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Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-10-01-ALL

DATE: **October 2, 2009**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

Director
Freedom of Information Group

SUBJECT: State Survey Agency Treatment of Subpoenas Duces Tecum for Federal and Joint Federal/State Documents

Memorandum Summary

- This memorandum provides guidance for the handling of subpoenas duces tecum that seek disclosure of records in the possession of the State Survey Agency (SA) as a result of the SA's implementation of its Agreement with the Secretary, Health and Human Services under §1864 of the Social Security Act (§ 1864 Agreement).
- Guidance contained herein is based upon 45 C.F.R. Part 2, as amended by 73 FR 53148, dated September 15, 2008.[1]
- It is effective immediately and supersedes previous instructions ***related to subpoenas for records treated as Freedom of Information requests***.

BACKGROUND

45 C.F.R. Part 2, entitled "Testimony by Employees and the Production of Documents in Proceedings Where the United States Is Not a Party" was initially published in 52 FR 37146 on October 5, 1987 **(Attachment A)**. It establishes the rules to be followed when an employee or former employee of the Department of Health and Human Services (DHHS) is requested or subpoenaed to provide testimony in a deposition, trial, or other similar proceeding concerning information acquired in the course of performing official duties or because of such person's official capacity with DHHS. It also sets forth procedures for the handling of subpoenas duces tecum (a specific form of subpoena requiring the production of documents) and other requests for any document in the possession of DHHS (other than the Food and Drug Administration), and for the processing of requests for certification of copies of documents.

1 Although 45 C.F.R. Part 2 also provides Department of Health and Human Services policy regarding subpoenas for testimony, this particular guidance pertains only to subpoenas duces tecum for the production of records.

By 73 FR 53148, dated September 15, 2008 **(Attachment B)** DHHS amended 45 C.F.R. Part 2 by including in the definition of "Employee of the Department" current and former "[*e*]*mployees of a contractor, subcontractor, or state agency performing survey, certification, or enforcement functions under title XVIII of the Social Security Act or Section 353 of the Public Health Service Act but only to the extent the requested information was acquired in the course of performing those functions and regardless of whether documents are also relevant to the state's activities.*" See 45 C.F.R. § 2.2.

Attachment C to this document discusses the immediate impact of this new definition in light of other provisions of 45 C.F.R. Part 2 that affect the SA's processing of subpoenas duces tecum for federal or joint federal/state survey, certification, and enforcement documents and the certification of such records.

The information below provides implementation procedures for processing subpoenas duces tecum for Federal or joint Federal/State survey, certification and enforcement documents that are deemed as Freedom of Information Act (FOIA) requests and handled pursuant to the DHHS FOIA rules established at 45 C.F.R. Part 5.

Attachment D to this document provides a sample response letter to requesters and a sample Regional Office (RO) transmittal memorandum that the SA may use in fulfilling some of the instructions set forth below. These samples were constructed to cover multiple scenarios. When using the samples, the SA must be certain to check only the appropriate blocks and insert or remove information, as applicable.

Attachment E is a listing of CMS RO FOIA Coordinators, and **Attachment F** sets forth a summary of the FOIA exemptions frequently invoked by CMS to protect records/information from disclosure.

Finally, **Attachment G** is the Form CMS 632-FOIA discussed in Section C below, and **Attachment H** contains questions/issues raised by certain SAs after review of the draft of this guidance, and CMS's responses to those questions/issues.

RELEASE OF CMS-2567 AND FREEDOM OF INFORMATION ACT (FOIA)

In response to FOIA requests by members of the public, including the media, copies of CMS-2567s are directly releasable by the SA or RO in paper or electronic format without further review by the CMS Freedom of Information Group as previously articulated in S&C-09-34. The request can be in writing or via e-mail or fax, and the RO or SA may release the document(s) in hardcopy or via e-mail as a PDF file. States may also post the CMS-2567 on a State Web site. Any individual identifiers (other than standard patient/resident or staff alphanumeric identifiers, e.g. "Patient 1" "Physician 2," etc.) must be deleted from the document prior to release.

Form CMS-2567 for Surveyed Providers and Suppliers (Other than Skilled Nursing Facilities (SNF) or Nursing Facilities (NFs)):

The SA may release the Form CMS-2567 consistent with the provisions contