the disallowed amounts is enclosed.

NOTICE OF ADJUSTMENT: As this disallowance includes FFP previously paid the State for expenditures for services furnished on or after October 1, 1980, it is subject to the provisions of section 961(a) of the Omnibus Reconciliation Act of 1980 (Public Law 96-499) as amended by section 2163 of the Omnibus Reconciliation Act of 1981 (Public Law 97-35). If you appeal this disallowance as provided below, Public Law 96-499 provides you the option of retaining the funds disallowed by this notice pending a final administrative decision. If the final decision upholds the disallowance and you elected to retain the funds during the appeal process, the proper amount of the disallowance, plus interest computed pursuant to Public Laws 96-499 and 97-35, will be offset in a subsequent grant award. You may exercise your option to retain the disputed funds by notifying the Regional Administrator in writing no later than 30 days after the postmarked date of this letter. In the absence of your notification that you elect to retain the funds, the Secretary will recover the disputed funds pending the final decision of the Grant Appeals Board.

APPEAL RIGHTS: Under section 1116(d) of the Social Security Act, you have the right to request reconsideration of this disallowance. Your reconsideration request must be submitted to the Executive Secretary, Departmental Grant Appeals Board, U.S. Department of Health and Human Services, Washington, DC 20201, no later than 30 days after your receipt of this letter. Your request must include a copy of this decision, a brief statement of the amount in dispute in your appeal, and a brief statement as to why you believe this decision is incorrect. Please send one copy of your request to me and one copy to the Associate Regional Administrator, Division of Health Standards and Quality. Your request will be processed pursuant to the rules and regulations of the Departmental Grant Appeals Board which are currently found at 45 CFR part 16, subpart C. (See Federal Register, Vol.43, No. 44, published March 6, l978.)

RO/DHSQ PROGRAM CONTACT: Should you require further details regarding this matter, please contact the Associate Regional Administrator, Division of Health Standards and Quality at (area code and telephone).

Sincerely,

(Regional Administrator)

Enclosure (if any)

cc:
Central Office
Regional Audit Director

Exhibit 62

Model Letter
State Agency Advising a Provider or Supplier of an
Impending Federal Survey

Dear (Administrator):

The (Name of Institution) has been selected by the Health Care Financing Administration for an onsite Federal survey on (Date).

The purpose of the survey is to determine that the Medicare/Medicaid certification program conducted in this State is consistent with applicable Federal regulations, policies, and guidelines. The Federal surveyors will determine that by comparing their survey findings with those of the State surveyors who visited your institution on (Date).

The (Name of Institution) was selected at random. This Federal survey does not constitute a regular resurvey inspection, though if recontact is necessary as a result of the survey, it will be by the (State agency). The Federal surveyors will be accompanied by (Name of State Surveyor). If any special problems have arisen since the last State survey, you should bring them to (His)(Her) attention.

If you have further questions about this survey, please direct them to this office.

Sincerely,

EXHIBIT 63

List of Documents in Certification Packet

	Title	Form Number
	Recertification - Accredited JCAHO/AOA Hospitals - Short-Term Acute (Includes Medical-Surgical Units)	
	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility (By Surveyor)	HCFA-1514
	Ownership and Control Interest Disclosure Statement	HCFA-1513
*	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
	Survey Team Composition and Workload Report	HCFA-670
	Initial Certification - Accredited JCAHO/AOA Hospitals - Psychiatric	
	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility	HCFA-1514
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
*	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
**	Psychiatric Hospital Survey Report	HCFA-1537A
	Survey Team Composition and Workload Report	HCFA-670
	Send the following to the RO as soon as received, even if prior to the survey:	
	Health Insurance Benefit Agreement (signed originals)	HCFA-1561
	Title VI form (and applicable attachments)	HHS-441
	Statement of Financial Solvency	HCFA-2572
	Statement of Intermediary Preference	
	Recertification - Accredited JCAHO/AOA Hospitals - Psychiatric	
	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility (By Surveyor)	HCFA-1514
	Ownership and Control Interest Disclosure Statement	HCFA-1513
*	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
**	Psychiatric Hospital Survey Report (pp. 7-8)	HCFA-1537A
	Survey Team Composition and Workload Report	HCFA-670

** As required by §2720 of the State Operations Manual.

Initial Certification - Hospitals - Short-Term Acute (Includes Medical-Surgical Units)

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility	HCFA-1514
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
	Crucial Data Extract - Health (with appropriate attachments)	HCFA-1537E
	Crucial Data Extract - Life Safety Code	HCFA-2786E
	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
	Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
***	Hospital Survey Report	HCFA-1537
*/***	Fire Safety Survey Report	HCFA-2786A or F
***	Survey Report Form (CLIA)	HCFA-1557
	Laboratory Personnel Report (CLIA)	HCFA-209
	Blood Bank Inspection Checklist and Report (if applicable) (Form FDA 2609)	HCFA-282
	Utilization Review Plan	---
	Survey Team Composition and Workload Report	HCFA-670

Send the following to the RO as soon as received, even if prior to the survey:

Health Insurance Benefit Agreement (signed originals)	HCFA-1561
Title VI form (and applicable attachments)	HHS-441
Statement of Financial Solvency	HCFA-2572
Statement of Intermediary Preference	---

** Recertification - Unaccredited Hospitals - Short-Term Acute (Includes Medical-Surgical Units)

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility (By Surveyor)	HCFA-1514
	Ownership and Control Interest Disclosure Statement	HCFA-1513
	Crucial Data Extract - Health (with appropriate attachments)	HCFA-1537E
	Crucial Data Extract - Life Safety Code	HCFA-2786E
	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
	Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
*/***	Fire Safety Survey Report	HCFA-2786A,C or F

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* If FSES is applied, the following are needed: HCFA-2786D or G for all zones, table 8 for entire facility. Do not send LSC survey report to RO if it is a 2786A or F, and no use of FSES or waivers.

** Hospitals not in compliance, RN waiver requests, and hospitals no longer accredited--Send complete survey reports.

*** As required by §2720 of the State Operations Manual.

	Blood Bank Inspection Checklist and Report (if applicable) (Form FDA 2609)	HCFA-282
	Survey Team Composition and Workload Report	HCFA-670

Initial Certification - Unaccredited Psychiatric Hospitals and Psychiatric Distinct Parts

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility	HCFA-1514
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
	Crucial Data Extract - Health (with appropriate attachments)	HCFA-1537E
	Crucial Data Extract - Life Safety Code	HCFA-2786E
	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
	Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
**	Psychiatric Hospital Survey Report	HCFA-1537A
**	Hospital Survey Report HCFA-1537	
*/***	Fire Safety Survey Report	HCFA-2786A or F
**	Survey Report Form (CLIA)	HCFA-1557
	Laboratory Personnel Report (CLIA)	HCFA-209
	Blood Bank Inspection Checklist and Report (if applicable) (Form FDA 2609)	HCFA-282
	Utilization Review Plan	---

Send the following to the RO as soon as received, even if prior to the survey:

Health Insurance Benefit Agreement (signed originals)	HCFA-1561
Title VI form (and applicable attachments)	HHS-441
Statement of Financial Solvency	HCFA-2572
Statement of Intermediary Preference	---
Survey Team Composition and Workload Report	HCFA-670

Recertification - Unaccredited Psychiatric Hospitals and Psychiatric Distinct Parts**

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility (By Surveyor)	HCFA-1514
	Ownership and Control Interest Disclosure Statement	HCFA-1513
	Crucial Data Extract - Health (with appropriate attachments)	HCFA-1537E
	Crucial Data Extract - Life Safety Code	HCFA-2786E
*/***	Fire Safety Survey Report	HCFA-2786A,C or F

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* If FSES is applied, the following are needed: HCFA-2786D or G for all zones, table 8 for entire facility. Do not send LSC survey report to RO if it is a HCFA-2786A or F and no use of FSES or waivers.

* As required by §2720 of the State Operations Manual.

	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
	Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
	Blood Bank Inspection Checklist and Report (if applicable) (Form FDA 2609)	HCFA-282
	Survey Team Composition and Workload Report	HCFA-670
	<u>Initial Certification - CLIA Laboratories</u>	
	Certification and Transmittal	HCFA-1539
	Clinical Laboratory Application	HCFA-116
***	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
***	Ownership and Control Interest Disclosure Statement	HCFA-1513
****	Survey Report Form (CLIA)	HCFA-1557
	Laboratory Personnel Report (CLIA)	HCFA-209
	Blood Bank Inspection Checklist and Report (if applicable) (Form FDA 2609)	HCFA-282
	Statement of Deficiencies and Plan of Correction	HCFA-2567
	Survey Team Composition and Workload Report	HCFA-670
	Certification - Recommendation - CLIA Laboratory	HCFA-197
	<u>Recertification - CLIA Laboratories</u>	
	Certification and Transmittal	HCFA-1539
**	Survey Report Form (CLIA) (cover page)	HCFA-1557
	Laboratory Personnel Report (CLIA)	HCFA-209
	Ownership and Control Interest Disclosure Statement	HCFA-1513
	Crucial Data Extract - Laboratory (with appropriate attachments)	HCFA-1557E
	Statement of Deficiencies and Plan of Correction	HCFA-2567
	Survey Team Composition and Workload Report	HCFA-670
	Certification - Recommendation - CLIA Laboratory	HCFA-197
	<u>Advance Approval/Expansion - End-Stage Renal Disease Facilities</u>	
	Certification and Transmittal	HCFA-1539
	ESRD Facility Survey Report	HCFA-3427
	Ownership and Control Interest Disclosure Statement	HCFA-1513
	Narrative Report Describing Services to be Provided	---
	Certificate of Need in the States Where it is Required	---
	Survey Team Composition and Workload Report	HCFA-670

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* As soon as you receive these, send them to the RO.

** If there is a change in name, address, ownership, or services at the time of recertification, send in the same information as for an initial certification.

*** The Form HCFA-855 is only to be completed for laboratories that participate in Medicare. If a laboratory does not participate in Medicare, the laboratory will complete the HCFA-1513.

**** As required by §2720 of the <u>State</u> <u>Operations</u> <u>Manual</u>.

Initial Certification - End-Stage Renal Disease Facilities

	Certification and Transmittal	HCFA-1539
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
	Statement of Deficiencies and Plan of Correction	HCFA-2567
**	ESRD Facility Survey Report	HCFA-3427
*	Narrative Report Describing Services to be Provided	---
*	Certificate of Need in the States Where it is Required	---
	Survey Team Composition and Workload Report	HCFA-670

Expansion With No Survey - End-Stage Renal Disease Facilities

	Certification and Transmittal	HCFA-1539
	Narrative Report Describing Services to be Provided	---
	Certificate of Need in the States Where it is Required	---

Recertifications - End-Stage Renal Disease Facilities

	Certification and Transmittal	HCFA-1539
	Ownership and Control Interest Disclosure Statement	HCFA-1513
	Statement of Deficiencies and Plan of Correction	HCFA-2567
*	ESRD Facility Survey Report (page 2)	HCFA-3427
	Survey Team Composition and Workload Report	HCFA-670

Initial Certification - Home Health Agencies

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility	HCFA-1515
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
	Crucial Data Extract - HHA	HCFA-1572E
	Statement of Deficiencies and Plan of Correction	HCFA-2567
*	Home Health Agency Survey Report	HCFA-1572
	Survey Team Composition and Workload Report	HCFA-670

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* Only if these documents have not been sent in with the request for advance approval.

* * As required by §2720 of the State Operations Manual.

Send the following to the RO as soon as received and prior to the survey:

Health Insurance Benefit Agreement (signed originals)	HCFA-1561
Title VI form (and applicable attachments)	HHS-441
Statement of Financial Solvency	HCFA-2572
Statement of Intermediary Preference	---

Recertification - Home Health Agencies

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility (By Surveyor)	HCFA-1515
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - HHA	HCFA-1572E
Statement of Deficiencies and Plan of Correction	HCFA-2567
Survey Team Composition and Workload Report	HCFA-670

Initial Certification - Outpatient Physical Therapy - Speech Pathology

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility	HCFA-1856
Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
Crucial Data Extract - OPT-SP	HCFA-1893E
Statement of Deficiencies and Plan of Correction	HCFA-2567
* OPT-SP Survey Report	HCFA-1893
Survey Team Composition and Workload Report	HCFA-670

Send the following to the RO as soon as received and prior to the survey:

Health Insurance Benefit Agreement (signed originals)	HCFA-1561
Title VI form (and applicable attachments)	HHS-441
Statement of Financial Solvency	HCFA-2572
Statement of Intermediary Preference	---

Recertification - Outpatient Physical Therapy - Speech Pathology

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility	HCFA-1856
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - OPT-SP	HCFA-1893E
Statement of Deficiencies and Plan of Correction	HCFA-2567
Survey Team Composition and Workload Report	HCFA-670

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* As required by §2720 of the State Operations Manual.

** Needed only if expansion of services or stations done at time of recertification.

Initial Certification - Portable X-Ray

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility	HCFA-1880
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
	Crucial Data Extract - PX-R	HCFA-1882E
	Statement of Deficiencies and Plan of Correction	HCFA-2567
*	Portable X-Ray Survey Report	HCFA-1882
	Survey Team Composition and Workload Report	HCFA-670

Recertification - Portable X-Ray

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility (By Surveyor)	HCFA-1880
	Ownership and Control Interest Disclosure Statement	HCFA-1513
	Crucial Data Extract - PX-R	HCFA-1882E
	Statement of Deficiencies and Plan of Correction	HCFA-2567
	Survey Team Composition and Workload Report	HCFA-670

Initial Certification - Rural Health Clinics

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility	HCFA-29
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
	Crucial Data Extract - RHC	HCFA-30E
	Statement of Deficiencies and Plan of Correction	HCFA-2567
*	Rural Health Clinic Survey Report	HCFA-30
	Survey Team Composition and Workload Report	HCFA-670

Send the following to the RO as soon as received and prior to the survey:

Health Insurance Benefit Agreement (signed originals)	HCFA-1561a
Title VI form (and applicable attachments)	HHS-441
Request to Establish Eligibility	HCFA-29

Recertification - Rural Health Clinics

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility (By Surveyor)	HCFA-29
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - RHC	HCFA-30E
Statement of Deficiencies and Plan of Correction	HCFA-2567
Survey Team Composition and Workload Report	HCFA-670

* As required by §2720 of the State Operations Manual.

Initial Certification - Comprehensive Outpatient Rehabilitation Facilities

	Certification and Transmittal	HCFA-1539
	Request to Establish Eligibility	HCFA-359
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
	Crucial Data Extract - CORF	HCFA-360E
	Statement of Deficiencies and Plan of Correction	HCFA-2567
*	CORF Survey Report	HCFA-360
	Survey Team Composition and Workload Report	HCFA-670

Send the following the RO as soon as received and prior to the survey:

Health Insurance Benefit Agreement (signed originals)	HCFA-1561
Title VI form (and applicable attachments)	HHS-441
Statement of Financial Solvency	HCFA-2572

Recertification - Comprehensive Outpatient Rehabilitation Facilities

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility (By Surveyor)	HCFA-359
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - CORF	HCFA-360E
Statement of Deficiencies and Plan of Correction	HCFA-2567
Survey Team Composition and Workload Report	HCFA-670

Independent Physical Therapists

	Certification and Transmittal	HCFA-1539
	Statement of Deficiencies and Plan of Correction	HCFA-2567
*	Physical Therapists in Independent Practice Survey Report	HCFA-3042
	Request for CertificationHCFA-262	
	Survey Team Composition and Workload Report	HCFA-670

Above documents listed are required for initial and recertification packets. Omit request for certification on relocation survey packets.

Medicare General Enrollment Health Care Provider/Supplier Application (only required for initial certifications)	HCFA-855

* As required by §2720 of the State Operations Manual.

Emergency Hospitals

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility	HCFA-1514
Survey Team Composition and Workload Report	HCFA-670

Initial Certification - Ambulatory Surgical Centers

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility	HCFA-377
Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
Crucial Data Extract - ASC	HCFA-378E
Crucial Data Extract - Life Safety Code	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
** Ambulatory Surgical Center Survey Report	HCFA-378
*/**Fire Safety Survey Report	HCFA-2786H
Survey Team Composition and Workload Report	HCFA-670

Send the following to the RO as soon as received and prior to the survey:

Health Insurance Benefit Agreement (signed originals)	HCFA-370
Title VI form (and applicable attachments)	HHS-441

Recertification - Ambulatory Surgical Centers

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility (By Surveyor)	HCFA-377
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - ASC	HCFA-378E
Crucial Data Extract - Life Safety Code	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
*/**Fire Safety Survey Report	HCFA-2786H
Survey Team Composition and Workload Report	HCFA-670

* If a waiver of a LSC item is requested, send HCFA-2786H and all necessary documentation.

** As required by §2720 of the State Operations Manual.

Initial Certification - Hospices

	Hospice Request for Certification in the Medicare Program	HCFA-417
	Certification and Transmittal	HCFA-1539
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
**	Hospice Survey Report	HCFA-449
	Survey Team Composition and Workload Report	HCFA-670

Send the following to the RO as soon as received and prior to the survey:

	Health Insurance Benefit Agreement (signed originals)	HCFA-1561
	Title VI form (and applicable attachments)	HHS-441
	Statement of Financial Solvency	HCFA-2572

Freestanding - in addition to the forms noted above, freestanding hospices require:

**	Freestanding Hospice Survey Report	
*/**	Fire Safety Survey Report	HCFA-2786A or F
	Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567

Recertification - Hospices

	Certification and Transmittal	HCFA-1539
	Hospice Request for Certification (By Surveyor)	HCFA-417
	Ownership and Control Interest Disclosure Statement	HCFA-1513
	Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
	Survey Team Composition and Workload Report	HCFA-670

Freestanding - in addition to the forms noted above, freestanding hospices with inpatient units require:

*/**	Fire Safety Survey Report	HCFA-2786A or F
	Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567

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* If FSES is applied, the following are needed: HCFA-2786D or G for all zones and Table 8 for the entire facility. Do not send LSC Survey Report to RO if it is 2786A or F and no use of FSES or waivers.

** As required by §2720 of the State Operations Manual.

EXHIBIT 63 (Cont.)

Initial Certification - Title XVIII Skilled Nursing Facilities

Certification and Transmittal	HCFA-1539
Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
Crucial Data Extract - Life Safety Code	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
Post Certification Revisit Report - Health (if applicable)	HCFA-2567B
Post Certification Revisit Report - LSC (if applicable)	HCFA-2567B
Skilled Nursing Facility and Nursing Facility	
Long-Term Care Facility Application for Medicare and Medicaid	HCFA-671
Resident Census and Conditions of Residents	HCFA-672
Extended/Partial Extended Survey Worksheet	HCFA-673
Resident Rights and Quality of Life: Individual Interview Guide	HCFA-674
Resident Rights and Quality of Life: Family Interview Guide	HCFA-674A
Resident Rights and Quality of Life: Group Interview Guide	HCFA-675
Quality of Care Assessment Worksheet	HCFA-676
Quality of Care Assessment Worksheet, MDS+	HCFA-676A
Medication Pass Worksheet	HCFA-677
Environmental Quality Assessment Worksheet	HCFA-678
Dietary Services System Worksheets	HCFA-679A,B,C
Closed Records Discharge Review Worksheet	HCFA-680
Surveyor Notes Worksheet	HCFA-681
Resident Roster	HCFA-682
*/** Fire Safety Survey Report	HCFA-2786A B, or F
Waiver (if applicable)	--
Utilization Review Plan	
Survey Team Composition and Workload Report	HCFA-670

Send the following to the RO as soon as received and prior to the survey:

Health Insurance Benefit Agreement (signed originals)	HCFA-1561
Title VI form (and applicable attachments)	HHS-441
Statement of Financial Solvency	HCFA-2572
Statement of Intermediary Preference	--

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* If FSES is applied, the following is needed: HCFA-2786D or G for all zones and Table 8 for the entire facility. Do not send LSC Survey Report to RO if it is 2786A or F and no use of FSES or waivers.

** As required by §2720 of the State Operations Manual.

Recertification - Title XVIII Skilled Nursing Facilities

Certification and Transmittal	HCFA-1539
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - Life Safety Code	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
Post Certification Revisit Report - Health (if applicable)	HCFA-2567B
Post Certification Revisit Report - LSC (if applicable)	HCFA-2567B
*/** Fire Safety Survey Report	HCFA-2786A B, C, or F
Survey Team Composition and Workload Report	HCFA-670

Initial Certification - Title XIX Nursing Facilities

Certification and Transmittal	HCFA-1539
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - Life Safety Code	HCFA-2586E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
Post Certification Revisit Report - Health (if applicable)	HCFA-2567B
Post Certification Revisit Report - LSC (if applicable)	HCFA-2567B
Skilled Nursing Facility and Nursing Facility	
Long-Term Care Facility Application for Medicare and Medicaid	HCFA-671
Resident Census and Conditions of Residents	HCFA-672
Extended/Partial Extended Survey Worksheet	HCFA-673
Resident Rights and Quality of Life: Individual Interview Guide	HCFA-674
Resident Rights and Quality of Life: Family Interview Guide	HCFA-674A
Resident Rights and Quality of Life: Group Interview Guide	HCFA-675
Quality of Care Assessment Worksheet	HCFA-676
Quality of Care Assessment Worksheet, MDS+	HCFA-676A
Medication Pass Worksheet	HCFA-677
Environmental Quality Assessment Worksheet	HCFA-678
Dietary Services System Worksheets	HCFA-679A,B,C
Closed Records Discharge Review Worksheet	HCFA-680
Surveyor Notes Worksheet	HCFA-681
Resident Roster	HCFA-682
*/** Fire Safety Survey Report	HCFA-2786A B, or F

* If FSES is applied, the following are needed: HCFA-2786D or G for all zones and Table 8 for the entire facility. Do not send LSC Survey Report to RO if it is 2786A or F and no use of FSES or waivers.

** As required by §2720 of the State Operations Manual.

Initial Certification - Title XIX Nursing Facilities - Continued

Survey Team Composition and Workload Report	HCFA-670

SNF XIX-only:

If waivers are requested (Health or LSC), forward two copies of the waiver recommendation and the applicable survey report prior to sending the survey packet.

Recertification - Title XIX Nursing Facilities

Certification and Transmittal	HCFA-1539
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - Life Safety Code	HCFA-2586E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
Post Certification Revisit Report - Health (if applicable)	HCFA-2567B
Post Certification Revisit Report - LSC (if applicable)	HCFA-2567B

The same waiver as in initial certification requires submittal of only page 1 of Fire Safety Report

*/** Fire Safety Survey Report	HCFA-2786A B, or F
Survey Team Composition and Workload Report	HCFA-670

SNF XIX-only:
Waiver requests (Health or LSC) must come in prior to the survey packet.

Recertification - Medicare Skilled Nursing Facilities While Subject to Denial of Payments for New Admissions

Certification and Transmittal	HCFA-1539
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - Life Safety Code	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
NOTE: Plan of correction may or may not be submitted by the provider.	
Statement of Deficiencies and Plan of Correction - Life Safety Code	HCFA-2567
Fire Safety Survey Report*	HCFA-2786A,B, C, or F
Survey Team Composition and Workload Report	HCFA-670

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* If FSES is applied, the following are needed: HCFA-2786D or G for all zones and Table 8 for the entire facility. Do not send LSC Survey Report to RO if it is 2786A or F and no use of FSES or waivers.

** As required by §2720 of the State Operations Manual.

Revisit After Credible Allegation - Medicare Skilled Nursing Facilities While Subject to Denial of Payments for New Admissions

Certification and Transmittal	HCFA-1539
Statement of Deficiencies and Plan of Correction (for deficiencies found not corrected)	HCFA-2567
Post-Certification Revisit Report (for deficiencies found to have been corrected)	HCFA-2567B
Survey Team Composition and Workload Report	HCFA-670

Recertification - Medicaid-Only Nursing Facilities While Subject to Denial of Payments for New Admissions

Certification and Transmittal	HCFA-1539
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - Life Safety Code	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
NOTE: Plan of Correction may or may not be submitted by the provider.	
Statement of Deficiencies and Plan of Correction - Life Safety Code	HCFA-2567
Fire Safety Survey Report*	HCFA-2786 A, B, C, or F
(The same waiver as in initial certification requires submittal of only page 1 of Fire Safety Report)	
Survey Team Composition and Workload Report	HCFA-670

Revisit After Credible Allegation - Medicaid-Only Nursing Facilities While Subject to Denial of Payments for New Admissions

Certification and Transmittal	HCFA-1539
Statement of Deficiencies and Plan of Correction (for deficiencies found not corrected)	HCFA-2567
Post-Certification Revisit Report (for deficiencies found to have been corrected)	HCFA-2567B
Survey Team Composition and Workload Report	HCFA-670

* If FSES is applied, the following are needed: HCFA-2786D or G for all zones, and Table 8 for the entire facility. Do not send LSC Survey Report to RO if it is a HCFA-2786A, B or F and no use of FSES or waivers.

EXHIBIT 63 (Cont.)

Initial Certification - Intermediate Care Facilities for the Mentally Retarded

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility	HCFA-1516
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - Health	HCFA-3070BE
Crucial Data Extract - Life Safety Code	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
*** Institutions of Mentally Retarded or Persons with Retarded Conditions Survey Report	HCFA-3070B
*/*** Fire Safety Survey Report for each building involved, or for each construction type for any building having more than one construction type	HCFA-2786A or F
** Life Safety Code Waivers ---	
Listing of QMRPs with Qualifications	---
Direct Care Staffing Information - Individual Units	---
Description of Living Units	---
Map of Campus Which Identifies Each Resident Living Unit	---
Survey Team Composition and Workload Report	HCFA-670

Recertification - Intermediate Care Facilities for the Mentally Retarded**

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility (By Surveyor)	HCFA-1516
Ownership and Control Interest Disclosure Statement	HCFA-1513
Crucial Data Extract - Health	HCFA-3070BE
Crucial Data Extract - Life Safety Code	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC	HCFA-2567
Listing of QMRPs with Qualifications	---
Direct Care Staffing Information - Individual Units	---
Description of Living Units	---
Survey Team Composition and Workload Report	HCFA-670

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* If FSES is applied, the following are needed: HCFA-2786D or G for all zones and Table 8 for the entire facility. Do not send LSC Survey Report to RO if it is a HCFA-2786A or F and no use of FSES or waivers.

** When a waiver is granted for the first time, send in the complete Fire Safety Report. Subsequent requests for approval of the same waiver require submittal of only page 1 of Fire Safety Report.

*** As required by §2720 of the State Operations Manual.

1861(j)(l) Certifications

	Certification and Transmittal - Spell of Illness, 1861(j)(1) Supplement	HCFA-1539A
	1861(j)(1) Determinations - Computation of Nurse to Resident Ratio Form	---
*	Intermediate Care Facility Survey Report (page 24)	HCFA-3070
	Survey Team Composition and Workload Report	HCFA-670

Post-Certification Revisit Report - All Facilities Except Long-Term Care

Post-Certification Revisit Report - Health (if applicable)	HCFA-2567B
Post-Certification Revisit Report - LSC (if applicable)	HCFA-2567B
Survey Team Composition and Workload Report	HCFA-670

Post Certification Revisit Report with Amended HCFA-1539

Certification and Transmittal	HCFA-1539
Post-Certification Revisit Report - Health (if applicable)	HCFA-2567B
Post-Certification Revisit Report - LSC (if applicable)	HCFA-2567B
Survey Team Composition and Workload Report	HCFA-670

Addition and/or Deletion of Services

Certification and Transmittal	HCFA-1539
Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
Appropriate Request to Establish Eligibility (By Surveyor)	---
Statement of Deficiencies and Plan of Correction (if applicable)	HCFA-2567
Survey Team Composition and Workload Report	HCFA-670

*As required by §2720 of the State Operations Manual.

Address and/or Name Change

Medicare Change of Information Health Care Provider/Supplier Application	HCFA-855C
Certification and Transmittal	HCFA-1539

Change of Ownership - Title XVIII or XVIII-XIX Providers

	Certification and Transmittal	HCFA-1539
*	Health Insurance Benefit Agreement (signed originals)	HCFA-1561
*	Title VI form (and applicable attachments)	HHS-441
*	Statement of Financial Solvency	HCFA-2572
	Request to Establish Eligibility (for applicable provider)	---
	Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
**	Long Term Care Facility Application for Medicare and Medicaid	HCFA-671

Change of Ownership - Providers - Title XIX Nursing Facilities

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility	HCFA-1516
Long Term Care Facility Application for Medicare and Medicaid	HCFA-671
Ownership and Control Interest Disclosure Statement	HCFA-1513
Survey Team Composition and Workload Report	HCFA-670

Change of Ownership - Suppliers

Certification and Transmittal	HCFA-1539
Request to Establish Eligibility (for applicable supplier)	---
Medicare General Enrollment Health Care Provider/Supplier Application	HCFA-855
Survey Team Composition and Workload Report	HCFA-670

General Complaint

Medicare/Medicaid/CLIA Complaint Form	HCFA-562
Narrative Report	
Statement of Deficiencies and Plan of Correction (if applicable)	HCFA-2567
Portions of: Health or Fire Safety Code Survey Report (as applicable)	
Survey Team Composition and Workload Report	HCFA-670

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* Send in as soon as available.

** Required for skilled nursing facilities and nursing facilities only.

Accredited Hospital Complaint/Validation

Certification and Transmittal	HCFA-1539
Medicare/Medicaid/CLIA Complaint Form	HCFA-562
Authorization by Accredited Hospital to Disclose JCAHO/AOA Accreditation Survey	HCFA-2674
Crucial Data Extract - Health (if applicable)	HCFA-1537E
Crucial Data Extract - Life Safety Code (if applicable)	HCFA-2786E
Statement of Deficiencies and Plan of Correction - Health (if applicable)	HCFA-2567
Statement of Deficiencies and Plan of Correction - LSC (if applicable)	HCFA-2567
Narrative Report (Complaints)	---
* Hospital Survey Report (applicable parts for partial complaints surveys)	HCFA-1537
Fire Safety Survey Report (if applicable)	HCFA- 2786A,B or F
Survey Team Composition and Workload Report	HCFA-670

Follow-up reports on hospitals under SA monitoring should contain the following:

Certification and Transmittal (Item 11 completed with either box 2 or box 4 checked)	HCFA-l539
Post-Certification Revisit Report	HCFA-2567B

* As required by §2720 of the State Operations Manual.

THIS PAGE IS RESERVED FOR EXHIBIT 64
"AMBULATORY SURGICAL CENTER REQUEST FOR CERTIFICATION IN THE MEDICARE PROGRAM"

PAGES 9-114 - 9-133

ARE RESERVED FOR EXHIBITS

64 - Ambulatory Surgical Center Request for Certification in the Medicare Program

65 - Health Insurance Benefits Agreement

69 - Certification Recommendation-CLIA Laboratory

71 - Fire Safety Survey Report --Short Form

72 - Hospice Request for Certification in the Medicare Program

73 - Psychiatric Unit Criteria Work Sheet

74 - Survey Team Composition and Workload Report

If the survey is more than one day, and if you perform survey work after you leave the facility but before you have completed the survey, (e.g., the survey is conducted Monday and Tuesday and you work at your motel on Monday night) include this as on-site work only if it is activity that normally would be done at the facility (e.g., determination of deficiencies). Enter these hours per surveyor in the appropriate time band(s).

If you write the formal Statement of Deficiencies or the survey report on-site, include this time as on-site time, not in off-site report preparation.

Travel Hours (H) - Document the total time traveling to and from the facility, excluding meal stops. If surveyors meet at the office and proceed from there, the starting time is the time they leave the office. If, however, surveyors leave their residences, travel toward the facility, and meet on the way to the facility, travel time should be no longer than the time required to travel from the primary duty station to the facility.

If, on completion of one survey, travel, travel is made directly to another facility, travel hours should be shared between the two facilities (i.e., to report two hours of travel from your office or residence for Facility A and Facility B, report one hour travel for Facility A and one hour travel for Facility B.

Off-site Report Preparation Hours (I) - Enter the time necessary for all the activities performed to produce a report. Include the time spent discussing the survey activities during supervisory review, and the time spent to rewrite the report after supervisory review.

If you investigate a complaint or conduct a follow up visit by phone or letter, include in this section the time to conduct these activities. Fill out a separate HCFA-670 each time these activities occur, whether or not this work is performed onsite or from the office via phone or letter.

Likewise, include in this column the total number of off-site hours spent with all sanction, appeal, and change-of-ownership activities.

Total Supervisory Review Hours - Include all time spent in review of the survey team's decisions. If supervisory personnel make the deficiency determination, include the time spent reviewing data and making the deficiency determination.

Total Clerical/Data Entry Hours - Enter the number of clerical and/or data entry hours involved in the survey. Clerical duties include, but are not limited to, typing, transcribing, filing, retrieving from files, and travel arrangements. Data entry includes all direct entry or survey data.

Do not include survey team time spent in formulating and typing the report directly from notes. Include that activity in Off-site Report Preparation Hours.

Was Statement of Deficiencies given to the provider on-site at completion of the survey? - Enter the letter Y or N in the block provided to indicate if the formal Statement of Deficiencies was given to the provider/supplier on-site at the completion of the survey.

HCFA-670 Survey Team Composition and Workload Report

This form provides information on resource utilization applicable to survey activity in all Medicare and/or Medicaid provider/supplier types and CLIA laboratories. (HCFA CO's system will compute the appropriate share of time spent on Medicare/Medicaid and/or licensure inspections based on the annual rate negotiated between the ROs and the State Agencies.)

Provider/Supplier Number - Leave this item blank on all initial certifications. The RO assigns the Federal identification numbers for all new providers and suppliers of health services. On subsequent actions such as resurveys, followups, and life safety code surveys, insert the facility's assigned 6 or 10 digit provider/supplier number.

Provider/Supplier Name - Enter the provider or supplier name in the space provided.

Type of Survey - Using the letters to the right of the blocks, enter the type(s) of survey being conducted. More than one entry may apply.

Extent of Survey - Using the letters to the right of the blocks, enter the extent(s) of the survey being conducted. More than one entry may apply. For example, for HHAs, it is possible that a survey would include a standard, extended, and partial extended survey.

Surveyor Identification (ID) Number (A) - Enter, on the lines provided, the unique 5-digit ID number of each surveyor participation in the survey. If you do not know your ID number, contact your State or Regional Office Training Coordinator.

First Date Arrived (B) - Enter the date(s) (MMDDYY) each surveyor on the team arrived at the provider/supplier.

Last Date Departed (C) - Enter the final date(s) (MMDDYY) each surveyor on the team departed the provider/supplier. For example, if a surveyor arrived on Monday to begin the survey, left the facility Tuesday on another assignment but returned to finish on Thursday, Thursday would be shown as the Last Date Departed.

Pre-survey Preparation Hours (D) - Enter the number of hours each surveyor spent in preparing for the survey. This includes telephone calls, conferences pertaining to the survey, file retrieval, analyzing the individual facility profile, copying and organizing material. Record hours to the nearest decimal quarter hour, e.g., two hours and ten minutes would be reported as 2.25 hours.

On-Site Hours (E), (F), and (G) - Enter each surveyor's working hours spent on-site, within the time bands specified. Report the hours, as outlined above, to the nearest decimal quarter hour. Do not include meal times as working hours in these columns unless, during meals, you perform survey activities that would otherwise be performed during other times on-site.

PAGES 9-136 - 9-137 ARE RESERVED FOR EXHIBIT

75 - Medicare\Medicaid\CLIA Compliant Form

EXHIBIT 76

Model Letter to Clinics, Rehabilitation Agencies and Public Health Agencies Initially Applying to Serve as Providers of Outpatient Occupational Therapy Services

Dear _____:

This is in response to your inquiry regarding participation in the Medicare program as a provider of outpatient occupational therapy services (OOT). To participate in Medicare as a provider of these services, your clinic or agency must be approved by the Health Care Financing Administration (HCFA). The statutory basis for the OOT services benefit is found at section l861(g) of the Social Security Act (the Act). The new subsection, 1861(g), which became effective July 1, 1987, gives the term "outpatient occupational therapy ser-vices" the meaning of "outpatient physical therapy services" by substituting "occupational" for "physical" each place it appears in section 1861(p) of the Act.

Because coverage of outpatient occupational therapy services became effective July 1, 1987 and final rules establishing specific Medicare requirements for OOT services have not yet been published, we have adopted the existing process used to establish the eligibility of providers of outpatient physical therapy/outpatient speech pathology services (OPT/OSP) (including compliance with State and local licensure requirements) to determine the eligibility of an organization to participate in the Medicare program as a provider of OOT services. Instructions, forms, and procedures applicable to OPT/OSPs have been modified accordingly. We anticipate that the final Conditions of Participation and the approval process for OOTs will be similar to the existing Conditions and approval process for OPT/OSPs. In order to participate in Medicare you must be in compliance with the enclosed requirements except for 42 CFR 405.1718(a)(1) and (b) and 42 CFR 405.1719. The (name of State agency) assists HCFA in determining whether clinics and agencies in this State meet the Medicare requirements.

Enclosed is a copy of the Request to Establish Eligibility (HCFA Form 1856) and instructions for its completion which have been amended to include occupa-tional therapy, where appropriate. You will also find two copies of the HCFA Form 1561, the agreement which your organization must enter into with the Secretary of the Department of Health and Human Services, if you qualify for participation. The HCFA-1561 has been revised to delete the references to Title VI of the Civil Rights Act of 1964. The individual signing the HCFA-1561 must also initial and date this change in the margin of the form. If you wish to participate in the program, please complete the amended HCFA-1856 and retain a copy for your records. If you do not wish to participate at this time, please complete item I on one copy of the amended HCFA-1856 and return all of the forms to us as soon as possible in the enclosed, preaddressed envelope so that we can make the proper adjustment to our records.

After receiving your Request to Establish Eligibility, we will conduct a survey of your organization to determine whether it meets the requirements for participation. If your agency is cited for significant deficiencies you will be informed, and given an opportunity to correct these deficiencies.

If your organization is found eligible for Medicare participation, a represen-tative of the HCFA regional office will countersign the agreement for the Secretary. The effective date of the agreement, can be no earlier than the date your facility meets all Medicare health and safety requirements and, for OOT services, no earlier than July l, l987. Please be sure to sign, initial, and date the HCFA-1561 where indicated, and return both copies with all but the last copy of the amended HCFA-1856.

Sincerely yours,

Enclosure

EXHIBIT 77

Model Letter to Approved Medicare Clinics, Rehabilitation Agencies and Public Health Agencies that Request to add Outpatient Occupational Therapy Services

Dear _____:

This is in response to your inquiry regarding the addition of outpatient occupational therapy (OOT) services to the services you are furnishing as a Medicare approved provider of outpatient physical therapy/speech pathology services (OPT/OSP). To participate as a Medicare provider of OOT services your organization must comply with additional requirements. The statutory basis for requirements for providers of OOT is found at section 1861(g) of the Social Security Act (the Act) and the benefit became effective July 1, 1987. It gives the term "outpatient occupational services" the meaning of "outpatient physical therapy services" by substituting "occupational" for "physical" each place it appears in section 1861(p) of the Act.

Because the Medicare requirements for providers of OOT services have not yet been published in regulations, we are using guidelines, policies and procedures applicable to clinics, rehabilitation agencies and public health agencies to determine whether such entities, already approved by Medicare as providers of OPT/OSP services, may also provide OOT services. Approved clinics and agencies will be eligible to provide OOT services if such services are provided by qualified personnel. Occupational therapists must meet the definition of an occupational therapist contained in 42 CFR 405.1202(f). Occupational therapy assistants must meet the definition of an occupational therapy assistant in 42 CFR 405.1202(g). (See the enclosed regulations.) You should provide this agency with documentation that personnel providing OOT services for your facility meet these requirements. In addition, OOT services are to be provided consistent with the requirements established for outpatient physical therapy services in 42 CFR 405.1718(c) and (d). Also, the facility and its personnel must be in compliance with all applicable State and local licensure laws and regulations.

It is not necessary for us to conduct an onsite survey of your facility for OOT services at this time. You should be aware that pursuant to section 2298 B. of The State Operations Manual - Provider Certification services provided at an extension site must also be provided at the primary location.

In order to determine if you are eligible to participate in Medicare as a provider of OOT services, you must send to this agency:

1. Written notification that you plan to offer OOT services;

2. The address of each location where the services will be offered;

3. The names of the personnel who will be providing the services; and

4. Documentation that the personnel providing the services are in compliance with all applicable State and local laws and regulations and the pertinent Medicare personnel qualification requirements (42 CFR 1202(f) or 42 CFR 1202(g)).

Based on this information we will make a determination concerning whether your organization is eligible to provide OOT services and the effective date the service is approved for Medicare. However, your organization will not be paid for OOT services furnished to beneficiaries prior to the effective date (July 1, 1987) established for Medicare coverage of OOT services.

EXHIBIT 79

Model Letter to Individuals Requesting to Participate in Medicare
As Occupational Therapists in Independent Practice

Dear _____:

This is in response to your inquiry regarding participation in the Medicare program as an occupational therapist in independent practice (OTIP). As a result of a change in title XVIII of the Social Security Act (the Act), out-patient occupational therapy services (OOT) under Medicare include, effective July l, l987, the services of an (OTIP) when the services are furnished in the therapist's office or in the Medicare beneficiary's residence. Patients are accepted for treatment on the order of a physician and the services must be furnished under a plan established by a physician or occupational therapist which is periodically reviewed by a physician. To participate in the Medicare program as an OTIP you must meet the enclosed requirements.

The statutory basis for the OOT services benefit is found at section 1861(g) of the Act. Section 1861(g) gives the term "outpatient occupational therapy services" the meaning of "outpatient physical therapy services" by substituting "occupational" for "physical" each place it appears in 1861(p) of the Act. Although the outpatient therapy services benefit became effective July 1, 1987, final rules establishing specific Medicare requirements for an OTIP have not yet been published. Therefore, we are using guidelines, policies and proce-dures based on the existing process used to establish the eligibility of physical therapists in independent practice, (including compliance with State and local licensure requirements) to determine the eligibility of individuals requesting to participate in the Medicare program as OTIPs. Requirements, forms, instructions and procedures applicable to physical therapists in inde-pendent practice have been modified as appropriate to make them applicable to OTIPs. We anticipate that the final requirements and approval process for occupational therapists will be similar to the existing requirements and approval process for physical therapists. All occupational therapists who wish to participate as independent practitioners must be approved as being in compliance with the enclosed requirements in order to qualify for payment under this provision of the Act. If more than one office is maintained by an individual occupational therapist (including therapists in group practices and those who have formed partnerships and corporations), each office must meet the pertinent requirements.

If you relocate your office you must contact this agency for a determination concerning whether the new location meets the pertinent Medicare requirements.

Please complete the enclosed Request to Establish Eligibility and return all but the last copy to this agency so that an initial determination may be made on your request for participation. You will be contacted regarding this determination, and informed of any additional procedures that must be under-taken.

The (State Agency) is responsible for determining compliance with Medicare regulations and certifying its findings to the HCFA regional office, which will make the decision as to whether you qualify for participation in the Medicare program. An OTIP participating in the Medicare program under this approval process on the effective date of the final requirements, will continue to be eligible to participate until a determination is made concerning compliance with the final requirements.

Please direct any questions you may have about this program to (State agency).

Sincerely yours,

(State agency)

Enclosure

PAGES 9-141 - 9-149 ARE RESERVED FOR EXHIBITS

80 - Itermediate Care Facility for the Mentally Retarded Survey Report

81 - Request for Approval as a Hospital Provider of Extended Care Services (Swing-Bed) in the Medicare Medicaid Programs

Exhibit 81 (Cont.)

Instructions - Form HCFA-605

Submission of this form initiates the process for obtaining a decision as to whether the requirements are met. Assistance in completing the form is available from the State survey agency serving your area.

CALCULATION OF BED COUNT

Exclude from the bed count, beds that, because of their special nature (e.g., newborn and intensive care beds), are not available for swing-bed use. Also, exclude beds in separately certified "distinct part" SNFs and NFs, and beds in a distinct part psychiatric or rehabilitation unit that is excluded from the prospective payment system. A hospital licensed for more than 49 beds may be eligible for swing-bed approval in the 49 or fewer bed category if it consistently utilizes and staffs for fewer than 50 beds. Likewise, a hospital licensed for more than 99 beds may be eligible for approval in the 50-99 bed category. At a minimum, include the number of beds the hospital is operating, staffing schedules and census information for the previous 12 months.

5 WEEKDAY TRANSFER REQUIREMENT

Hospitals of more than 49 and fewer than 100 beds are subject to the 5 weekday transfer requirement in §1883(d)(1)(A) of the Social Security Act.

(NOTE: The 30-day transfer rule at 42 CFR 483.12(a)(5) does not apply to swing-bed hospitals.)

These hospitals must have an availability agreement with each Medicare-participating SNF in the geographic region (excluding SNFs not willing to enter into agreements). The agreement must specify that:

- The SNF will notify the hospital of available beds;
- The hospital agrees to transfer the patient to a SNF within 5 weekdays (excluding weekends and holidays) of the availability date unless the patient's physician certifies that a transfer is not medically appropriate; and
- In the event of multiple SNFs with available beds, the patient will choose the SNF to which he or she will transfer. The transfer must occur, however, within 5 weekdays from the day the first bed becomes available.

Attach to the application:

- Two copies of a list of all SNFs with which the hospital has availability agreements;
- One copy of the hospital's policy regarding transfer of extended care patients; and
- One copy of each availability agreement.

GEOGRAPHIC REGION REQUIREMENT

Swing-bed hospitals must have an availability agreement with each Medicare-participating SNF in their geographic regions unless the SNF is not willing to enter into an agreement. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area that includes all the SNFs within 50 miles of the hospital (unless the hospital can demonstrate that the SNFs are inaccessible to its patients).

Exhibit 82

Model Letter - Swing Bed Applicants

NAME
STREET
TOWN, STATE OF HOSPITAL

Dear (Hospital Representative):

In response to your request to establish eligibility in the Medicare and Medicaid programs as a provider of posthospital skilled nursing facility (SNF) care services, I have enclosed Form HCFA-605, Request for Approval as a Hospital Provider of Extended Care Services (Swing-bed) in the Medicare and Medicaid Programs, a copy of Form HCFA-1537C, Medicare/Medicaid Hospital Swing-bed Survey Report and a copy of section 1883 a-d(3) of the Social Security Act (the Act). This provision authorizes approval of rural hospitals with greater than 49 and fewer than 100 beds to provide posthospital SNF care services.

If your hospital is in the greater-than-49 and fewer-than-100 bed category, you must meet the requirements applicable to rural hospitals with 49 or fewer beds, and the additional requirements of section 1883(d)(2)(A) of the Act, as well as the special requirements at 42 CFR 482.66(a)(6)-(7) for hospitals in the greater-than-49 and fewer-than-100 bed category. This law requires swing-bed hospitals to comply with the 5-weekday transfer rule, which is explained on the enclosed application form.

When you believe that your hospital meets all the requirements, promptly return Form HCFA-605. If your hospital is in the greater-than-49 and fewer-than-100 bed category, please enclose:

- Two copies of your policy covering the 5 weekday transfer requirement,
- Two copies of a list of any SNFs with which your hospital has availability agreements,
- One copy of the hospital's policy regarding transfer of posthospital SNF care patients, and
- One copy of each of the availability agreements with each of the SNFs in your geographic region.

If you have any questions, please call _____.

Sincerely yours,

Enclosures

Exhibit 83

Sections 1883 (a)-(d)(3) of the Social Security Act
Hospital Providers of Extended Care Services

Sec. 1883. (a)(1) Any hospital (other than a hospital which has in effect a waiver under subparagraph (A) of the last sentence of section 1861(e)) which has an agreement under section 1866 may (subject to subsection (b)) enter into an agreement with the Secretary under which its inpatient hospital facilities may be used for the furnishing of services of the type which, if furnished by a skilled nursing facility, would constitute extended care services.

(2)(A) Not withstanding any other provision of this title, payment to any hospital for services furnished under an agreement entered into under this section shall be based upon the reasonable cost of the services as determined under subparagraph (B).

(B)(i) The reasonable cost of the services consists of the reasonable cost of routine services (determined under clause (ii)) and the reasonable cost of ancillary services (determined under clause (iii)).

(ii) The reasonable cost of routine services furnished during any calendar year by a hospital under an agreement under this section is equal to the product of-

(I) The number of patient-days during the year for which the services were furnished, and

(II) The average reasonable cost per patient-day, such average reasonable cost per patient-day being the average rate per patient-day paid for routine services during the most recent year for which cost reporting data are available with respect to such services (increased in a compounded manner by the applicable increase for payments for routine service costs of skilled nursing facilities under section 1888 for subsequent cost reporting periods and up to and including such calendar year) under this title to freestanding skilled nursing facilities in the region (as defined in section 1886(d)(2)(D)) in which the facility is located.

(iii) The reasonable cost of ancillary services shall be determined in the same manner as the reasonable cost of ancillary services provided for inpatient hospital services.

(b) The Secretary may not enter into an agreement under this section with any hospital unless-

(1) Except as provided under subsection (g), the hospital is located in a rural area and has less than 100 beds, and

(2) The hospital has been granted a certificate of need for the provision of long-term care services from the State health planning and development agency (designated under section 1521 of the Public Health Service Act) for the State in which the hospital is located.

(c) An agreement with a hospital under this section shall, except as otherwise provided under regulations of the Secretary, be of the same duration and subject to termination on the same conditions as are agreements with skilled nursing facilities under section 1866 and shall, where not inconsistent with any provision of this section, impose the same duties, responsibilities, conditions, and limitations, as those imposed under such agreements entered into under section 1866; except that no such agreement with any hospital shall be in effect for any period during which the hospital does not have in effect an agreement under section 1866, or during which there is in effect for the hospital a waiver under subparagraph (A) of the last sentence of section 1861(e). A hospital with respect to which an agreement under this section has been terminated shall not be eligible to enter into a new agreement until a two-year period has elapsed from the termination date.

(d)(1) Any agreement with a hospital under this section shall provide that payment for services will be made only for services for which payment would be made as post-hospital extended care services if those services had been furnished by a skilled nursing facility under an agreement entered into under section 1866; and any individual who is furnished services, for which payment may be made under an agreement under this section, shall, for purposes of this title (other than this section), be deemed to have received post-hospital extended care services in like manner and to the same extent as if the services furnished to him had been post-hospital extended care services furnished by a skilled nursing facility under an agreement under section 1866.

(2)(A) Any agreement under this section with a hospital with more than 49 beds shall provide that no payment may be made for extended care services which are furnished to an extended care patient after the end of the 5-day period (excluding weekends and holidays) beginning on an availability date for a skilled nursing facility, unless the patient's physician certifies, within such 5-day period, that the transfer of the patient to that facility is not medically appropriate on the availability date. The Secretary shall prescribe regulations to provide for notice by skilled nursing facilities of availability dates to hospitals which have agreements under this section and which are located within the same geographic region (as defined by the Secretary).

(B) In this paragraph:

(i) The term "availability date" means, with respect to an extended care patient at a hospital, any date on which a bed is available for the patient in a skilled nursing facility located within the geographic region in which the hospital is located.

(ii) The term "extended care patient" means an individual being furnished extended care services at a hospital pursuant to an agreement with the Secretary under this section.

(3) In the case of an agreement for a cost reporting period under this section with a hospital that has more than 49 beds, payment may not be made in the period for patient-days of extended care services that exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the hospital in the period, except that such payment shall continue to be made in the period for those patients who are receiving extended care services at the time the hospital reaches the limit specified in this paragraph.

(e) During a period for which a hospital has in effect an agreement under this section, in order to allocate routine costs between hospital and long-term care services for purposes of determining payment for inpatient hospital services, the total reimbursement due for routine services from all classes of long-term care patients (including title XVIII, title XIX, and private pay patients) shall be subtracted from the hospital's total routine costs before calculations are made to determine title XVIII reimbursement for routine hospital services.

(f) A hospital which enters into an agreement with the Secretary under this section shall be required to meet those conditions applicable to skilled nursing facilities relating to discharge planning and the social services function (and staffing requirements to satisfy it) which are promulgated by the Secretary under section 1819. Services furnished by such a hospital would otherwise constitute posthospital extended care services if furnished by a skilled nursing facility shall be subject to the same requirements applicable to such services when furnished by a skilled nursing facility except for those requirements the Secretary determines are inappropriate in the case of these services being furnished by a hospital under this section.

(g) The Secretary may enter into an agreement under this section on a demonstration basis with any hospital which does not meet the requirement of subsection (b)(1), if the hospital otherwise meets the requirements of this section.

PAGES 9-154 - 9-245 ARE RESERVED FOR EXHIBITS

84 - ESRD Facility Survey Report--Addendum

85 - Long Term Care Facility Application for Medicare and Medicaid--HCFA-671

86 - Resident Census and Conditions of Residents--HCFA-672

87 - Extended/Partial Extended Survey Worksheet--HCFA-673

88 - Medication Pass Worksheet--HCFA-677

89 - Offsite Survey Preparation Worksheet--HCFA-801

91 - General Observations of the Facility--HCFA-803

92 - Kitchen/Food Service Observation--HCFA-804

93 - Resident Review Worksheet--HCFA-805

94 - Quality of Life Assessment--HCFA-806 A, B, and C

95 - Surveyor Notes Worksheet--HCFA-807

96 - OSCAR Report 3 (History Facility Profile) and OSCAR Report 4 (Full Facility Profile)

NOTE: There are no Exhibits from 97-102

Exhibit 103

INSTRUCTIONS FOR THE HOME HEALTH FUNCTIONAL ASSESSMENT INSTRUMENT (FAI)

This assessment instrument must be used for all patients selected for clinical record review with home visit, and for patients selected for clinical record review without home visits. It is your work sheet.

The form contains 5 modules--Clinical Record Review Modules A and B, Home Visit Module C, Patient Function and Care Summary Module D, and an Agency Function and Care Summary Module E.

Write whatever notes you need in the Surveyor Notes section of each module. There are certain instances when you must write brief notes to explain your answers. Make every effort to be succinct in your responses.

Use the calendar work sheet attached to the FAI to determine whether the frequency and mix of visits was in compliance with the plan of care.

NOTE: Public reporting burden for this collection of information is estimated to average 1 hour per response. This includes time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Health Care Financing Administration, P.O. Box 26684, Baltimore, Maryland 21207, and to the Office of Information and Regulatory Affairs, Office of Management and Budget,Washington, D.C. 20503. Paperwork Reduction Project (0938-0355).

Module A

Patient Condition and Anticipated Outcomes

Survey Date: Enter the date on which you begin the record review of this patient.

Provider Medicare ID: Enter the HHA's Medicare ID number in the upper right hand corner of Module A.

Patient HI Claim No.: Enter the patient's Medicare Claim number. This is also referred to as an HI (Health Insurance) claim number. If patient does not have a Medicare number, enter N/A.

PATIENT INFORMATION

A1. Patient Name: Write in the name of the patient. This information will remain confidential. However, it is necessary for keeping track of your assessments.

A2. Date of Birth/Age: Enter patient's date of birth (DOB). Format should be month-day-year. If DOB not known, but age is, enter age. This should only be a two-digit (or perhaps three-digit) number. If six digits do not appear in this space, it will be assumed to be age.

A3.	Sex:	Check the appropriate box -- M = male; F = female.
A4.v	Referral Date:	This is the date the HHA received a referral (either written or telephone) from the physician or hospital. This is not the date that the patient's family first called. (For Medicare patients, this date can typically be found on the HCFA-485.)
	Hospital D/C Date:	Hospital discharge (d/c) date. This is the date that the patient was discharged from the hospital prior to this HHA admission. If patient was not hospitalized immediately prior to referral to HHA, enter N/A.
A5.	Start of Care:	The date of the first payable visit. (For Medicare patients, this date can typically be found on the patient's HCFA-485.)
A6.	Admitted From:	Check appropriate box. This refers to the patient's last source of care.
A7.	Patient Risk Factors:	Check the patient risk factors that are related to medical diagnoses that apply. Chronic conditions refer to those conditions that the patient may have but which don't qualify as primary or other pertinent diagnoses. Check "None Known" if there is not evidence in the record that the patient has any factors or conditions that would impact on the problems for which the patient was admitted to home health.
A8.	Family Situation / Living Arrangement:	Check only one. If the patient lives with a person other than a spouse, specify the relationship (e.g., son, daughter, friend, significant other). In some cases, the patient may live with a spouse and a child; if they live in the child's home, select child; if they live in the patient's home, select spouse.
A9.	Primary Informal Caregiver(s):	Check all that apply. The primary informal caregiver(s) is/are the person(s) the HHA has identified who will assume/share primary responsibility for looking after the patient.

A10.	Instructions:	The HHA should have ascertained whether or not the available primary informal caregiver(s) is/are able to receive instructions and provide patient care. It should not always be assumed that because there is a spouse or other person in the home that they are capable of providing care.
A11.	Living Environment:	Does the record indicate that there is reason to believe that the patient's living environment might detract from the HHA's ability to implement or complete the plan of care? (For example, bathroom does not have needed safety bars, therefore, patient will not be able to toilet self).

CONDITION/PROBLEM

A12.	Principal Diagnosis:	Enter the ICD-9-CM code and name of principal diagnosis for which patient is being treated. If known, give date of onset. (This information should be contained on the HCFA-485. For non-Medicare patients, check the HHA initial assessment and/or hospital discharge notes/plan.)
A13.	Surgical Procedure:	List all recent surgical procedures performed. Give ICD-9-CM codes (V-codes, if applicable), name, and date procedure performed.
	Other Pertinent Diagnoses:	List the name, code, and date of onset of all other presenting conditions.
A15.	Impairments:	Check all that apply.
A16.	Medications:	Review the types of medications being taken by the patient. Enter the total number of different medications that the patient is taking. There are a number of things to look for when reviewing a patient's medications orders: known contraindications that the HHA may not be aware of; HHA awareness of allergies or drug sensitivities; prescription(s) for psychotropic or mood altering drugs. If there are other situations or problems with medications noted in the patient's record, include them here. Do not list medications.
A17	Prognosis:	This refers to the HHA/physician judgment as to the patient's prognosis at the start of care. For Medicare patients, this information can typically be found on the HCFA-485. Check only one.

A18.	Medical Condition at Review:	Check the one that applies. "At review" refers to the survey review period. From reading the chart and talking with the HHA caregiver, you need to determine whether or not the patient's medical condition since admission to the HHA has improved, deteriorated, or is unchanged. You may need to wait until after the home visit to complete this assessment item.
A19.	Visits/ Services:	Review the HHA's plan of care. Also, look for interim orders. Using the calendar work sheet provided, jot down the type and frequency of visits and services ordered. You may need to ask the HHA when their "treatment week" begins. As you go through the medical record, record the number and type of visits actually made. From the data you have gathered on the work sheet, determine whether or not HHA services were delivered as ordered. Check the appropriate answer.
A20	Anticipated Outcomes:	Another word for anticipated outcomes is goals. Request that a member of the clinical staff show you the places in the clinical record where anticipated outcomes for patient care are recorded. Include in your review Form HCFA-485, "Home Health Certification and Plan of Care," and/or other records. Note any anticipated patient care outcomes that are related to the medical, nursing, and rehabilitative services ordered for this patient. These outcomes should be specific and measurable. For example, "Return to previous level of functioning" is inadequate if the medical record does not indicate what that level was, or how the HHA plans to measure its success. An adequate statement might be "Patient will return to full ambulation status, without ambulation aids, in 3 months." Since it is possible that outcomes could be revised during the course of care, include the date that the outcome was set. The HHA statute at '1891(c)(2)(C)(i)(II) requires that the standard survey include "A survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care." Therefore, it is essential that you identify how the HHA defines, plans for, delivers and measures anticipated outcomes for patients.
Multiple Outcomes:		If there are more than 6 outcomes for a patient, continue to list these outcomes on the back of Module A.
Discharge Planning:		From the record, determine if there is evidence that the HHA has begun planning toward discharge for this patient. Check the appropriate box.

Level of Achievement: For each of the outcomes listed, check the level of achievement reached by the patient. Obtain information to answer this item from the medical record, the home visit, and conversations with the HHA caregiver.

The term "Completely" implies that the patient has reached, at a minimum, the expected level of change (e.g., wound has healed, patient able to bear full weight, etc.).

The term "Partially" implies that the patient did not reach the HHA's full expectation for improvement (for whatever reason). If you check this box, explain your choice (e.g., not enough time has elapsed, patient's condition changed such that outcome achievement is delayed, etc.) If you check "Partially" there should be some indication that the patient has made progress towards achieving the goal (e.g., Stage III/IV decubitus is now a Stage II).

The term "Not at all" implies that no progress has been made toward outcome achievement. There are any number of reasons why this may be the case: "Outcome A" must be achieved before HHA can begin activities to achieve "Outcome B;" too early to determine/assess whether outcome has been met or whether measurable progress has been made. Explain your reasons for selecting this response.

Progress Notes: Does the patient's medical record contain written progress notes that describe and support the level of achievement for each of the anticipated patient care outcomes? Select the appropriate answer.

Module B

Activities of Daily Living (ADLs), Instrumental Activities of Daily Living (IADLs), Behavior, and Aids/Appliances

In this module, you will assess the patient's functioning level in the ADLs and the IADLs. USE MODULE TO REVIEW AND RECORD PERTINENT INFORMATION ONLY IF THE PATIENT'S ADMITTING DIAGNOSIS(ES) OR COMPLICATIONS OF THE SECONDARY DIAGNOSIS(ES) DIRECTLY AFFECT THE PATIENT'S POTENTIAL TO MEET HIS OR HER OWN ACTIVITIES OF DAILY LIVING OR INSTRUMENTAL ACTIVITIES OF DAILY LIVING, AND IF THERE IS RELEVANT INFORMATION THAT WOULD AFFECT THE HHA's PLANNING AND CARE OF THE PATIENT. You will also be asked to note any of the patient's behavioral or mental problems that are documented in the medical record.

The major objective of this module is to provide the surveyor with as complete a picture of the patient as possible. When preparing its plan of care, the HHA takes into consideration the patient's ability to perform certain functions for him/herself and the need for additional help; psychosocial factors, such as depression or disorientation, can also affect the patient's prognosis. In order for you to assess the appropriateness of the patient's plan of care and the anticipated outcomes, you should understand all of the factors that the HHA had to consider in dealing with this patient.

The HHA should have performed a thorough assessment on each patient at the time of admission to the agency. Review this assessment (and subsequent therapy assessments) to ascertain the patient's level of functioning at admission. Complete items B1-B6. Be sure to use the boxes marked "At Admission."

You should complete as much of Module B as possible given the information contained in the patient's medical record and what you learn from the HHA caregiver and the home visit. If the HHA is not treating one or more of these problem areas (ADLs, IADLs), it is quite possible that there will be no follow-up information about the patient's ability to perform these activities. You need only complete the "Record Review" and "Home Visit" portion of the patient and the reason(s) he/she is in home care.

NOTE: In the section that deals with IADLs, there are only two reference points -- "Record Review" and "Home Visit." Under "Record Review," include any and all information that you found in the medical record, whether it was recorded in the patient's initial assessment, or was documented subsequent to the start of care. Information that you obtained as a result of the home visit you make to the patient, record under "Home Visit."

In many instances, the HHA will have included changes in ADLs as part of the anticipated outcomes for a patient, e.g., post-stroke patients receiving physical therapy. Progress notes should indicate changes in the patient's functioning level. From your review of the clinical record, assess the patient's most current documented functioning level and check the most appropriate box under the "Record Review" line. Information about patient progress should be found somewhere in the chart.

B1-B12 Responses: Needs no assistance--this implies that the patient is capable of performing this activity by himself/herself, without the assistance of another person. If patient uses a mechanical device but performs the activity without the help of another, patient is considered to "need no assistance." For example, a patient uses a walker or cane and is capable of ambulating without the help of another; he/she is, therefore, considered to "need no assistance."

Helped by a person--this implies that the patient is able to perform some major part of the activity, but requires the assistance of another person with some portion of the activity. For example, patient is capable of bringing food to his/her mouth, but he/she cannot cut meat or butter bread.

Unable to do--this implies that the patient cannot carry out any significant portion of the activity--the entire function is performed for the patient by another person. For example, patient can walk to the bathroom but is neither able to transfer self to the toilet nor clean self afterwards, or patient uses bedpan that is emptied by another person.

If there is insufficient information to allow you to determine the functioning level of the patient, record this finding in the surveyor notes.

Needs More Help: Check "yes" if there is evidence that the patient needs more help than he/she already has at "Record Review" time and "home visit". Use your own judgment as to whether or not more help is needed. Please remember that "needs more help" is not a wish list of services the patient "could use". If you indicate that the patient "needs more help", you must provide an explanation for your decision, and describe the kind of help you feel the patient needs. You must also note in your explanation whether or not the medical record documents indicate that the HHA is planning to provide additional help.

B1-B6 Summary For the ADL, compare the patient's current functioning level with that at admission. Determine whether or not you think the patient has improved, is unchanged, or has deteriorated. If the patient has improved or deteriorated, provide a brief explanation. Check only one answer for each ADL.

B13.Behavioral/ Mental:	Write down all behavioral or mental conditions noted in the record (e.g., Alzheimer's disease, patient tends to wander, patient alert, etc.).
B14. Appliances:	Check the appropriate list of appliances and aids used by the patient. Note that there are two columns -- "Record" and "Home Visit." Check under "Record" all of the appliances and aids noted in the medical record; check under "Home Visit" all of the aids or appliances used by the patient that you saw in the home.

Exhibit 103 (Cont.)

Module C

Home Visit Module

This module must be used during the home visit. The purpose of the home visit is to allow the surveyor to see the patient, assess his/her understanding of the medical reasons that Medicare/Medicaid home care is being provided, assess the functioning level in ADLs and IADLs (if appropriate), and ascertain the presence of behavioral/mental problems. During this visit, the surveyor will also need to determine if there are environmental factors that could influence progress in the course of care. The home visit provides several sources of information--conversations with the HHA caregiver, conversations with the patient and the informal caregiver (if present), and direct observation. Good interviewing skills are a prerequisite to a successful home visit. You must not appear to be reading questions. You should try to establish a rapport with the patient/family. Try not to depend too heavily on the HHA caregiver. However, you should maximize your role as observer in an effort to minimize the need to ask a lot of questions.

FAMILY SITUATION

C1. Living Arrangement:	Through conversation with the patient and/or the informal caregiver, verify the information contained in the medical record and recorded on Module A. Check the appropriate answer. If there is a discrepancy between the record and information obtained during the home visit, please explain. You may ask the HHA caregiver to explain. (For example, the daughter may have been living with the patient, but has since returned to her own home.)
C2. Primary Caregiver:	Verify who the primary informal caregiver(s) is(are) for this patient. Refer back to information recorded on Module A. Explain any discrepancy.
C3. Instructions:	Is(Are) the informal caregiver(s) able to receive instructions and provide the necessary care to the patient? You should determine this through conversation with and observation of the informal caregiver(s) who is(are) present during your home visit. Do not simply ask caregivers if they understand instructions. They should give you an example of what it is they do for the patient. You should include at least one example in your surveyor notes.

MEDICAL CONDITION PROBE

Through observation and conversations with the patient, the informal caregiver(s), and the HHA caregiver, determine the influence that the HHA has had in helping the patient/caregiver understand the patient's medical condition. There are seven things that you will focus on -- their understanding of the primary condition, how the care received relates to the condition, how to report changes in the patient condition, their understanding of medication regime, diet, patient rights, and how to use the State home health hotline.

C4-C10 Responses: Yes, Patient -- Yes, the patient has provided evidence that he/she understands
.

Yes, Caregiver -- Yes, the caregiver has provided evidence that he/she understands.

Yes, Both -- Both the patient and the caregiver have provided evidence that they understand. Check this answer only if both have actually shown some understanding. Do not assume that because one understands, the other does too
.

No -- Neither the patient nor the informal caregiver have demonstrated a sound understanding of the question.

Unknown -- Check this only if you were unable to ascertain the level of understanding. If "unknown," provide an explanation.

FUNCTIONAL CAPACITY PROBE

C11. ADLs: Determine the patient's functioning level in the relevant ADLs. You can do this through direct observation as well as through conversation with the patient and/or the informal caregiver. Record your responses on the ADL section of Module B.

C12. IADLs: Determine the patient's functioning level in the relevant IADLs. You can do this through conversation with the patient and/or the informal caregiver. Record your responses on the IADL section of Module B.

ENVIRONMENTAL PROBE

C13. Influence of Environmental Factors: Through conversation and observation, determine whether there is anything in the patient's living environment that could influence the plan of care and/or progress toward meeting anticipated outcomes. If you identify environmental factors, ascertain whether these influences have been discussed with the patient/caregiver by HHA staff and recorded in the clinical record, if appropriate. Explain in brief.

BEHAVIORAL/MENTAL PROBE

C14. Influence of Patient Behavior Problems/Mental Status: Through conversation and observation, determine whether the patient exhibits any behavioral or mental problems that could influence the course of care and/or progress. You must also consider whether behavior problems or mental status could influence the patient's response to instructions about his/her rights. Explain in brief.

Exhibit 103 (Cont.)

Module D

Patient Function and Care Summary

This module should be filled out for each patient after the home visit and record review have been completed. Use the Surveyor Notes section to explain your answers. This will prove extremely useful when completing the Agency Summary Form.

D1. Review Area:

Record Completeness. -- Check only one answer. Did your review of the record indicate that the required documentation was present in the record? Was the documentation informative? Are the records up-to-date? Possible responses include:

- o Substantially complete -- All (or nearly all) of the required documentation was in the record and was up-to-date.
- o Partially complete -- The patient's record was lacking some of the required documentation (even though the documentation was produced when the surveyor asked for it), or the documentation that was present was not informative or descriptive of patient condition/services provided.
- o Substantially incomplete -- Major portions of the required documentation could not be found in the record.

Record Agreement with In-Home Observation. -- Check only one answer. Does the patient's medical record accurately reflect what you observed during your home visit? (IF NO HOME VISIT MADE TO THIS PATIENT, NOTE THIS IN SURVEYOR NOTES SECTION AND PROCEED TO NEXT REVIEW AREA.) Possible responses include:

- o Substantially -- For the most part, the record paints an accurate picture of the patient's medical condition, functioning level, and home environment (including ability of informal caregiver to provide care).
- o Partially -- There are some discrepancies between what the record states and the patient's actual situation. Please explain your choice.
- o Not at all -- There is very little resemblance between what the record states and what you observed during the home visit. Please explain your choice.

Adherence to Plan of Care. -- Review the plan of care, and any subsequent change orders (the calendar work sheet should be useful for this). Determine whether or not the HHA followed the plan of care, in terms of number and type of visits made as well as the types of services delivered. The adherence to the plan of care for the medical condition should be viewed separately from the plan of care that deals with the ADLs. (If there is no care plan that deals with ADLs, check the appropriate box in the ADL line.) Possible responses include:

- Complete Adherence -- HHA was thorough in following the established plan of care. (Be careful to take into consideration the fact that the case may still be active.)

- Partial adherence -- HHA, in some cases, did not provide the prescribed number and type of services, and there is not a change order in the record to explain any diversion from the original plan of care. Explain the reasons for your choice.

- No adherence -- HHA has habitually disregarded the plan of care in providing services to this patient. Explain the reasons for your choice.

Patient Condition. -- To complete this review area, you must consider what the patient looked like at admission, and what you know the patient to look like at the time of your review (based on record review and/or home visit).

The Patient Status for Medical Condition Should be Viewed Separately From That for ADLs.-- If ADLs are not relevant to this case, check the appropriate box in the ADL line. Possible responses include:

- Improved -- The condition of the patient is better now than it was at the time of admission.

- Unchanged -- The condition of the patient has essentially not changed since he/she was first admitted to the HHA. (In many cases, change may not be expected, so don't view this necessarily as a negative judgment.) Briefly explain your choice.

- Deteriorated -- The condition of the patient has measurably deteriorated since the time of admission to the HHA for care. Briefly explain your choice.

SUMMARY EVALUATION OF PATIENT'S CARE

This section of the summary contains a set of eight questions that address your assessment of the appropriateness of the HHA's assessment, plan of care, and anticipated outcomes. Be sure to write surveyor notes to support your answers.

D2.	Assessment	Determine whether the assessments that the HHA made of the patient's medical ,nursing, and rehabilitative needs were appropriate at the start of care, and as care progressed. If you answer "No," provide an explanation under surveyor notes.
D3.	Plan of Care	Determine whether the types and frequencies of the services prescribed in the initial plan of care are appropriate. Consider such factors as the patient's condition at admission and the HHA's anticipated patient outcomes. If you answer "No," provide an explanation under surveyor notes.
D4.	Changes to The Plan of Care	Was the plan of care changed appropriately during the course of treatment to reflect any changes in the medical, nursing, and rehabilitative needs of the patient? Note that this refers to unanticipated changes in patient needs. For example: patient discharged sooner, or patient being treated for diabetes fell and broke a limb, additional home health aide services were ordered. If you answer "No," provide an explanation under surveyor notes.
D5.	Coordi-nation of Services	Did you see evidence of coordination of services between (and among) the various disciplines treating this patient? If you do not find evidence in the medical record, it might be necessary to review HHA minutes of care planning meetings. If you answer "No," provide an explanation under surveyor notes.
D6	Therapy Services	Did the therapists treating this patient specify the procedures and modalities to be used, as well as the amount, frequency, and duration of these services? If you answer "No," provide an explanation under surveyor notes.
D7.	Patient Progress	Did the information you obtained through observation and conversation during your home visit lead you to conclude that the patient's progress (or lack of progress) was appropriate, given the patient's admitting and current medical and functional status? If you answer "No," provide an explanation under surveyor notes.

D8.	HHA Services Patient Status	Does the information you have reviewed on this case lead you to conclude that the HHA intervened appropriately and that the services provided to the patient made a difference in the patient's current medical and functional capacity? If you answer "No," provide an explanation under surveyor notes.
D9.	Additional Service Needs	In your judgment, could the HHA have done more to assist the patient in meeting medical, nursing, and/or rehabilitative needs within the range of usual HHA practice? If you answer "Yes," provide an explanation under surveyor notes and cite specific examples.

Exhibit 103 (Cont.)

Module E

Agency Function and Care Summary

Survey Dates: Enter the dates that cover the period of time spent in this HHA's survey.

HHA Name: Enter the name of the HHA. (If this is a chain, or multi-site HHA, enter the city/town of this particular agency.)

Medicare Provider ID: Enter the HHA's Medicare Provider Number.

Service Area: Check only one service area type. If you are unsure how to describe an HHA's service area, ask the administrator.

No. Records/ Home Visits: Number of records reviewed with home visits.-- Enter the total number of patients for whom you conducted both a record review and made a home visit.

This module is to be completed only after you have reviewed the requisite number of records and conducted the required number of home visits.

Number of records reviewed, no home visit.-- Enter the total number of patients for whom you conducted a record review only -- that is, you did not conduct a home visit.

Number of home visits with no record review.-- Enter the total number of patients for whom you conducted a home visit but did not complete a record review.

Total number records reviewed.-- Enter the total number of records reviewed during this survey, whether or not you conducted a home visit.

Total number of home visits.-- Enter the total number of patients for whom you conducted home visits, whether or not you completed a record review.

Summary Observation: Check only one box for each of the review areas. These review areas are similar to those contained on the individual patient function and care summaries. Refer back to those when summarizing the HHA here. The responses include:

Favorable for most patients -- For the most part, the HHA receives high marks.

Favorable for some patients -- The HHA does not consistently receive favorable marks for patients in this review area. Explain your choice.

Unfavorable for most patients -- The HHA has demonstrated a pattern of inadequate marks in this review area. Explain your choice.

Review Areas:

Appropriateness of Assessments.-- Determine whether the assessments that the HHA made of its patients' medical, nursing, and rehabilitative needs were appropriate at the start of care and as the care progressed.

Appropriateness of Care Plans and Services.-- Determine whether the types and frequencies of the services prescribed in the initial plans of care were appropriate for the patients in this HHA.

Adherence to Plan of Care.-- Determine whether the HHA followed the plans of care it established for the patients included in your review. This includes the frequency, type and duration of the services prescribed.

Coordination of Services Between Disciplines.-- Determine whether there is evidence of coordination of services between (and among) the various disciplines treating patients in this HHA.

Completeness of Documentation.-- Determine whether the medical records of the patients you reviewed were complete, that is, they contained all of the requisite documentation and that documentation was informative and up-to-date.

Treatment Contribution of HHA.-- Determine whether the HHA intervened appropriately and whether the services provided to its patients made a difference in meeting their medical, nursing, and rehabilitative needs.

Surveyor Summary:

Before completing the surveyor summary, evaluate compliance with 42 CFR 484.12(a) and (b) and 42 CFR 484.36. (See '2204.) Read each of your 3 choices carefully before deciding whether there is evidence of a need for further action. Explain your decision.

Exhibit 103 (Cont.)

Calendar Work Sheet

The last page of the FAI is the Calendar Work Sheet (HCFA-1515F). Use it to determine whether the frequency and mix of visits is in compliance with the plan of care. This information is necessary to determine compliance with 42 CFR 484.18(a) and (b).

Before completing the work sheet, find out how the HHA defines its work week, that is, does its work week begin on a Sunday or the Start of Care (SOC) date? Also, find out from the HHA where the actual service dates are recorded in the patient's record.

To complete the work sheet, record the SOC date in the space provided. Complete the upper left-hand section which describes the planned frequency and duration of visits for each discipline. Put the calendar dates (June 1, June 2, etc.) for the period being evaluated in the upper left-hand corner of each box in the work sheet. Record the services actually provided in each day's box using the abbreviations for the disciplines. Use the most recent (re)certification period during which care was given to evaluate compliance with this regulatory requirement.

Determine whether the actual frequency of care delivered was in compliance with the frequency of care ordered by the physician. Circle any discrepancies.

PAGE 9-262 IS RESERVED FOR EXHIBIT

104 - Consent for Home Visit--HCFA-36 U3

Exhibit 105

State Test Administration Plan

Design your State's Test Administration Plan for the Surveyor Minimum Qualifications Test (SMQT) according to the instructions contained in "4009.1 and 4009.2 as follows:

1. Proposed Test Site Locations: **State:**_____

Name(s) of City/Town	Location(s)	N Rooms & Room capacity per Location

2. State Test Coordinator:

Name:
Position:
Agency:
Mailing Address:

Phone Number:

3. State Test Monitor(s) (Also include the names of Substitute Test Monitors who will fill in if necessary):

Name:
Position:
Agency:
Mailing Address:

Phone Number:

Name:
Position:
Agency:
Mailing Address:

Phone Number:

Name:
Position:
Agency:
Mailing Address:

Phone Number:

PAGES 9-264 AND 9-265 ARE RESERVED FOR EXHIBIT

106 - Laboratory Personnel Report (CLIA)--HCFA-209

Exhibit 107

REQUEST FOR VALIDATION SURVEY OF LABORATORY

1. Name of State	2. Name and Address of Laboratory
	CLIA #

3. Lab Accredited By:

4. [ ] This validation is based on sample selection. Please conduct full survey within 60 days per SOM instructions. Survey should be unannounced.

5. [ ] This validation is based on a substantial allegation of noncompliance. Please investigate areas checked below. Survey should be unannounced.

6. Area(s) to be Inspected

CONDITION(S)	STANDARD(S) OR SPECIALTIES/SUBSPECIALTIES
[ ] Proficiency Testing	
[ ] Patient Test Management	
[ ] Quality Control	
[ ] Personnel	
[ ] Quality Assurance	
[ ] Other	(i.e., waivered lab performing non-waived tests)

7. Remarks:

8. Regional Representative	9. Region	10. Date

HCFA-2802A

Exhibit 108

LABORATORY AUTHORIZATION FORM

Laboratories may meet their legal obligations for accreditation or CLIA exemption as mandated by CLIA either by maintaining accreditation status by a Federally approved accreditation organization, or by being exempt from CLIA by virtue of the fact of being located in a State with a HCFA-approved laboratory licensure program.

As representative of a laboratory, which fits either of these categories, I am authorizing, by my signature below, the accreditation organization which accredits my laboratory, or the State which licenses my laboratory, to release a copy of this laboratory's most recent accreditation report, or most recent licensure survey report, respectively to the Secretary of Health and Human Services (and the Secretary's designated agents).

Signature_____

Name (typed):_____

Title:_____

Date:_____

Name of accrediting organization:_____

or

Name of approved State laboratory program:_____

Exhibit 110

Compliance Warning Letter
Failure to Apply for Certificate

CERTIFIED MAIL -- RETURN RECEIPT REQUESTED

Dear (Laboratory Director):

It has come to the attention of the Health Care Financing Administration (HCFA) that your laboratory is performing laboratory testing without the appropriate CLIA certificate.

Section 353(b) of the law states that "No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure." Therefore, you are in violation of CLIA.

Laboratory testing must be discontinued immediately and remain discontinued until the laboratory is properly certified as stipulated by CLIA. A written response to this letter is required within 15 days after certified receipt date. Failure to respond will result in further investigation.

Your response should be directed to:

(Name) _____

(Address) _____

(Attention) _____

For immediate response you may call:

Sincerely,

Exhibit 111

Model Letter Notifying Laboratory of Cited Deficiencies
and Requesting a Plan of Correction

CLIA Number:

Dear (Name of Laboratory Director):

The (name of State survey agency) conducted a certification survey of your laboratory on (date). Enclosed is the Statement of Deficiencies found during that survey (HCFA Form 2567).

You are requested to indicate your Plan of Correction on the right side of the form, keying your responses to the deficiency on the left. Please indicate your anticipated completion dates in the appropriate space.

Please return the Form HCFA-2567, dated and signed by the director, within 10 days of receipt.

If you have any questions, please call _____.

Sincerely,

Enclosure

Exhibit 112

CLIA REQUIREMENTS NOT MET - LABORATORY OUT OF COMPLIANCE

CLIA Number:

Dear:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, and bill for services provided to Medicare beneficiaries or Medicaid recipients under Titles XVIII and XIX of the Social Security Act, it must comply with all CLIA Requirements (42 CFR 493). The date of survey and date(s) of revisit(s) reports of your laboratory have been reviewed by this office and transmitted to the Division of Health Standards and Quality Regional Office.

The survey reports reveal there are areas of deficiencies that are preventing your laboratory from being in compliance with the CLIA Requirements. Based on our review, the following Conditions are not in compliance:

(List all Condition level regulatory citations)

The Plan of Correction you have submitted has been reviewed and forwarded to the Regional Office. Since your facility does not comply with all requirements, we are recommending a certification of non-compliance to the Regional Office and that the following sanction(s) be imposed and/or enforcement action(s) be taken:

(List alternative and/or principal sanctions to be imposed
and/or enforcement action(s) to be taken)

The Regional Office has final authority for this determination and will inform you of its determination and the appeals procedures.

If you have any questions regarding this matter, please contact _____.

Sincerely,

Enclosures

Exhibit 113

CLIA REQUIREMENTS NOT MET - IMMEDIATE JEOPARDY

CLIA Number:

Dear:

Our records indicate that (name of laboratory) is certified to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578.

Federal regulations require surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with such regulations is a condition of certification for the federal program.

The (name of State survey agency) conducted a survey on (the last date of survey) and issued a Statements of Deficiencies and Plan of Correction (HCFA-2567). At that time it was determined that the following deficiencies exist, which pose immediate jeopardy to the patients served by your laboratory:

(List all Condition level regulatory citations)

Because of the seriousness of these deficiencies, your laboratory no longer meets the requirements to perform testing under CLIA. As a result, this office has contacted the Health Care Financing Administration's (HCFA) Regional Office (RO), and has recommend a certification of non-compliance and the following sanction(s) be imposed and/or enforcement action(s) be taken:

(List sanctions to be imposed including rationale, projected effective date, duration of the proposed sanction(s) and/or enforcement actions(s) to be taken)

Please be advised that sanctions and/or enforcement action can be rescinded only when compliance with the above deficiencies is verified. If you believe that correction has been accomplished, it is your responsibility to contact the RO with a credible allegation of compliance, so that the removal of the jeopardy can be verified.

The RO will advise you of the sanctions(s) to be imposed and/or enforcement action which will be taken if the jeopardy is not removed. At that time you will also be notified of your appeal rights.

If you have any questions, or would like additional information, please contact (State agency contact person) at (telephone number) or the HCFA-RO directly.

Sincerely,

State Agency Representative

Enclosures

Exhibit 114

Model Letter Warning CLIA Laboratory of Possible Sanction -
Failure to Disclose Financial Interest and Ownership Information

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

CLIA Number:

Dear _____:

Laboratories which provide services under the Clinical Laboratory Improvement Amendments (CLIA) program are required by law to provide ownership and financial control information. To date, we have not received the requested information from your laboratory.

Enclosed is another copy of the Disclosure of Ownership and Control Interest Statement, HCFA-1513, to be completed by your laboratory if you wish to participate in the CLIA program.

* If this information is not received within 20 days, your laboratory may be sanctioned.

* If this information is not received within 20 days, your request to participate in the CLIA program may be denied.

Sincerely yours,

Enclosure

*Use applicable sentence.

Exhibit 115

Model Letter
CHANGE OF OWNERSHIP - LABORATORIES

CLIA Number:

Dear:

We have been notified that your laboratory changed ownership effective date. When a laboratory undergoes a change of ownership, the existing CLIA Identification number is automatically assigned to the new owner. The new owner is subject to all terms and conditions under which the existing number was issued. Your laboratory continues to be approved to provide the same tests and procedures as performed under the previous ownership.

OPTIONAL PARAGRAPH--DEFICIENCIES
At the time of the last survey, certain deficiencies were cited. You must comply with the plan of correction submitted for those deficiencies.

OPTIONAL PARAGRAPH--MEDICARE CERTIFIED LABORATORY
The name of carrier/fiscal intermediary has been authorized to process your Medicare claims. Your laboratory has been assigned the identification number shown above. This number should be entered on all forms and correspondence relating to the CLIA and Medicare programs.

You should notify the State agency if there is a change in your legal status as owner of this facility. You should also report to the State agency any changes in staffing, services, or organization which might affect your certification status.

We welcome your participation and look forward to working with you in the administration of the CLIA or CLIA and Medicare program(s).

Sincerely,

PAGES 9-274 - 9-451 ARE RESERVED FOR EXHIBITS

116 - Budget Requests, Clinical Laboratory Improvement Amendments Program--HCFA-102

117 - Quarterly Expenditure Report Clinical Laboratory Improvement Admendments Program--HCFA-103

118 - Budget Notice of Approval, Clinical Laboratory Improvement Amendments Program--HCFA-104

119 - Planned Workload Report, Clinical Laboratory Improvement Amendments Program--HCFA-105

120 - Standard Form 1199A, Director Deposit Sign-Up Form

121 - Payment Management System, SMARTLINK II User=s Manual

122 - OMB Circular No. A-102

123 - Blood Bank Inspection Checklist and Report, HCFA-282

124 - Laboratory Personnel Report--HCFA-114

125 - Clinical Laboratory Application--HCFA-116

Exhibit 126

Model Letter Accompanying Self-Attestation Work Sheets

Name of PPS-Excluded Hospital or Hospital
Containing PPS-Excluded Unit
Address
City, State, Zip

Dear Name of Hospital/Unit :

If this facility or unit continues to be eligible for exemption from the Medicare Prospective Payment System (PPS) for the fiscal year beginning ___, the Administrator or Chief Executive Officer of the hospital (i.e., the individual principally responsible for the operation of the hospital) must complete and return the attached attestation statement and work sheet. Hospitals and units may be excluded from PPS if they meet certain requirements of 42 CFR Parts 412.23 through 412.30 and '2803 of the Provider Reimbursement Manual. Excluded units are paid under cost reimbursement rules at 42 CFR Part 413. If a hospital/unit does not in fact meet the exclusion criteria, Medicare payment will be made under the PPS.

According to our records the (name of PPS-excluded hospital or unit) will need to be reverified by (date). In order to continue to receive payment under Medicare and Medicaid as a (type of PPS-excluded hospital or unit), an officer of the hospital/unit must certify, at least 90 days prior to the beginning of the next cost reporting period, that the hospital or unit currently meets and will continue to meet all of the PPS-exclusion criteria.

In order to receive the certification in a timely manner, the Administrator or Chief Executive Officer, as appropriate, of the hospital must:

- Respond to every item on the attached worksheet;

- Sign and date the front page of the attached worksheet (Form HCFA-437, 437A or 437B, as appropriate) in the space marked, "Verified By:"; and

- Return both the signed attestation statement and the signed completed work sheet to (State agency address) by (date that is 90 days prior to the beginning of the cost reporting period).

Please note that the hospital/unit should notify the Regional Office (RO address) immediately if it does not wish to continue as a PPS-excluded hospital/unit. In addition, if hospitals/units are not interested or otherwise unable to use the self-attestation process to apply for continued exclusion from PPS, a survey process may be used to determine if the hospital/unit should continue to be excluded from PPS.

Please note that hospitals/units are under a continuing obligation to notify the State agency if the hospital or unit fails to meet one of the applicable requirements in the period between the attestation and the start of the fiscal year. HCFA will continue to verify separately, through the appropriate fiscal intermediary, compliance with certain criteria (e.g., the 75% requirement for rehabilitation units) currently verified by the fiscal intermediary. Please be advised that HCFA may validate the compliance of any requirement without prior notice.

If there are any questions about the requirements or completion of the worksheet or the attestation, please contact (name, address and telephone number of contact person).

State Agency Director
Signature

Exhibit 127

Attestation Statement for Exclusion from PPS
for Fiscal Year Beginning: _____

Name of State Agency Director
Name of State Agency
Address
City, State, Zip

Dear (State Agency Director):

This attestation must be signed by the Administrator/Chief Executive Officer of the hospital (including hospitals with excluded units).

ATTENTION: Read the following carefully before signing.

STATEMENTS OR ENTRIES GENERALLY: Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (18 U.S.C., Sec.1001)

Based upon my personal knowledge and belief, I attest that the responses on the attached prospective payment system (PPS) exclusion work sheet are true and correct, and that (name of PPS-Excluded Hospital or Unit) currently meets and will continue to meet the applicable requirements for exclusion from PPS for the period beginning (first day of hospital's fiscal year), as set out in Subpart B of 42 CFR Part 412. I agree that if the (hospital or unit) fails to meet any of these requirements between the date of attestation and the first day of the hospital's fiscal year, I will notify the Regional Office (name and address of RO) of the change immediately in order to permit a valid determination of distinct part status prior to the beginning of the fiscal year. (Include the next sentence for units only): The unit is located in (enter building name, room numbers and address), and consists of square feet.

I understand that the Health Care Financing Administration (HCFA) or its representative has the right to conduct an on-site survey at any time to validate whether the statements made on the attached work sheet are true.

Signature_____
(Administrator/Chief Executive Officer of the hospital)
Title_____
Date_____

Fill in blanks before sending the form to the facility.

Exhibit 128

MODEL CONSENT FOR HOSPICE HOME VISIT FORM

_____

BENEFICIARY NAME ADDRESS

_____

By this document, I hereby consent to have State/Federal survey personnel visit me at home to ensure that Federal requirements are met and to evaluate the effectiveness and quality of the hospice services provided by

_____.
(Name of Hospice)

I understand that consent for this visit is voluntary and that my rights to confidentiality or privacy are not waived by my consent.

I also understand that refusal to consent to a home visit or refusal to permit entry into my home, if previous consent was given, will have no effect on the level or nature of the Medicare/Medicaid benefits to which I am entitled.

_____
Beneficiary (or Representative of the Beneficiary) Signature / Date

_____
State/Federal Representative Signature / Date

Copy Designations

File Copy
Hospice Copy
Patient Copy

PAGES 9-456 AND 9-457 ARE RESERVED FOR EXHIBIT

129 - Hospice Survey and Deficiencies Report--HCFA-643

Exhibit 130

MODEL LETTER TO ENTITY SEEKING PARTICIPATION IN MEDICARE AS A COMMUNITY MENTAL HEALTH CENTER (CMHC) PROVIDING PARTIAL HOSPITALIZATION SERVICES

Dear _____:

If you desire to participate in the Medicare program as a CMHC providing partial hospitalization services, you must submit your request to this office. Your signed agreement will be considered an official application and agreement to abide by the requirements for CMHCs. The information in the Crucial Data Extract Form must also be provided to us as part of your request. (See enclosures.)

If it is determined that all Federal requirements are met, you will receive notification that your facility has been approved to furnish these services, and you will be assigned a CMHC identification number. The effective date of the agreement for the CMHC benefit will be the date that we receive attestation from you that all Federal requirements are met if we concur and certify that your facility is determined to meet the Federal requirements on that date. The final decision is made by the regional office.

Those facilities that are denied approval to participate in the Medicare program will be notified and given the reasons for the denial, and informed of any appeal rights.

You are required to notify the Health Care Financing Administration (HCFA) at the time you plan a transfer of the ownership of the CMHC. If operation of the entire facility is later transferred to another owner, ownership group, or to a lessee, the CMHC identification number will be automatically assigned to the successor following notification.

Each facility must independently meet the Federal requirements for CMHCs and be assigned a separate CMHC identification number. The facility must also conform to the provisions of section 1866 of the Social Security Act.

Please do not hesitate to contact this office if you have any questions.

Sincerely yours,

Enclosures

Exhibit 131

Community Mental Health Center Crucial Data Extract

_____ _____
Provider No. Facility Name/Address Date

Telephone No: (____)

Is this part of a Medicare/ Medicaid Provider? _____Yes _____No

If "Yes" indicate either: A. Hospital Provider No. _____
B. Home Health Agency Provider No. _____
C. Other Provider No. _____

Type of Ownership or Control: Enter number: _____

___ (01) Proprietary
___ (02) Church related
___ (03) Nonprofit Corp.
___ (04) Other nonprofit
___ (05) State
___ (06) Local
___ (07) Federal

Enter number of full time equivalents (FTEs) providing services below:

	Directly	Under Arrangement/Contract
M.D. (Psychiatrist)	_____.___	_____.
M.D. (Other)	_____.___	_____.
Psychologist	_____.___	_____.
Nurse	_____.___	_____.
Social Worker (B.S.W.)	_____.___	_____.
Social Worker (M.S.W.)	_____.___	_____.
Therapist (Recreational)	_____.___	_____.
Therapist (Occupational	_____.___	_____.
Therapist (Group)	_____.___	_____.
Other (Specify)	_____.___	_____.
Total Services:	_____.___	_____.

The following data are to be completed by the State Agency:

_____ State/County Code: _____ _ _ _ _ _
State/Region Code:____

Exhibit 132

Public Health Service Act - Section 1916 (c)(4)

Section 1916(c)(4) requires the community mental health center (CMHC) to provide:

- Outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically ill, and residents of the CMHC's mental health service area who have been discharged from inpatient treatment at a mental health facility;
- 24 hour-a-day emergency care services;
- Day treatment, other partial hospitalization services, or psychosocial rehabilitation services;
- Screening for patients being considered for admission to State mental health facilities to determine appropriateness of such admission; and
- Consultation and education services.

Exhibit 133

HEALTH INSURANCE BENEFIT AGREEMENT

(Agreement between the Secretary of Health and Human Services and Community Mental Health Center Pursuant to Section 1866 and Section 1861(ff) of the Social Security Act (the Act), as amended, and Title 42 Code of Federal Regulations (CFR) Chapter IV, Parts 400, 410, 424, and 489)

For purposes of establishing eligibility for payment under title XVIII of the Act, (name of facility) hereinafter referred to as the Community Mental Health Center, hereby agrees to:

(A) Maintain compliance with §1861(ff)(3)(B)(i) of the Act by providing the services described in §1916(c)(4) of the Public Health Service Act;

(B) Maintain compliance with §1861(ff)(3)(B)(ii) of the Act by meeting applicable licensing or certification requirements for community mental health centers in the State in which it is located; and

(C) Maintain compliance with the requirements set forth in Parts 400, 410, 424, and 489 of Chapter IV, Title 42 of the CFR, and to report promptly to the HCFA any failure to do so.

I certify that I have reviewed each Federal requirement indicated above and that (name of facility) was and continues to be in compliance with the applicable requirements effective (effective date). I also certify that I agree to comply with the provisions of §1866 of the Act.

ATTENTION: Read the following provision of Federal law carefully before signing:

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years or both. (18 U.S.C. §1001).

Name _____ Title

Date

This agreement, upon submission by the community mental health center and upon acceptance for filing by the Secretary of Health and Human Services, shall be binding on the community mental health center and the Secretary. The agreement may be terminated by either party in accordance with regulations. In the event of termination, payment will not be available for community mental health center services furnished on or after the effective date of termination.

In the event of a transfer of ownership, this agreement is automatically assigned to the new owner, subject to the conditions specified in this agreement and 42 CFR 489, and includes existing plans of correction and the duration of this agreement.

This agreement shall become effective on the date specified below by the Secretary or the Secretary's delegate.

Accepted for the provider of services by:

Name (Signature): _____

Title:_____

Date: _____

Accepted by the Secretary of Health and Human Services by:

Name (Signature): _____

Title:_____

Date:_____

Exhibit 134

Model Letter: Letter Transmitting Materials to
Rural Primary Care Hospitals (RPCHs)

Name of RPCH Administrator,
CEO, or Responsible Individual
Name of RPCH
Street Address
City, State, Zip

Dear _____:

This letter concerns the requirements and procedures through which (name of facility) may be approved under Medicare as a Rural Primary Care Hospital (RPCH). This State agency (SA) certifies and periodically recertifies RPCHs to assist the Health Care Financing Administration (HCFA) in determining whether they meet the Medicare Conditions of Participation for RPCHs at 42 Code of Federal Regulations (CFR) Part 485. Such approval is prerequisite to qualifying for participation in the Medicaid program as well.

To be eligible for certification under Medicare as an RPCH, (name of facility) must first be designated as an RPCH by the State in which you are located or by HCFA under the authority in §1820(i)(2) of the Social Security Act (the Act). In addition, it must also:

- Have a Medicare participation agreement as a hospital and be in compliance with the Medicare hospital Conditions of Participation (CoPs) (if name of facility has closed, it must meet the criteria for closed facilities found at §1820(f)(1)(B) of the Act) (copy enclosed);

- Be located in a rural area as defined at §1866(a) of the Act (copy enclosed);

- Agree to cease providing inpatient care as defined at §1820(f)(1)(F) of the Act, i.e., in not more than six inpatient beds (or no more than 12 beds, if the facility has a Medicare swing-bed agreement) for a period of time not to exceed 72 hours, unless transfer to a hospital is precluded because of inclement weather or other emergency conditions;

- Agree to make available 24-hour emergency care; and

- Meet the requirements of the CoPs for RPCHs found at 42 CFR Part 485 (copy enclosed).

The enclosed application forms, "Hospital Request for Certification in the Medicare/Medicaid Program" (Form HCFA-1514) and the "Ownership and Control Interest Disclosure Statement" (Form HCFA-1513), must be completed and signed if the facility wishes to be approved. Except for the first copy of the Form HCFA-1513, which you may retain, complete and return all other copies of the enclosed forms.

While your facility's basic eligibility is being decided, we will arrange to perform a survey of its compliance with the CoPs. An early survey assures the earliest possible effective date of coverage. Our surveyors will inspect the facility, interview you and members of your staff, review documents, and undertake other procedures necessary to evaluate the extent to which the facility meets the CoPs. If the facility has significant deficiencies in any of the CoPs, you will be informed and given an opportunity to correct them.

Exhibit 134 (Cont.)

Please be advised that (name of facility) may not be paid as an RPCH prior to the effective date for certification in the Medicare program.

Please do not hesitate to contact this office at (Telephone Number for SA) if you have any questions regarding the RPCH survey process.

Sincerely yours,

State Agency

Official
Enclosures: Section 1820(f)(1)(B) of the Act
Section 1866(a) of the Act
Hospital Request for Certification in the Medicare/Medicaid Program (Form HCFA-1514)
Ownership and Interest Control Disclosure Statement (Form HCFA-1513)

Exhibit 135

Model Letter: Notification to Rural Primary Care Hospital
Regarding Scheduling a Survey

Name of RPCH Administrator
CEO, or Responsible Individual
Name of RPCH
Street Address
City, State, Zip

Dear _____:

The purpose of this letter is to notify you that (Name of RPCH) has been scheduled for a health and safety survey for compliance with the Conditions of Participation at 42 CFR Part 485 on (Date of Survey).

Please make available for review at the time of the survey the following material:

o A copy of the facility's written policies, procedures, agreements and/or arrangements covering: emergency services, bed size and length-of-stay, organizational structure and lines of authority, staffing and staff responsibilities, provision of services, clinical records, and periodic evaluation and quality assurance (QA);

NOTE: If QA requirement at 42 CFR 485.641(b) is provided by arrangement with a Medicare-participating hospital, the individual responsible for the RPCH QA program must be available to meet with the survey team. That individual must also make available documentation needed by the survey team to conduct an evaluation of the facility QA program.)

o A list of all services the facility provides directly and services provided through agreements or arrangements;

o Names, and evidence of appropriate licensure for all facility personnel, where applicable;

o Evidence of professional qualification for all physician assistants, clinical nurse specialists and/or nurse practitioners who are members of the facility staff;

o Evidence that the facility has an agreement or arrangement with a doctor of medicine or osteopathy to meet facility requirements at 42 CFR §485.618(e) and §485.631(b); and

o Evidence that the facility has an agreement or arrangement with one or more Medicare-approved hospitals for referral and admission of the facility's patients.

(Insert the following if the RPCH belongs to a rural health network)

o A copy of the facility's rural health network agreement; and

o A copy of the facility's agreement to participate in the rural health network's communications system, if the network has a communications system.

As part of the survey, we will be reviewing a random sample of the facility's inpatient and outpatient records to determine if the requirements of the regulations are met.

Should you need additional information about the survey, do not hesitate to call us. In the event that it is not possible for the facility to participate in a survey on the date scheduled, please call (Name and Telephone Number) at State Agency Location.

Sincerely,

State Agency Official

Enclosure: Conditions of Participation for RPCHs (42 CFR Part 485)

PAGES 9-468 AND 9-469 ARE RESERVED FOR EXHIBITS

136 - Request for Survey of 42 CFR §489.20 and 42 CFR §489.24 Essentials of Provider Agreements: Responsibilities of Medicare Participating Hospitals in Emergency Cases--HCFA-1541A

137 - Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report--HCFA1541B

Exhibit 138

PHYSICIAN REVIEW OUTLINE FOR
EMERGENCY CARE OBLIGATIONS OF MEDICARE HOSPITALS

SECTION I
(RO COMPLETES IN MOST CASES. IF SA PHYSICIAN PERFORMS REVIEW, SA PHYSICIAN MAY COMPLETE)

COMPLAINT CONTROL NUMBER:
NAME OF PATIENT: AGE:
NAME OF ALLEGED VIOLATING HOSPITAL:
CITY, STATE: PROVIDER NUMBER:
DATE AND TIME OF ADMISSION TO EMERGENCY SERVICES:
DATE AND TIME OF DISCHARGE FROM EMERGENCY SERVICES:

NAME OF RECEIVING HOSPITAL (if applicable):
CITY, STATE: PROVIDER NUMBER:
DATE AND TIME OF ADMISSION TO 2ND HOSPITAL (if applicable):
MANNER OF TRANSPORT:
LOCATION AND DISTANCE FROM SENDING HOSPITAL:

SECTION II
(COMPLETED BY REVIEWING PHYSICIAN)

MEDICAL SCREENING EXAMINATION

1. Did the individual come to the hospital?

   YES ___ NO
   REMARKS:_____
   _____
   _____

2. Was a request made for examination or treatment for a medical condition?

   YES ___ NO
   REMARKS:_____
   _____
   _____

3. Did the hospital provide, within the capacity of its emergency department, including ancillary services routinely available to the department, for a medical screening examination which was
   - Appropriate to the individual's medical complaint, and
   - Sufficient to determine whether or not an **EMERGENCY MEDICAL CONDITION** (as defined below) existed?

   YES ___ NO
   Remarks/Rationale:
   _____
   _____
   _____
   _____
   _____
   _____

EMERGENCY CONDITION

4. Did this individual have an **EMERGENCY MEDICAL CONDITION**?

   a. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health, and with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

   YES ___ NO ___
   Remarks/Rationale:

   _____
   _____
   _____
   _____
   _____
   _____
   _____

   or
   b. Was this individual a pregnant woman who was having contractions?
   YES ___ NO ___ NOT APPLICABLE ___
   Remarks/Rationale:

   _____
   _____
   _____
   _____
   _____
   _____
   _____

   If yes, at the time of transfer, could it be determined with reasonable medical certainty that there would be adequate time to effect a safe transfer to another hospital before delivery?

   YES ___ NO ___ NOT APPLICABLE ___
   Remarks:

   _____
   _____
   _____
   _____

   At the time of transfer could it be determined, with reasonable medical certainty, that the transfer might have posed a threat to the health and safety of the patient or her unborn child?

   YES ___ NO ___ NOT APPLICABLE ___
   Remarks:

   _____
   _____
   _____
   _____
   _____

Note to Physician Reviewer:

If part a. above is answered in the negative, or if under part b. it is determined that there was adequate time for the transfer, and that the transfer would not have posed a threat to the health and safety of the patient or her unborn child, the individual did not have an "emergency medical condition" as defined in section 1867(e) of the Social Security Act and the requirements of an appropriate transfer, as defined in section 1867(c) of the Social Security Act do not apply. If this is the case, the Physician Reviewer should skip to Questions #12 and #13, and sign this form.

STABILIZING TREATMENT

5. Did the transferring hospital provide further examination and treatment (stabilizing treatment), within its capacity, to minimize the risks to the individual's health?

   YES ___ NO ___ NOT APPLICABLE ___
   Rationale/Remarks:
   _____
   _____
   _____
   _____
   _____
   _____
   _____
   _____

6. a. At the time of transfer, was the individual's emergency medical condition stabilized (meaning that no material deterioration of the condition was likely, within reasonable medical probability, to result from or occur during the transfer of the individual from the facility, or that the woman had delivered the child and the placenta)?

   YES ___ NO ___ NOT APPLICABLE ___
   Rationale/Remarks:
   _____
   _____
   _____
   _____

   b. If no, was the hospital equipped with such staff, services or equipment as necessary to substantially minimize the risk of this particular transfer?

   YES ___ NO ___ NOT APPLICABLE ___
   Rationale/Remarks:
   _____
   _____
   _____
   _____

7. If the individual refused to consent to necessary stabilizing treatment or to an appropriate transfer, is there evidence that the hospital first offered the individual the further medical examination and treatment or appropriate transfer, informing him/her of the risks and benefits, and obtained the individual's written refusal?

   YES ___ NO ___ NOT APPLICABLE ___
   Remarks:
   _____
   _____
   _____

   Note to PRO Reviewer:
   If the answer to questions 5, 6a. and 7 are "NO", then the individual was not "stabilized" as defined at section 1867(e)(3)(B) of the Social Security Act, and he/she requires an "APPROPRIATE" transfer.

8. In your medical judgment, did the individual require a supervised transfer because material deterioration of the individual's medical condition was likely to result from, or occur during a transfer or if the individual was discharged?

   YES ___ NO ___
   Remarks/Rationale:
   _____
   _____
   _____
   _____
   _____
   _____
   _____

   (If "YES", the individual Was NOT "STABILIZED" as defined in §1867(e), and he/she required an "APPROPRIATE" transfer.)

   or, if this individual was a pregnant woman who was having contractions, did she deliver the child (including the placenta) prior to the transfer?

   YES ___ NO ___ NOT APPLICABLE ___
   Remarks/Rationale:
   _____
   _____
   _____
   _____
   _____
   _____
   _____

   (If "NO", the individual was not "STABILIZED" as defined in section 1867(e) of the Social Security Act, and she required an "APPROPRIATE" transfer).

APPROPRIATE TRANSFERS

9. a. Did the transferring hospital obtain the agreement of the receiving hospital to accept the transfer and to provide appropriate medical treatment? If yes, how was this documented?

YES ___ NO ___ NOT APPLICABLE ___
Rationale/Remarks:
_____
_____
_____
_____
_____

b. Did the transferring hospital send to the receiving facility all medical records related to the medical condition? Were the required records sent with the transferred individual?

YES ___ NO ___ NOT APPLICABLE ___
Remarks:
_____
_____
_____
_____
_____

c. Did the transfer of the individual require the use of qualified personnel and transportation equipment, including life support measures if medically appropriate?

YES ___ NO ___ NOT APPLICABLE ___
Remarks:
_____
_____
_____

d. Were the transportation equipment and personnel provided appropriate to the transferred individual's needs?

YES ___ NO ___ NOT APPLICABLE ___
Remarks/Rationale:
_____
_____
_____

10. At the time of transfer, did a physician, or if a physician is not physically present, another qualified medical personnel (in consultation with a physician, who subsequently has countersigned) sign a certification that, based upon the reasonable risks and benefits to the individual, and based upon information available at the time of transfer, the medical benefits reasonably expected from medical treatment at another facility outweighed the increased risks to the patient from effecting the transfer?

YES ___ NO ___ NOT APPLICABLE ___
Remarks/Rationale:
_____
_____

If "YES," do you agree that at the time of transfer, based upon the reasonable risks and benefits to the individual and based upon information available at the time, the medical benefits reasonably expected from medical treatment at another facility outweighed the increased risk to the patient from effecting the transfer and that the certification was therefore appropriate?

YES ___ NO ___ NOT APPLICABLE ___
Remarks/Rationale:

_____
_____
_____
_____
_____
_____
_____

If "NO", did the individual (or a legally responsible person acting on the individual's behalf) request the transfer in writing, after being informed of the hospital's obligations and of the risks of transfer?

YES ___ NO ___ NOT APPLICABLE ___
Remarks:

_____
_____
_____
_____
_____
_____

11. Was there any evidence that a participating hospital that has specialized capabilities or facilities refused to accept an appropriate transfer of an individual who required such specialized capabilities or facilities if the hospital had the capacity to treat an individual?

YES ___ NO ___ NOT APPLICABLE ___
Remarks:

_____
_____
_____
_____
_____
_____
_____

DELAY IN TREATMENT

12. Is there any evidence that the hospital delayed the provision of an appropriate medical screening examination or further medical examination and treatment in order to inquire about the individual's method of payment or insurance status?

YES ___ NO ___
Remarks:

_____
_____
_____
_____
_____

QUALITY

13. Aside from the transfer issue, do you have any specific concerns about the quality of care rendered to this patient?

YES ___ NO ___
Remarks:
_____
_____
_____
_____

SUMMARY OF FINDINGS:

Exhibit 138 (Cont.)

I agree to provide medical advice on any necessary additional development of this case to properly adjudicate any issues and to testify as an expert witness if necessary.

PHYSICIAN SIGNATURE: _____ DATE _____ -

Exhibit 139

Model Letter to Provider (Send with Form HCFA-2567)
(Immediate Jeopardy Does Not Exist)

(NOTE: The language provided below should be changed appropriately for surveys conducted by HCFA.)

IMPORTANT NOTICE - PLEASE READ CAREFULLY

Dear (Nursing Home Administrator):

On (date) a survey was conducted at your facility by the (State survey agency) to determine if your facility was in compliance with Federal participation requirements for nursing homes participating in the Medicare and/or Medicaid programs. This survey found that your facility was not in substantial compliance with the participation requirements.

All references to regulatory requirements contained in this letter are found in Title 42, Code of Federal Regulations.

Plan of Correction (PoC)

A PoC for the deficiencies must be submitted by (10 days after the facility receives its Form HCFA-2567). Failure to submit an acceptable PoC by, (date indicated above as the due date for submission of a PoC) may result in the imposition of remedies by (20 days after due date for submission of a PoC).

Your PoC must contain the following:

- What corrective action(s) will be accomplished for those residents found to have been affected by the deficient practice;
- How you will identify other residents having the potential to be affected by the same deficient practice and what corrective action will be taken;
- What measures will be put into place or what systemic changes you will make to ensure that the deficient practice does not recur; and,
- How the corrective action(s) will be monitored to ensure the deficient practice will not recur, i.e., what quality assurance program will be put into place.

Remedies will be recommended for imposition by the (Health Care Financing Administration (HCFA) Regional Office and/or the State Medicaid Agency) if your facility has failed to achieve substantial compliance by (the date certain). Informal dispute resolution for the cited deficiencies will not delay the imposition of the enforcement actions recommended (or revised, as appropriate) on (the date certain). A change in the seriousness of the noncompliance on (the date certain) may result in a change in the remedy selected. When this occurs, you will be advised of any change in remedy.

Recommended Remedies

USE FOR CATEGORY 1 REMEDIES WHEN NO OTHER REMEDIES ARE RECOMMENDED - USE IN LIEU OF PREVIOUS PARAGRAPH:

Based on the deficiencies cited during your survey, we are imposing, as authorized by the HCFA Regional Office or the State Medicaid Agency, the following remedies:

ADD TO PARAGRAPH APPLICABLE REMEDIES:

[] Directed plan of correction effective (15 days from the date of receipt of this notice) (§488.424)
[] State monitoring effective (give date) (§488.422)
[] Directed in-service training effective (15 days from the date of receipt of this notice) (§488.425)

USE UNLESS ONLY CATEGORY 1 REMEDIES ARE IMPOSED OR IF REMEDIES ARE BEING IMPOSED IMMEDIATELY:

The remedies which will be recommended if substantial compliance has not been achieved by (date certain) include the following:

ADD TO PARAGRAPH THE APPLICABLE REMEDIES:

[] Denial of payment for new admissions effective (date certain + 20 days). [§488.417(a)]
[] Civil money penalty ($50 - $3,000 per day), effective (the date the facility was first found out of compliance). (This remedy is generally reserved for situations of serious noncompliance as described in §7510.) (§488.430)
[] Temporary management effective (date certain + 20 days) (this remedy may be used for actual harm/widespread) (§488.415)
[] State monitoring effective (date certain + 5 days) (§488.422)
[] Directed plan of correction effective (date certain +20 days) (§488.424)
[] Directed in-service training effective (date certain + 20 days) (§488.425)
[] Specify alternative State remedies effective (date certain + 20 days) (State law)

USE IF REMEDY(IES) IMPOSED IMMEDIATELY (POOR PERFORMING FACILITIES):

Based on the deficiencies cited during your survey, we are recommending to the HCFA Regional Office and/or (State Medicaid Agency) that:

[] A civil money penalty be imposed effective (the date the facility was first found out of compliance). If the Regional Office or the State Medicaid Agency decides to impose the recommended civil money penalty, a notice of imposition will be sent to you. The penalty will continue to accrue until the deficiencies are corrected and your facility is found to be in substantial compliance, or your provider agreement is terminated.

[] [Recommended remedy(ies)] be imposed effective (the date of the final notice plus 15 days), except for State monitoring, which can be imposed immediately.

USE IF DENIAL OF PAYMENT FOR NEW ADMISSIONS WAS NOT A REMEDY INDICATED IN THE PREVIOUS LIST:

If you do not achieve substantial compliance within 3 months after the last day of the survey identifying noncompliance, the HCFA Regional Office and/or State Medicaid Agency must deny payments for new admissions.

We are also recommending to the HCFA Regional Office and/or State Medicaid Agency that your provider agreement be terminated on (no later than 6 months from the last day of survey) if substantial compliance is not achieved by that time.

USE IF SUBSTANDARD QUALITY OF CARE (SQC) IS IDENTIFIED:

Your facility's noncompliance with the following (cite regulations) has been determined to constitute SQC as defined at §488.301. Sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Social Security Act and 42 CFR 488.325(h) require that the attending physician of each resident who was found to have received SQC as well as the State board responsible for licensing the facility's administrator be notified of the SQC. In order for us to satisfy these notification requirements, and in accordance with §488.325(g), you are required to provide the following information to this agency within 10 working days of your receipt of this letter:

> The name and address of the attending physician of each resident found to have received SQC, as identified below:
>
> List of affected residents:
>
> _____
> _____
> _____
> _____
> _____

Please note that, in accordance with §488.325(g), your failure to provide this information timely will result in termination of participation or imposition of alternative remedies.

USE IF SUBSTANDARD QUALITY OF CARE (SQC) HAS BEEN IDENTIFIED ON 3 CONSECUTIVE STANDARD SURVEYS:

The finding(s) of SQC found during this survey constitute(s) 3 repeated findings of SQC, i.e., findings of SQC on the last 3 consecutive standard surveys of this facility. As a result, regardless of other remedies, (HCFA and/or the State Medicaid Agency) must deny payment for all new admissions, effective on (last day of survey + 20 days) and impose State monitoring, effective (last day of survey + 5 days).

<u>Allegation of Compliance</u>

If you believe these deficiencies have been corrected, you may contact (name, title, address, and telephone and fax number of survey agency representative) with your written credible allegation of compliance. If you choose and so indicate, the PoC may constitute your allegation of compliance. We may accept the written allegation of compliance and presume compliance until substantiated by a revisit or other means. In such a case, neither the HCFA Regional Office nor the State Medicaid Agency will impose the previously recommended remedy(ies) at that time.

If, upon the subsequent revisit, your facility has not achieved substantial compliance, we will recommend that the remedies previously mentioned in this letter be imposed by the (HCFA Regional Office or the State Medicaid Agency) beginning on (the date the facility was first found out of compliance, i.e., last date of survey) and continue until substantial compliance is achieved. Additionally, the HCFA Regional Office or State Medicaid Agency may impose a revised remedy(ies), based on changes in the seriousness of the noncompliance at the time of the revisit, if appropriate.

Informal Dispute Resolution (IDR)

In accordance with §488.331, you have one opportunity to question cited deficiencies through and IDR process. You may also contest scope and severity assessments for deficiencies which resulted in a finding of SQC or immediate jeopardy. To be given such an opportunity, you are required to send your written request, along with the specific deficiencies being disputed, and an explanation of why you are disputing those deficiencies (or why you are disputing the scope and severity assessments of deficiencies which have been found to constitute SQC or immediate jeopardy) to (name, title, address and telephone number and fax number of the person you will be conducting the IDR process). This request must be sent during the same 10 calendar days you have for submitting a PoC for the cited deficiencies. An incomplete IDR process will not delay the effective date of any enforcement action.

ADD TO THE ABOVE PARAGRAPH IF THE SURVEY WAS CONDUCTED BY HCFA:

IDR in no way is to be construed as a formal evidentiary hearing. It is an informal administrative process to discuss deficiencies. If you will be accompanied by counsel, you must indicate this in your request for IDR so that we may also have counsel present. You will be advised verbally of our decision relative to the informal dispute, with written confirmation to follow.

If you have any questions concerning the instructions contained in this letter, please contact (name, title, address, phone number and fax number of appropriate survey agency official).

Sincerely,

Signature
Name and Title

cc:
HCFA Regional Office
and/or
State Medicaid Agency

Model Letter Notifying Provider of
Acceptance of Allegation of Compliance

(NOTE: The language provided below should be changed appropriately for surveys conducted by HCFA.)

IMPORTANT NOTICE - PLEASE READ CAREFULLY

Dear (Nursing Home Administrator):

On (date) a survey was conducted at your facility. You have alleged that the deficiencies cited on that survey have been corrected. We are accepting your allegation of compliance and presume that you achieved substantial compliance on (date certain or earlier alleged by provider, if applicable). Based on this presumed compliance, we are not forwarding to the (Health Care Financing Administration (HCFA) Regional Office and/or the State Medicaid Agency) our recommendation that the remedies we indicated in our letter to you of (date of initial notice) be imposed at this time.

We will be conducting a revisit of your facility to verify that substantial compliance has been achieved and maintained. We will certify your facility in compliance effective (date of presumed compliance), if we find that your facility is in substantial compliance at the time of the revisit. If we find that your facility has failed to achieve or maintain substantial compliance, we will recommend that the following remedy(ies) be imposed:

[] Remedy(ies) recommended in the initial letter, effective on (presumed date of receipt of this notice + 15 days, except in the case of State monitoring). (If a CMP was recommended in the initial letter for serious noncompliance, please include the range of penalty amounts from which the per day amount would be chosen; the effective date for accrual which would be the last day of the survey; and the fact that the CMP would continue to accrue until the facility comes into substantial compliance or is terminated from participation.)

If you have any questions concerning the instructions contained in this letter, please notify _____ at _____.

Sincerely,

Signature
Name and Title

Exhibit 141

Model Letter Notifying Provider
of Results of Revisit

(NOTE: The language provided below should be changed appropriately for surveys conducted by HCFA.)

IMPORTANT NOTICE - PLEASE READ CAREFULLY

Dear (Nursing Home Administrator):

On (date) we conducted a revisit to verify that your facility had achieved and maintained compliance. We had presumed, based on your allegation of compliance, that your facility was in substantial compliance as of (date certain or earlier date). However, based on our revisit conducted (date), we found that your facility is not in substantial compliance with the following participation requirement(s):

LIST PARTICIPATION REQUIREMENTS THAT ARE DEFICIENT

As a result of our finding that your facility is not in substantial compliance, we will recommend that the following remedy(ies) be imposed:

USE IF THERE HAS BEEN NO CHANGE IN THE SERIOUSNESS OF THE NONCOMPLIANCE:

[] Remedy(ies) recommended in the initial letter.

USE IF THERE HAS BEEN A CHANGE IN THE SERIOUSNESS OF THE NONCOMPLIANCE RESULTING IN A CHANGE IN THE REMEDY(IES) TO BE RECOMMENDED:

[] (Any other remedy(ies), other than those recommended in the initial letter.) The change in the seriousness of the noncompliance on (the revisit) has resulted in a change in the remedy(ies) we will recommend from those previously mentioned to you in the initial letter.

If the (Regional Office or State Medicaid Agency) decides to impose the recommended remedy(ies), that office will send you a notice of the imposition of the remedy(ies).

Informal Dispute Resolution (IDR)

In accordance with §488.331, you have one opportunity to question cited deficiencies through an IDR process. As a result of the revisit, you may also contest the continuation of cited deficiencies, new deficiencies, and the scope and severity assessment for deficiencies which result in a finding of substandard quality of care or immediate jeopardy. A second IDR will not be offered on the existence of the deficiency(ies) as of the date of the first survey. To be given an opportunity for IDR, you are required to send your written request, along with the specific deficiencies being disputed, and an explanation of why you are disputing those deficiencies (or why you are disputing the scope and severity assessments of deficiencies which have been found to constitute substandard quality of care or immediate jeopardy) to (name, title, address, and telephone number and fax number of the person who will be conducting the IDR process). This request must be sent during the same 10 calendar days you have for submitting a PoC for the cited deficiencies. An incomplete IDR process will not delay the effective date of any enforcement action.

Exhibit 142

Model Letter to Provider (Imposition of Remedies)
(Immediate Jeopardy Does Not Exist)

(Note: The language provided below should be changed appropriately for surveys conducted by HCFA.)

IMPORTANT NOTICE - PLEASE READ CAREFULLY

Dear (Nursing Home Administrator):

On (date), a survey was conducted at your facility by the (State survey agency) to determine if your facility was in compliance with the Federal participation requirements for nursing homes participating in the Medicare and/or Medicaid programs. This survey found that your facility was not in substantial compliance with the participation requirements.

As a result of the survey findings listed on the Statement of Deficiencies and Plan of Correction (Form HCFA-2567) which was forwarded to you after the survey, the (State survey agency) notified you that it would recommend to the Health Care Financing Administration (HCFA) and/or the State Medicaid agency that the following remedies be imposed if you did not submit an acceptable plan of correction by (survey date plus 10 days) or did not achieve substantial compliance by (date certain).

LIST REMEDIES.

USE THESE 2 PARAGRAPHS IF CREDIBLE ALLEGATION OF COMPLIANCE WAS RECEIVED:

On [date(s)], you submitted a plan of correction and credible allegation of compliance to the (State survey agency), and based on the presumption of substantial compliance, the (State survey agency) suspended its recommendations for enforcement action. However, on (date), a revisit was made to verify correction, and found that you were not in substantial compliance.

Because you did not correct deficiencies as alleged, the following remedies, which were to have been recommended on (date certain), will be imposed (15 days after presumed receipt of this notice), and a civil money penalty will be imposed retroactive to (date of the survey).

LIST REMEDIES.

USE THIS PARAGRAPH IF NO CREDIBLE ALLEGATION OF COMPLIANCE WAS RECEIVED:

As a result of your failure to come into compliance as evidenced by your failure to submit an acceptable plan of correction by (survey date plus 10 days) either containing a credible allegation of compliance or in addition to a separate allegation of compliance, the following remedies previously recommended by the (State survey agency) will be imposed (15 days after presumed receipt of this notice).

LIST REMEDIES.

USE THIS PARAGRAPH IF UPON REVISIT IMMEDIATE JEOPARDY WAS FOUND:

The (State survey agency) conducted a revisit on (date), and found that conditions in your facility had deteriorated to the point that immediate jeopardy to residents now exists. As a result of the change in the seriousness of your noncompliance, the remedy category from which an enforcement response must be selected has changed. The remedies to which you will now be subject are as follows: (list remedies and their effective dates - refer to language in Exhibit 143, "Imposition of Remedies, Immediate Jeopardy Exists.")

If you disagree with this determination, you or your legal representative may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in 42 CFR 498.40, et seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. Such a request may be made to:

Associate Regional Administrator,
Division of Health Standards and Quality
Health Care Financing Administration
(Street Address)

At your option you may instead submit a hearing request directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
Civil Remedies Division
Attention: Gerald P. Choppin
Room 637-D
HHH Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Send a copy of your request to this office.

A request for a hearing should identify the specific issues, and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense.

If you have any questions, please contact (name, title, address, fax number and telephone number of regional office contact).

Sincerely,

Signature
Name and Title

Enclosure

Exhibit 143

Note: This letter would follow the SA's notice as required by §7309.

Model Letter to Provider (Imposition of Remedies)
(Immediate Jeopardy Exists)

(Note: The language provided below should be changed appropriately for surveys conducted by HCFA.)

IMPORTANT NOTICE - PLEASE READ CAREFULLY

Dear (Nursing Home Administrator):

On (date) a survey was conducted at your facility by the (State survey agency) to determine if your facility was in compliance with Federal participation requirements for nursing homes participating in the Medicare and/or Medicaid programs. This survey found that your facility was not in substantial compliance with the participation requirements, and the conditions in your facility constituted immediate jeopardy to resident health or safety.

As a result of the survey findings, the (State survey agency) notified you (date, method) that it would recommend to the (Health Care Financing Administration (HCFA) Regional Office and/or the State Medicaid agency) that (temporary management or termination, and other remedies, if applicable) be imposed.

All references to regulatory requirements contained in this letter are found in Title 42, Code of Federal Regulations.

Plan of Correction (PoC)

A PoC for the deficiencies must be submitted by (10 days after the facility receives its Form HCFA-2567). Failure to submit an acceptable PoC by (date indicated above as the due date for submission of a PoC) may result in the imposition of (list remedies) by (20 days after due date for submission of a PoC).

Your PoC must contain the following:

- What corrective action(s) will be accomplished for those residents found to have been affected by the deficient practice;
- How you will identify other residents having the potential to be affected by the same deficient practice and what corrective action will be taken;
- What measures will be put into place or what systemic changes you will make to ensure that the deficient practice does not recur; and,
- How the corrective action(s) will be monitored to ensure the deficient practice will not recur, i.e., what quality assurance program will be put into place.

A change in the seriousness of the noncompliance to non-immediate jeopardy may result in a change in the remedy selected. When this occurs, you will be advised of any change in remedy.

Allegation of Compliance

If you believe these deficiencies have been corrected, you may contact (name, title, address, and telephone and fax number of survey agency representative) with your written credible allegation of compliance.

Informal Dispute Resolution (IDR)

In accordance with §488.331, you have one opportunity to question cited deficiencies and to specifically contest scope and severity assessments for deficiencies which result in a finding of substandard quality of care (SQC) or immediate jeopardy through an IDR process. To be given such an opportunity, you are required to send your written request, along with the specific deficiencies being disputed, and an explanation of why you are disputing those deficiencies (or why you are disputing the scope and severity assessments of deficiencies which have been found to constitute SQC or immediate jeopardy) to (name, title, address, and telephone number and fax number of the person who will be conducting the IDR process). This request must be sent during the same 10 calendar days you have for submitting a PoC for the cited deficiencies. An incomplete IDR process will not delay the effective date of any enforcement action.

ADD TO THE ABOVE PARAGRAPH IF THE SURVEY WAS CONDUCTED BY HCFA:

IDR in no way is to be construed as a formal evidentiary hearing. It is an informal administrative process to discuss deficiencies. If you will be accompanied by counsel, you must indicate this in your request for IDR so that we may also have counsel present. You will be advised verbally of our decision relative to the informal dispute, with written confirmation to follow.

Appeal Rights

If you disagree with this determination, you or your legal representative may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in §498.40, et seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. Such a request may be made to:

Associate Regional Administrator,
Division of Health Standards and Quality
Health Care Financing Administration
(Street Address)

At your option, you may instead submit a hearing request directly (accompanied by a copy of this letter) to:

Departmental Appeals Board
Civil Remedies Division
Attention: Gerald P. Choppin
Room 637-D
HHH Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Send a copy of your request to this office.

A request for a hearing should identify the specific issues, and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense.

USE THESE 3 PARAGRAPHS IF IMPOSING TEMPORARY MANAGEMENT:

We concur with the (State survey agency)'s recommendation. As a result, a temporary manager will be installed in your facility on (date that is no sooner than 2 days after receipt of the notice and no later than 10 days after the survey date). You are expected to relinquish to the temporary manager the authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and otherwise manage the facility to correct the deficiencies identified in its operation. You will be responsible for paying the salary and related costs of the temporary manager, which will be set by the (State survey agency).

If you refuse to relinquish authority to the temporary manager or to pay his/her salary, your facility will be terminated on (date that does not exceed 23 calendar days from the survey date), if the immediate jeopardy is not removed prior to this date.

If you relinquish authority to the temporary manager, the temporary management will end when your facility has achieved substantial compliance and is capable of remaining in substantial compliance, or when your facility's provider agreement is terminated. Termination will occur on (date that is 23 calendar days from the last day of the survey) if the immediate jeopardy is not removed.

USE THESE 2 PARAGRAPHS IF IMPOSING TERMINATION:

We concur with the (State survey agency)'s recommendation. Your (Medicare or Medicaid) provider agreement will be terminated on (date that is no sooner than 2 days after receipt of the notice and no later than 23 days after the survey date) if the immediate jeopardy to resident health or safety is not removed. (NOTE: If Medicaid, add: We will notify the State Medicaid Agency to terminate your Medicaid provider agreement.)

We are required to provide the general public with notice of an impending termination and will publish a notice in (paper's name) prior to the effective date of termination.

USE THIS PARAGRAPH IF IMPOSING A CIVIL MONEY PENALTY (CMP)

In addition to (temporary management or termination), a CMP has been imposed in the amount of (amount) per day commencing on (the date that the facility was first found out of compliance). The CMP will continue to accrue until the deficiencies are corrected and your facility is found to be in substantial compliance, or your provider agreement is terminated. The CMP will not be collected until after it has stopped accruing and a final administrative decision upholding its imposition has been made, if a hearing is requested. If you waive your right to a hearing within 60 calendar days from (the date the CMP stops accruing), the amount of your CMP will be reduced by 35%.

USE THIS PARAGRAPH IF SUBSTANDARD QUALITY OF CARE IS IDENTIFIED:

Your facility's noncompliance with the following (cite regulations) has been determined to constitute substandard quality of care as defined at §488.301. Sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Social Security Act, as well as implementing regulations at §488.325(h), require that the attending physician of each resident who was found to have received substandard quality of care as well as the State Board responsible for licensing the facility's administrator, be notified of the substandard quality of care. In order for us to satisfy these notification requirements, and in accordance with §488.325(g), you are required to provide the following information to this agency within 10 working days of your receipt of this letter:

The name and address of the attending physician of each resident found to have received substandard quality of care, as identified below:

List of affected residents:

_____
_____
_____
_____
_____

Please note that, in accordance with §488.325(g), your failure to provide this information timely will result in termination of participation or imposition of alternative remedies.

USE THIS PARAGRAPH IF SUBSTANDARD QUALITY OF CARE HAS BEEN IDENTIFIED ON 3 CONSECUTIVE STANDARD SURVEYS:

The finding(s) of substandard quality of care found during this survey constitute(s) 3 repeated findings of substandard quality of care, i.e., findings of substandard quality of care on the last 3 consecutive standard surveys of this facility. As a result, regardless of other remedies, (HCFA and/or the State Medicaid Agency) must deny payment for all new admissions, effective on (last day of survey + 20 days) and impose State monitoring, effective (last day of survey + 5 days).

If you have any questions, please contact (name, title, address, phone number and fax number of appropriate survey agency official).

Sincerely,

Signature
Name and Title

cc:
HCFA Regional Office
and/or
State Medicaid Agency

Exhibit 144

Notice of Imposition of a Civil Money Penalty
(Insert to Formal Notice)

As a result of the survey findings listed on the attached Statement of Deficiencies and Plan of Correction (Form HCFA-2567), the (name of State survey agency) recommended that the (State Medicaid Agency or Health Care Financing Administration) impose a civil money penalty on (facility name). In accordance with sections 1819(h) and 1919(h) of the Social Security Act and the enforcement regulations specified at 42 Code of Federal Regulations (CFR), part 488, we are imposing a civil money penalty effective on (date) in the amount of (dollar amount) for each day that (facility name) is not in substantial compliance with the participation requirements. We considered (list the applicable factors specified in the regulation at 42 CFR 488.438(f)) in determining the amount of the civil money penalty that we have imposed for each day of noncompliance.

The civil money penalty continues to accrue at the amount specified above until you have made the necessary corrections to achieve substantial compliance with the participation requirements or your provider agreement is terminated. However, the amount of the civil money penalty (Select the appropriate statement: may be increased if we find that the noncompliance cited above worsens from a situation in which immediate jeopardy did not exist to a situation in which immediate jeopardy exists; or would be decreased if we find that immediate jeopardy has been removed but the noncompliance continues.)

If you would like to waive your right to a hearing, you must do so in writing within 60 calendar days from the date of this notice. If you waive your right to a hearing in accordance with the requirements specified at 42 CFR 488.436, the amount of the civil money penalty will be reduced by thirty-five percent. You will be notified of the total amount due, based on the revised daily amount, after you have achieved substantial compliance or your provider agreement is terminated.

Exhibit 145

Notification of Change in the Amount of the Civil Money Penalty

Dear (Provider):

On (date) (the State Medicaid Agency or the Health Care Financing Administration) imposed a civil money penalty in the amount of (dollar amount) per day on (facility name and provider number). The civil money penalty was imposed after it was determined through a survey conducted by (name of the State survey agency or regional office) on (date of survey) that (facility name) was not in substantial compliance with the Medicare/Medicaid participation requirements that are specified at §§1819(b), (c), (d), and (e) and 1919(b), (c), (d), and (e) of the Social Security Act and the corresponding regulations in 42 CFR Part 483.

The amount of the civil money penalty is (increased or decreased) as a result of (include detail regarding one of the following):

- Specific findings during a revisit, such as:
  - The removal of immediate jeopardy although the noncompliance continues, or
  - A change in noncompliance from a situation in which immediate jeopardy did not exist to a situation in which immediate jeopardy exists.

The revised amount of the civil money penalty is (dollar amount) per day and the effective date for the accrual of this adjusted amount is (date substantiating the change in the noncompliance).

The civil money penalty will continue to accrue in the amount of (new adjusted dollar amount) until the necessary corrections have been made to bring (facility name) into substantial compliance with the requirements or the provider agreement is terminated. When the necessary corrections have been made, please contact (person in the State survey agency) so that the survey agency can verify that (facility name) is in substantial compliance with the requirements.

Sincerely,

Regional Office Official or
State Medicaid Agency Official

Exhibit 146

Notice of Receipt of the Written Request
of Waiver of Right to a Hearing

Dear (Nursing Home Administrator):

On (date), a civil money penalty in the amount of ($_____) per day was imposed on (facility name) for noncompliance with the participation requirements found at 42 Code Of Federal Regulations (CFR), part 483, subpart B. We received your written request to waive your right to a hearing on the noncompliance. In accordance with the requirements at 42 CFR 488.436, the civil money penalty will be reduced 35 percent. You will be notified of the payment amount that is due and payable after the total number of days of noncompliance is determined.

Sincerely,

Regional Office Official or
State Medicaid Agency Official

Exhibit 147

Notice of Payment Amount Due and Payable

Dear (Provider):

In accordance with the statutory provisions of §1819(h) and/or 1919(h), and the regulations at §488.430, a civil money penalty in the amount of (dollar amount per day) was imposed on (facility name) for noncompliance with the participation requirements. This is to inform you that the civil money penalty imposed on (effective date of the penalty) is due and payable on (date).

The total amount of the civil money penalty due is (total dollar amount). This total represents the imposition of a civil money penalty in the amount of (dollar amount) per day for (number of days of noncompliance) [and (dollar amount) per day for (number of days of noncompliance at a different range of penalty amounts)]. (If applicable, include: This total amount reflects a 35 percent reduction in the amount of the civil money penalty for your waiver of your right to a hearing on the noncompliance, as specified at 42 Code of Federal Regulations, Subpart 488.436.)

The civil money penalty is due on (provide the due date in accordance with the requirements provided in 42 CFR 488.442). The civil money penalty is payable by check to:

If a check is not received by the due date of the penalty, the civil money penalty and any interest accrued after the due date will be deducted from sums owing to you.

Sincerely,

Regional Office Official or
State Medicaid Agency Official

Exhibit 148

Notification of Deduction of Civil Money Penalty
from Money Owing to the Provider

Dear (Provider):

As a result of the survey findings on (date) the (State Medicaid Agency or Health Care Financing Administration) imposed a civil money penalty on (facility name) for noncompliance with the participation requirements in accordance with sections 1819(h) and/or 1919(h) of the Social Security Act and the enforcement regulations specified at 42 CFR part 488. On (date of notice of amount due and payable) we informed you that the civil money penalty imposed on (effective date of the penalty) was due and payable on (date).

As of the above due date, we have not received payment of the civil money penalty. Consequently, we will deduct the civil money penalty amount and any accrued interest from the sums owing to you.

Sincerely,

Regional Office Official or
State Medicaid Agency Official

THIS PAGE RESERVED FOR FUTURE USE

Model Letter: EACH Approval Notification

Name/Title of EACH Administrator
or CEO
Hospital Name
Street Address
City, State, Zip

Dear _____:

We are pleased to notify you that this office has verified that (name of EACH) meets the requirements at 42 Code of Federal Regulations (CFR), Part 412.109 for designation as an Essential Access Community Hospital (EACH).

The Social Security Act, section 1886(d)(5)(D)(iii)(III), states that a hospital designated by the Secretary, Department of Health and Human Services, as an EACH meets the definition of sole community hospital (SCH). Regulations at 42 CFR 412.92, Special treatment: Sole community hospitals, provide that SCH status is effective 30 days after the date of HCFA's written notification of approval. Therefore, (name of EACH) will acquire SCH status effective (insert effective date). The payment methodology for SCHs is set forth at 42 CFR 412.92(d). To retain its status as an EACH, (name of EACH) must remain in compliance with the requirements at 42 CFR 412.109.

The affiliated rural primary care hospital (RPCH) is (name of RPCH). (name of RPCH) was notified, by letter dated, (insert RPCH notification date), of its effective participation date in the Medicare program as an RPCH.

Questions regarding sole community hospital status should be directed to your fiscal intermediary, (name of fiscal intermediary).

We welcome your participation in the EACH program.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosures

cc:
Fiscal Intermediary
Regional Administrator, Region ____
State Department of Health
HCFA Central Office

Exhibit 150

Model Letter: RPCH Approval Notification

Name/Title of RPCH Administrator,
CEO, or Responsible Individual
Name of RPCH
Street Address
City, State, Zip

Dear _____:

We are pleased to notify you that (name of RPCH) meets the requirements at 42 Code of Federal Regulations (CFR), Part 485, for participation in the Medicare program as a rural primary care hospital (RPCH). The effective date of this approval is (effective date).

We have verified that (name of RPCH) has met the requirements at 42 CFR 485.10(a)(1), (a)(2), and (a)(3), and 42 CFR 485.12(a)(1) and (a)(2). Effective with the approval of (name of RPCH) as an RPCH, its participation as an acute care hospital under provider number (hospital provider number) has been cancelled, effective (date before RPCH effective date). Your new provider number for RPCH status is (RPCH provider number). Your RPCH provider number should be used on all correspondence and billing for the Medicare program.

(Insert next two paragraphs if necessary):

(name of RPCH) has been furnished a "Statement of Deficiencies and Plan of Correction" (Form HCFA-2567). The deficiencies on that form reflect the evaluation of your compliance with the Conditions of Participation for RPCHs. Under "Provider Plan of Correction" on the right-hand side of this form (name of RPCH) has listed its response to each deficiency. A complete copy of that form is subject to public disclosure.

The State survey agency (SA) will continue to work with (name of RPCH) on its correction plan. The SA will complete a "Post-Certification Revisit Report" (Form HCFA-2567B) documenting the corrections (name of RPCH) has made. If (name of RPCH) has not corrected all deficiencies, it will be asked to explain why they have not been corrected and a new Plan of Correction must be submitted.

(Insert next paragraph if necessary):

(Name of RPCH) has also been approved to provide post-hospital skilled nursing facility care as specified in 42 CFR Part 409.30. Swing-bed RPCHs are assigned an additional number which contains an alpha-character in the third position. The third character, the letter "Z", indicates that the RPCH has been approved as a swing-bed RPCH. Therefore, the swing-bed identification number for (name of RPCH) will be (swing-bed provider number).

The change in status of (name of RPCH) will require that limited services begin no later than (RPCH effective date). (For closed hospitals that have reopened as RPCHs, substitute the following sentence to begin this paragraph: The certification of (name of RPCH) as an RPCH and the first date that RPCH services may be provided is (RPCH effective date). You may operate no more than (enter either 6 beds or 12 Beds, as appropriate) inpatient beds with a maximum stay of 72 hours. All billing for patient services through (last date before effective date), should be billed under provider number (hospital provider number). All services furnished on or after (RPCH effective date), should be billed under provider number (RPCH provider number).

Your fiscal intermediary continues to be (or "will be", as appropriate) (name of fiscal intermediary). Billings for services should be made under (RPCH provider number). (Insert next sentence if necessary:) The "Z" number is to be used for all billings for services for Title XVIII SNF services. Questions concerning billings and other fiscal matters should be directed to (name of fiscal intermediary). Questions related to the Conditions of Participation for RPCHs should be referred to your SA.

(Insert next sentence if necessary):

(Name of affiliated EACH) has been approved as your affiliated Essential Access Community Hospital.

We welcome your participation in the RPCH program.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosures

cc:
Fiscal Intermediary
Regional Administrator, Region _____
_____ State Department of Health

Exhibit 151

Model Letter: EACH Denial Letter

Name/Title of EACH Administrator
or CEO
Hospital Address
Street Address
City, State, Zip

Dear _____:

This is to inform you that (name of EACH) no longer meets the requirements at 42 Code of Federal Regulations (CFR), Part 412.109 for designation as an Essential Access Community Hospital (EACH).

The Social Security Act, section 1886(d)(5)(D)(iii)(III), states that a hospital designated by the Secretary, Department of Health and Human Services, as an EACH meets the definition of sole community hospital (SCH), and is therefore, eligible to receive the sole community rate. As you know, (name of EACH) must have remained in compliance with the requirements at 42 CFR 412.109 to retain its SCH status.

(Insert when the EACH fails to remain in compliance with 42 CFR 412.109):

After a careful review of the facts, including the findings of the (name of State agency), the Health Care Financing Administration has determined that (name of EACH) is no longer in compliance with (state the specific area of noncompliance in 42 CFR 412.109 (e.g., 42 CFR 412.109(c)(3)(iii), failure to accept patient transfers from an affiliated RPCH in the same rural health network)). Therefore, the (name of EACH) is no longer designated as an EACH and may no longer receive the sole community rate, effective (enter date sole community rate is terminated).

(Insert when the only RPCH in the same network as the EACH has been terminated):

Compliance with the requirements at 42 CFR 412.109 requires that (name of EACH) be a member of a rural health network as defined at 42 CFR 485.603 with at least one facility that has been certified as a RPCH. As a result of the recent termination action to (name of network RPCH), your hospital is no longer in compliance with the requirements at 42 CFR 412.109.

If (name of EACH) does not agree with this determination, it may request an intermediary hearing by contacting (enter name, address and telephone number of fiscal intermediary), under procedures established at 42 CFR Part 405. This decision applies only to the SCH status of (name of EACH), and does not affect the hospital's status as a Medicare participating hospital.

If you need additional information, please contact (name and telephone number of RO staff who will respond).

Sincerely yours,

Regional Administrator
Health Care Financing Administration

Enclosure: Subpart R - Provider Reimbursement Determinations and Appeals,
42 CFR 405.1801 through 405.1889

Exhibit 151 (Cont.)

cc:
Fiscal Intermediary
___ State Department of Health
HCFA Central Office

Exhibit 152

Model Letter: RPCH Denial Letter

Name/Title of RPCH Administrator,
CEO, or Responsible Individual
Name of RPCH
Street Address
City, State, Zip

Dear _____:

After a careful review of the facts, the Health Care Financing Administration (HCFA) has determined that the (name of RPCH facility) no longer meets the requirements for participation as a provider of services as a Rural Primary Care Hospital (RPCH) in the Medicare program under Title XVIII of the Social Security Act (the Act).

To continue to participate in the Medicare program, an RPCH must meet the appropriate statutory provisions of section 1820 of the Act and be in compliance with the Conditions of Participation (CoPs) at 42 CFR Part 485. RPCHs with swing-bed approvals must also comply with the skilled nursing facility requirements for RPCHs at 42 CFR 485.645(b).

We find that (name of RPCH facility) does not meet the requirement(s) contained in (insert the specific requirement(s) that have not been met and a brief explanation of the circumstances of noncompliance).

The (name of State agency) which certifies to HCFA whether RPCHs meet the CoPs at 42 CFR Part 485, has discussed the (state the specific CoP(s)) with you on numerous occasions. Based on the record of the State agency's visits, findings, and recommendations, we have determined that the requirement is not met now and is not likely to be met within an acceptable time.

The date on which the agreement terminates is (date of termination). The Medicare program will not make payment for inpatient RPCH services furnished for patients admitted after the (date of termination). For patients admitted prior to (date of termination), payment may continue to be made for a maximum of 72 hours for RPCH inpatient services furnished on or after (date of termination). For swing-bed patients receiving a SNF level of care who are admitted prior to (date of termination), payment may continue to be made for a maximum of 30 days after (date of termination). You should submit, as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your RPCH on (date of termination) to the (name and address of HCFA regional office involved) to facilitate payment for these individuals.

We will publish a public notice of termination in the (name of local newspaper). You will be advised of the publication date for the notice.

You may, of course, take steps to meet the participation requirements and establish the RPCH's eligibility to participate as a provider of services. The (State agency) is available to provide assistance you may need in order to accomplish this.

If you wish to be readmitted to the program, you must demonstrate to the (State agency) and HCFA that you are able to maintain compliance. Readmission to the program will not be approved until you are able to demonstrate compliance for a period of not less than (insert number of days) consecutive days.

If you do not believe this determination is correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Department Appeals Board. Procedures governing this process are set out in the regulations at 42 CFR 498.40 et. seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. For expedited handling, such a request may be made to the following:

_____(Name)
Associate Regional Administrator (or its equivalent)
_____(street)
___(city, State, zip)

At your option, you may instead submit a hearing request directly (accompanied by a copy of this letter) to the Departmental Appeals Board, Civil Remedies Division, Attention: Director, Departmental Appeals Board, Room 637-D, HHH Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, and send a copy of your request to this office.

A request for a hearing should identify the specific issues, and the findings of fact and conclusions that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense.

We will forward your request to the Chief Administrative Law Judge in the Office of Hearings and Appeals.

If you have any questions concerning this, please contact _(name of contact)_at __(phone number)

Sincerely,

Associate Regional Administrator
(or its equivalent)

Enclosure: Form HCFA-2567, Statement of Deficiencies

cc:
Fiscal Intermediary
___ State Department of Health
HCFA Central Office

Exhibit 153

NOTICE OF TECHNICAL DENIAL - CERTIFICATE OF NEED DENIED

(Applicant Insists on a Determination Despite Certificate of Need Denial)

Provider Number _____ (If Assigned)

Dear _____:

This is in response to your request to participate in Medicare's End Stage Renal Disease (ESRD) program. For us to approve your application for (initial approval) (expansion-addition of a new service) (advance approval) as a supplier of ESRD services, the Request for Approval, HCFA-3402, must be accompanied by evidence of (name of State) Certificate of Need approval.

We note that the State agency having jurisdiction has denied your request for Certificate of Need. Accordingly, we have no alternative but to deny your application on the basis of non-compliance with Federal regulations, 42 CFR 405.2135, which requires Certificate of Need approval.

(Insert statement where expansion involved)--The denial of your current expansion request has no effect on your previously approved participation in the end-stage renal disease program.

If you believe that this determination is not correct, you may request that it be reconsidered. The request must be submitted in writing to this office within 60 days of the date you receive this notice. You may submit with the reconsideration request any additional information that you feel may have a bearing on the determination.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 154

NOTICE OF INITIAL APPROVAL OF END-STAGE RENAL DISEASE (ESRD) FACILITY

Provider Number

Dear _____:

We have carefully considered your request for approval as a supplier of renal services in the Medicare program under the (ESRD) regulations, and have determined that your facility meets program requirements and is eligible for payment under section l88l of the Social Security Act.

Your facility has been approved as (renal transplantation center) (renal dialysis center) (renal dialysis facility) (special purpose renal dialysis facility) to furnish the following service(s). The total number of approved stations is __.

Services	Number of Stations
___ Transplantation	
___ Staff Assisted Dialysis	
___Hemodialysis	
___Peritoneal	
___ Self-Dialysis	
___ Patient Dialysis Training	
___Hemodialysis	
___Peritoneal	
___ Other (Specify)	

Based upon the review of utilization data, your facility has been assigned the following minimal utilization rate classification status:

___ Transplantation

___Conditional
___Unconditional
___Exception

(Include as appropriate)

l. If MUR classification is conditional, your facility has four calendar years following the current year in which to attain unconditional status. Conditional status cannot be renewed.

2. If MUR exception status is granted, it must be periodically reviewed and renewed.

3. (New Applicant)--Based upon projected utilization set forth in your proposed Plan of Operation, your participation is contingent upon attaining conditional status by the end of your second calendar year of participation following the current year, and unconditional status during the fourth calendar year.

4. In the recent survey of your facility for compliance with the Conditions for Coverage, the following items were not met:

Please submit your Plan of Correction, HCFA-2567, by _____.

5. (For former participants, add the following sentence:) This determination supersedes all prior determinations made under the ESRD program regulations.

Your intermediary for payment of renal treatment procedures is _____. You must maintain separate cost centers for all renal services. Your intermediary will contact you shortly and explain the special payment procedures to be followed. Enter your provider number, shown above, on all forms and correspondence relating to the Medicare renal treatment program.

If you contemplate any further expansion, relocations, renovation, change of ownership, or additions to your renal treatment services, including reuse, after the date of this approval, you must notify us as soon as possible, by filing a new application. Your application should include all pertinent information concerning the nature and effect of the proposed change. We will then determine whether the contemplated changes meet program requirements.

Should you have any questions in regard to your participation in the Medicare renal treatment program, please contact this office.

If you believe that this determination is not correct in any respect, you may request that the decision be reconsidered. The request must be submitted in writing to this office within 60 days of the date of this notice. You may submit any additional information that you feel may have a bearing on the determination with the reconsideration request.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 155

END-STAGE RENAL DISEASE (ESRD) DENIAL NOTICE

Dear _____:

We have carefully considered your request for approval as a supplier of renal services in the Medicare program under the (ESRD) regulations, and have determined that your facility is NOT eligible for reimbursement under Section 1881 of the Social Security Act.

In order to qualify for reimbursement under Medicare, suppliers of ESRD services must be in compliance with the Conditions for Coverage. On the basis of the deficiencies listed on the enclosed sheet, you do not qualify for participation as an (RTC) (RDC) (RDF) (SPRDF).

(Include the following paragraph when appropriate.)

Although your facility does not meet the definition of (renal transplantation center) (renal dialysis center) (renal dialysis facility) for which you have sought program approval, you may wish to reapply for approval in a different category. If so, please contact (name, address of State agency). If you reapply within 60 days from the date of this letter, a resurvey of your facility may not be necessary.

In addition, you may, of course, take steps to correct the deficiencies and reapply to establish your eligibility. The State agency is available to provide any consultation or assistance you may need to accomplish this.

If you believe that this determination is not correct, you may request that the decision be reconsidered. The request must be submitted in writing to this office within 60 days of the date of this notice. You may submit with the reconsideration request any additional information that you feel may have a bearing on the determination.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

PAGE 9-505 IS RESERVED FOR EXHIBIT

156 - Provider Tie-In Notice--HCFA-2007

Exhibit 157

NOTICE - EXPANSION AND/OR ADDITIONAL SERVICE
(APPROVAL, PARTIAL APPROVAL OR DENIAL) OF ESRD FACILITY

Provider Number _____ (If Assigned)

Dear _____:

We have carefully considered your request for (expansion and or addition of a new service as a (RTC)(RDC)(RDF)(SPDF) (for each category considered separate notification will be necessary) under the end-stage renal disease regulations, and have determined that:

(Approval) -- Your facility is approved for ___ additional dialysis stations effective (date). It is now approved for a total of stations.

(Partial Approval) -- Your facility is approved for ____ of the ___ additional dialysis stations requested effective (date). It is now approved for a total of _____ dialysis stations. (Include rationale citing reasons whey all of the additional stations requested were not approved.)

(Denial) -- Further (expansion-addition of a service) is not warranted at this time. (Include rationale in support of denial.)

Your facility is now approved for the following (include all stations approved to date).

Total of approved dialysis stations

Services	Number of Stations
___ Transplantation	
___ Staff Assisted Dialysis	
___ Self-Dialysis	
___ Patient Dialysis Training	
___ Other (Specify)	

Should you have any questions in regard to your participation in the Medicare renal treatment program, please contact this office.

If you contemplate or experience a change in ownership, physical relocation, change in service or any further expansion of your facility after the date of this approval, you must notify us as soon as possible. Failure to do so may result in the suspension of ESRD program payments.

If you believe that this determination is not correct in any respect, you may request that the decision be reconsidered. The request must be submitted in writing to this office within 60 days of the date of this notice. You may submit with the reconsideration request any additional information that you feel may have a bearing on the determination.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 158

NOTICE - RECERTIFICATION OF ESRD FACILITY
(Not Used for Special Purpose Renal Dialysis Facilities)

Provider Number:

Dear _____:

We have reviewed the recent State agency survey findings and recommendations relating to your End Stage Renal Disease (center/facility). We have determined that your facility continues to meet program requirements and is approved as a (renal transplantation center) (renal dialysis center) (renal dialysis facility) with stations to furnish the following services:

___ transplantation ___ CAPD

___ staff assisted dialysis ___ CCPD

___ self-care ___ home training

The State agency has furnished you with a report of the deficiencies found during the most recent survey. Your plan of correction for these deficiencies has been reviewed and found acceptable. The State agency may revisit your facility to assess the progress of corrective actions to confirm all corrections are being completed in accordance with the time schedules you have provided.

If you plan changes in ownership, location, or services (including expansions), you must notify the State agency as soon as possible. Failure to do so may result in the suspension of payment for covered services.

We look forward to working with you on a continued basis in the administration of the Medicare program.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
State Agency
Central Office

Exhibit 159

LIST OF VA HOSPITALS HAVING SHARING ARRANGEMENTS
WITH PARTICIPATING ESRD HOSPITALS

1. Albuquerque, New Mexico
2. Ann Arbor, Michigan
3. Birmingham, Alabama
4. Denver, Colorado
5. Durham, North Carolina
6. Hines, Illinois
7. Indianapolis, Indiana
8. Iowa City, Iowa
9. Lexington, Kentucky
10. Little Rock, Arkansas
11. Madison, Wisconsin
12. Nashville, Tennessee
13. Oklahoma City, Oklahoma
14. Richmond, Virginia
15. St. Louis, Missouri
16. Salem, Virginia
17. Salt Lake City, Utah
18. San Juan, Puerto Rico
19. Seattle, Washington
20. Tucson, Arizona
21. Northport, New York

Exhibit 160

Notice to ESRD Facility - Alternative Sanction for Failure
to Participate with Network Goals and Objectives

Provider Number:

Dear _____:

To participate as a supplier of end stage renal disease (ESRD) services in the Medicare program, the __(name of facility)__ must be in compliance with the conditions of coverage established by the Secretary of Health and Human Services. These conditions require that the facility participate in the goals and objectives of the ESRD network organization of its geographic area (42 CFR 405.2134). The ESRD network organization of your geographic area informs us that your facility is not in compliance with this requirement for the following reasons. [List deficiencies and rationale for finding of noncompliance.]

Section 1881(c) of the Social Security Act authorizes us to impose sanctions, other than termination, against your facility as an alternative to termination from the Medicare program. These sanctions may be applied if your facility fails to comply with network goals and objectives and patient health and safety is not in jeopardy and the deficiency does not justify termination. Therefore, we are imposing the following sanction against your facility. We will [deny payment for services furnished to patients first accepted for care after [insert effective date]; reduce payment for all ESRD services by 20 percent for each 30-day period after [insert effective date]; withhold all payments, without interest, for all ESRD services furnished after [insert effective date] (Choose one of the three sanctions. The effective date should be 45 days from the date of the letter.)]

This sanction shall remain in effect until we find that you are in substantial compliance with the requirement to participate in network activities and pursue network goals, or we terminate coverage for lack of compliance. You must demonstrate and document that the reason for the sanction has been eliminated. To remove the sanction, you must [specify what is required for correction of the problem].

If you disagree with this determination, you may request a reconsideration of this finding within 15 days from the receipt of this letter. If you request a reconsideration, we will provide an informal hearing by a HCFA official who was not involved in making the decision to apply the sanction. During the hearing, you may be represented by counsel; have access to the information on which the allegation was based; and may present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

If the written decision of the informal hearing supports application of the alternative sanction, we will provide you and the public with written notice at least 30 days before the effective date of the sanction.

If you do not request a hearing, we will proceed with the [specify sanction], which will take effect on (effective date of sanction) .

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
ESRD Network Organization
Central Office

Exhibit 161

NOTICE OF INTERIM APPROVAL OF CAPD SERVICES

Provider Number

Dear _____:

We have considered your request to furnish directly continuous ambulatory peritoneal dialysis (CAPD) patient training and support services (which may be provided via an agreement or arrangement with another approved ESRD facility).

Your facility has been approved on a temporary basis to furnish CAPD training and support services, effective __(date)__. This approval is subject to later review and reevaluation upon publication of specific regulations reciting program requirements, and Certificate of Need approval where required by State Law.

The Medicare law requires that all ESRD facilities, including those offering self-dialysis training programs, be subject to minimal utilization requirements intended to prevent proliferation of unnecessary facilities and programs while providing all needed ESRD services in the most efficient and economical manner possible. Upon adoption of final regulations, in addition to complying with the adopted conditions of coverage and health and safety factors, the facility must comply with the utilization rate that will be established for CAPD training programs.

Your intermediary will contact you shortly to explain any special reimbursement procedures to be followed for CAPD. Use your provider number, shown above, on all billings and correspondence concerning CAPD services.

Should you have any questions regarding your furnishing of CAPD services, please contact this office.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
Fiscal Intermediary
State Agency
Central Office

Exhibit 162

Approval Letter for Extended Care Services (Swing-beds)
in Hospitals (50 - 99 Beds)

Dear Hospital Administrator:

We are pleased to inform you that you are approved to provide posthospital skilled nursing facility (SNF) care (swing-bed services) in your hospital. However, because your hospital is in the greater-than-49 and fewer-than-100 bed category, section 1883(d)(2)(A) of the Social Security Act provides that no payment may be made for Medicare patients after the end of the 5-weekday period (excluding weekends and holidays) beginning on an availability date for a SNF bed, unless the patient's physician certifies within this 5-weekday period, that the transfer of that patient to that facility is not medically appropriate on the availability date.

The SNF(s) in your geographic region, with which you have an availability agreement, must inform your hospital when they have an available bed and the date the bed becomes available. When a SNF bed is available, you must transfer that patient within the 5-weekday period unless the patient's physician certifies that the transfer of that patient to that facility is not medically appropriate on the availability date.

Availability date, in reference to a posthospital SNF care patient, means the latter of the following:

- The date a bed is available in a Medicare-participating SNF with which you have an availability agreement,
- The date you learn that the bed is available, or
- If the notice is prospective, the date that the bed will become available.

We welcome your participation in the Medicare swing-bed program. If you have any further questions concerning your participation, please let me know.

Sincerely yours,

Signature left up to RO)

cc:
Central Office

Exhibit 163

Notice to Skilled Nursing Facilities that a Hospital
Has Been Approved to Provide Extended Care Services (Swing-bed Services)

Dear Administrator:

The purpose of this letter is to inform you that (Name, City, State of approved Swing-bed Hospital) has been approved on an interim basis to provide extended care services (swing-bed services) under the Medicare and Medicaid programs. We have determined that (Name of Hospital) is located within your geographic region. Since the hospital has greater than 49 and fewer than 100 beds, Section 1883(d)(2)(A) of the Social Security Act provides that no payment may be made to the hospital for extended care services after the end of the 5 weekday period (excluding weekends and holidays) beginning on the day that a skilled nursing facility (SNF) bed becomes available in the geographic region, unless the patient's physician certifies, within the 5 day period, that the transfer of the patient to the SNF is not medically appropriate on the availability date.

The burden is on your facility to inform the swing-bed hospital of the availability of a SNF bed in your facility. In the event a SNF bed is available in more than one SNF in the geographic region, the patient will choose to which SNF he/she wishes to be transferred. The transfer must occur, however, within 5 weekdays from the day the first bed becomes available in the hospital's geographic region.

Please be aware that these are interim procedures subject to change with the publication of final regulations. Please be assured that is any changes are implemented by final regulations, we will let you know. If you have questions concerning your obligations, please let me know.

Sincerely yours,

Associate Regional Administrator

(or its equivalent)

cc:
Approved Swing-Bed Hospital

Exhibit 164

RO Adjudication of SA Certification Actions

A. Fundamental Information

1. Name and address of provider/supplier - reimbursement (provider/vendor) number.

2. Action being taken, e.g., recertification, termination, merger approval.

3. State's findings and supporting rationale.

B. Health and Safety Compliance

1. Time Frames

(a) Was the survey conducted on time?

(b) Was the PoC received on time?

(c) Did the SA process the case on time?

(d) Was the certification received in the RO within 60 days of the date of the survey?

(e) Was the 2567 disclosed on time?

2. Health and Safety Review

(a) Does the HCFA-2567 accurately state the deficiencies cited on the survey report form or data abstract?

(b) Are the deficiencies clearly and comprehensively stated?

(c) Are 2567's reviewed for the above prior to disclosure?

(d) Do the deficiencies alone or in combination present a hazard to patient health and safety? Should the certification be sent to PRB for review?

(e) Are the cited deficiencies predictable, i.e., are they the same as cited during the last several surveys as evidenced by MMACs? Do surveyors or SAs tend to "specialize" in certain deficiencies? Should this provider or supplier be nominated to PRB for a monitoring survey? (Is the surveyor using the form to upgrade the level of care beyond what is required?

(f) Are there any inconsistencies in the State's findings between the Life Safety Code survey and the health and safety survey?

(g) Do you agree that standards cited as deficient affect (or do not affect) the applicable condition? Should this certification be referred to PRB?

3. Plan of Correction

   (a) Has the provider/supplier responded to each cited deficiency? Is the response comprehensive and clearly stated?

   (b) Do you agree with the anticipated correction data? Is it reasonable? Could it be donc sooner?

   (c) Do you agree with the State in its acceptance or rejection of the plan? What of patient health and safety in the interim? Should PRB be consulted?

   (d) Are the deficiencies the same as cited on previous surveys based on MMACS data? Has the provider demonstrated good faith efforts to correct previously cited deficiencies? Is this a marginal provider or supplier? Are consultation efforts by the SA necessary?

4. Waivers

   (a) Are the requested waivers justified and documented in terms of patient health and safety and financial hardship on the provider?

   (b) Are the deficiencies waiverable?

   (c) How does the waiver interface with other health and safety findings? Should PRB be consulted?

   (d) Was the waiver received by ROFEC? If not, should they be consulted?

C. Provider Agreements

1. Time Limited Agreements

   (a) Has the effective date recommended been established in accord with existing regulations and guidelines?

   (b) Do you agree that the type of time limited agreement recommended, should have been? Is it supported by the findings?

   (c) If a cancellation clause is used, is the cancellation data correctly set?

   (d) If a short-term agreement is recommended, is it correct?

2. Change of Ownership

   (a) Has the SA fully documented the changed in ownership? Are you convinced that a change took place?

   (b) If the agreement has been assigned to the new owner, are you satisfied that a survey is not necessary?

(c) Has the SA documented that the provider was informed of the implications of assignment?

(1) Has the new owner submitted a HCFA-1513, Ownership and Financial Interest Disclosure Statement?

(2) Has the Office for Civil Rights been notified of the need for a title VI investigation?

(3) Has the SA continued to follow up on the existing PoC, new ownership notwithstanding?

D. Providership/Certification Issues

1. Distinct Part Certification

(a) Have all the criteria for distinct part certification been adequately documented?

(b) See C1 for propriety of agreement.

2. Mergers

(a) Have all the criteria been met and documented?

3. Deferred Certification

(a) Has the SA adequately documented the deferred certification?

E. Overall Assessment of the SA's Performance

(Answer the following by checking the appropriate "YES" or "NO" block. If "NO", explain.)

1. The SA conducted the survey on time.

2. The survey and certification were received in the RO on time.

3. The HCFA-2567 was complete, legible, and acceptable, as approved by the SA.

4. The HCFA-2567 was disclosed on time.

5. Waivers approved by the SA were properly documented and acceptable to the RO.

6. The SA's recommendations were consistent with its findings.

7. The certification kit contained all essential information.

8. The term of the provider agreement recommended is correct, e.g., short-term, conditional 12-month, unconditional 12-month.

9. A followup with the SA was necessary.

10. The SA adequately documented all providership issues.

11. SA findings show no hazard to patient health and safety.

12. The SA followed procedural guidelines in preparing its certification.

13. If applicable, the denial or termination recommendation was fully developed and documented.

Exhibit 165

Notice to a Provider That Agreement
Was Accepted

Provider Number:

Dear _____:

Your agreement for participation as a (identify type of provider) under the Medicare program has been accepted by the Health Care Financing Administration. Your effective date of participation is _____. Enclosed is one copy of the completed agreement for your records.

Enter the provider number shown above on all forms and correspondence relating to this program.

If deficiencies were found during the survey of your establishment, it is expected that you will proceed to correct these deficiencies as stated in your plan of correction. The (State agency) will monitor the progress made in correcting the identified deficiencies.

We welcome your participation and look forward to working with you.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure: HCFA-1561

Exhibit 166

Notice of Approval of Supplier of Services

Provider Number:

Dear _____:

Your request for approval as a supplier of _____ under the Medicare program has been approved. Your effective date of coverage is _____.

You should report to the (State agency) any changes in staffing, services or other characteristics which may affect compliance with the Conditions prescribed in the regulations. The State agency will visit you periodically to determine that the Conditions for Coverage of services are still met. It will notify you in advance of the date a full survey will be made.

Enter the provider number shown above on all forms and correspondence relating to the Medicare program.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

PAGES 9-521 - 9-524 ARE RESERVED FOR EXHIBIT

167 - HCFA-567, HCFA-567A, Organ Procurement Organization Application and Agreement

Exhibit 168

ORGAN PROCUREMENT ORGANIZATION
REPORT FORM

1.	Name of OPO	2.	Street Address	3.	City and/or Country
4.	State:	5.	Zip Code	6.	Medicare OPO Number
7.	Name of CEO	8.	State/Region Code	9.	Dates of Review (Begin/End Date
10.	Review End Date	11.	Type of Review Initial Review	12.	Facility Service Area (Include Map With Service Area clearly marked)

13. List Surveyors' Names and Titles

For Certification: I certify that I have reviewed each Condition for Coverage and related Standard(s) and unless indicated on this form, the Organization was found to be in compliance with the Standard and/or the Condition for Coverage.

Signature: _____ Title: _____ Date:
Signature: _____ Title: _____ Date:
Signature: _____ Title: _____ Date:
Signature: _____ Title: _____ Date:

For Review: For purposes of a review, I certify that I reviewed each Condition for Coverage and related Standard(s) found not to be in compliance during the review on _____ and unless indicated on this form, the facility was found to be in compliance with the standard and/or the Condition for Coverage.

Signature: _____ Title: _____ Date:
Signature: _____ Title: _____ Date:
Signature: _____ Title: _____ Date:
Signature: _____ Title: _____ Date:
Signature: _____ Title: _____ Date:

FORM HCFA

PAGES 9-526 - 9-557 ARE RESERVED FOR EXHIBIT

169 - United Network for Organ Sharing Members

Model Letter: Organ Procurement Organization Denial--Failure to Meet Requirements

Dear _____:

We have carefully considered your request for designation as an Organ Procurement Organization (OPO) for your service area pursuant to §1138 of the Social Security Act (the Act). We have denied that application.

To quality for reimbursement under Medicare or Medicaid, organs which are procured from an OPO must have been procured from an entity designated under the requirements specified under §1138(b)(1) of the Act. That legislation directs the Secretary to designate no more than one OPO for each service area. The following are reasons you do not qualify for designation: (List deficiencies).

You may appeal the decision not to designate you as the OPO for your service area under Health Care Financing Administration regulations at 42 CFR Part 498. The request must be submitted to this office (name, address and telephone number) within 60 days of receipt of this notice. Your request should state the issues or findings of fact with which you disagree and the reasons for your disagreement. You may also submit written evidence and statements that are relevant and material within a reasonable time after your request for reconsideration.

If you have any questions concerning this decision, please let us know.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 171

Model Letter: Organ Procurement Organization Denial--Competing Applications

Dear _____:

Thank you for your recent request for designation as an Organ Procurement Organization (OPO) pursuant to §1138 of the Social Security Act (the Act). To qualify for reimbursement under Medicare or Medicaid, organs which are procured from an OPO must have been procured from an entity designated or re-designated under the requirements specified under §1138(b)(1) of the Act. That legislation directs the Secretary to designate or re-designate no more than one OPO for each service area.

While your organization meets the standards for qualification as an OPO, we regret to inform you that your application has been denied. Since more than one qualified organization applied for designation within your defined service area, we utilized the following tie breaker factors at 42 CFR 486.316(a) in determining which OPO to designate or re-designate:

- Prior experience, including the previous year's experience in terms of the number of organs procured and wasted and average cost per retrieved organ;
- Actual number of donors compared to the number of potential donors;
- The nature of relationships and degree of involvement with hospitals in the organization's service area;
- Bed capacity associated with the hospitals with which the organizations have a working relationship;
- Willingness and ability to place organs within the service area; and
- Proximity of the OPO to the donor hospitals.

After careful review of the competing applications of OPOs for your defined service area, we have designated or redesignated (Insert name of designated or redesignated OPO) to serve as the designated OPO for that area. Our decision to deny your application was based on the following specific factors:

(List deciding factors)

You may appeal the decision not to designate or redesignate you as the OPO for your service area under Health Care Financing Administration regulations at 42 CFR Part 498. The request must be submitted to this office (name, address and telephone number) within 60 days of receipt of this notice. Your request should state the issues or findings of fact with which you disagree and the reasons for your disagreement. You may also submit written evidence and statements that are relevant and other relevant material within a reasonable time after your request for reconsideration.

If you have any questions, please let us know.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 172

Model Letter: Organ Procurement Organization Approval

Provider Number: _____

Dear _____:

Your application for designation as an Organ Procurement Organization (OPO) for the Medicare and Medicaid programs under §1138 of the Social Security Act has been approved by the Health Care Financing Administration. Effective _____ you are designated as the OPO for the service area (specified in your application) or: (for the following service area:_____). Enclosed is one copy of the completed agreement for your records.

Enter the provider number shown above on all forms and correspondence relating to this program. (For non-hospital based organizations - The Aetna Insurance Company has been authorized as your Fiscal Intermediary and it can provide you with information concerning payment procedures.)

If you believe the above information is not correct (i.e., service area, effective date), please submit your reason(s), in writing, to this office within 60 days of receipt of this notice. We welcome your participation and look forward to working with you.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc:
Central Office

Exhibit 173

Model Letter: Organ Procurement Organization Notice of Termination

Dear _____:

This is to inform you that we have determined that (name of organization) did not achieve and/or maintain compliance with the Organ Procurement Organization (OPO) provisions of §1138 of the Social Security Act. The organization has not demonstrated that it can achieve and maintain compliance with (list requirements not met).

Therefore, the (name of organization) is scheduled for termination from the Medicare and Medicaid programs effective (enter the effective date of termination).

You may appeal this decision to terminate under HCFA regulations at 42 CFR Part 498. The request must be submitted to this office (name address and telephone number) within 60 days of receipt of this notice. Your request should state the issues or findings of fact with which you disagree and the reasons for your disagreement. You may also submit written evidence and materials within a reasonable time after your appeal request. You may be represented by legal counsel at the appeal proceedings.

The service area now has been opened to new applicants. You may, however, apply for approval even though your current agreement is being terminated. Enclosed are the necessary application materials: Form HCFA-576, Request for Organ Procurement Organization Approval to Participate in the Medicare and Medicaid Program; and Form HCFA-576A, Health Insurance Benefits Agreement for OPO. To be considered, you must demonstrate how you achieved compliance with these requirements.

If you wish to apply, it is essential that you complete the application materials and forward them to this office. We will consider all applications to service the open area that are received by (enter date by which new applications must be received). Please make a copy of the application and agreement for your records.

If you have any questions, please let us know.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 174

Model Letter: Organ Procurement Organization Notice
To Public and State Medicaid/Medicare Agencies

Name of OPO
Address of OPO

"Notice is hereby given that on ___(date)___ the agreement between (name of OPO), and the Secretary of Health and Human Services, as a designated Organ Procurement Organization (OPO) for the:

(Service area)

is to be terminated.

The Health Care Financing Administration has determined that the (name of OPO) is not in compliance with Medicare conditions for coverage.

Payment for any services rendered by the OPO after (effective date of termination) will not be made after (date).

The above stated service area is now open to any organization that wishes to be designated for all or part of the area. Applications for participation can be obtained from (respective RO).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 175

Model Letter: Organ Procurement Organization Notice to Bordering OPOs

Dear OPO Administrator:

This is to inform you that (name of terminated OPO) is being terminated from participation in the Medicare and Medicaid programs, because of failure to achieve and/or maintain compliance with provisions of §1138 of the Social Security Act. The service area that is open for competitive application is:

(List service area)

If you wish to participate as the Organ Procurement Organization (OPO) for the service area or any portion of it, you must submit an application. Enclosed are the necessary application materials: Form HCFA-576, Request for Organ Procurement Organization Approval to Participate in the Medicare and Medicaid Program; and Form HCFA-576A, Health Insurance Benefits Agreements for OPOs. We are sending these materials to you only because of your involvement in Medicare's organ procurement activities. As you will note in the materials, we are authorized to approve only one OPO in any given service area.

If you wish to apply for the above-cited service area or any part thereof, it is essential that you complete the application materials and forward them to this office. We will consider all applications to service the open area that are received by (enter date that all applications are due). Please make a copy of the application and agreement for your records.

If you have any questions concerning the application process, please contact me at _____.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosures

Exhibit 176

Model Letter: Organ Procurement Organization Corrective Action Notice

Dear _____:

On (date) we conducted a recertification review of the (name of organization) to determine whether the organization has maintained compliance with the provisions of §1138 of the Social Security Act applicable to Organ Procurement Organizations (OPO) and the Conditions for Coverage for Organ Procurement Organizations found at 42 CFR Part 486, Subpart G. We have determined that the (organization name) is not in compliance with: (list requirements with which the OPO is deficient).

If the deficiencies are not corrected you will be scheduled for termination. The effective date of the termination will be (enter the effective date of termination). As soon as you determine that you are in full compliance, contact the Regional Office.

You may appeal this decision under HCFA regulations at 42 CFR Part 498. The request must be submitted to this office (name, address, telephone number) within 30 days of receipt of this notice. Your request should state the issues or findings of fact with which you disagree and the reasons for your disagreement. You may also submit written evidence and statements that are relevant and other relevant material within a reasonable time after your appeal request.

If you have any questions, please let us know.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 177

ATTESTATION STATEMENT FOR FEDERALLY QUALIFIED HEALTH CENTERS

Complete the following attestation statement.

The _____(name of entity) complies with all applicable Federal requirements related to the following provision of §1861(aa)(4) of the Social Security Act (check the appropriate box):

____ (A)(i) is receiving a grant under §330 of the Public Health Service Act, or

____ (ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under §330 of such Act;

____ (B) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Centers for Medicare and Medicaid Services (CMS) to meet the requirements for receiving such a grant: or

____ (C) Is an outpatient health program or facility operated by a tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act.

The _____(name of the entity) agrees to remain in compliance with the all of the federally qualified health center requirements specified in 42 CFR Part 405 Subpart X, and Part 491, as described in §405.2434(a).

I certify that I have reviewed each Federal requirement in §1861(aa)(4) of the Social Security Act and the federally qualified health center requirements specified in 42 CFR Part 405 Subpart X, and Part 491, as described in §405.2434(a) and that _____(name of facility) is currently in compliance with these requirements and regulations. I agree to inform CMS of any changes that result in noncompliance.

Attention: Read the following provisions of Federal law carefully before signing:

STATEMENTS OR ENTRIES GENERALLY: Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years or both. (18 U.S.C. §1001).

Signature_____ Title _____ Date _____

Printed Name _____

Accepted for the Secretary of Health and Human Services by:

Signature_____ Title _____ Date _____

Exhibit 178

FEDERALLY QUALIFIED HEALTH CENTER CRUCIAL DATA EXTRACT

Name of Entity _____

Street Address _____

County_____ State_____ Zip Code_____

Telephone number _____ Date _____

Is this entity a part of an existing Medicare/Medicaid Provider?
___ Yes *__ No If yes, Provider Number _____

Is this entity a Medicare-approved rural health clinic (RHC)?
_____ Yes** ____ No If yes, RHC Provider Number _____

Type of Ownership or Control: Enter number:

(01) Religious Affiliation (04) Proprietary
(02) Private (05) State/County
(03) Other (06) Combination Govt./Vol.

_____
_____

These items are to be completed by the Centers for Medicare and Medicaid Services.

____State/County Code: _____ State/Region Code:

_____
_____

* The center is an integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (i.e., a provider of services), and is operated with other departments of the provider under common licensure, governance and professional supervision.

** If you are approved as an FQHC, your rural health clinic Medicare provider number will be retired.

Exhibit 179

MODEL LETTER TO APPLICANTS FOR PARTICIPATION IN MEDICARE AS A FEDERALLY QUALIFIED HEALTH CENTER

If you desire to participate in the Medicare program as a Federally Qualified Health Center (FQHC), you must complete and submit to your Centers for Medicare and Medicaid Services (CMS) regional office the enclosed forms, date the Exhibits 177 and 178, and sign the attestation statement contained in Exhibit 177. You must also submit to your fiscal intermediary a completed Form CMS-855, Medicare Enrollment Form. You may obtain the Form CMS-855 from (FI/Name/Address). If you have not already done so, enclose a copy of the following, if applicable:

1. Entity's State license;
2. Entity's CLIA certificate;
3. Health Services Resources Administration's approval form, "Notice of Grant Award;" and
4. A letter from the Tax Board approving "not for profit" status (this may apply if you are under private, proprietary, State/County or Government ownership).

Failure to provide this information may delay your Medicare application.

The signed and dated attestation statement serves as an agreement that you agree to comply with §1861(aa)(4) of the Social Security Act (the Act), and the requirements contained in the Medicare federally qualified health center regulations. Each entity, whether operated as part of another Medicare provider or supplier, or as part of a group of entities under common ownership, must independently meet the Federal requirements for FQHCs and be assigned a separate FQHC identification number.

If it is determined by this CMS regional office that all Federal requirements are met, we will notify you of the effective date that you have been approved to participate in the Medicare program as an FQHC and issue you an FQHC identification number. If you provide services to Medicare beneficiaries prior to your effective date, these services will not be covered.

If you are denied approval to participate in the Medicare program as an FQHC, you will be notified and given the reasons for denial as well as your appeal rights.

Please report any changes in staffing, services, office location, or other characteristics which might affect your approval status to this office. You must notify this office if you are contemplating or negotiating a change of ownership. We will process a change of ownership in accordance with the FQHC regulation at 42 CFR 405.2444. You must also notify the State survey agency and fiscal intermediary of such changes as well.

NOTICE TO ACCREDITED PSYCHIATRIC
HOSPITAL OF INVOLUNTARY TERMINATION

Dear _____: Provider Number:

Institutions accredited as hospitals by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are deemed to meet all of the Medicare Conditions of Participation for hospitals, with the exception of utilization review and the special staffing and medical record requirements for psychiatric hospitals. Section 1864 of the Social Security Act authorizes the Secretary of Health and Human Services to conduct surveys of accredited hospitals participating in the Medicare program as a means of validating reliance on the accreditation process.

When a hospital, regardless of its JCAHO accreditation status, is found to be out of compliance with the special staffing or medical record requirements for psychiatric hospitals, a determination must be made that the facility no longer meets the requirements for participation as a provider of services in the Medicare program. Such a determination has been made in the case of (hospital name) and accordingly, the Medicare provider agreement between (hospital name) and the Secretary of the Department of Health and Human Services is being terminated.

A survey conducted at (name of hospital) on (date) found that the hospital was not in compliance with the Medicare health and safety requirements for Special Medical Record Requirement (42 CFR 482.61) and Special Staff requirement (42 CFR 482.62) for psychiatric hospitals.

A listing of all deficiencies found and a narrative report are enclosed. These deficiencies have been determined to be of such a serious nature as to substantially limit the hospital's capacity to provide adequate care.

The date on which the agreement terminates is (date). The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after (date of termination). For patients admitted prior to (date of termination), payment may continue to be made for a maximum of 30 days of inpatient hospital services furnished on or after (date of termination). You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your hospital on (date of termination) to the (name and address of the RO involved) to facilitate payment for these individuals.

We will publish a public notice in the (local newspaper). You will be advised of the publication date for the notice. If you feel that these findings are incorrect, you have 15 days from the date of this notice to request an informal review of the findings by this office as provided by 42 CFR 488.456 (c)(2). Include in the request any evidence and arguments which you may wish to bring to the attention of the Centers for Medicare and Medicaid Services.

Termination can only be averted by correction of the deficiencies within 45 days of your receipt of this letter. Your plan of correction (written on the enclosed statement of Deficiency and Plan of Correction forms) should be returned to us as soon as possible.

After termination if you wish to be readmitted to the program, you must demonstrate to the (State agency) and CMS that you are able to maintain compliance. Readmission to the program will not be approved until you are able to demonstrate compliance for a period of not less than __* consecutive days.

If you do not believe this termination decision is correct, you may request a hearing before an Administrative Law Judge (ALJ) as outlined in Title 42 of the Code of Federal Regulations, Section 405.1530 et. seq. To be effective, a written request for a hearing must be filed not later than 60 days after the date you receive this letter. Such a request may be made to the Associate Regional Administrator for Health Standards and Quality, (address) who will forward your request to the Regional Chief ALJ in the Office of Hearings and Appeals. The request for a hearing should state why the decision is considered incorrect, and should be accompanied by any evidence and arguments you may wish to bring to the attention of the Department of Health and Human Services. Evidence and arguments may be presented at the hearing, and you may be represented by counsel.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

*Insert number of days
Enclosures

Exhibit 181

Notice To Hospital Provider of Involuntary Termination

Provider Number:

Dear _____:

After a careful review of the facts, the Health Care Financing Administration has determined that the _____ no longer meets the requirements for participation as a provider of services in the Health Insurance for the Aged and Disabled Program (Medicare) established under Title/XVIII of the Social Security Act.

To continue to participate in the Medicare program, a hospital must meet all of the statutory provisions of section 1861(e) of the Act and be in compliance with the Conditions of Participation issued as regulations by the Secretary of Health and Human Services.

Example:

> We find that ___(name)_____ does not meet the requirements contained in Regulations 42 CFR 405.1024(b) implementing section 1861(e)(5) of the Act. This requirement states in part that a hospital "provides 24-hour nursing service rendered or supervised by a registered professional nurse." For a protracted period the records show that your hospital has an RN on the day shift seven days a week and that evening and night shifts are covered by LPN's who perform nursing duties without RN supervision.

The (State agency) which certifies to the Health Care Financing Administration whether hospitals meet the Conditions of Participation, has discussed the 24-hour nursing requirement with you on numerous occasions. Based on the record of the State agency's visits, findings, and recommendations, we have determined that the requirement is not now and is not likely to be met within an acceptable time.

The date on which the agreement terminates is (date of termination). The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after (date of termination). For patients admitted prior to (date of termination), payment may continue to be made for a maximum of 30 days of inpatient hospital services furnished on or after (date of termination). You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your hospital on (date of termination) to the (name and address of the RO involved) to facilitate payment for these individuals.

We will publish a public notice in the (local newspaper). You will be advised of the publication date for the notice.

You may, of course, take steps to meet the participation requirements and establish the hospital's eligibility to participate as a provider of services. The (State agency) is available to provide consultation or assistance you may need in order to accomplish this.

If you wish to be readmitted to the program, you must demonstrate to the (State agency) and HCFA that you are able to maintain compliance. Readmission to the program will not be approved until you are able to demonstrate compliance for a period of not less than __* consecutive days.

If you do not believe this termination decision is correct, you may request a hearing before an administrative law judge as outlined in Title 42 of the Code of Federal Regulations, Section 405.1530 et. seq. To be effective, a written request for a hearing must be filed not later than 60 days after the date you receive this letter. Such a request may be made to the Associate Regional Administrator for Health Standards and Quality, (address) who will forward your request to the Regional Chief Administrative Law Judge in the Office of Hearings and Appeals. The request for a hearing should state why the decision is considered incorrect, and should be accompanied by any evidence and arguments you may wish to bring to the attention of the Department of Health and Human Services. Evidence and arguments may be presented at the hearing, and you may be represented by counsel.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

*Insert number of days

Exhibit 182

Notice of Termination To Supplier

Provider Number:

Dear_____:

After a careful review of the facts, the Health Care Financing Administration has determined that (name)____ no longer meets the Conditions for Coverage of _____. The Conditions for Coverage are issued as regulations of the Health Care Financing Administration in accordance with the provisions of Title/XVIII of the Social Security Act. You must be in compliance with them in order for your services to Medicare patients to be reimbursed under the Medicare program. The _____State agency, which has surveyed your services to assist us, has furnished information from which we have determined that you no longer meet these requirements: (state reason(s) for termination) .

It is necessary, therefore, that we terminate coverage of your _____ services effective (date). We will arrange to publish a routine notice in the (local newspaper). You will be advised of the publication date of the notice. This action, and the reasons therefore, will also be made known to the professional users of your services.

If you believe that this determination is not correct, you may request a hearing before an administrative law judge of the Bureau of Hearings and Appeals as outlined in Title 42 of the Code of Federal Regulations, Section 405.1530 et. seq. If you desire a hearing, you must request it not later that 60 days from the date you receive this letter. Such a request may be made to Health Care Financing Administration, Division of Health Standards and Quality, (address) . Your request will be forwarded to the Regional Chief Administrative Law Judge in the Office of Hearings and Appeals.

The request for a hearing should state why the decision is considered incorrect and should be accompanied by any evidence and arguments you may with to bring to the attention of the Department of Health and Human Services. Evidence and arguments may be presented at the hearings, and you may be represented by counsel.

Sincerely yours,

Association Regional Administrator
(or its equivalent)

Exhibit 183

Model Public Notice of Medicare Termination
of Provider Agreement

(Name and Address)
(of SNF)

"Notice is hereby given that on (effective date), the agreement between (name and address of SNF), and the Secretary of Health and Human Services, as a provider of services in the Health Insurance for the Aged and Disabled Program (Medicare) is to be terminated.

The Health Care Financing Administration has determined that (name of SNF) is not in compliance with Medicare safety requirements in that several provisions of the Life Safety Code are not met. Also, the provider and its Administrator are not currently licensed in accordance with State and local law.

Payment for inpatient skilled nursing services rendered to beneficiaries admitted prior to (effective date) will not be made for stays after ____ *_____."

Associate Regional Administrator
(or its equivalent)

*Date shown will be 30th day following effective date of termination.

PAGES 9-574 - 9-575 ARE RESERVED FOR EXHIBIT

184 - Advertising Order, SF-1143, and Public Voucher for Advertising, SF-1144

Exhibit 185

Model Telegram

Notice of Termination to a Medicaid ICF/MR Following "Look Behind" Survey: Immediate and Serious Threat to Patient Health and Safety.

Provider Number:

Dear _____:

On __(date)__ representatives of the Health Care Financing Administration conducted a survey of (name of facility). At the conclusion of this survey, our findings were discussed with you or your representative (name) and (you, he, she) (was, were) informed that conditions within (name of facility) might pose an immediate and serious threat to the health and safety of clients. Specifically, the facility does not meet the requirements of Section 1905(d) of the Social Security Act and the Conditions of Participation for ICFs/MR. This letter is to inform you that we have determined that the conditions found do, in fact, pose an immediate and serious threat to the health and safety of clients.

If you have not corrected this situation by (insert date 5 working days after date of telegram), the Health Care Financing Administration will terminate your participation in the Medicaid program. Termination will be effective (same date as above). Should we not hear from you, we will assume that the situation has not been corrected.

If you have removed the threat or achieved compliance, please advise us immediately. If you notify us by (date)__ that corrections have been made, representatives of the Health Care Financing Administration will revisit the facility within 2 working days to verify necessary corrections. If the Health Care Financing Administration determines that the reasons for termination remain, the effective date of the termination remains ___(date) , and you will be so informed in writing. If corrections have been made to remove the threat and if total compliance has been achieved, the termination procedures will be halted, and you will be notified in writing. If the threat has been removed, but compliance with all the conditions of participation has not been achieved, additional time may be granted for correction. However, if compliance is not achieved by (termination date), termination will occur.

If you wish to appeal this determination, a written request for a hearing before an administrative law judge must be filed no later than 60 days from the date of receipt of this notice. However, the hearing will be afforded after the effective date of the termination based on immediate and serious threat deficiencies. You may file it with this office or any other office of the Department of Health and Human Services, to be forwarded to the Regional Chief Administrative Law Judge of the Office of Hearings and Appeals. Your request should state why the decision is considered incorrect, and should be accompanied by any evidence and arguments you may wish to bring to the attention of the Department of Health and Human Services.

Associate Regional Administrator
(or its equivalent)

Exhibit 186

Sample Memorandum Disallowing Claims
for Federal Payments
(Used in Look-Behind Disapprovals)

FROM: Associate Regional Administrator
(or its equivalent)
Region

SUBJECT: Recommendations to Disallow Claims for Federal Payments (Name of Facility)

TO: Associate Regional Administrator
(or its equivalent)
Division of Financial Operations
Region

As you are aware, title XIX regulations (42 CFR 442.30) provide for HCFA to examine the validity of title XIX provider agreements issued to SNFs and ICFs by the State Medicaid agency. Further, these regulations provide that where HCFA finds that such agreements are not valid for purposes of Federal financial participation due to improper actions by the State agencies,claims for Federal payment may be denied.

This Division, in the course of monitoring the title XIX SNF/ICF survey and certification process, has determined that the (_____) nursing home, a swing bed/skilled nursing/intermediate care facility, received title XIX funds during the period from October 1, 1984, through February 13, 1988, despite the absence of a valid provider agreement.

You will note that we asked the State Medicaid agency in a letter dated June 15, 1986, to provide us with any evidence which would have indicated that there was a valid provider agreement. We have received no response to this letter.

Accordingly, we are proceeding to disallow all claims for Federal payments made by the Department of Health and Human Services for expenses on behalf of the (institution) for the period October 1, 1984, through February 13, 1988.

We have attached copies of the most pertinent data. Our entire file is available for your review if you require further documentation.

Attachments

Exhibit 187

Notification to Previously Approved Supplier Of
A Pending Termination

Provider Number:

Dear_____:

In order to have its services reimbursed under the Medicare Program, a supplier of services must meet certain requirements established in accordance with the provisions of title XVIII of the Social Security Act. The _____ State agency, which assists us in the Medicare certification process, has advised us that you no longer meet the requirements for approval of services because:

Accordingly, action has been initiated to terminate coverage of your
_____ service in the Medicare program.

Following a careful review of all the facts, you will receive formal notice of our determination. If an adverse determination is made, you will receive written notice informing you of the date of termination, and of your appeal rights. At the same time, we will place a notice in a local newspaper to advise the community of the date of termination, and the reasons for termination.* This action, and the reasons therefor, will be made known to the professional users of your services.

If you have already taken steps to meet the requirements or if you have definitive plans for doing so, please get in touch with this office immediately.

Sincerely yours,

Assistant Regional Administrator
(or its equivalent)

Enclosure

*Newspaper notification optional

Exhibit 188

Notification: Voluntary Termination of Provider Agreement Approved

Provider Number:

Dear _____:

Your request to terminate your participation in Medicare as a provider of services has been accepted. Accordingly, your agreement with the Secretary of Heath and Human Services will be terminated effective (date of termination). Please notify your medical and administrative staff.

In accordance with your Health Insurance Benefits Agreement, public notice of termination of the agreement is necessary. Please publish a notice in the local newspaper with the widest circulation, as soon as possible, but at least 15 days before the effective termination date. The notice should be along the following lines:

> The (name and address of institution) will no longer participate in the Medicare Program (title XVIII of the Social Security Act) effective (date of termination). The agreement between the (name of institution) and the Secretary of Health and Human Services will be terminated on (date of termination) in accordance with the provisions of the Social Security Act.
>
> The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after (date of termination). For patients admitted prior to (date of termination), payment may continue to be made for up to 30 days of inpatient services furnished on or after (date of termination).
>
> Name of authorized official
> Name of institution

Please send us a copy of the published notice. An envelope is enclosed for your convenience in replying.

Please note that payment for inpatient services rendered to Medicare beneficiaries admitted prior to the effective date of termination is specifically limited to 30 days from (date of termination). Please provide us with a list showing the names and health insurance claim numbers of beneficiaries in your facility on (date of termination) to facilitate the payment of bills for these individuals.

You should be in touch with (name of fiscal intermediary) to make arrangements for completing a final cost report and to adjust any outstanding current financing or accelerated emergency payments.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

Exhibit 189

Notification: Approval of Voluntary Termination of a Supplier

Provider Number:

Dear _____:

Your request to terminate your Medicare coverage as a supplier of services has been accepted. Accordingly, your coverage under the program will be terminated effective (date of termination).

Since this action may be of interest to the public, we will publish a notice in the local newspaper with the widest circulation as soon as possible but at least 15 days before the effective termination date. The notice will give the effective date of termination and state that payment for services will not be made on or after that date.* This action will be made known to professional users of your services.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

*Newspaper Notification Optional

Exhibit 190

Notification to Provider that Has Ceased or is Ceasing Operation

Provider Number:

Dear _____:

We have been notified that _____ (closed, will close) on (date of closing). Under the provisions of regulations 42 CFR 405.615(e), your provider agreement with the Secretary of Health and Human Services (terminated, will terminate) effective with that date. No payment can be made under the Medicare program for services rendered on or after (date of closing).

In accordance with your Health Insurance Benefits Agreement, public notice of termination of the agreement is necessary. Please publish a notice in the local newspaper with the widest circulation as soon as possible. The notice should be along the following lines:

> The (name and address of your institution) will no longer participate in the Medicare Program (title XVIII of the Social Security Act) effective (date of cessation of business). The agreement between the (name of institution) and the Secretary of Health and Human Services (will be, has been) terminated on (date of termination) in accordance with the provisions of the Social Security Act.
>
> The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after (date of termination). For patients admitted prior to (date of termination), payment may continue to be made for up to 30 days of inpatient services furnished on or after (date of termination).

Name of authorized official
Name of agency

You should be in touch with your fiscal intermediary to make arrangements for completing a fiscal cost report and to make provision for the return of any outstanding current financing or emergency payment.

If your (hospital, provider of OPT, home health agency) is reopened and you again wish to participate as a provider of services, you should contact the (State agency). They will assist you in taking action necessary to become certified for participation as a provider.

Please let us know if you have any questions concerning this action.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 191

Notification To Supplier That Has Ceased or is Ceasing Operation

Provider Number:

Dear_____:

We have been notified that your (facility type) (closed, will close) on (date of closing). Therefore, your participation in the Medicare program (terminated, will terminate) effective with that date. No payment can be made under the Medicare program for services rendered on or after (date of closing).

Since this action may be of interest to the public, we will publish a notice in the local newspaper with the widest circulation as soon as possible. The notice will give the effective date of termination and the state that payment for laboratory services will not be made on or after that date.* This action will be made known to professional users of your services.

If your (facility type) is reopened and you again wish to be covered under the Medicare program, you should contact the (State agency). They will assist you to become certified for coverage of your services.

Please let us know if you have any questions concerning this action.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

*Newspaper notification optional

Exhibit 192

Acknowledgement of Request for Hearing

Provider Number:

Dear _____:

This will acknowledge receipt of your request for a hearing in the matter of (name of institution).

We have provided the Office of Hearings and Appeals with a copy of your request and the following documents that will be considered by the hearings officer:

(list)

These are also enclosed for your convenience.

The Office of Hearings and Appeals will notify you very soon of the designation of an Administrative Law Judge to act on your request.

Sincerely
yours,

Enclosures

Exhibit 193

Model Letter Informing PPS-Excluded Hospitals/Units
That Reverification Has Been Approved

Name of PPS-Excluded Hospital or Hospital
Containing PPS-Excluded Unit
Address
City, State, Zip

Dear Hospital Administrator:

I am pleased to inform you that (name of hospital/unit) is reverified for participation in the Medicare and Medicaid programs and will be excluded from the perspective payment system (PPS), effective (enter effective date).

This reverification is based on your self-attestation statement and checklist of (date statement signed by the hospital/unit) that to the best of your knowledge and belief the (name of hospital/unit) meets all of the applicable regulatory requirements found at (42 CFR 412.23, 412.25, 412.27, 412.29 and/or 412.30 - enter whichever is directly applicable to the hospital/unit).

Please be advised that the Health Care Financing Administration has authorized the State survey agency (SA) to conduct a validation survey of a sample of all PPS-excluded hospitals and units. The SAs will continue to conduct complaint surveys as in the past. If these surveys find that the hospital/unit did not in fact meet the applicable requirements for exclusion, Medicare payments will be made under PPS. In addition, if your hospital or unit undergoes any expansion or downsizing, or, if your hospital or unit no longer complies with our exclusion criteria, you are required to notify the SA immediately.

ARA, Region _____

Exhibit 194

MODEL LETTER ANNOUNCING COMPLIANCE WITH ALL SURVEYED MEDICARE CONDITIONS OF PARTICIPATION AFTER A SAMPLE VALIDATION OR SUBSTANTIAL ALLEGATION SURVEY

Hospital Name

(Provider Number)

Address

Dear M_____:

I am pleased to inform you that as a result of the (State agency's) (samplevalidation)(substantial allegation) survey, (name of hospital) was found in compliance with all the Medicare Conditions of Participation and will continue to be "deemed" to meet applicable Medicare requirements based upon accreditation by the (Joint Commission on Accreditation of Healthcare Organizations) (American Osteopathic Association).

The (State agency) advised you of the Medicare deficiencies noted during the (sample validation)(substantial allegation) survey of your hospital, and we are enclosing a complete listing of all deficiencies found by the (State agency). We have forwarded a copy of this letter and our findings from this survey (optional--and your plan and timetable for correcting the Medicare deficiencies cited) to the (Joint Commission on Accreditation of Healthcare Organizations) (American Osteopathic Association) for its review. The (State agency) has also been sent a copy of this letter. The (Joint Commission on Accreditation of Healthcare Organizations) (American Osteopathic Association) may be in touch with you to discuss the Medicare survey findings.

Since your hospital has been found "in compliance," you do not have to submit a plan for correcting any of the Medicare deficiencies cited by the (State agency). However, under Federal disclosure rules a copy of the findings of this Medicare survey must be publicly disclosed within 90 days of the completion. You may therefore wish to submit for public disclosure, if you have not already done so, your comments on the survey findings, and any plans you may have for correcting the cited deficiencies.

We thank you for your cooperation and look forward to working with you on a continuing basis in the administration of the Medicare program.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure: HCFA-2567

cc:
Central Office
JCAHO/AOA
State Agency

Exhibit 195

MODEL TELEGRAM NOTICE ANNOUNCING TO AN ACCREDITED HOSPITAL THAT THE HOSPITAL DOES NOT COMPLY WITH ALL THE CONDITIONS OF PARTICIPATION AND THAT THERE IS IMMEDIATE OR SERIOUS THREAT TO PATIENT HEALTH AND SAFETY

Hospital Name

(Provider Number)

Dear M_____, Administrator

Institutions accredited as hospitals by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are deemed to meet all of the Medicare Conditions of Participation for hospitals, with the exception of utilization review and the special staffing and medical record requirements for psychiatric hospitals. Section 1864 of the Social Security Act authorizes the Secretary of Health and Human Services to conduct surveys of accredited hospitals participating in the Medicare program as a means of validating reliance on the accreditation process.

A survey was conducted at (name of hospital) on (date). At the conclusion of this survey, the findings were discussed with (you or your representative's name) and (you, he, she) (was, were) informed that conditions within (name of facility) posed an immediate and serious threat to the health and safety of patients. Specifically, the facility does not meet (cite Conditions of Participation).

When a hospital, regardless of its JCAHO accreditation status, is found to be out of compliance with one or more Condition of Participation, and immediate or serious threat to patient health and safety exists, a determination must be made that the facility no longer meets the requirements for participation as a provider of services in the Medicare program. Such a determination has been made in the case of (name of hospital) and, accordingly, the Medicare provider agreement between (name of hospital) and the Secretary of the Department of Health and Human Services is being terminated. This termination will be effective (date).

The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after (date of termination). For patients admitted prior to (date of termination), payment may continue to be made for a maximum of 30 days for inpatient hospital services furnished on or after (date of termination). You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your hospital on (date of termination) to the (name and address of the RO involved) to facilitate payment for these individuals.

We will publish a public notice in the (local newspaper). You will be advised of the publication date for the notice. Termination can only be averted by correction of these deficiencies by (insert date 5 days after date of telegram). Should we not hear from you, we will assume that the situation has not been corrected. If you have corrected this situation, please advise us immediately. If you notify us by (date) that corrections have been made, representatives of the Health Care Financing Administration will revisit the facility within 2 working days to verify necessary corrections. If the Health Care Financing Administration determines that the reasons for termination remain, the effective date of the termination remains (date), and you will be so informed in writing. If corrections have been made, the termination procedures will be halted, and you will be notified in writing.

If you do not believe this termination decision is correct, you may request a hearing before an Administrative Law Judge (ALJ) as outlined in Title 42 of the Code of Federal Regulations, Section 405.1530 et. seq. To be effective, a written request for a hearing must be filed not later than 60 days after the date you receive this letter. Such a request may be made to the Associate Regional Administrator for Health Standards and Quality, (address) who will forward your request to the Regional Chief ALJ in the Office of Hearings and Appeals. The request for a hearing should state why the decision is considered incorrect, and should be accompanied by any evidence and arguments you may wish to bring to the attention of the Department of Health and Human Services. Evidence and arguments may be presented at the hearing, and you may be represented by counsel.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

*Insert number of days

Exhibit 196

MODEL LETTER ANNOUNCING TO ACCREDITED HOSPITAL AFTER A SAMPLE VALIDATION SURVEY THAT THE HOSPITAL DOES NOT COMPLY WITH ALL CONDITIONS OF PARTICIPATION
(Do Not Use When Immediate and Serious Threat to Patient Health or Safety Deficiencies Exists)

Hospital Name (Provider Number)

Dear M _____, Administrator

Section 1865 of the Social Security Act and pursuant regulations provide that a hospital accredited by the (Joint Commission on Accreditation of Healthcare Organizations [JCAHO]) (American Osteopathic Association [AOA]) will be "deemed" to meet all Medicare health and safety requirements with the exception of those relating to utilization review. (For psychiatric hospitals add: "and special medical record and staffing requirements for psychiatric hospitals." For swing-bed hospitals add: "and special requirements for hospital providers of long-term care services ("swing-beds"). Section 1864 of the Act authorizes the Secretary of Health and Human Services to conduct, on a selective sampling basis, surveys of accredited hospitals participating in Medicare, as a means of validating reliance on the accreditation process. If, in the course of such a survey, a hospital is found to have significant deficiencies with respect to compliance with Medicare requirements, we are required, following timely notification of the accrediting body, to keep the hospital under Medicare State agency survey jurisdiction until its significant Medicare deficiencies have been corrected, and it is in compliance with all Medicare Conditions of Participation.

Sample Language:

We have received a report of deficiencies found by the (State agency) during the recent validation survey of your hospital. The (name of hospital) was found not in compliance with the provisions of the National Fire Protection Association's Life Safety Code (1981 edition) which are included in the Medicare health and safety regulatory requirements for hospitals (42 CFR 482.41(b)), Medicare health and safety requirements for Nursing Services (42 CFR 482.23) and Pharmaceutical services (42 CFR 482.25). In addition, a number of deficiencies were found in other Medicare requirements.

A complete listing of all deficiencies found by the (State agency) was previously furnished to you and another copy is enclosed (HCFA-2567, Statement of Deficiencies and Plan of Correction). These deficiencies have been found to be of such serious nature as to substantially limit your hospital's capacity to render adequate care and prevent it from being in compliance with all the Conditions of Participation for hospitals.

You are therefore requested to submit to the (State agency) a plan of correction, with acceptable time schedules, which will lead to the correction of the cited deficiencies. Enter on the right side of the HCFA-2567, opposite the deficiencies, your planned action to correct the deficiencies and the expected completion date. Retain the fifth copy and return all others to the State agency within 10 days of receipt of this letter. (Use if applicable--You may also submit a request for waiver of National Fire Protection Association's Life Safety Code deficiencies, including rationale justifying the request.)

The requirement that the (name of hospital) must submit a plan to correct its Medicare deficiencies does not affect its accreditation, its Medicare payments, or its current status as a participating provider of hospital services in the Medicare program. When the plan of correction has been implemented, major Medicare deficiencies have been corrected, and it has been found that all the Conditions of Participation are met, you will not be subject to any further State agency followup.

Under HCFA regulations 42 CFR 405.1505(n), this notice of findings is an administrative action, not an initial determination by the Secretary, and therefore formal reconsideration and hearing procedures do not apply. However, if you feel that these findings are incorrect, you have 15 days from the date of this notice to request an informal review of the findings by this office (42 CFR 405.1901(e)(6)). Include in the request any evidence and arguments which you may wish to bring to the attention of the Health Care Financing Administration.

Copies of this letter are being forwarded to the (State agency) and to (JCAHO)(AOA). You can pursue your concerns with the (JCAHO)(AOA) at any time, if you so prefer.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure: HCFA-2567

cc:
Central Office
JCAHO/AOA
State Agency

Exhibit 197

NOTICE TO ACCREDITED HOSPITAL ANNOUNCING APPROVAL OF PLAN OF CORRECTION AND COMPLETION SCHEDULE

Hospital Name (Provider Number)

Address

Dear M_____,

I am pleased to inform you that the (name of hospital)'s plan of correction for its Medicare deficiencies, and the time schedule for completion of the plan, has been found acceptable.

When (name of hospital)'s plan of correction has been implemented, its major Medicare deficiencies have been corrected, and we have concluded that it meets all the Medicare Conditions of Participation for hospitals, it will no longer be subject to State agency followup. Failure to correct deficiencies in a timely manner will result in termination of the Medicare provider agreement.

Copies of this letter are being forwarded to the (State agency) and the (JCAHO) (AOA).

We thank you for your cooperation and look forward to working with you on a continuing basis in the administration of the Medicare program.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
Central Office
JCAHO/AOA
State agency

Exhibit 198

MODEL LETTER ANNOUNCING COMPLIANCE WITH ALL CONDITIONS OF PARTICIPATION AFTER THE EFFECTUATION OF AN ACCEPTABLE PLAN OF CORRECTION

Hospital Name (Provider Number)

Address

Dear _____:

Based upon a report by the (State agency) of their recent Medicare survey of (name of hospital), we find that your institution is now in compliance with all the Medicare Conditions of Participation. (Use if applicable-This finding is also based upon the information received in support of your hospital's request for waiver of the (cite deficiency), considered a deficiency under the National Fire Protection Association's Life Safety Code, (1981 edition) Section __. We have determined that equivalent safety has been established.)

In view of your implementation of the plan of correction (use if applicable-and the equivalent fire safety achieved) the (name of hospital) can again be recognized as meeting Medicare requirements by virtue of its accreditation by the (Joint Commission on Accreditation of Healthcare Organizations [JCAHO]) (American Osteopathic Association [AOA]).

We have forwarded a copy of this letter and our findings from this survey to the (JCAHO) (AOA).

We appreciate your efforts and the steps taken to correct the Medicare deficiencies cited by the (State agency). We thank you for your cooperation, and look forward to working with you on a continuing basis in the administration of the Medicare program.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
Central Office
JCAHO/AOA
State agency

Exhibit 199

MODEL LETTER ANNOUNCING TO ACCREDITED HOSPITAL AFTER A SUBSTANTIAL ALLEGATION SURVEY THAT THE HOSPITAL DOES NOT COMPLY WITH ALL CONDITIONS OF PARTICIPATION
(Do Not Use When Immediate and Serious Threat To Patient or Safety Deficiencies Exists)

Hospital Name (Provider Number)

Address

Dear M_____, Administrator

Section 1865 of the Social Security Act and implementing regulations (42 CFR 405.1901(d)), provide that a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association will be "deemed" to meet all the Medicare Conditions of Participation with the exception of utilization review. (For psychiatric hospitals add: "and special medical staffing and medical record requirements for psychiatric hospitals.") For swing-bed hospitals add: "and special requirements for hospital providers of long-term care services ("swing-bed")"). Section 1864 of the Act requires the Secretary of Health and Human Services to conduct a survey of an accredited hospital participating in Medicare if there is a substantial allegation of a serious deficiency or deficiencies which would, if found to be present, adversely affect the health and safety of patients. If, in the course of such a survey, a hospital is found to have significant deficiencies with respect to compliance with the Conditions of Participation, we are required, following timely notification to the accrediting body, to keep the hospital under Medicare State agency survey jurisdiction until the hospital is in compliance with all the Conditions of Participation.

We have received a report of the deficiencies found by the (State agency) during its recent substantial allegation survey of your hospital. Based on this report, we find that the (name of hospital) is not in compliance with all the Conditions of Participation for hospitals. A complete listing of all deficiencies found by the (State agency) was previously furnished to you and another copy is enclosed. These deficiencies have been determined to be of such serious nature as to substantially limit your hospital's capacity to render adequate care and prevent it from being in compliance with all the Conditions of Participation for hospitals.

Sample Language:

> The (name of hospital) was found not in compliance with the provisions of the National Fire Protection Association's Life Safety Code (1981 Edition) which are included in the Medicare health and safety regulatory requirements for hospitals (42 CFR 482.41(b)), Nursing services (42 CFR 482.23) and Pharmaceutical services (42 CFR 482.25). In addition, a number of deficiencies were found in other Medicare requirements.

In accordance with section 1865(b) of the Social Security Act, the (State agency) will shortly conduct a complete Medicare survey of your facility to assess compliance with the other Conditions of Participation which were not surveyed during the recent survey. They will also furnish you with a complete listing of any other deficiencies noted during the full survey.

After the completion of the Medicare survey (name of hospital) will be asked to submit to the (State agency) a plan with acceptable completion dates for correction of all its cited deficiencies. (Use if applicable--You will also be able to submit a request for waiver of National Fire Protection Association's Life Safety Code deficiencies, including rationale justifying the request.)

The requirement that the (name of hospital) must submit a plan to correct its Medicare deficiencies does not affect its accreditation, its Medicare payments, or its current status as a participating provider of hospital services in the Medicare program. When (name of hospital)'s plan of correction has been implemented and it has been found to meet all the Medicare Conditions of Participation for hospitals, the State agency will discontinue its survey jurisdiction.

Under HCFA regulations 42 CFR 405.1505(n), this notice of findings is an administrative action, not an initial determination by the Secretary, and therefore formal reconsideration and hearing procedures do not apply. However, if you feel that these findings are incorrect, you have 15 days from the date of this notice to request an informal review of the findings by this office as provided by 42 CFR 405.1901(e)(6). Include in the request any evidence and arguments which you may wish to bring to the attention of the Health Care Financing Administration.

Copies of this letter are being forwarded to the (State agency), and the (Joint Commission on Accreditation of Healthcare Organizations)(American Osteopathic Association). The (State agency) will contact you shortly to complete its Medicare survey. You can pursue your concerns with the (Joint Commission)(AOA) at any time, if you so prefer.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure:
HCFA-2567

cc:
Central Office
JCAHO/AOA
State Agency

Exhibit 200

Model Letter Acknowledging Complaint Alleging
Noncompliance with 42 CFR 489.24 and/or the Related Requirements
of 42 CFR 489.20 Investigation Not Warranted

(name)
(address)

Dear _____:

We have reviewed the information you provided concerning (hospital, city, State), and appreciate the interest you have shown in bringing this matter to our attention. Enclosed please find a copy of 42 CFR 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases and related requirements of 42 CFR 489.20, for your information. Our responsibility is to assure compliance of Medicare participating hospitals with the health and safety requirements of the law.

We have not authorized any further investigation of your complaint. Our review did not find that the situation you describe indicates any violation of the law. Based on your individual situation, however, you may wish to consider the civil enforcement provisions of §1867 of the Social Security Act on an independent basis.

Thank you for taking the time to bring this matter to our attention.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

Exhibit 201

Model Letter Acknowledging Complaint Alleging
Noncompliance with 42 CFR 489.24 and/or the Related Requirements
of 42 CFR 489.20: Investigation Warranted

(name)
(address)

Dear _____:

We have reviewed the information you provided concerning (hospital, city, State), and appreciate the interest you have shown in bringing this matter to our attention. Enclosed please find a copy of 42 CFR 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases and related regulations of 42 CFR 489.20, for your information. Our responsibility is to assure compliance of Medicare-participating hospitals with the health and safety requirements of the law.

We have authorized an investigation of the situation you described. Upon receipt of the investigation report, we will contact you again to advise you of the results.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

Exhibit 202

Model Letter Requesting Physician Review Of
A Possible Violation Of 42 CFR 489.24

(date)
(name)
(PRO name)
(street address)
(City, State, Zip)

Dear (physician consultant or PRO executive director):

Enclosed is a case we have identified as a potential violation of 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases. Section 489.24 places special responsibilities on Medicare-participating hospitals that offer emergency services.

Please have this case reviewed by a physician who is a specialist in either the specialty of the physician who attended the patient or the type of service under review. Whenever possible, the physician reviewer should practice in a similar setting as that of the physician who attended the patient.

This review is necessary for the purpose of assisting us in making a compliance determination on an alleged 42 CFR 489.24 violation. We have the onsite investigation findings and require a medical opinion on this case. In order to prevent further situations endangering the community's access to quality emergency care, please sign, date and return this packet to us within 5 working days.

Since the physician reviewer could be needed to serve as an expert witness in the case, secure from the physician a statement of willingness to provide service on the additional development needed to properly adjudicate any issues and to testify as an expert witness.

To assist you in performing your review, we have enclosed:

- A copy of the patient's medical record (at both hospitals, if pertinent),
- A copy of 42 CFR 489.24 and related parts of 42 CFR 489.20; and
- The form "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals", upon which the physician should document his/her findings. Your response is not limited to the space provided on the form, however, you may use additional paper as needed. It is important that the physician thoroughly document the rationale for each response.

Thank you for your assistance. If you wish to discuss this case further, please contact (policy person in RO) at (phone number).

Sincerely,

Associate Regional Administrator
(or its equivalent)

Enclosures

Exhibit 203

Model Letter Following Investigation Into Alleged
Violation Of 42 CFR 489.24 And/Or
The Related Requirements Of 42 CFR 489.20
Facility In Compliance

(date)
(name)
(hospital)
(street address)
(City, State, Zip)

Re: Provider Identification Number: (number)

Dear (hospital administrator):

This office authorized the (State) State agency to conduct a complaint survey of (hospital) on (date). The complaint concerned an alleged violation of 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases and/or the related provisions of 42 CFR 489.20.

I am pleased to inform you that as a result of the survey, your facility was found in compliance with the requirements regarding the emergency care obligations of Medicare facilities.

Thank you for your cooperation during the survey. If you have any questions or concerns about this matter, please contact (name of contact) at (phone number).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc: Central Office
State Agency Title XVIII
Accrediting Body
Complainant

Exhibit 204

Model Letter For A Violation Of 42 CFR 489.24:
Preliminary Determination Letter
(Immediate and Serious Threat)

(date)
(name)
(hospital)
(street address)
(City, State, zip)

Re: Provider Identification Number: (number)

Dear (hospital administrator):

To participate in the Medicare program, a hospital must meet the requirements established under title XVIII of the Social Security Act (the Act) and the regulations established by the Secretary of Health and Human Services under the authority contained in §1861(e) of the Act. Further, §1866(b) of the Act authorizes the Secretary to terminate the provider agreement of a hospital that fails to meet these provisions.

Your hospital was surveyed on (date) by the (State survey agency) based on an allegation of noncompliance with the requirements of 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases. After a careful review of the findings, we have determined that your hospital violated the requirements of 42 CFR 489.24 based on: [select as appropriate]

> failure to screen, failure to treat, failure to appropriately transfer, failure to accept an individual who required the hospital's specialized capabilities, delay in examination or treatment to inquire about an individual's method of payment or insurance status, or adverse action taken against a physician, qualified medical person or hospital employee.

The deficiencies identified are listed on the enclosed form HCFA-2567, Statement of Deficiencies.

We have determined that the deficiencies are so serious that they constitute an immediate threat to the health and safety of any individual who comes to the emergency department and requests examination or treatment for an emergency medical condition. Further, under 42 CFR 489.53, a hospital that violates the provisions of 42 CFR 489.24 is subject to termination of its provider agreement. Consequently, we plan to terminate (name of hospital) participation in the Medicare program.

This preliminary determination letter serves to notify you of the violation. The projected date on which your agreement will terminate is (date - 23rd day from the date of this letter for immediate and serious threats).

You will receive a "notice of termination letter" on (2-4 days prior to the termination date, which is also the 19th-21st day from the date of this preliminary determination letter). This final notice will be sent to you concurrently with notice to the public, in accordance with regulations at 42 CFR 489.53.

You may avoid termination action and notice to the public either by providing credible allegation or credible evidence of correction of the deficiencies, or by successfully proving that the deficiencies did

not exist prior to the projected public notification date. In either case, the information must be furnished to this office so that there is time to verify the corrections. A credible allegation of correction by the hospital requires a resurvey to verify the corrections. However, when evidence of correction is provided by the hospital, this office must decide whether the evidence of correction is sufficient to halt the termination action. If the evidence is not sufficient in itself to establish that the hospital is in compliance, a resurvey is required for verification of correction. If we verify your corrective action or determine that you successfully refuted the findings contained in this letter by proving the allegations were in error, your termination from the Medicare program will be rescinded.

If you have any questions concerning this preliminary determination letter, please contact (name of contact) at (phone number).

Sincerely,

Associate Regional Administrator
(or its equivalent)

Enclosure: Form HCFA-2567 Statement of Deficiencies

cc: Central Office
State Agency Title XVIII
State Agency Title XIX
OIG
OCR/FO
PRO
Accrediting Body
Complainant
State Licensing Body
DHHS Congressional Liaison Office
HCFA Office of Legislation and Policy

Exhibit 205

Model Letter For A Violation Of 42 CFR 489.24 And/Or
The Related Requirements Of 42 CFR 489.20
Preliminary Determination Letter (90 Day Termination Track)

(date)
(name)
(hospital)
(street address)
(City, State, Zip)

Re: Provider Identification Number: (number)

Dear (hospital administrator):

To participate in the Medicare program, a hospital must meet the requirements established under title XVIII of the Social Security Act (the Act) and the regulations established by the Secretary of Health and Human Services under the authority contained in §1861(e) of the Act. Further, §1866(b) of the Act authorizes the Secretary to terminate the provider agreement of a hospital that fails to meet these provisions.

Your hospital was surveyed on (date) by the (State survey agency) based on an allegation of noncompliance with the requirements of 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases and/or the related requirements at 42 CFR 489.20. After a careful review of the findings, we have determined that your hospital violated: [select as appropriate]

- The requirements of 42 CFR 489.24 based on (failure to screen, failure to treat, failure to appropriately transfer, failure to accept an individual who required the hospital's specialized capabilities, delay in examination or treatment to inquire about an individual's method of payment or insurance status, or adverse action taken against a physician, qualified medical person or hospital employee).

- The related anti-dumping provisions found at 42 CFR 489.20 based on the hospital's failure to (have and enforce policies to ensure compliance with the requirements of 42 CFR 489.24, maintain transfer records, maintain a list of physicians on call, maintain a central emergency services log, report the reception of a dump, or meet the sign posting requirements).

The deficiencies identified are listed on the enclosed form HCFA-2567, Statement of Deficiencies.

Under 42 CFR 489.53, a hospital that violates the provisions of 42 CFR 489.20 or 42 CFR 489.24 is subject to termination of its provider agreement. Consequently, we plan to terminate name of hospital participation in the Medicare program.

This preliminary determination letter serves to notify you of the violation. The projected date on which your agreement will terminate is (date - 90th day from the date of this letter).

You will receive a "notice of termination letter" on (75th day from the date of this preliminary determination letter). This final notice will be sent to you concurrently with notice to the public, in accordance with regulations at 42 CFR 489.53.

You may avoid termination action and notice to the public either by providing credible allegation or credible evidence of correction of the deficiencies or by successfully proving that the deficiencies did not exist prior to the projected public notification date. In either case, the information must be furnished to this office so that there is time to verify the corrections. A credible allegation of correction by the hospital requires a resurvey to verify the corrections. However, when evidence of correction is provided by the hospital, this office must decide whether the evidence of correction is sufficient to halt the termination action. If the evidence is not sufficient in itself to establish that the hospital is in compliance, a resurvey is required for verification of correction. If we verify your corrective action or determine that you successfully refuted the findings contained in this letter by proving the allegations were in error, your termination from the Medicare program will be rescinded.

If you have any questions concerning this preliminary determination letter, please contact (name of contact) at (phone number) .

Sincerely,

Associate Regional Administrator
(or its equivalent)

Enclosure: Form HCFA-2567 Statement of Deficiencies

cc: Central Office
State Agency Title XVIII
State Agency Title XIX
OIG
OCR/FO
PRO
Accrediting Body
Complainant
State Licensing Body
DHHS Congressional Liaison Office
HCFA Office of Legislation and Policy

Exhibit 206

Model Letter To Complainant Following Investigation
Of Alleged Violation of 42 CFR 489.24 And/Or
The Related Requirements of 42 CFR 489.20
Complaint Not Substantiated

(name)
(address)

Dear _____:

We have received the report from the investigation that we authorized in response to your allegation that (name and location of hospital) violated the emergency care obligations of 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases and/or the related requirements of 42 CFR 489.20. The situation you described was not found to be a violation of 42 CFR 489.24 or 42 CFR 489.20. Based on your individual situation, however, you may wish to consider the civil enforcement provisions of §1867 of the Social Security Act on an independent basis.

Thank you for bringing this matter to our attention.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 207

Model Letter To Complainant Following Investigation
of Alleged Violation Of 42 CFR 489.24 And/Or
The Related Requirements of 42 CFR 489.20
Complaint Substantiated

(name)
(address)

Dear _____:

We have received the report from the investigation that we authorized in response to your allegation that (name and location of hospital) violated the emergency care obligations of 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases and/or the related provisions at 42 CFR 489.20. The situation you described was found to be a violation of [select as appropriate]

42 CFR 489.20 42 CFR 489.24

Enclosed is a copy of the letter we sent to the hospital. If the hospital violated 42 CFR 489.24, we are notifying the Office of Inspector General because it has responsibility for the enforcement of the civil monetary penalties prescribed by §1867 of the Social Security Act (the Act). In addition, we are notifying the Office for Civil Rights because it may take action under the Hill-Burton Subpart G Community Service regulations. Also, based on your individual situation, you may wish to consider the civil enforcement provisions of §1867 of the Act on an independent basis.

It is our goal to help health care facilities provide the best possible care to patients. Thank you for bringing this matter to our attention.

Sincerely yours,

Associate Regional Administrator
(or its equivelant)

Enclosure

Exhibit 208

Model Letter For Referring A Violation of 42 CFR 489.24
To The Office Of Inspector General

_____(date)
_____(name)
____(director)
(Office of Inspector General)
__(street address)
__(City, State, Zip)

Re: Provider Identification Number: _(number)
Hospital__(hospital name)

Dear (__OIG director's name__):

In order to participate in the Medicare program, a hospital must meet the requirements established under title XVIII of the Social Security Act (the Act) and must also meet the additional requirements established by the Secretary of Health and Human Services under the authority contained in §1861(e) of the Act. Further, §1866(b) of the Act authorizes the Secretary to terminate the provider agreement of a hospital that fails to meet these provisions.

This office authorized the (State) State agency to conduct a (an) (sample, complaint, recertification, initial) survey of (hospital) on (date). As a result of that survey, it was determined that the facility violated 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases. The deficiencies cited in the enclosed Statement of Deficiencies posed an **[select as appropriate]**

__ immediate and serious threat to the health and safety of patient in need of emergency medical care, **[23 day termination track]**

__ threat to the health and safety of patients in need of emergency care, **[90 day termination track]**,

and we initiated termination action on ___(date)___.

We are referring this case to the Office of the Inspector General because you have responsibility for the enforcement of the civil monetary penalties prescribed by §1867 of the Act.

If you have any questions or concerns about this matter, please let us know.

Sincerely yours,

Associate Regional Administrator
(or its equivanent)

Enclosures

Exhibit 209

Model Letter For Referring A Violation of 42 CFR 489.24
To The Regional Office For Civil Rights

_____(date)
_____(name)
__(regional director)
(Office of Civil Rights)
__(street address)
__(City, State, Zip)

Re: Provider Identification Number: __(number)
Hospital __(hospital name)

Dear (__OCR director's name__):

In order to participate in the Medicare program, a hospital must meet the requirements established under title XVIII of the Social Security Act (the Act), and must also meet the additional requirements established by the Secretary of Health and Human Services under the authority contained in §1861(e) of the Act. Further, §1866(b) of the Act authorizes the Secretary to terminate the provider agreement of a hospital that fails to meet these provisions.

This office authorized the (State) State agency to conduct a (an) (sample, complaint, recertification, initial) survey of (hospital) on (date). As a result of that survey, it was determined that the facility violated 42 CFR §489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases. The deficiencies cited in the enclosed Statement of Deficiencies posed an immediate and serious threat to the health and safety of patient in need of emergency medical care, and we initiated termination action on ___(date)___.

We are referring this case to the regional Office for Civil Rights because you may take action under the Hill-Burton Subpart G Community Service regulations at 42 CFR 124.603(b)(1).

If you have any questions or concerns about this matter, please let us know.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

Exhibit 210

Model Letter For A Past Violation of 42 CFR 489.24 And/Or
The Related Requirements Of 42 CFR 489.20:
No Termination

(date)
(name)
(hospital)
(street address)
(City, State, Zip)

Re: Provider Identification Number: (number)

Dear (hospital administrator):

In order to participate in the Medicare program, a hospital must meet the requirements established under title XVIII of the Social Security Act (the Act), and must also meet the additional requirements established by the Secretary of Health and Human Services under the authority contained in §1861(e) of the Act. Further, §1866(b) of the Act authorizes the Secretary to terminate the provider agreement of a hospital that fails to meet these provisions.

This office authorized the (State) State agency to conduct a (an) (sample, complaint, recertification, initial) survey of (hospital) on (date). As a result of that survey, it was determined that your facility violated 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases and/or the related provisions of 42 CFR 489.20. The deficiencies identified are cited in the enclosed Statement of Deficiencies.

During the survey the State agency found that you discovered the violation and implemented corrective action that has been effective in the long term prior to the State agency survey. Therefore we are not terminating your Medicare provider agreement with the Secretary of Health and Human Services.

[NOTE: Only include the following paragraph if the requirements of 42 CFR 489.24 were violated.]

As the requirements for participation in the Medicaid program under 42 CFR 440.10(a)(3)(iii) include meeting Medicare requirements, we are notifying the appropriate State officials concerning your hospital's past violation of the requirements of 42 CFR 489.24. We are also notifying the Office of Inspector General because it has responsibility for the enforcement of the civil monetary penalties prescribed by §1867 of the Act. In addition, we are notifying the regional Office for Civil Rights because it may take action under the Hill-Burton Subpart G Community Service regulations at 42 CFR 124.603(b)(1).

If you have any questions or concerns about this matter, please contact (name of contact) at (phone number).

Sincerely,

Associate Regional Administrator
(or its equivalent)

Enclosure: Form HCFA-2567 Statement of Deficiencies

cc: Central Office
State Agency Title XVIII
State Agency Title XIX
OIG
OCR/FO
PRO
Accrediting Body
Complainant
State Licensing Body
DHHS Congressional Liaison Office
HCFA Office of Legislation and Policy

Exhibit 211

Model Letter For A Violation Of 42 CFR 489.24 And/Or
The Related Provisions Of 42 CFR 489.20
Notice of Termination

(date)
(name)
(hospital)
(street address)
(City, State, Zip)

Re: Provider Identification Number: (number)

Dear (hospital administrator):

In order to participate in the Medicare program, a hospital must meet the requirements established under title XVIII of the Social Security Act (the Act) and must also meet the additional requirements established by the Secretary of Health and Human Services under the authority contained in §1861(e) of the Act. Further, §1866(b) authorizes the Secretary to terminate the provider agreement of a hospital that fails to meet these provisions.

After a careful review of the facts, we have determined that (hospital) no longer meets the requirements for participation as a provider of services in the Health Insurance for the Aged and Disabled Program (Medicare). Our review of the (date) survey conducted by the (State survey agency) indicates that your hospital violated: [select as appropriate]

- The requirements of 42 CFR 489.24, Responsibilities of Medicare Participating Hospitals in Emergency Cases, based on: (failure to screen, treat, appropriately transfer, or accept an individual who required the hospitals specialized capabilities: or delay in examination or treatment, a penalty or adverse action taken against a physician, qualified medical person or hospital employee).

- The related anti-dumping provisions of 42 CFR 489.20 based on the hospital's failure to: (have and enforce policies to ensure compliance with the requirements of §1867 of the Act, maintain transfer records, maintain an on-call list of physicians, maintain a central emergency services log, report the reception of a dump, or meet the sign posting requirements).

The deficiencies cited by the (State survey agency) are listed on the enclosed Statement of Deficiencies.

Under 42 CFR 489.53, a hospital that violates the provisions of 42 CFR 489.24 and/or the related provisions of 489.20 is subject to termination of its provider agreement in accordance with §1866(b) of the Act. Consequently, we are terminating your participation in the Medicare program.

The date on which your agreement terminates is (date). The health insurance program will not make payment for services furnished to patients admitted on or after (termination date). For patients admitted prior to (termination date), payment may continue to be made for up to 30 days of services furnished on or after (termination date). A list showing the names and health insurance claim numbers of beneficiaries in your facility on (day before termination date) should be forwarded to (intermediary and address).

If you have taken corrective action which ensures that no further violations will occur, please notify this office immediately, in writing. If terminated, you may, of course, take steps to come into compliance and reapply to establish your facility's eligibility to participate as a provider of services under title XVIII of the Act.

As the requirements for participation in the Medicaid program under 42 CFR 440.10(a)(3)(iii) include meeting Medicare requirements, we are notifying the appropriate State officials concerning your hospital's violation of 42 CFR 489.20 and/or 42 CFR 489.24.

[Insert for 42 CFR 489.24 violation]

(We are also notifying the Office of Inspector General because it has responsibility for the enforcement of the civil monetary penalties prescribed by §1867 of the Act. In addition, we are notifying the regional Office of Civil Rights because it may take action under the Hill-Burton Subpart G Community Service regulations at 42 CFR 124.603(b)(1).)

If you believe this determination is not correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in regulations at 42 CFR 498.40 et seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. For expedited handling, such a request may be made to the following:

(name)
Associate Regional Administrator
(or its equivalent)
(street)
(City, State, Zip)

At your option, you may instead submit a hearing request directly (accompanied by a copy of this letter) to the Departmental Appeals Board, Civil Remedies Division, Room 637-D, HHH Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, and send a copy of your request to this office.

A request for a hearing should identify the specific issues, the findings of fact and the conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense.

We will forward your request to the regional Chief Administrative Law Judge in the Office of Hearings and Appeals.

If you have any questions concerning this, please contact (name of contact) at (phone number).

Sincerely,

(name of ARA)
Associate Regional Administrator
(or its equivalent)

Enclosure: Form HCFA-2567 Statement of Deficiencies

Page 3 - (name of administrator)

cc: Central Office
State Agency Title XVIII
State Agency Title XIX
OIG
OCR/FO
PRO
Accrediting Body
Complainant
State Licensing Body
DHHS Congressional Liaison Office
HCFA Office of Legislation and Policy

Exhibit 212

Model Letter Requesting PRO Review Of A Confirmed Violation Of 42 CFR 489.24 For Purposes Of Assessing Civil Monetary Penalties (CMPs) Or Excluding Physicians

(date)
(name)
(PRO name)
(street address)
(City, State, Zip)

Dear (PRO executive director):

Enclosed is a case that we determined was a violation of 42 CFR 489.24, which places special responsibilities on Medicare-participating hospitals that offer emergency services. Because the Office of the Inspector General (OIG) has the authority to assess CMPs and exclude physicians from the Medicare program for violations of §1867, we referred our confirmed violation decision to the OIG for their review.

In accordance with 42 CFR 489.24(g), before CMPs may be assessed or physicians may be excluded from the Medicare program for a violation of 42 CFR 489.24, the appropriate Peer Review Organization (PRO) must review the case to assess whether the individual had an emergency medical condition which had not been stabilized, and provide a report on its findings. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall request such a review before effecting a sanction, and shall provide a period of at least 60 days for such review. During the 60 days, you are to provide the hospital and/or affected physician with an opportunity to discuss the case and submit additional information.

Please have this case reviewed by a physician who is a specialist in either the specialty of the physician who attended the patient or the type of service under review. Whenever possible, the physician reviewer should practice in a similar setting as that of the physician who attended the patient. Since the physician reviewer could be needed to serve as an expert witness in the case, secure from the physician a statement of willingness to provide service on the additional development needed to properly adjudicate any issues and to testify as an expert witness.

To assist you in performing your review, we have enclosed:

- A copy of the patient's medical record (at both hospitals, if pertinent);
- A copy of 42 CFR §489.24 and related provisions of 42 CFR 489.20; and
- The form "Physician Review Outline for Emergency Care Obligations of Medicare Hospitals", upon which the physician will document his/her findings. Your response is not limited to the space provided on the form. It is important that the physician thoroughly document the rationale for each response.

Thank you for your assistance. If you wish to discuss this case further, please contact (policy person in RO) at (phone number).

Sincerely,

(name of ARA)
Associate Regional Administrator
(or its equivalent)

Enclosures:

Exhibit 213

State Test Administration Plan

Each State will design its own Test Administration Plan for the Surveyor Minimum Qualifications Test (SMQT) according to the instructions contained in the State Operations Manual, §§4009.1 and 4009.2. The information each State will provide is as follows:

1. Proposed Test Site Locations: **STATE:**_____

Names(s) of City/Town	Location(s)	No. Rooms & Room Capacity per Location

2. State Test Coordinator:

Name:_____ _____ _____
Position: _____
Agency: _____
Mailing Address: _____
_____
Phone Number: _____

3. State Test Monitor(s) (Also, include the names of Substitute Test Monitors who will fill in if necessary):

Name: _____
Position: _____
Agency: _____
Mailing Address: _____
_____
Phone Number: _____

Name: _____
Position: _____
Agency: _____
Mailing Address: _____
_____
Phone Number: _____

Name: _____
Position: _____
Agency: _____
Mailing Address: _____
_____
Phone Number: _____

Exhibit 214

MODEL LETTER ANNOUNCING TO STATE SURVEY AGENCY
REQUIREMENTS FOR ADMINISTERING THE
LONG TERM CARE SURVEYOR MINIMUM QUALIFICATIONS TEST (SMQT)

Dear _____:

This is to announce that the Long Term Care Surveyor Minimum Qualifications Test will be administered on _____. You are to submit, no later than 60 days from the date of this letter, your Test Administration Plan to _____. The Plan must:

- List the individuals who will be taking the SMQT and the Test Module(s) each will take;
- Identify proposed test site(s); and
- Designate a State Test Coordinator and a State Test Monitor(s) who will assist in the administration of the test.

Staff assigned to administer the test should be assigned in such a way as to avoid real or potential conflicts of interest.

Each test site must have a minimum of one regional staff member. However, at a single test site you may have multiple testing rooms. You should provide at least one State Test Monitor onsite for every 50 candidates or portion thereof. Because the number of RO staff assigned to oversee onsite test activities is ___, the maximum number of test sites that can be approved for your State is ___.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Exhibit 215

Notification To Provider/Supplier Warning of Possible Termination -
Failure to Disclose Financial Interest and Ownership Information

Provider Number:
(if assigned)

Dear_____:

Institutions which provide services under Medicare and Medicaid are required by law to provide ownership and financial control information. To date, we have not received the requested information.

Enclosed is another copy of the Disclosure of Ownership and Control Interest Statement, HCFA-l5l3, to be completed by your institution if you wish to participate in the Medicare and Medicaid programs.

* If this information is not received within 20 days, your institution may be terminated from the Medicaid program.

or

* If this information is not received within 20 days, your request to participate in the Medicare program may be denied.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

*Use applicable sentence.

PAGES 9-616 - 9-627 ARE RESERVED FOR EXHIBITS

216 - Report on Initial Survey Activity

217 - Aging Report on Pending Initial Survey Activity

218 - Pre-release Notification Documentation

219 - Model Audit Disallowance Letter--Title XVIII

220 - Model Audit Disallowance Letter--Title XIX

222 - Audit Clearance Document

Exhibit 223

Model Letter Announcing To Accredited Laboratory
That It Is in Compliance With All CLIA Conditions After
The Correction of Deficiencies

Director
Laboratory Name (CLIA Number)
Address

Dear _____:

Based upon a report by the (State agency) of their recent survey of (name of laboratory), we find that your laboratory is now in compliance with all applicable Clinical Laboratory Improvement Amendments (CLIA) of 1988 Conditions and can again be recognized as meeting CLIA requirements by virtue of your accreditation by the (name of accreditation organization).

We have forwarded a copy of this letter and our findings from this survey to the (name of accreditation organization).

We appreciate your efforts and the steps taken to correct the CLIA deficiencies cited by the (State agency). We thank you for your cooperation.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
Accreditation Organization
State Agency or HCFA Agent

Exhibit 224

Notice To Accredited Laboratory Announcing
Approval of Plan of Correction and Completion Schedule
For Correcting Deficiencies

Director
Laboratory Name (CLIA Number)
Address

Dear _____:

I am pleased to inform you that (name of laboratory)'s plan of correction for its Clinical Laboratory Improvement Amendments of 1988 (CLIA) deficiencies, and the time schedule for completion of the plan, has been found acceptable by the Health Care Financing Administration.

When (name of laboratory)'s plan of correction has been implemented and its deficiencies have been corrected, and we have concluded that the laboratory meets all the CLIA Conditions, it will no longer be subject to State agency monitoring sanctions and follow-up surveys. Failure to correct deficiencies in a timely manner will result in revocation of your CLIA certificate.

Copies of this letter are being forwarded to the (State agency and the accreditation organization or other HCFA agent, as appropriate).

If you have any questions, please feel free to contact our office.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
State Agency or HCFA Agent
Accreditation Organization

Exhibit 225

Model Letter Announcing Compliance With Applicable CLIA Conditions After Sample Validation or Substantial Allegation of Noncompliance Survey

Director
Name of Laboratory (CLIA Number)
Address

Dear _____:

I am pleased to inform you that as a result of the (State agency's) (sample validation) (complaint) survey, (name of laboratory) was found to be in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Conditions and will continue to be deemed to meet applicable CLIA requirements based upon accreditation by the (name of accreditation organization)

The (State agency) advised you, however, of other deficiencies noted during the (sample validation) (complaint) survey of your laboratory, and we are enclosing a complete listing of all deficiencies identified. We have forwarded a copy of this letter and our findings from the survey (optional--and your plan and timetable for correcting the deficiencies cited) to the (accreditation organization) for its review. The (State agency) has also been sent a copy of this letter. The (accreditation organization) may be in touch with you to discuss the survey findings.

Since your laboratory has been found to be in compliance with applicable condition-level requirements, you do not have to submit a plan for correcting the deficiencies cited by the (State agency). However, under Federal disclosure rules a copy of the findings of this survey must be publicly disclosed within 90 days of the completion of the survey. You may therefore wish to submit for public disclosure, if you have not already done so, your comments on the survey findings, and any plans you may have for correcting the cited deficiencies.

We thank you for your cooperation.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure:

Form HCFA-2567

cc:
State Agency
Accreditation Organization

Exhibit 226

ACCREDITED LABORATORY ALLEGATION(S) REPORT

1. NAME AND ADDRESS OF LABORATORY

2. CLIA NUMBER

3. LAB ACCREDITED BY:

4. DATE ALLEGATION REPORTED TO HCFA

5. DATE CASE CLOSED

6. SOURCE OF ALLEGATION (CHECK ALL APPLICABLE BOXES)

[] CONGRESSIONAL INQUIRY
[] PATIENT OR PATIENT'S FAMILY
[] LAB OR EX-LAB STAFF
[] NEWS MEDIA
[] LICENSURE REPORT
[] MEDICAID REPORT
[] MEDICARE INTERMEDIARY
[] PEER REVIEW ORGANIZATION (PRO)
[] OTHER (SPECIFY)

7. REGIONAL OFFICE SCREENING AND REFERRALS (CHECK ALL APPLICABLE BOXES)

[] NO INVESTIGATION WARRANTED
[] REFERRED FOR INVESTIGATION
[] STATE AGENCY (COMPLETE ITEM 8)
[] MEDICARE INTERMEDIARY
[] STATE LICENSURE
[] INSPECTOR GENERAL
[] DEPARTMENT OF JUSTICE
[] OTHER

8. AREA OF STATE AGENCY INVESTIGATION (CHECK ALL APPLICABLE BOXES)

[] PROFICIENCY TESTING
[] PATIENT TEST MANAGEMENT
[] QUALITY CONTROL
[] PERSONNEL
[] QUALITY ASSURANCE
[] OPERATING WITHOUT CERTIFICATION OF ACCREDITATION
[] OTHER

9. FINDINGS

a. [] IN COMPLIANCE WITH ALL CLIA CONDITION(S)

b. [] OUT OF COMPLIANCE WITH THE FOLLOWING CLIA CONDITION(S):

c. [] LABORATORY PLACED UNDER STATE AGENCY, HCFA OR HCFA AGENT MONITORING [DATE: ___]

d. [] ADVERSE ACTIONS RECOMMENDED (LIST)

10. REMARKS

11. SIGNATURE OF REGIONAL REPRESENTATIVE | 12.REGION | 13. DATE

Form HCFA-2878A (5-92)

Exhibit 227

Model Letter Announcing to the CLIA-Exempt Laboratory
After a Sample Validation or Substantial Allegation of
Noncompliance Survey, That It Does Not Comply
With Applicable Program Requirements

Director (CLIA Number)
Name of Laboratory
Address

Dear _____:

Section 353(p) of the Public Health Service Act, permits the Secretary to exempt a laboratory in a State that has demonstrated that its laboratory licensure laws are equal to or more stringent than the Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements. Based on this authority, the Health Care Financing Administration conducts sample validation surveys to ensure that CLIA requirements continue to be met by approved State licensure programs and the laboratories they license (CLIA-exempt laboratories). If, in the course of such a survey, a CLIA-exempt laboratory is found to have deficiencies with respect to compliance with CLIA requirements, the State in which you are licensed is required to take the appropriate enforcement action and monitor the correction of deficiencies.

A (sample or complaint) validation survey was conducted at (name of laboratory) on (date). At the conclusion of this survey, the findings were discussed with (director's or designee's name) and (he, she) was informed that conditions within (name of laboratory) pose an immediate jeopardy (indicate whether or not deficiencies cited constitute immediate jeopardy). Specifically, the laboratory does not comply with the following CLIA Condition(s) and/or standard(s): (cite Conditions and/or standards).

We have enclosed a complete listing of all deficiencies (Form HCFA-2567, Statement of Deficiencies and Plan of Correction) found by HCFA surveyors.

When a laboratory, regardless of its CLIA-exempt status, is found to be out of compliance with one or more comparable CLIA Conditions based on a (sample or complaint) survey and immediate jeopardy has been determined to exist, the laboratory must take prompt action to remove the jeopardy.

We have informed the State of the survey findings and have recommended that the State take enforcement action if the cited deficiencies are not corrected by _____.

The results of this survey may be made available to the public in accordance with the Federal Freedom of Information Act disclosure provisions.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc:
Central Office
HCFA Agent (if applicable)

Exhibit 228

Model Letter Announcing to the State Laboratory Program,
After a Sample Validation or Substantial Allegation of
Noncompliance Survey, That a CLIA-Exempt Laboratory Does Not
Comply With Applicable Program Requirements

Re: (Name of CLIA-Exempt Laboratory)
(CLIA Number)

Name and Address of State
Laboratory Program

Dear _____:

Section 353(p) of the Public Health Service Act permits the Secretary to exempt a laboratory in a State that has demonstrated that its laboratory licensure laws are equal to or more stringent than Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements. Based on this authority, the Health Care Financing Administration (HCFA) conducts sample and complaint validation surveys to ensure that CLIA requirements continue to be met by approved State licensure programs and the laboratories they license. If, in the course of such a survey, a CLIA-exempt laboratory is found to have deficiencies with respect to compliance with CLIA requirements, you are required to take the appropriate enforcement action and monitor the correction of deficiencies.

A (sample or complaint) survey was conducted at the (name of laboratory) on (date). HCFA found Conditions within the laboratory that pose an immediate jeopardy to the general public. We have enclosed a listing (Form HCFA-2567, Statement of Deficiencies and Plan of Correction) of all deficiencies found by the HCFA surveyors during the survey.

We have informed the (name of laboratory) of our survey findings and that you will contact the laboratory regarding correction of the deficiencies and enforcement action.

We will contact you within 15 days from the date of this notice to verify that you have taken appropriate enforcement action. Unless an appropriate enforcement action is taken or the deficiencies have been corrected we may bring suit in the U.S. District Court to enjoin continuation of the activity that is causing the hazard or enjoin the continued operation of the laboratory in accordance with 42 CFR 493.1846.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc:
Central Office

Exhibit 229

Model Letter Announcing to the CLIA-Exempt Laboratory
That HCFA Will Seek a Temporary Injunction or Restraining Order

Director (CLIA Number)
Name of Laboratory
Address

Dear _____:

Section 353(j) of the Public Health Service Act and implementing regulations specify that if the Secretary has reason to believe that the continuation of any activity by a laboratory would constitute a significant hazard to the public health, the Secretary may bring suit in U.S. District Court to enjoin continuation of the specific activity or, if necessary, to enjoin the continued operation of the laboratory.

A survey was conducted at (name of laboratory) on (date). At the conclusion of this survey the findings were discussed with (you or director's name) and (you, he, she) was informed that the Conditions within (name of laboratory) pose a significant hazard to the public health. Specifically, the laboratory does not meet the following Clinical Laboratory Improvement Amendments (CLIA) Condition(s) and/or standards: (cite Condition(s) and/or standard(s)).

We have enclosed a complete listing (Form HCFA-2567, Statement of Deficiencies and Plan of Correction) of all deficiencies found by the Health Care Financing Administration (HCFA) surveyors.
We informed the (name of State) on (date) of these deficiencies. However, because the (name of State) failed to take the appropriate enforcement action against your laboratory, HCFA has filed suit in the U.S. District Court for the district in which your laboratory is located to enjoin the continued operation of the (name of laboratory). This action can only be averted by correction of the deficiencies that caused the significant hazard to the public health.

If you have corrected these deficiencies, please advise us immediately to permit verification of the necessary corrections.

The results of this survey will be made available to the public in accordance with the Federal Freedom of Information disclosure requirements.

A copy of this letter is being forwarded to the (State).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc:
Central Office

Exhibit 230

Model Letter Announcing to the State Laboratory Licensure Program That HCFA Will Seek a Temporary Injunction or Restraining Order to Enjoin Continued Operation

Re: (Name of CLIA-Exempt Laboratory)
(CLIA Number)

Name and Address of State
Laboratory Program

Dear _____:

Section 353(j) of the Public Health Service Act and implementing regulations specifies that if the Secretary has reason to believe that the continuation of any activity by a laboratory would constitute a significant hazard to the public health, the Secretary may bring suit in U.S. District Court to enjoin continuation of the specific activity or, if necessary, to enjoin the continued operation of the laboratory.

A survey was conducted at (name of laboratory) on (date). At the conclusion of this survey the findings were discussed with the (director's name) and (you, he, she) was informed that the Conditions within (name of laboratory) pose a significant hazard to the public health. Specifically, the laboratory does not meet the following Clinical Laboratory Improvement Amendments of 1988 (CLIA) Condition(s) and/or standards: (cite Condition(s) and/or standard(s)).

We have already informed the (name of laboratory) on (date) of these deficiencies. However, because you failed to take the appropriate enforcement action against the (name of laboratory), we will file suit in the U.S. District Court (for the district in which the laboratory is located) to enjoin the continued operation of the (name of laboratory). Additionally, your refusal to take the necessary enforcement action, may jeopardize the approval and/or renewal of your licensure program.

This action can only be averted by correction of the deficiencies that cause the significant hazard to the public health or by the imposition of an appropriate enforcement action by your office.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc:
Central Office

Exhibit 231

Model Letter Announcing to the CLIA-Exempt Laboratory
After A Sample Validation or Substantial Allegation of
Noncompliance Survey, That It Does Not Comply
With Applicable Program Requirements
(No Immediate Jeopardy)

Director (CLIA Number)
Name of Laboratory
Address

Dear _____:

Section 353(p) of the Public Health Service Act permits the Secretary to exempt a laboratory in a State that has demonstrated that its laboratory licensure laws are equal to or more stringent than Clinical Laboratory Improvement Amendments of 1988 requirements. Based on this authority, the Health Care Financing Administration conducts sample validation surveys to ensure that CLIA requirements continue to be met by approved State licensure programs and the laboratories they license (CLIA-exempt laboratories). If, in the course of such a survey, a CLIA-exempt laboratory is found to have deficiencies with respect to compliance with CLIA requirements, the State in which you are licensed is required to take appropriate enforcement action and monitor the correction of deficiencies.

A (sample or complaint) validation survey was conducted at (name of laboratory) on (date). At the conclusion of this survey, the findings were discussed with (director's or designee's name) and (he, she) was informed that the laboratory does not comply with the following CLIA Condition(s) and/or standard(s): (cite Conditions and/or standards).

We have enclosed a complete listing of all deficiencies (Form HCFA-2567, Statement of Deficiencies and Plan of Correction) found by HCFA surveyors.

We have informed the State of the survey findings, and it will be responsible for monitoring the correction of your deficiencies. We have directed the State to take enforcement action if the cited deficiencies are not corrected within an acceptable period of time. The State will report any enforcement action taken to us.

The results of this survey may be made available to the public in accordance with the Federal Freedom of Information Act disclosure provisions.

A copy of this letter has been forwarded to the (name of State laboratory program).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc:
Central Office
HCFA Agent (if applicable)

Exhibit 232

Model Letter Announcing to the State Laboratory Program,
After a Sample Validation or Substantial Allegation of
Noncompliance Survey, That a CLIA-Exempt Laboratory Does Not
Comply With Applicable Program Requirements
(No Immediate Jeopardy)

Re: (Name of CLIA-Exempt Laboratory)
(CLIA Number)

Name and Address of State
Laboratory Program

Dear _____:

Section 353(p) of the Public Health Service Act permits the Secretary to exempt a laboratory in a State that has demonstrated that its laboratory licensure laws are equal to or more stringent than Clinical Laboratory Improvement Amendments of 1988 requirements. Based on this authority, Health Care Financing Administration conducts sample and complaint validation surveys to ensure that CLIA requirements continue to be met by approved State licensure programs and the laboratories they license. If, in the course of such a survey, a CLIA-exempt laboratory is found to have deficiencies with respect to compliance with CLIA requirements, you are required to take appropriate enforcement action and monitor the correction of deficiencies.

A (sample or complaint) survey was conducted at the (name of laboratory) on (date). HCFA found that the laboratory does not comply with applicable CLIA requirements. We have enclosed a listing (Form HCFA-2567, Statement of Deficiencies and Plan of Correction) of all deficiencies found by HCFA surveyors during the survey.

We have informed the (name of laboratory) of our survey findings and that you will contact the laboratory regarding correction of the deficiencies and enforcement action. Obtain an acceptable plan of correction and forward a copy of it to us.

Take appropriate enforcement action if the laboratory does not meet its plan of correction and report the enforcement action taken to us. Unless an appropriate enforcement action is taken or the deficiencies have been corrected we may bring suit in the U.S. District Court to enjoin continuation of any activity that is causing a hazard or enjoin the continued operation of the laboratory in accordance with 42 CFR 493.1846.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

Exhibit 233

FRAUD AND ABUSE

OFFICE OF INSPECTOR GENERAL, OFFICE OF INVESTIGATIONS FIELD OFFICES

STREET ADDRESS	MAILING ADDRESS	STATES
BOSTON		
Room 1405 JFK Federal Bldg. Boston, MA 02203 (617) 565-2660	HHS, OS, OIG, OI P.O. Box 8767 Boston, MA 02114	onnecticut Maine Massachusetts New Hampshire Rhode Island Vermont
NEW YORK		
Room 3800 B Federal Building 26 Federal Plaza New York, NY 10278 (212) 264-1691	HHS, OS, OIG, OI P.O. Box 3209 Church St. Station New York, NY 10008	New Jersey New York Puerto Rico Virgin Islands
PHILADELPHIA		
Room 4430 3535 Market Street Philadelphia, PA 19104 (215) 596-6796	HHS, OS, OIG, OI P.O. Box 8049 Philadelphia, PA 19101	Delaware Pennsylvania West Virginia Maryland except: - Prince Georges Co. - Montgomery Co. Virginia except: - Fairfax Co. - Arlington Co. - City of Alexandria - City of Falls Church
ATLANTA		
Room 1004 101 Marietta Tower Atlanta, GA 30323 (404) 331-2131/2556	HHS, OS, OIG, OI P.O. Box 2288 Atlanta, GA 30301	Alabama Florida Georgia Kentucky Mississippi North Carolina South Carolina Tennessee
CHICAGO		
23rd Floor 105 West Adams Chicago, IL 60603 (312) 353-2740	HHS, OS, OIG, OI 23rd Floor 105 West Adams Chicago, IL 60603	Illinois Indiana Michigan Minnesota Ohio Wisconsin

Exhibit 233 (Cont.)

FRAUD AND ABUSE

DALLAS

Room 4E1B 1100 Commerce Street Dallas, TX 75242 (214) 767-8406	HHS, OS, OIG, OI Room 4E1B 1100 Commerce Street Dallas, TX 75242	Arkansas Louisiana New Mexico Oklahoma Texas

DENVER

Room 1334 1961 Stout Street Federal Bldg. Denver, CO 80294 (303) 844-5621	HHS, OS, OIG, OI P.O. Box 2692 Denver, CO 80201	Colorado Iowa Kansas Missouri Montana Nebraska North Dakota South Dakota Wyoming Utah

SAN FRANCISCO

Room 174 50 U. N. Plaza San Francisco, CA 94102 (415) 556-7747	HHS, OS, OIG, OI P.O. Box 42516 San Francisco, CA 94101	Arizona California Guam Hawaii Nevada Samoa

SEATTLE SUB-OFFICE

Room 209 2201 Sixth Avenue Seattle, WA 98121 (206) 442-0547	HHS, OS, OIG, OI P.O. Box 61220 Seattle, WA 98121 Washington	Alaska Idaho Oregon

WASHINGTON, DC

Room 5193 Cohen Building Independence Ave., SW Washington, D.C. 20201 (202) 472-7900	HHS, OS, OIG, OI Room 5193 Cohen Bldg. 330 Independence Ave., SW Washington, D.C. 20201	District of Columbia Maryland Counties: - Prince Georges - Montgomery Virginia Counties: - Arlington Virginia Cities: - Alexandria - Falls Church

Exhibit 234

CLIA Notice of Noncompliance and Proposed Sanction(s)
(No Immediate Jeopardy)

CLIA Number: _____

(Fill in address and salutation):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578) and bill for services provided to Medicare beneficiaries and Medicaid recipients under Titles XVIII and XIX of the Social Security Act, it must comply with all CLIA requirements at Title 42 Code of Federal Regulations, Part 493.

This is to inform you that the survey conducted by the (fill in the exact title of the State survey agency) on (fill in date) has identified noncompliance with the CLIA Conditions as specified on the attached list and citations of statutory and regulatory authority, and the attached Form HCFA-2567, Statement of Deficiencies and Plan of Correction. This noncompliance does not pose immediate jeopardy to patients served by the laboratory. If these deficiencies remain uncorrected, we will impose, as of (fill in projected effective date and duration) the following alternative sanctions:).

(Specify which sanctions are to be imposed. If a civil money penalty will be imposed, state the amount of the penalty and specify whether the amount is for each day of noncompliance or each violation. Also clarify that the penalty amount is not collected prior to the hearing, but will accrue until the outcome of the hearing or correction of the noncompliance. Explain that civil money penalty amounts may be increased or decreased prior to the hearing if noncompliance worsens, e.g., if an immediate jeopardy situation develops or is partially corrected.)

(If State on-site monitoring is imposed, include the expected frequency and length of time the monitor will be in the laboratory. Include also the hourly rate that will apply.)

(If a directed plan of correction is imposed, include the letter which specifically addresses the imposition of this sanction.)

(If principal sanctions, i.e., suspension, limitation, or revocation of the CLIA certificate) are proposed, note that they will be effective following the administrative hearing decision, if the Health Care Financing Administration prevails in its determination of noncompliance.)

Within 10 days after the receipt of this notice, you may submit to (fill in the exact title of the State survey agency) or to HCFA written evidence or any other information against the imposition of these (this) sanction(s). You may also request an administrative hearing within 60 days of your receipt of this notice. The request must be in writing by you or your legal representative, and must contain the following information:

1. The specific issues or findings with which you disagree; and

2. The specific basis for contending that the State agency's or HCFA's findings of noncompliance are incorrect. Additional evidence may also be presented at the hearing, and you may be represented by counsel.

Administrative hearings are conducted by the Departmental Appeals Board of the Department of Health and Human Services (HHS). If additional expenses are incurred to conduct future visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for an attendance at an Administrative Law Judge hearing, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform these activities.

The alternative sanctions listed above will be effective prior to the hearing or until HCFA determines that the noncompliance on which the sanctions are based has been corrected.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency

Exhibit 235

Notice of Suspension or Limitation of the CLIA Certificate

Immediate Jeopardy

Overnight Mail

CLIA Number:_____

Re: Suspension or Limitation of the CLIA Certificate

Clinical Laboratory Improvement Amendments of 1988; 42 U.S.C. 263a

[Fill in address and salutation]:

This is to inform you that the Clinical Laboratory Improvement Amendments of 1988 certificate for your laboratory will be (fill in suspended or limited) due to noncompliance which we have determined constitutes immediate jeopardy to the health and safety of patients served by your laboratory, based on the survey conducted by (State Agency) on (date) and the information provided to us on the Statement of Deficiencies and Plan of Correction (Form HCFA 2567). This action is taken under the authority of CLIA, §353 of the Public Health Service Act (PHSA), 42 U.S.C. 263a and the provisions of 42 CFR, Part 493, Subpart R.

(In the case of a limitation of the CLIA certificate, insert the following:)

Due to the noncompliance with the CLIA Conditions specified in the enclosure, under a limitation of your CLIA certificate, you will be prohibited to test in the following specialties and/or subspecialties:

(List specialties/subspecialties, along with the rationale for the determination of immediate jeopardy). You will be issued a revised certificate.

(In the case of a suspension of the CLIA certificate, also list the Conditions which are out of compliance, and the rationale for the determination of immediate jeopardy.)

In accordance with §353 of the PHSA, the (fill in suspension or limitation) will be imposed on (insert date of at least 5 days following the receipt of this letter, which should be sent via overnight mail), and will continue to be imposed until you remove the immediate jeopardy, or an administrative hearing decision is rendered if you appeal the determination. (The revisit which was conducted by the (fill in the exact title of the State survey agency) on (fill in date) showed that an immediate jeopardy situation still exists in your laboratory.

Additionally, the alternative sanctions of (list them, if you determine to impose them) will be imposed on (insert date of at least 5 days following the receipt of this letter).

Approval to receive payment from Medicare and Medicaid for services rendered will be cancelled on (insert same date as other sanctions (5 days following the date of receipt of this letter).

If you disagree with this determination, you may request an administrative hearing within 60 days of your receipt of this notice. The request must be in writing by you or your legal representative and must contain the following information:

1. The specific issues or findings with which you disagree; and

2. The specific basis for contending that the State agency's or the Health Care Financing Administration's findings are incorrect. Additional evidence may also be presented at the hearing, and you may be represented by counsel.

Administrative hearings will be conducted by the Departmental Appeals Board of the Department of Health and Human Services (HHS). If additional expenses are incurred to conduct future visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for an attendance at an Administrative Law Judge hearing, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform these activities.

Please notify us immediately if you believe that the immediate jeopardy has been removed.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency

Exhibit 236

Notice of Imposition of Sanction(s);
Acknowledgement of Information Received

[Date] CLIA Number: _____

[Fill in address and salutation]:

This is to inform you that we have received the written (fill in information or evidence), which you sent in response to our Notice of Noncompliance and Proposed Sanctions. We have reviewed it and have determined that your laboratory remains (out of compliance/is now in compliance) with the Conditions previously specified. Therefore, the sanctions of (specify sanctions will/will not) be imposed on (specify effective date) (will be lifted on (specify date), according to the authority in §353(h) of the Public Health Service Act and Title 42 of the Code of Federal Regulations, Part 493, Subpart R. Cite only Part 493, Subpart R, if the documentation provides credible evidence that the noncompliance has been corrected, and the sanctions either will not be imposed or will be lifted.)

If applicable include:

Your request for an administrative hearing has been received. Once a hearing date has been set by the Departmental Appeals Board of the Department of Health and Human Services, we will inform you of it.

If you have a credible allegation of compliance between now and the date of the hearing, please contact (insert name of State representative and telephone number).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency

Exhibit 237

Model Letter Announcing to an Accredited Laboratory
After a Sample Validation Survey or a Substantial Allegation
of Noncompliance Survey That It Does Not Comply With All
CLIA Conditions And That There Exists
Immediate Jeopardy to the Health and Safety
of Individuals or That of the General Public

Director
Laboratory Name (CLIA Number)
Address

Dear _____:

Section 353(e) of the Public Health Service Act (PHSA) and implementing regulations provide that a laboratory accredited by an approved accreditation organization will be deemed to meet the conditions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). 42 CFR Part 493, Subpart E, requires the Health Care Financing Administration (HCFA) or its agent to conduct a survey of an accredited laboratory on a representative sample basis or in response to a substantial allegation of noncompliance. If, in the course of such a survey, a laboratory is found to have deficiencies with respect to compliance with applicable CLIA Conditions, HCFA will monitor the correction of any deficiencies until such time compliance is achieved or the certificate of accreditation is revoked. Laboratories accredited by (name of accreditation organization) are deemed to meet CLIA Conditions.

A survey was conducted at (name of laboratory) by the (State survey agency) on (date). At the conclusion of this survey, the findings were discussed with (you or director's name) and (you, he, she) was informed that conditions within (name of laboratory) posed an immediate jeopardy situation. Specifically, the laboratory does not meet the following CLIA condition(s): (cite conditions).

(Attach Form HCFA-2567 and/or explanation of the immediate jeopardy findings.)

When a laboratory, regardless of its accreditation status, is found to be out of compliance with one or more CLIA Conditions, and immediate jeopardy exists, the laboratory is at risk of losing its certificate of accreditation. Such a determination has been made in the case of (name of laboratory) and, accordingly, this laboratory will be subject to (cite sanctions imposed/proposed).

If the immediate jeopardy is not removed by (no more than 23 days from the last day of the survey) we will (suspend or limit) your CLIA certificate on (date) (and suspend all or part of your Medicare payment) (if applicable). If you provide this office with a credible allegation of compliance, the (State agency) will conduct a follow-up visit as soon (or date) as possible. A credible allegation of compliance is a statement or documentation:

o Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

- o That is realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- o That indicates the removal of the immediate jeopardy or the resolution of the deficiencies.

If the immediate jeopardy is removed, but one or more Conditions remain out of compliance, we will not suspend or limit your certificate. You will be given additional time to come into compliance. However, we may impose one or more of the following alternative sanctions until compliance is reached:

- Directed plan of correction and directed portion of a plan of correction;
- Suspension of all or part of Medicare payments (if laboratory participates in the Medicare program);
- State onsite monitoring; and/or
- Civil money penalty.

In accordance with §353(i)(2) of the PHSA, the (**suspension or limitation**) may be imposed prior to an administrative hearing, and will continue to be imposed until you remove the immediate jeopardy, or an administrative hearing decision is rendered. In accordance with 42 CFR 493.1844, if you disagree with this determination, you may request an administrative hearing within 60 days of your receipt of this notice. The request must be in writing by you or your legal representative to this office, and must contain the following information:

- o The specific issues or findings with which you disagree; and
- o The specific basis for contending that the State agency's or HCFA's findings are incorrect.

Administrative hearings will be conducted by the Departmental Appeals Board of the Department of Health and Human Services (HHS). If additional expenses are incurred to conduct future visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for an attendance at an Administrative Law Judge hearing, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform these activities.

If you have any questions, or would like additional information, please contact (State agency representative) at (telephone number) or the HCFA Regional Office at (telephone number).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
Accreditation Organization
State Agency or other
HCFA Agent (if applicable)

Exhibit 238

Model Letter Announcing to an Accredited Laboratory After a Sample Validation Survey That the Laboratory Does Not Comply With All the CLIA Conditions No Immediate Jeopardy

Director
Name of Laboratory (CLIA Number)
Address

Dear _____:

Section 353(e) of the Public Health Service Act, and implementing regulations, provide that a laboratory accredited by an approved accreditation organization will be deemed to meet all conditions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

42 CFR Part 493, Subpart E, authorizes the Health Care Financing Administration (HCFA) to conduct, on a representative sample basis or in response to substantial allegations of noncompliance, surveys of accredited laboratories as a means of validating the performance of an accreditation organization. If, in the course of such a survey, a laboratory is found to have deficiencies with respect to compliance with CLIA requirements, we are required to keep the laboratory under State survey agency review, until its CLIA deficiencies have been corrected, and it is in compliance with all applicable CLIA conditions.

A sample validation survey was conducted at (name of laboratory) by the (State survey agency) on (date). Based on this survey we find that your laboratory is not in compliance with all applicable CLIA Conditions. A complete listing of all deficiencies found by the (State survey agency) was previously furnished to your laboratory, and another copy is enclosed with this letter. These deficiencies have been found to be of such a serious nature as to substantially limit your laboratory's capacity to render adequate services, and prevent it from being in compliance with the CLIA Conditions. Specifically, your laboratory does not meet the following CLIA Condition(s): (cite Conditions).

If you have not already done so, you are requested to submit to the (State survey agency) a plan of correction no later than 10 days from the date you receive this letter. In addition to the plan of correction, if you provide this office with a credible allegation of compliance, we will conduct a follow-up visit as soon as possible. A credible allegation of compliance is a statement or documentation that:

- Is made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- Is realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- Indicates the resolution of the deficiencies.

Facilities that do not meet one or more CLIA Conditions may not be certified for participation in the CLIA program. You must take steps to bring any unmet conditions into compliance immediately.

In accordance with the enforcement provisions specified in 42 CFR Part 493, Subpart R of the regulations, failure to comply with the CLIA conditions may result in HCFA imposing one or more of the following alternative sanctions until compliance has been reached:

- Directed plan of correction and directed portion of a plan of correction;
- Suspension of all or part of Medicare payments (if laboratory participates in the Medicare program);
- State on-site monitoring; and/or
- Civil money penalty.

If you are found to be out of compliance with any CLIA condition at the time of the followup survey, HCFA may also take the following principal sanctions against your CLIA certificate:

- Limitation of the CLIA certificate;
- Suspension of the CLIA certificate; or
- Revocation of the CLIA certificate; and
- Cancellation of the laboratory's approval to receive Medicare payment for its services (if laboratory participates in the Medicare program).

When your deficiencies have been corrected and it has been found that all applicable CLIA Conditions are met, your laboratory will not be subject to further sanctions or State agency followup surveys.

Within 10 days after the receipt of this notice, you may submit to (State survey agency) or to HCFA written evidence or any other information relating to the deficiencies found. In accordance with 42 CFR 493.1844, you may also request an administrative hearing within 60 days of your receipt of this notice. The request must be in writing by you or your legal representative to this office and must contain the following information:

1. The specific issues or findings with which you disagree; and
2. The specific basis for contending that the State agency's or HCFA's findings are incorrect.

Administrative hearings will be conducted by the Departmental Appeals Board of the Department of Health and Human Services (HHS). If additional expenses are incurred to conduct future visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for an attendance at an Administrative Law Judge hearing, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform these activities.

If you request an administrative hearing, alternative sanctions may be imposed prior to the hearing or until HCFA determines that the noncompliance on which the sanctions are based has been corrected.

Copies of this letter are being forwarded to the (State survey agency) and to the (accreditation organization).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
Accreditation Organization
State Agency or other
HCFA Agent (if applicable)

PAGES 9-649 - 9-660 ARE RESERVED FOR EXHIBIT

239 - Clinical Laboratory Improvement Amendments (CLIA)
Alternate Quality Assessment Survey--HCFA-667

Exhibit 240

Notice of Proposed Limitation of the CLIA Certification
and Suspensions of Medicare Payments When a Laboratory
Has Failed to Participate Successfully
in a Proficiency Testing Program

[Fill in address and salutation]

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578), it must satisfy all applicable requirements contained in §353 of the Public Health Service Act and be in compliance with the Conditions contained in Title 42, of the Code of Federal Regulations (CFR), Part 493.

During the (first, second, third) testing event of (year), (laboratory's name) performed proficiency testing for (analyte, subspecialty, specialty) and reported its results to (PT program name). This testing event was graded as being unsatisfactory. Our records also indicate that yourlaboratory was also unsatisfactory in the (indicate previous failed event) making the (laboratory's name) performance unsuccessful. After a careful review of these facts, I have determined that (laboratory's name) is not in compliance with the following CLIA Condition: 42 CFR 498.803 Successful Participation (List PT Condition(s) related to each affected specialty).

In accordance with 42 CFR 493.803(b), I am proposing to limit your certificate in (analyte, subspecialty, or specialty) to be effective 60 days from receipt of this notice or following the administraive hearing decision, if HCFA prevails in this decision. Effective (date), I will suspend your approval to receive Medicare payment for testing in (analyte, subspecialty, or specialty) pursuant to 42 CFR 493.1826. Under a limitation of your CLIA certificate, you would be prohibited to test in (analyte, subspecialty, or specialty). The Medicaid State agency will also be notified of this action.

Your laboratory may request reinstatement of its certification under CLIA for (analyte, subspecialty, or specialty) when two consecutive proficiency testing events are successfully completed and a minimum of six months has passed as required by 42 CFR 493.807(a) and (b).

If you believe that the results of the proficiency testing events are not correct, you may submit written or other evidence for my review no later than (date). If I determine that this action is not warranted, the decision to limit your certification will be rescinded.

If you do not submit a response, or if after review of your response I determine that limitation of the certificate and suspension of your approval to receive Medicare payment are warranted, I will arrange to publish a routine notice in the newspaper to advise the public of these actions. I also reserve the right to notify physicians, providers, suppliers and other clients doing business with (laboratory's name). In addition, your laboratory will be listed in the laboratory registry that is published annually by HCFA and made available to physicians and the general public as a laboratory whose CLIA certificate has been limited, suspended, or revoked.

If you believe this determination is not correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are 42 CFR 493.1844 and 498.40 et seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. For expedited handling, such a request may be made to the Associate Regional Administrator, Division of Health Standards and Quality, **(complete mailing address of RO).** At your option, you may instead submit a hearing request directly to the Departmental Appeals Board, Civil Remedies Division, Attention: Room 637-D, HHH Building, 200 Independence Avenue, S.W., Washington, DC 20201, and send a copy of your request to this office.

A request for a hearing should identify the specific issues and findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense.

If your laboratory requests a hearing, it will retain its original CLIA certification until a decision is rendered by the administrative law judge.

If you have any questions regarding this matter, please contact me at **(phone)**.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency

Exhibit 241

Model Letter Announcing To Accredited Laboratory After a Substantial Allegation of Noncompliance Survey That the Laboratory Does Not Comply With All CLIA Conditions (Complaint)

Director (CLIA Number)
Name of Laboratory
Address

Dear _____:

Section 353(e) of the Public Health Service Act (PHSA), and pursuant regulations provide that a laboratory accredited by an approved accreditation organization will be deemed to meet the conditions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). 42 CFR Part 493, Subpart E, requires the Health Care Financing Administration to conduct a survey of an accredited laboratory on a representative sample basis or in response to substantial allegations of noncompliance. If there is a substantial allegation of a serious deficiency or deficiencies which would, if found to be present, adversely affect the health and safety of patients or that of the general public. If, in the course of such a survey, a laboratory is found to have deficiencies with respect to compliance with the CLIA Conditions, HCFA will monitor the correction of any deficiencies until such time as compliance is achieved or the certificate of accreditation is revoked. Laboratories accredited by (name of accreditation organization) are deemed to meet the CLIA Conditions.

A complaint survey was conducted at (name of laboratory) by the (State survey agency) on (date). Based on this survey, we find that your laboratory is not in compliance with all of the CLIA Conditions. A complete listing of all the deficiencies found by the survey agency was previously furnished to you and another copy is enclosed. These deficiencies have been determined to be of such serious nature as to substantially limit your laboratory's capacity to render adequate services and prevent it from being in compliance with the CLIA Conditions. Specifically, your laboratory does not meet the following CLIA Condition(s): (cite Conditions).

Facilities that do not meet one or more CLIA Conditions may not be certified for participation in the CLIA program. You must take steps to bring any unmet Conditions into compliance immediately. If you have not already done so, you are, therefore, requested to submit to the (State survey agency) within 10 days from the date of this letter a plan of correction, with acceptable time schedules, which will lead to the correction of the cited deficiencies. In addition to the plan of correction, if you provide this office with a credible allegation of compliance, we will conduct a follow-up visit as soon as possible. A credible allegation of compliance is a statement or documentation that:

- Is made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;
- Is realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and
- Indicates the resolution of the deficiencies.

In accordance with the enforcement provisions specified in 42 CFR Part 493, Subpart R of the regulations, failure to comply with the CLIA Conditions may result in HCFA imposing one or more of the following alternative sanctions until compliance has been reached:

- Directed plan of correction and directed portion of a plan of correction;
- Suspension of all or part of Medicare payments (if laboratory participates in the Medicare program)
- State onsite monitoring; and/or
- Civil money penalty.

If you are found to be out of compliance with any CLIA Condition at the time of the followup survey, HCFA may also take the following principal sanctions against your CLIA certificate:

- Limitation of the CLIA certificate;
- Suspension of the CLIA certificate; or
- Revocation of the CLIA certificate; and
- Cancellation of a laboratory's approval to receive Medicare/Medicaid payment for its services. (If laboratory participates in the Medicare and/or Medicaid programs.)

When your deficiencies have been corrected and it has been found that all the CLIA Conditions are met, your laboratory will not be subject to further sanctions or State agency followup surveys.

Within 10 days after the receipt of this notice, you may submit to (State survey agency) or to HCFA written evidence or any other information relating to the deficiencies found. In accordance with 42 CFR 493.1844, you may also request an administrative hearing within 60 days of your receipt of this notice. The request must be in writing by you or your legal representative to this office, and must contain the following information:

1. The specific issues or findings with which you disagree; and
2. The specific basis for contending that the State agency's or HCFA's findings are incorrect.

Administrative hearing will be conducted by the Departmental Appeals Board of the Department of Health and Human Services (HHS). If additional expenses are incurred to conduct future visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for an attendance at an Administrative Law Judge hearing, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform these activities.

If you request an administrative hearing, alternative sanctions may be imposed prior to the hearing or until HCFA determines that the noncompliance on which the sanctions are based has been corrected.

Copies of this letter are being forwarded to the (State survey agency) and the (accreditation organization).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc:
Accreditation Organization
State Agency or
HCFA Agent (if applicable)

Exhibit 242

REQUEST FOR VALIDATION OF ACCREDITATION SURVEY FOR LABORATORIES

1. Name and Address of State

2. Name and Address of Laboratory

CLIA #

3. Lab Accreditation By:

4.[] This validation is based on sample selection. Please conduct full survey of applicable accredited specialties and subspecialties within 60 days per State Operations Manual instructions in §5495.

5.[] This validation is based on a substantial allegation of noncompliance.
Please investigate areas checked below.

6. Area(s) to be Inspected

CONDITION(S)	STANDARD(S) OR SPECIALTIES/SUBSPECIALTIES
[] Proficiency Testing	
[] Patient Test Management	
[] Quality Control	
[] Personnel	
[] Quality Assurance	
[] Operating Without Certificate of Accreditation	

7. Remarks:

8. Regional Representative 9. Region 10. Date

HCFA-2802A

Exhibit 243

Model Letter Announcing to a CLIA-Exempt Laboratory That it is in Compliance With the CLIA Conditions After a Sample Validation or Substantial Allegation of Noncompliance Survey

Director
Name of Laboratory (CLIA Number)
Address

Dear _____:

I am pleased to inform you that as a result of the Health Care Financing Administration's (HCFA) (sample validation) (complaint) survey, the (name of laboratory) was found to be in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Conditions.

The HCFA surveyors advised you, however, of other deficiencies noted during the (sample validation) (complaint) survey of your laboratory, and we are enclosing a listing of all deficiencies found by them. We have forwarded a copy of this letter and our findings from the survey (optional--and your plan and timetable for correcting the deficiencies cited) to the State agency for further action. The (State agency) will be in touch with you to discuss the survey findings and to monitor the correction of the deficiencies.

Under Federal disclosure rules, a copy of the findings of this survey must be publicly disclosed within 90 days of the completion of the survey. You may therefore wish to submit for public disclosure, if you have not already done so, your comments on the survey findings, and any plans you may have for correcting the cited deficiencies.

We thank you for your cooperation.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc:
Central Office

Exhibit 244

Model Letter Announcing to the State Laboratory Program,
That a CLIA-Exem/pt Laboratory is in Compliance With
the CLIA Conditions After a Sample Validation or
Substantial Allegation of Noncompliance Survey

Name and Address of State
Laboratory Program
Address

Re: (Name of Laboratory)
(CLIA Number)

Dear _____:

I am pleased to inform you that as a result of the Health Care Financing Administration's (HCFA) (sample validation) (complaint) survey, the (name of laboratory) was found to be in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Conditions.

The HCFA surveyors have advised the (name of laboratory), however, of other deficiencies noted during the (sample validation (complaint) survey of the laboratory, and we are enclosing a listing of all deficiencies found by them. We have informed the (name of laboratory) that you will be in touch with them to discuss the survey findings and to monitor the correction of the deficiencies.

Under Federal disclosure rules, the results of the findings of this survey are available for public disclosure within 90 days of the completion of the survey.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

Exhibit 246

Model Letter From the Regional Office Notifying a State-Operated Laboratory of Cited Deficiencies and Requesting a Plan of Correction

CLIA Number:

Dear (Name of Laboratory Director):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578), and bill for services provided to Medicare beneficiaries or Medicaid recipients under Titles XVIII and XIX of the Social Security Act, it must comply with all CLIA requirements (42 CFR, Part 493).

The (Name of Regional Office) conducted a certification survey of your laboratory on (insert date). The attached Statement of Deficiencies and Plan of Correction (Form HCFA 2567) identifies the noncompliance with CLIA requirements which was found during that survey. Specifically, the following CLIA Condition(s) was (were) not met: (cite the Conditions which are out of compliance). Additionally, your laboratory is out of compliance with the following standard level requirements: (list them).

Facilities that do not meet a CLIA Condition may not be certified for participation in the CLIA program. You must take immediate steps to correct the condition-level noncompliance.

We request that you indicate your plan of correction on the right side of the form, matching your responses with each deficiency on the left. Please indicate your anticipated completion dates in the appropriate spaces. The plan of correction should be signed and dated by you and returned to our offices no later than (10 days from the date of this letter).

In addition to the plan of correction, if you provide this office with a credible allegation of compliance, we will conduct a followup visit within approximately 30-45 days from the date of the original survey. A credible allegation of compliance is a written statement or written documentation that is:

- Is presented by a representative of a laboratory which has a history of a commitment to compliance and taking corrective action when required;
- Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation of compliance; and
- Indicates correction of the noncompliance.

If you are found to still be out of compliance with any CLIA Condition at the time of the followup visit, we may impose sanctions.

If you have any questions, please call [the State representative in RO].

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency or other

Exhibit 247

Notice of [Limitation or] Revocation
of a Laboratory's CLIA Certificate

NO IMMEDIATE JEOPARDY

(THE LABORATORY HAS NOT REQUESTED A HEARING)

CLIA Number:

Dear [Laboratory Director]:

As set forth at §353(i) of the Public Health Service Act, the Clinical Laboratory Improvement Amendments of 1988 (CLIA), a laboratory's CLIA certificate may be suspended, limited, or revoked if, following a survey, the laboratory is found to be noncompliant with CLIA Conditions. For Condition-level noncompliance which does not pose immediate jeopardy, these sanctions may not be imposed until after an administrative hearing, if one is requested.

A survey of your laboratory conducted on (date) identified the following Condition-level noncompliance: (list).

Based on the findings of non compliance listed above and because you have not requested a hearing within 60 days of receiving the notice of sanction of [insert date], we will [limit] revoke your [insert type of CLIA certificate] on [insert date]. This action will concurrently cancel approval for your laboratory to bill Medicare and Medicaid for services rendered.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

NOTE: If the laboratory's noncompliance poses immediate jeopardy, send the laboratory the letter found in Exhibit 4-198, impose adverse action(s), and then follow-up with this one to inform the laboratory of the impending revocation if a hearing is not requested.

cc: State Agency

Exhibit 248

Notice of Proposed Limitation, Suspension, or Revocation of the CLIA Certificate; Opportunity for a Hearing

No Immediate Jeopardy

CERTIFIED MAIL -- RETURN RECEIPT REQUESTED

CLIA Number:_____

Re: Notice of Proposed Limitation, Suspension, or Revocation of the CLIA Certificate; Opportunity for a Hearing

Clinical Laboratory Improvement Amendments of 1988: 42 U.S.C. 263a

[Fill in address and salutation]:

Notice is hereby given that we propose to (fill in suspend, limit, or revoke) your Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate, which was issued to your laboratory on (fill in date) under the authority of the (CLIA) (Section 353 of the Public Health Service Act, 42 U.S.C. 263a) and the provisions of Title 42 of CFR, Part 493. This action will be effective (date).

[In the case of a limitation of the CLIA certificate, insert the following:]

Due to the noncompliance with the CLIA Conditions specified in the enclosure, under a limitation of your CLIA certificate, you would be prohibited to test in the following specialties and/or subspecialties: (list them).

You will be issued a revised certificate.

If you disagree with this determination, you may request an administrative hearing within 60 days of your receipt of this notice. The request must be in writing by you or your legal representative, and must contain the following information:

1. The specific issues or findings with which you disagree; and

2. The specific basis for contending that the State agency's or the Health Care Financing Administration's findings are incorrect.

Administrative hearings are conducted by the Departmental Appeals Board of the Department of Health and Human Services (HHS). If you request a hearing, the (fill in: limitation, suspension, or revocation) of your CLIA certificate will not be effective until after the hearing decision is rendered. If you do not request a hearing, the (fill in: limitation, suspension, or revocation) of your CLIA certificate will become effective (date), unless you correct the noncompliance. If we determine that any of your deficiencies has become more serious so as to be considered to pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, we may suspend or limit your CLIA certificate prior to the hearing.

If additional expenses are incurred to conduct future visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for an attendance at an Administrative Law Judge hearing, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform these activities.

In the interim we will be imposing the following alternative sanction (list). If a hearing is requested, your CLIA certificate will remain in effect, and may need to be reissued if it is due to expire, until a hearing decision is effective.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency

Exhibit 249

Model Letter to be Sent to the Laboratory in Conjunction with the Notice of Sanction, in Order to Officially Inform the Laboratory That the Responsibility Lies with the Laboratory to Achieve Compliance, Even If They Have Successfully Completed The Directed Plan of Correction

[Date] CLIA Number: _____

[Laboratory name and address]

Dear (Laboratory Director):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578) and bill the Medicare and Medicaid programs for its services under Titles XVIII and XIX of the Social Security Act, it must comply with the applicable CLIA requirements in Title 42 of the Code of Federal Regulations, Part 493.

We have determined, as noted in the Notice of Sanction which was sent to you on (date), to impose a directed plan of correction in order to assist you in achieving compliance with applicable CLIA requirements. If you successfully complete the directed plan of correction, but HCFA determines that you still have not corrected your deficiencies, it remains your responsibility to take actions necessary to come back into compliance with Conditions with which you are noncompliant.

If you have any questions, please call me.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc: State Agency

Exhibit 250

Notice of the Reissuance of a CLIA Certificate in Order
to Keep a Laboratory Operational if its Certificate is due to
Expire Prior to the Administrative Hearing

[Date]

[Address and Salutation]

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578) and bill the Medicare and Medicaid programs for its services under Titles XVIII and XIX of the Social Security Act, it must comply with the applicable CLIA requirements in Title 42 of the Code of Federal Regulations, Part 493. The CLIA certificate, which is reissued biennially, must remain current.

Because your (fill in type of CLIA certificate) is due to expire on (date), we are reissuing it for another two-year period so that you may continue to operate until a hearing decision is rendered.

Please be aware, however, that the reissuance of your (fill in type of CLIA certificate) does not indicate a determination of compliance with your Condition-level deficiencies. The sanctions of (list them) remain in effect until the hearing decision or correction of all or part of the noncompliance is present in your laboratory.

If you have any questions, please contact me.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure

cc: State Agency

Exhibit 251

Model Letter Offering the Opportunity for a Reconsideration if the Addition of Specialties or Subspecialties by a Laboratory is Denied by HCFA

[Date]

[Address and Salutation]

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578) and bill the Medicare and Medicaid programs for its services under Titles XVIII and XIX of the Social Security Act, it must comply with the applicable CLIA requirements in Title 42 of the Code of Federal Regulations, Part 493. The CLIA certificate must remain current according to the specialties and subspecialties tested by the laboratory.

You requested to add the (subspecialties, specialties) of testing to your certificate on (date). However, on a survey conducted by the (insert the name of the State survey agency), on (insert date), the following CLIA Conditions (list them) in the area(s) for which you requested expanded testing authority were found to be out of compliance:

Therefore, your request to test in (list the specialties or subspecialties) is denied.

If you disagree with this determination, you or your legal representative may file for a reconsideration by submitting a written request to us or to the (name of State survey agency). This request must be received within 60 days of your receipt of this letter. The request must state the issues, or the findings of fact with which you disagree, and the reasons for the disagreement. If you are unable to file this request within 60 days, you may file a written request with us, stating the reasons why the request was not filed timely. The Health Care Financing Administration will extend the time for filing a request for reconsideration if you show good cause for missing the deadline.

The reconsidered determination will be communicated to you as soon as it is made. If the reconsidered determination is adverse, you may request an administrative hearing.

Please contact me if you have any questions.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

cc: State Agency

Exhibit 252

Dear Laboratory Director:

The authority for the solicitation of the following information is Section 353 of the Public Health Service Act (PHSA) (42 U.S.C. 263(a). The principal purpose for collecting this data is to determine compliance with the Clinical Laboratory Improvement Amendments (CLIA). The Alternate Quality Assessment Survey (AQAS) is used in certain situations in lieu of biennial inspections. Based on information from yourlast onsite CLIA inspection, your laboratory has been identified as a good performer, qualifying it to receive the AQAS questionnaire. The AQAS evaluates the quality of laboratory testing based on the facility's ongoing quality assurance program. The survey consists of the enclosed self-assessment questionnaire which you or your designee are to complete and return to the State Agency (see address below). **As part of this survey process, please submit a copy of your proficiency testing (PT) summary data for the last three PT events. In addition, please sign and date all AQAS questionnaires.**

The assessment consists of 45 questions. **PLEASE RESPOND TO ALL QUESTIONS** by circling either a YES (Y), NO (N) or NOT APPLICABLE (NA). Some questions may require written response, review dates, or submission of documentation. A checklist is provided at the end of the form to help you identify which questions require documentation. Please attach additional pages for your responses as needed. **Do not send original laboratory documents.**

Many of the questions contain several aspects of laboratory quality assurance. Please consider **all** of them before responding.

> NOTE: **Questions that concern a review of the laboratory's policies, procedures, records, etc., refer to a periodic review that is sufficient to demonstrate effective policies and procedures and remedy ineffective ones. Reviews must be documented.**
>
> **The term "representative sample" means a review of a variety of records, requisitions, specimens processed, etc., that is sufficient to demonstrate whether policies and procedures are being accurately and completely followed.**

The State Agency may contact you to clarify or verify your responses. There will be a 5% onsite verification of this survey process. Your facility may be randomly selected for an onsite verification survey to evaluate the effectiveness of this alternate survey process as well as verify the accuracy of your responses.

The AQAS must be completed and returned within 15 days of receipt to (State Agency return address). You will be notified of the laboratory's certification status upon completion of this survey process. In most cases, a certificate valid for the next two years will be issued provided applicable fees have been paid.

We applaud your good performance record and appreciate your efforts toward continuing compliance with the CLIA regulations.

If additional clarification regarding CLIA is needed, or if you have any questions concerning this assessment, please contact (State Agency phone number).

Enclosures

PAGE 9-677 IS RESERVED FOR EXHIBIT

253 - State Agency Quality Improvement Program (SAQIP)

EXHIBIT 254

Model Letter
Notification that Medicare General Enrollment Health Care
Provider/Supplier Application Has Been Denied

Provider Number: _____

Dear _____:

The Health Care Financing Administration is authorized to collect the information requested on the Form HCFA-855 in order to ensure that correct payments are made to providers and suppliers under the Medicare program established by Title XVIII of the Social Security Act. See, sections 1814 and 1815 of the Social Security Act for payment under Part A of Title XVIII [42 U.S.C. §§ 1395f(a)(1) and 1395g(a)] for payment under part B. In addition, HCFA is required to ensure that no payments are made to providers or suppliers who are excluded from participation in the Medicare program under section 1128 of Title XVIII [42 U.S.C. § 1320a-7] or who are prohibited from providing services to the federal government under section 2455 of the Federal Acquisition Streamlining Act of 1994, (P.L. 103-355) [31 U.S.C. § 6101 note].

Based upon a consideration of the facts and circumstances, your application to enroll as a provider (or supplier) in the Medicare program has been denied for the following reason(s):

* (Name (s) of excluded persons or organizations) is/are currently excluded from participating in the Medicare program by the Office of the Inspector General.

* (Name(s) of excluded persons or organizations) is/are currently excluded from participating in the Medicare program because you are on the Federal Government's (General Service Administration) List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

* You do not possess a current valid license that is required by Federal, State, or local government in order to furnish health care items or services of the type you purportedly furnish or intend to furnish to Medicare beneficiaries.

* You failed to furnish an address sufficient to readily identify the physical location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries; or having furnished such an address, you do not appear (on the basis of extrinsic evidence) to be furnishing items or services or otherwise operating from such location; or, if you are an individual practitioner who does not furnish or does not intend to furnish items or services to Medicare beneficiaries at or from a location controlled by you (e.g., a physician practicing exclusively as an employee), you failed to furnish an address sufficient to readily identify the physical location at which you can be personally served with required notice in the event that proves necessary.

* Your license, and any other information or documentation furnished by you with respect to such license, failed to show that such license was issued by a governmental entity having jurisdiction over a practice, service-delivery, or operating location designated by you as a location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries or that your license, if valid only for a specific physical location, is not valid for the physical location specified by you as the practice, service-delivery, or operating location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries.

EXHIBIT 254 (Cont.)

* Your (i) billing agreement, (ii) billing service contract, or (iii) other agreement that creates or maintains, directly or indirectly, a relationship between you and another entity for the purpose of billing, the sale or purchase or other transfer of accounts receivable, or other financial relationship effecting a transfer - directly or indirectly - of Medicare claims payment, or any other evidence, shows or furnish substantial evidence that you are violating Medicare rules on assignment or reassignment of claims.

If you believe that this decision is incorrect, you may request a reconsideration. To request a reconsideration, submit a written request to (name and address of designated individual at RO) within 60 days from the date of this notice. Your request should state why you consider the determination to be incorrect and should be accompanied by any evidence and arguments that you feel may have a bearing on the determination. An Office of the Inspector General or Federal exclusion cannot be appealed; however, you may appeal factual issues, such as exclusion status, if you feel the information is in error.

Sincerely yours,

Associate Regional Administrator

* Use applicable sentence

EXHIBIT 255A

Model Letter
Notification of Pending Involuntary Termination Based on CHOW Review
of the Medicare General Enrollment Health Care Provider/Supplier Application (HCFA-855)

Provider Number: _____

Dear _____:

Under the provisions of section 1866(b)(2)(A) and (c) of the Social Security Act (42 CFR 489.53) the Health Care Financing Administration (HCFA) may terminate an agreement with a provider of services if it is determined that the provider: is not complying with the terms of the agreement or the provisions of title XVIII and regulations; fails to furnish information that HCFA finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due; refuses to permit examination of its fiscal or other records by, or on behalf of HCFA, as necessary for verification of information furnished as a basis for claiming payment under Medicare; or fails to furnish ownership information.

The Health Care Financing Administration (HCFA) has examined your application for a change of ownership, and after a careful review of the facts and circumstances has determined that under the new ownership, your facility does not meet the requirements for participation as a provider/supplier of services in the Medicare program for the following reason(s):

* (Name (s) of excluded persons or organizations) is/are currently excluded from participating in the Medicare program by the Office of the Inspector General.

* (Name(s) of excluded persons or organizations) is/are currently excluded from participating in the Medicare program because (he/she/it) is on the Federal Government's (General Service Administration) List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

* You do not possess a current valid license that is required by Federal, State, or local government in order to furnish health care items or services of the type you purportedly furnish or intend to furnish to Medicare beneficiaries.

* You failed to furnish an address sufficient to readily identify the physical location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries; or having furnished such an address, you do not appear (on the basis of extrinsic evidence) to be furnishing items or services or otherwise operating from such location; or, if you are an individual practitioner who does not furnish or does not intend to furnish items or services to Medicare beneficiaries at or from a location controlled by you (e.g., a physician practicing exclusively as an employee), you failed to furnish an address sufficient to readily identify the physical location at which you can be personally served with required notice in the event that proves necessary.

* Your license, and any other information or documentation furnished by you with respect to such license, failed to show that such license was issued by a governmental entity having jurisdiction over a practice, service-delivery, or operating location designated by you as a location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries or that your license, if valid only for a specific physical location, is not valid for the physical location specified by you as the practice, service-delivery, or operating location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries.

EXHIBIT 255A (Cont.)

* Your (i) billing agreement, (ii) billing service contract, or (iii) other agreement that creates or maintains, directly or indirectly, a relationship between you and another entity for the purpose of billing, the sale or purchase or other transfer of accounts receivable, or other financial relationship effecting a transfer - directly or indirectly - of Medicare claims payment, or any other evidence, shows or furnishes substantial evidence that you are violating Medicare rules on assignment or reassignment of claims.

Based on the above information, action has been initiated to terminate coverage of (name of provider/supplier) in the Medicare program. You will receive a written notice informing you of the official date of termination. Please contact this office if you have taken steps to correct the violation.

If you believe that this determination is incorrect, you may request that the decision be appealed. Your request must be submitted in writing to (name and address of designated individual at RO) within 60 days of this notice. Your request should state why you consider the determination to be incorrect and should be accompanied by any additional information or documentation that you feel may have a bearing on the determination. An Office of the Inspector General or Federal exclusion cannot be reconsidered; however, you may contest factual issues, such as exclusion status, if you feel the information is in error.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

* Use applicable sentence

EXHIBIT 255B

Model Letter
Notification of Involuntary Termination Based on CHOW Review
of the Medicare General Enrollment Health Care Provider/Supplier Application (HCFA-855)

Provider Number: _____

Dear _____:

Under the provisions of section 1866(b)(2)(A) and (c) of the Social Security Act (42 CFR 489.53) the Health Care Financing Administration (HCFA) may terminate an agreement with a provider of services if it is determined that the provider: is not complying with the terms of the agreement or the provisions of title XVIII and regulations; fails to furnish information that HCFA finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due; refuses to permit examination of its fiscal or other records by, or on behalf of HCFA, as necessary for verification of information furnished as a basis for claiming payment under Medicare; or fails to furnish ownership information.

HCFA has examined your application for a change of ownership, and after a careful review of the facts and circumstances has determined that under the new ownership, your facility does not meet the requirements for participation as a provider/supplier of services in the Medicare program for the following reason(s):

* (Name (s) of excluded persons or organizations) is/are currently excluded from participating in the Medicare program by the Office of the Inspector General.

* (Name(s) of excluded persons or organizations) is/are currently excluded from participating in the Medicare program because (he/she/it) is on the Federal Government's (General Service Administration) List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

* You do not possess a current valid license that is required by Federal, State, or local government in order to furnish health care items or services of the type you purportedly furnish or intend to furnish to Medicare beneficiaries.

* You failed to furnish an address sufficient to readily identify the physical location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries; or having furnished such an address, you do not appear (on the basis of extrinsic evidence) to be furnishing items or services or otherwise operating from such location; or, if you are an individual practitioner who does not furnish or does not intend to furnish items or services to Medicare beneficiaries at or from a location controlled by you (e.g., a physician practicing exclusively as an employee), you failed to furnish an address sufficient to readily identify the physical location at which you can be personally served with required notice in the event that proves necessary.

* Your license, and any other information or documentation furnished by you with respect to such license, failed to show that such license was issued by a governmental entity having jurisdiction over a practice, service-delivery, or operating location designated by you as a location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries or that your license, if valid only for a specific physical location, is not valid for the physical location specified by you as the practice, service-delivery, or operating location at or from which you purportedly furnish or intend to furnish items or services to Medicare beneficiaries.

EXHIBIT 255B (Cont.)

* Your (i) billing agreement, (ii) billing service contract, or (iii) other agreement that creates or maintains, directly or indirectly, a relationship between you and another entity for the purpose of billing, the sale or purchase or other transfer of accounts receivable, or other financial relationship effecting a transfer - directly or indirectly - of Medicare claims payment, or any other evidence, shows or furnishes substantial evidence that you are violating Medicare rules on assignment or reassignment of claims.

Based on the above information, it is necessary to terminate coverage of your services. Notice is hereby given that effective at the close of (date of termination) , (name of provider/supplier) is no longer approved for participation as a provider/supplier in the Medicare program. The Medicare program will not make payment for (type of facility) services furnished to patients after the close of (date of termination)**.

A notice will be published in the (name of local newspaper) advising the public of the termination. You will be advised of the publication date for the notice.

If you believe this determination is incorrect, you may request a hearing before an administrative law judge as outlined in Title 42 or the Code of Federal Regulations, section 405.1530 et. seq. To be effective a written request for a hearing must be filed not later than 60 days after the date you receive this letter. Such a request may be made to the Associate Regional Administrator for Division of Medicaid and State Operations, (address), who will forward your request to the Regional Chief Administrative Law Judge in the Office of Hearings and Appeals. The request for a hearing should state why the decision is considered incorrect, and should be accompanied by any evidence and arguments you may wish to bring to the attention of the Department of Health and Human Services. Evidence and arguments may be presented at the hearing, and you may be represented by counsel.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

* Use applicable sentence

** This sentence may be used for all provider types with the exception of hospitals, SNFs, HHAs or hospices. Remove this sentence and replace with the following sentences for the type of facility indicated:

Hospital or SNF: The Medicare program will not make payment for inpatient hospital services (or skilled nursing services) furnished to patients who are admitted after the close of (date of termination). For patients admitted on (date of termination), or earlier, payment may continue for up to 30 days of inpatient hospital services (or skilled nursing facility services) furnished after (date of termination).

HHA or Hospice: The Medicare program will not make payment for home health (or hospice) services furnished to patients whose plan of treatment was established after the close of (date of termination). For patients whose plan of treatment was established before (date of termination), payment may be made for up to 30 days after (date of termination).

Exhibit 256 - 258 (pp. 9-685 - 9-730)
Are Reserved for Hardcopy Only

Exhibit 259

MINIMUM DATA SET AUTOMATION CONTRACT/AGREEMENT APPROVAL RO CHECKLIST

Background: All certified nursing homes are required to encode and transmit MDS records to a repository maintained by the State in accordance with HCFA-established record specifications and time frames. Provider costs will be compensated through the Medicare and Medicaid programs according to the rules for such reimbursement effective in each State. It is expected that overall responsibility for fulfilling requirements to operate the State MDS data system will rest with the State survey agency. However, the State survey agency may enter an agreement with the State Medicaid agency, another State component or a private contractor to perform day-to-day operations of the system. **Before entering an agreement with a subcontractor, i.e., if the State MDS system is operated by an entity other than the survey agency, the survey agency must receive HCFA RO approval. Such agreements must include the following provisions:**
****

1. Meets confidentiality requirements: Federal Privacy Act, 5 U.S.C. Section 522a; HIPAA of 1996; other applicable Federal data acts; Section 1902 (a)(7) of the Social Security Act; applicable State standards; and industry security standards.

2. Gives State survey agency real-time access to the system to fully support all MDS-driven functions which will be required of the survey agency (e.g., quality indicator reporting, survey targeting), or if contractor is performing analysis for State agency details how.

3. Complies with need for high capacity, fault-tolerant network connections to ensure reliable support for the State survey agencies, HCFA's national database and any other daily operations (e.g., FI Medical Case Review, OIG or DOJ Fraud and Abuse activities), which will be affected by this system. Assures hardware will be properly maintained and upgraded as necessary to meet any future HCFA or State survey agency requirements. Assures adequate backup of all data.

4. Covers State survey agency responsibilities for reporting MDS data to a central repository at HCFA. Designates responsibilities for edits and "cleanness" of data. Designates responsibilities for generating and communicating facility error reports. Describes what kinds of communication will be established, e.g., a State-specific Internet and/or Intranet web pages, newsletters, their content, and who will produce/maintain/distribute these communications. If there is a separate database, designates who is responsible for operating and maintaining the HCFA-provided equipment and who will assure the viability of the HCFA database.

5. Covers responsibilities of contractor and/or State for training and support operations: Including at least who will provide facility and MDS software vendor startup training, and on-going customer/facility support/troubleshooting; provide internal training and daily user support within the State agency; work with program staff to integrate the MDS system into State survey agency functions; train State survey agency staff on aspects of analytical system (e.g., ASPEN upgrades and performance measure/"quality indicator" linked reports); handle System Operations -- functions associated with transmission logging, error tracking and resolution, system archival and process reporting; designates who is responsible for determining facility transmission schedules.

6. Delineates how State will fund the monthly line charges associated with installation, maintenance, and transmission of the MDS data from the facilities to the contractor and between the contractor and State, e.g., built into contract costs or is an outside ongoing cost to the State survey agency.

7. Specifies whether it is the contractor's or the State survey agency's responsibility for systems maintenance for commercial "off-the-shelf" MDS hardware and software components. For example, are these covered under typical umbrella service agreements that the State or contractor may already have in place for maintenance of data processing equipment? If not, what is the process?

Exhibit 260 - Reserved for MDS 2.0 Discharge and Reentry Flowchart

PRIVACY ACT STATEMENT - HEALTH CARE RECORDS 8/9/2000

THIS FORM PROVIDES YOU THE ADVICE REQUIRED BY THE PRIVACY ACT OF 1974. THIS FORM IS NOT A CONSENT FORM TO RELEASE OR USE HEALTH CARE INFORMATION PERTAINING TO YOU.

1. AUTHORITY FOR COLLECTION OF INFORMATION, INCLUDING SOCIAL SECURITY NUMBER AND WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY.

Sections 1819(f), 1919(f), 1819(b)(3)(A), 1919(b)(3)(A), and 1864 of the Social Security Act.

Medicare and Medicaid participating long term care facilities are required to conduct comprehensive, accurate, standardized and reproducible assessments of each resident's functional capacity and health status. To implement this requirement, the facility must obtain information from every resident. This information also is used by the Federal Health Care Financing Administration (HCFA) to ensure that the facility meets quality standards and provides appropriate care to all residents. For this purpose, as of June 22, 1998, all such facilities are required to establish a database of resident assessment information, and to electronically transmit this information to the HCFA contractor in the State government, which in turn transmits the information to HCFA.

Because the law requires disclosure of this information to Federal and State sources as discussed above, a resident does not have the right to refuse consent to these disclosures.

These data are protected under the requirements of the Federal Privacy Act of 1974 and the MDS Long Term Care System of Records.

2. PRINCIPAL PURPOSES FOR WHICH INFORMATION IS INTENDED TO BE USED

The information will be used to track changes in health and functional status over time for purposes of evaluating and improving the quality of care provided by nursing homes that participate in Medicare or Medicaid. Submission of MDS information may also be necessary for the nursing homes to receive reimbursement for Medicare services.

3. ROUTINE USES

The primary use of this information is to aid in the administration of the survey and certification of Medicare/Medicaid long term care facilities and to improve the effectiveness and quality of care given in those facilities. This system will also support regulatory, reimbursement, policy, and research functions. This system will collect the minimum amount of personal data needed to accomplish its stated purpose.

The information collected will be entered into the Long Term Care Minimum Data Set (LTC MDS) system of records, System No. 09-70-1517. Information from this system may be disclosed, under specific circumstances (routine uses), which include: (1) a congressional office from the record of an individual in response to an inquiry from the congressional made at the request of that individual; (2) the Federal Bureau of Census; (3) the Federal Department of Justice; (4) an individual or organization for a research, evaluation, or epidemiological project related to the prevention of disease of disability, or the restoration of health; (5) contractors working for HCFA to carry out Medicare/Medicaid functions, collating or analyzing data, or to detect fraud or abuse; (6) an agency of a State government for purposes of determining, evaluating and/or assessing overall or aggregate cost, effectiveness, and/or quality of health care services provided in the State; (7) another Federal agency to fulfill a requirement of a Federal statute that implements a health benefits program funded in whole or in part with Federal funds or to detect fraud or abuse; (8) Peer Review Organizations to perform Title XI or Title XVIII functions, (9) another entity that makes payment for or oversees administration of health care services for preventing fraud or abuse under specific conditions.

4. EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION

The information contained in the Long Term Care Minimum Data Set is generally necessary for the facility to provide appropriate and effective care to each resident. If a resident fails to provide such information, for example on medical history, inappropriate and potentially harmful care may result. Moreover, payment for such services by third parties, including Medicare and Medicaid, may not be available unless the facility has sufficient information to identify the individual and support a claim for payment.

NOTE: Providers may request to have the Resident or his or her Representative sign a copy of this notice as a means to document that notice was provided. Signature is NOT required. If the Resident or his or her Representative agrees to sign the form it merely acknowledges that they have been advised of the foregoing information. Residents or their Representative must be supplied with a copy of the notice. This notice may be included in the admission packet for all new nursing home admissions.

Exhibit 262 - Reserved for Correction Policy for Locked Records

Exhibit 263 - Maximum timeframes for MDS Completion... Omitted

Pages 9-743 - 9-750
Reserved for Exhibit 264
Resident Census
This Exhibit is in printed format only.

PAGES 9-751- 9-787 ARE RESERVED FOR EXHIBITS 265 - 271
They are in hard copy only

Exhibit 265 - HCFA-802P - Roster/Sample Matrix

Exhibit 266 - HCFA-802P - Roster/Sample Matrix Provider Instructions (use with HCFA Form 802)

Exhibit 267 - HCFA-802S - Roster/Sample Matrix Instructions for Surveyors (Use with Form HCFA-802)

Exhibit 268 - Facility Characteristics

Exhibit 269 - Facility Quality Indicator Profile

Exhibit 270 - Resident Level Summary

Exhibit 271 - Quality Indicator Matrix

Exhibit 272 - Reserved for Overview of MDS Submission Record

Exhibit 273 - Correction Policy Summary Matrix

Exhibit 275

ATTESTATION STATEMENT

Complete the following attestation statement and return it with your letter requesting participation in the Medicare program as a Community Mental Health Center providing partial hospitalization services.

The _____ (name of facility) hereinafter referred to as the Community Mental Health Center (CMHC), hereby agrees to:

(A) Maintain compliance with §1861(ff)(3)(B)(i) of the Social Security Act (the Act) by providing the services described in §1913(c)(1) of the Public Health Service Act (PHSA) (which supersedes the former §1916(c)(4) of the PHSA);

(B) Maintain compliance with §1861(ff)(3)(B)(ii) of the Act by meeting applicable licensing or certification requirements for CMHCs in the State in which it is located; and

(C) Maintain compliance with the requirements set forth in Parts 400, 410, 424, and 489 of Chapter IV, Title 42 of the Code of Federal Regulations, and to report promptly to the Health Care Financing Administration any failure to do so.

I certify that I have reviewed each Federal requirement indicated above and that _____ (name of facility) is in compliance with the applicable requirements. I also certify that I agree to comply with the provisions of §1866 of the Act and Medicare regulations applicable to CMHCs.

ATTENTION: Read the following provision of Federal law carefully before signing.

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years or both. (18 U.S.C. §1001).

Name _____ Title _____
Date _____

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0770. The time required to complete this information collection is estimated to average four (4) hours per response, including the time to review instructions, searching existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: HCFA, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, Mail Stop N2-14-26, and to the Office of the Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

Exhibit 276

HEALTH INSURANCE BENEFIT AGREEMENT
(AGREEMENT WITH PROVIDER PURSUANT TO SECTION 1866 OF THE SOCIAL SECURITY ACT, AS AMENDED AND TITLE 42 CODE OF FEDERAL REGULATIONS (CFR) CHAPTER IV, PART 489)

AGREEMENT
BETWEEN
THE SECRETARY OF HEALTH AND HUMAN SERVICES
AND

_____
doing business as (DBA) _____
In order to receive payment under Title XVIII of the Social Security Act,_____
_____
D/B/A _____ as the provider of services, agrees to conform to the provisions of Section 1866 of the Social Security Act and applicable provisions in 42 CFR.

This agreement, upon submission by the provider of services of acceptable assurance of compliance with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 as amended, and upon acceptance by the Secretary of Health and Human Services, shall be binding on the provider of services and the Secretary.

In the event of a transfer of ownership, this agreement is automatically assigned to the new owner subject to the conditions specified in this agreement and 42 CFR 489, to include existing plans of correction and the duration of this agreement, if the agreement is time limited.

ATTENTION: Read the following provision of Federal law carefully before signing.

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years or both (18 U.S.C. Section 1001).

Name _____ Title _____
Date _____

_____
ACCEPTED FOR THE PROVIDER OF SERVICES BY:
_____
NAME (SIGNATURE)
_____
TITLE DATE
_____

_____
ACCEPTED BY THE SECRETARY OF HEALTH AND HUMAN SERVICES BY:
_____
NAME (SIGNATURE)
_____
TITLE DATE
_____
ACCEPTED FOR THE SUCCESSOR PROVIDER OF SERVICES BY:
_____
NAME (SIGNATURE)
_____
TITLE DATE

Exhibit 276 (Cont.)

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0770. The time required to complete this information collection is estimated to average fifteen minutes per response, including the time to review instructions, searching existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: HCFA, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, Mail Stop N2-14-26 and to the Office of the Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

Exhibit 277

FISCAL INTERMEDIARY (FI) MEDICARE PROVIDER BILLING NUMBER DEACTIVATION LETTER USED BY FI

XYZ Community Mental Health Center
Address:

Dear Sir or Madam:

The FI, acting on behalf of the Health Care Financing Administration (HCFA) to process and pay your Medicare claims, has observed that in the past 12 months no claims have been submitted under your Community Mental Health Center (CMHC) Medicare billing number, (insert billing number). Due to lack of activity, HCFA will deactivate your billing number, as of (add date of deactivation), rendering your CMHC an inactive Medicare provider. Deactivation occurs when a CMHC's provider agreement remains in effect, but the FI has suspended payment to the CMHC until the FI has received and verified the CMHC's updated Form HCFA-855 information.

You may wish to resume your CMHC's status as an active Medicare CMHC provider. However, to ensure that current data is on file, it will be necessary for you to complete an enrollment application, Form HCFA-855 if you have never done so, or completely update your current Form HCFA-855 when the CMHC resumes service to Medicare beneficiaries and bills for services rendered on their behalf. Any claims incurred before the reactivation of the CMHC billing number can be paid by the FI retroactively within the standard time limits for filing claims as specified in 42 CFR Part 424.44. You may obtain the Form HCFA-855 from your FI, State Licensing, and/or Survey and Certification Agency.

You may elect to submit a letter to the FI (insert fiscal intermediary address), State Licensing or Survey and Certification Agency (insert SA address) requesting a voluntary termination of your Medicare provider agreement, if you will no longer bill Medicare.

If you have any questions regarding this letter, please contact (insert name and phone number of FI contract).

cc:
HCFA Regional Office

FI Provider Enrollment Manager

Exhibit 278

MODEL DENIAL LETTER FOR CMHC APPLICANTS--
STATE RESTRICTIONS ON SCREENING

XYZ Community Mental Health Center
Address:

Dear Sir or Madam:

This is to inform you of the Health Care Financing Administration's initial determination (see 42 CFR Part 498.3) that your facility does not meet the requirements for certification to participate in the Medicare program as a community mental health center (CMHC) providing partial hospitalization services.

In order to be certified as a CMHC providing partial hospitalization services in the Medicare program, an entity must meet the statutory requirements for a CMHC. These requirements are found at §1861(ff)(3) of the Social Security Act, which requires that a CMHC provide the services described in §1916(c)(4) (now found at §1913(c)(1) of the Public Health Service (PHS) Act) and meet applicable licensing or certification requirements for a CMHC in the State in which it is located.

The services listed in the PHS Act that an entity must provide in order to be approved as a CMHC are as follows: outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of service areas of the centers who have been discharged from inpatient treatment at a mental health facility; 24 hour-a-day emergency care services; and screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

After a careful review, HCFA has determined that you do not meet the statutory requirements for a CMHC. This is because, as discussed in the attached statement of findings, you do not provide screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission, one of the services listed in §1913(c)(1) of the PHS Act, and required by §1861(ff)(3)(B) of the Social Security Act. Our review indicates that pertinent requirements (see attachment) for the State of [insert name of State] place restrictions on who may perform screening, and specifically preclude your facility from providing this service.

If you believe that this initial determination is not correct, you may request that it be reconsidered. The request must be submitted in writing to [insert name and address] within 60 days of the date you receive this notice in accordance with 42 CFR Part 498.22. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later. The request should state the legal and factual reasons why you consider the decision to be incorrect and should include any documentation supporting these legal and factual conclusions.

Sincerely,

Associate Regional Administrator
(or its equivalent)

Exhibit 279

MODEL LETTER
NOTICE OF FINDINGS OF NON-COMPLIANCE

XYZ Community Mental Health Center
Address:

Dear Sir or Madam:

After careful review of the facts, the Health Care Financing Administration (HCFA) has determined that [insert name of provider] fails substantially to meet the applicable provisions of §1861(ff)(3) of the Social Security Act (the Act) and regulations and/or fails to comply substantially with the provisions of its Health Insurance Benefit Agreement (provider agreement). In accordance with §1866 of the Act and 42 CFR Part 489.53, HCFA may terminate a Community Mental Health Center's (CMHC) provider agreement to participate in the Medicare program when it determines that a CMHC is not complying with the provisions of the Act, applicable regulations, or the provider agreement.

[Insert provider name] entered into a provider agreement as a CMHC on [insert date]. In that agreement, [insert provider name] agreed to: (A) Maintain compliance with §1861(ff)(3)(B)(i) of the Act by providing the services described in §1913(c)(1) of the Public Health Service Act (PHSA); (B) Maintain compliance with §1861(ff)(3)(B) of the Act by meeting applicable licensing or certification requirements for CMHCs in the State in which it is located; and (C) Maintain compliance with the requirements set forth in Parts 400, 410, 424 and 489 of the Chapter IV, Title 42 of the CFR, and to report promptly to HCFA any failure to do so.

To participate as a provider of partial hospitalization services in the Medicare program an entity must meet the statutory requirements for a CMHC. These requirements are found at §1913(c)(1) (formerly §1916(c)(4) of the PHSA). The core PHSA services that an entity must provide in order to be approved as a CMHC are as follows: Outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of service areas of the centers who have been discharged from inpatient treatment at a mental health facility; 24 hour-a-day emergency care services; day treatment or other partial hospitalization services, or psychosocial rehabilitation services; and screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission. A CMHC is also defined at 42 CFR Part 410.2. In accordance with the PHSA, the core services must actually be provided by a CMHC and not just be available to be provided. The core services must continue to be provided following Medicare approval.

Please see attached findings of noncompliance (Attachment 1). You have 15 calendar days from the date of receipt of this notification to respond to the attached findings. Please include any documentation you have which supports any factual assertions you make, as well as any legal conclusions with which you disagree.

This documentation should include any material that you consider relevant, for example, medical records, logs, and contractual documentation. While there is no maximum number of clinical records or materials that you may submit, we believe that 5 clinical records for each core service (a maximum of 25 patients) should generally suffice for purposes of this review.

If you demonstrate that [insert provider name] provides the requisite core services, no termination will be effected. However, if after review of the information as well as the review of the team's findings and documentation, HCFA still believes that you do not provide one or more of the required services, it will provide 15 calendar days notice of its decision to terminate [insert provider name] prior to termination.

Page 2

Please send the response in writing to:

(*Insert the following sentence as applicable. We have determined that the State of _____ precludes your facility from providing (list the core service(s)).

Sincerely,

Associate Regional Administrator
(or its equivalent)

Attachment

ATTACHMENT 1

STATEMENT OF FINDINGS

Provide the CMHC with an adequate explanation of HCFA's findings of non-compliance for each of the unmet core service requirements. For example:

> You previously attested over a penalty clause that you were providing all of the PHSA core services. However, an onsite visit was made to your facility on 00/00/00, and you were asked to provide any and all documentation to substantiate the provision of each of the core services. In order to demonstrate the provision of outpatient services for the elderly, you provided a patient record for JOHN DOE. Our review of this record determined that Mr. DOE was 14 years old. Therefore, this record did not substantiate the provision of outpatient services for the elderly. No other record or documentation was submitted for this core service. Therefore, we have concluded that you have failed to provide outpatient services for the elderly, one of the core services listed in §1913(c)(1) of the PHSA and required by §1861(ff)(3)(B) of the Social Security Act.

Exhibit 280

MODEL LETTER

NOTICE OF TERMINATION OF PROVIDER AGREEMENT

XYZ Community Mental Health Center
Address

Dear Sir or Madam:

On [insert date], we notified you of our findings that the [insert provider name] Community Mental Health Center (CMHC) failed to provide the following core Public Health Service Act (PHSA) services as mandated by §1913(c)(1) of the PHSA and required by §1861(ff)(3) of the Social Security Act (the Act) to qualify as a CMHC for Medicare purposes. We informed you that if you had additional evidence to show that you provided the core services that you had 15 calendar days to respond to our findings.

(The RO should choose one of the following statements:)

___ The 15 calendar day period has expired and you failed to submit evidence of having provided the following core services; or

___ On [insert date], you provided additional information in the form of [insert listing of materials submitted]. We have reviewed this documentation. It [does/does not] change our earlier decision that you failed to provide the core PHSA services.

(If the RO has determined that the additional material submitted by the CMHC changes the earlier decision of unmet PHSA core service requirements, the notification is complete.)

(If the CMHC presented additional materials as evidence of its compliance with the PHSA core requirements, and the RO has determined that this material does not change its earlier decision concerning the unmet core requirements, note the evidence submitted and respond to the information and documents; or lack thereof with respect to the core services you found the provider did not meet with a detailed explanation of why it has not changed the determination and insert the following paragraphs:)

As we informed you earlier, in accordance with §1866 of the Social Security Act and 42 CFR Part 489.53, HCFA may terminate a CMHC's provider agreement to participate in the Medicare program when it determines that a CMHC is not complying with the provisions of the Act, applicable regulations, or the provider agreement.

Based on our determination that [insert provider name] does not provide [insert list of core services not furnished] of the four core services, we conclude that it has failed substantially to comply with the provisions of its provider agreement, or to meet the provisions of §1861(ff)(3), which require it to provide all four of these services, and therefore, its provider agreement must be terminated in accordance with §1866 of the Act, and 42 CFR Part 489.53. The date on which the Medicare provider agreement terminates is [insert date].

We will publish a legal notice in the newspaper 15 calendar days prior to termination. You will be advised of publication of the notice.

If you believe this decision is not correct, in accordance with 42 CFR Part 498.5(a)(2), you must file a request with HCFA within 60 days from receipt of this notice for a hearing before an Administrative Law Judge. The request must state the issues, or the specific findings of fact with which you disagree, and the specific reasons for the disagreement. Your request for a hearing should be sent to:

If you have any additional questions concerning this determination, please direct your inquiry to:

Sincerely,

Associate Regional Administrator
(or its equivalent)

Exhibit 281

MODEL LETTER

COMMUNITY MENTAL HEALTH CENTER (CMHC) THAT HAS CEASED OPERATING

Provider Number: _____

XYZ Community Mental Health Center
Address

Dear Sir or Madam:

This is to notify you that we determined that [insert name and address of provider] has closed on [insert actual date of closing, or if unknown, date established by the RO]. Under the provisions of 42 CFR Part 489.52(b)(3), your provider agreement with the Secretary of Health and Human Services will be terminated [insert date]. No payment can be made under the Medicare program for services on or after that date.

This determination is based on the following: On [insert date], this office sent you a notice concerning [insert purpose of notice]. The notice which was sent to your facility's last address of record was subsequently returned to this office by the U.S. Postal Service as undeliverable. We then contacted [list the names of all other entities that were contacted; e.g., State survey agencies, State mental health associations, etc., and the date they were contacted] in an effort to locate your facility. Those attempts were unsuccessful. We also contacted [name of servicing intermediary] and were informed that your facility stopped billing [or has never submitted bills, if applicable] Medicare on [insert last day of billing].

The [insert name and address of provider] will no longer participate in the Medicare program (Title XVIII of the Social Security Act) effective [insert date]. The agreement between [insert name of provider] and the Secretary of Health and Human Services will be terminated on [insert date of termination] in accordance with the Social Security Act.

If you disagree with this notice, you must respond in writing to this office within 15 days of the date of this notice. We will publish a public notice of your facility's termination in the [insert name of local newspaper].

If your facility is reopened and you again wish to participate as a CMHC provider, you should contact [insert name of State survey agency]. They will assist you in taking the actions necessary to become certified for participation as a provider. Please let me know if you have any questions concerning this action.

Sincerely,

Associate Regional Administrator
(or its equivalent)

Exhibit 282

MODEL LETTER

PARTICIPATION IN MEDICARE AS A
COMMUNITY MENTAL HEALTH CENTER
PROVIDING PARTIAL HOSPITALIZATION SERVICES
(INCLUDING THRESHOLD AND SERVICE REQUIREMENTS)

XYZ Community Mental Health Center
Address

Dear:

In order to be certified as a CMHC for the purpose of providing partial hospitalization services in the Medicare program, an entity must meet the statutory requirements for a CMHC. These requirements are found at §1861(ff) of the Social Security Act, which requires that a CMHC provide the services described in §1916(c)(4) (now found at §1913(c)(1)) of the Public Health Service (PHS) Act) and meet applicable licensing or certification requirements for a CMHC in the State in which it is located.

The services listed in the PHS Act that an entity must provide in order to be approved as a CMHC are as follows: outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of service areas of the centers who have been discharged from inpatient treatment at a mental health facility; 24-hour-a-day emergency care services; day treatment or other partial hospitalization services; or psychosocial rehabilitation services; and screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

The statute requests that an applicant CMHC be providing the core services at the time of certification, not at some future point in time. Accordingly, HCFA will look for evidence that the applicant is already providing the core services as a pre-condition for certification. For example, HCFA will look to see that the applicant:

- o Is fully operational for a sufficient period of time that enables us to be reasonably assured of the facility's compliance with program requirements. We believe one business quarter would provide us with the information we need to assess compliance;
- o Has served, as evidenced by complete, onsite medical record documentation from within 3 months of the date of the initial Medicare application for new applicants or the date of sale for a change of ownership, a sufficient number of persons to enable us to be reasonably assured that the facility is, in fact, complying with basic program requirements. We believe, that to achieve this objective, a facility should have served at least 10 non-Medicare patients, including:
  - A minimum of three patients for which medical records demonstrate that the CMHC has:
    - + The legal capacity under State law to provide screening services for admission to State mental health facilities;
    - + The capability and clinical expertise to provide such screening services; and

+ Provided screening services the specific purpose (e.g. reason for referral) of which is to assess the patient's need for admission to a State mental health facility. Where there are State requirements for the completion of required forms, court documents or any other required documentation in response to the screening request, these documents would be evidence of providing the service. Otherwise, evidence in the screening assessment must include a clinical decision regarding the appropriate level of care and follow-up placement.

- A minimum of 3-day treatment or partial hospitalization or psychosocial rehabilitation patients (this is group treatment and three patients is the smallest number the CMHC could justify as a group); and

- At least one patient from each of the four outpatient categories:

  + Children;

  + Elderly;

  + Chronically mentally ill; and

+ Residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility.

At this time, there are no **prior service requirements** regarding the following core service:

24 hour a day emergency care services.

However, please be aware that your CMHC must be able to demonstrate that it can provide 24-hour emergency care services.

NOTE: If you are approved for Medicare participation, you are expected to continue to provide the non-Medicare services. Providing these services is ongoing and not a one-time qualifying event for Medicare participation.

The address shown in your provider agreement is where HCFA requires records of services, provided either directly or under an arrangement, be available, because the CMHC is responsible for all services.

A CMHC may provide one or more core services under arrangement with another individual, group, or entity only when the following criteria are met:

o Service Authorized by State Law--In no case may a CMHC provide a service under arrangement when the CMHC has not been given authority to provide the service itself directly under State statute, licensure, certification, or regulation.

• Full Legal Responsibility--A CMHC that provides a core service under arrangement with another entity remains the legally responsible authority through which comprehensive mental health services are provided. It is not sufficient for the arrangement to be a referral process where the CMHC does not assume overall management responsibility for the provision of core services by a separate individual, group, or entity. The CMHC must retain complete accountability for the services provided under the arrangement. The CMHC must retain legal, professional, and administrative responsibility to coordinate care, supervise and evaluate the services, and ensure the delivery of high quality mental health treatment.

- Written Agreement--If a CMHC provides services under arrangement, there must be a written agreement or contract between the two parties that specifies the services to be rendered and the manner in which the CMHC exercises its professional and administrative responsibility. Furthermore, for the agreement to serve as the vehicle through which the CMHC meets the requirement to provide one or more of the core services, the terms of the agreement must be adhered to in practice. In order to verify the nature of the relationship between the CMHC and the other party, the agreement must be accessible to HCFA or its agents, and the documentation for all services rendered under arrangement must be maintained by the CMHC at the site identified in the provider agreement.

We will also assign each CMHC a provider identification number .

Those facilities that are denied approval to participate in the Medicare program will be notified and given the reason(s) for the denial.

You are required to notify the HCFA RO at the time you are planning a transfer, deletion, addition, or relocation of a service area. If operation of the entire facility is later transferred to another owner, ownership group, or to a lessee, the CMHC identification number will be automatically assigned to the successor, following notification.

Each proposed CMHC must enroll with Medicare by completing a Form HCFA-855 and independently meet the Federal requirements for CMHCs, sign a separate CMHC provider agreement and receive a separate identification number. The facility must also conform to the provisions of §1866 of the Social Security Act and all Medicare regulations applicable to CMHCs.

In addition, your application must contain at least the following:

- The name and address of the facility;
- The name of the responsible agent, including the address and telephone number;
- The facility's Medicare provider number, if the facility is already participating in the Medicare program as another type of provider;
- The Medicare provider number of the entity, if the facility is operated as part of and under control of another entity that is participating in the Medicare program;
- The identification of the community your CMHC intends to serve, because in accordance with §1913(c)(1), CMHCs are required to provide mental health services to individuals who reside in a distinct and definable community. If a CMHC intends to operate an alternative site outside its community, the site must have a separate provider agreement/number because this would be a different community. HCFA must approve all alternative sites. If a CMHC operates a HCFA-approved alternative site, the site is not required to provide all of the core PHSA services. However, a patient must be able to access and receive the services he/she needs at the approved primary site, or at an alternative site that is within the distinct and definable community served by the CMHC;
- The type of ownership or control (i.e., nonprofit, government);
- The services provided with the number of full-time equivalent employees; and

o A signed Attestation Statement indicating that the facility complies with all of the Federal requirements in §1861(ff)(3)(B) of the Social Security Act.

Sincerely,

Associate Regional Administrator
(or its equivalent)

Exhibit 283

MODEL LETTER

Notice of Failure to Meet Threshold and Service Requirements

XYZ Community Mental Health Center
Address

Dear Sir or Madam:

This is to inform you of the Health Care Financing Administration's initial determination (see 42 CFR Part 498.3) that your facility does not meet the requirements to participate in the Medicare program as a community mental health center (CMHC) providing partial hospitalization services.

In order to be certified as a CMHC providing partial hospitalization services in the Medicare program, an entity must meet the statutory requirements for a CMHC. These requirements are found at §1861(ff) of the Social Security Act, which requires that a CMHC provide the services described in §1916(c)(4) (now found at §1913(c)(1) of the Public Health Service (PHS)) Act and meet applicable licensing or certification requirements for a CMHC in the State in which it is located.

The services listed in the PHS Act that an entity must provide in order to be approved as a CMHC are as follows: outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of service areas of the centers who have been discharged from inpatient treatment at a mental health facility; 24-hour-a-day emergency care services; day treatment or other partial hospitalization services; or psychosocial rehabilitation services; and screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

The statute requires that an applicant CMHC be providing the services listed in the PHSA at the time of certification, not at some future point in time. Accordingly, HCFA looks for evidence that the applicant is already providing the core services as a pre-condition for certification. For example, HCFA will look to see that the applicant:

- Is fully operational for a sufficient period of time that enables us to be reasonably assured of the facility's compliance with program requirements. We believe one business quarter would provide us with the information we need to assess compliance.

- Has served, as evidenced by complete, onsite medical record documentation from within three months of the date of the initial Medicare application for new applicants or date of sale for changes of ownership, a sufficient number of persons to enable us to reasonably assure that the facility is, in fact, complying with basic program requirements. We believe that to achieve this objective, a facility should have served at least 10 non-Medicare patients, including:

  - A minimum of three patients for which medical records demonstrate that the CMHC has:

    + The legal capacity under State law to provide screening services for admission to State mental health facilities;

    + The capability and clinical expertise to provide such screening services; and

+ Provided screening services for which the specific purpose (e.g., reason for referral) is to assess the patient's need for admission to a State mental health facility. Where there are State requirements for the completion of required forms, court documents, or any other required documentation in response to the screening request, these documents would be evidence of providing the service. Otherwise, evidence in the screening assessment must include a clinical decision regarding the appropriate level of care and follow-up placement.

- A minimum of 3-day treatment or other partial hospitalization or psychosocial rehabilitation patients (this is a group treatment and three patients is the smallest number the CMHC could justify as a group); and

- At least one patient from each of the four outpatient categories:

  + Children;

  + Elderly;

  + Chronically Mentally Ill; and

  + Residents of its mental health service area who have been discharged from inpatient treatment as a mental health facility.

We based our decision on the fact that your HCFA Medicare Enrollment Application, Form HCFA-855 and an on-site visit completed on (insert date) by the (insert name of site visit contractor) revealed that your facility did not meet these Federal requirement(s) for CMHCs. The unmet requirement(s) was/were:

(Provide the CMHC with an adequate explanation of HCFA's findings of noncompliance for each of the unmet threshold and service requirements.) For example:

HCFA has determined that all CMHCs seeking to participate in the Medicare program must meet minimum non-Medicare service requirements before enrollment into the Medicare program. As a result of the information you provided on the HCFA Medicare Enrollment Form HCFA-855 and/or at the time of the on-site visit to your facility, it was determined that your facility does not meet the requirements at §1913(c)(1) which we refer to as threshold and service requirements. You were then provided an opportunity to substantiate your ability to meet these requirements, but you failed to do so.

If you believe that this initial determination is not correct, you may request that it be reconsidered. The request must be submitted in writing to (insert name and address) within 60 days of the date you receive this notice in accordance with 42 CFR Part 498.22. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later. The request should state the legal and factual reasons why you consider the decision to be incorrect and should include any documentation supporting these legal and factual conclusions.

If you have any questions, please feel free to contact (insert name of staff) at (insert phone number).

Sincerely,

Associate Regional Administrator
(or equivalent)

Model Denial Letter
To a Home Health Agency (HHA) that Requested a Branch Office

Dear HHA Administrator:

This is to inform you of the Health Care Financing Administration's (HCFA's) decision to deny your request to establish a branch office in (City, County, State).

In order to be approved as a branch office of a parent HHA, an entity must meet the regulatory requirements for a branch. These requirements are found at 42 CFR Part 484.2. The branch must also meet applicable licensing or certification requirements for a branch in the State in which it is located and the State in which the parent is located, if different. The branch office is a location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency. The regulations require that a branch be "sufficiently close" to the parent to share administration, supervision, and services in a manner that makes it unnecessary for the branch to meet the conditions of participation on its own. To accomplish this, the parent agency must be physically located so that the sharing of administration, supervision, and services with the branch can occur on a daily basis.

After a careful review, HCFA has determined that the location you propose as a branch does not meet the regulatory requirements. This is because:

- The proposed location provides services in a different geographic area from the parent HHA;
- The proposed location is not sufficiently close to the parent to share administration, supervision and services on a daily basis;
- The proposed location does not meet State licensure or certification requirements for a branch; or
- The involved State agencies were unable to come to reciprocal agreement concerning surveys of the branch office.

If you wish to request that this location be considered as a subunit, please contact (name of contact).

Sincerely yours,

Associate Regional Administrator

(or its equivalent)

cc:
State Survey Agency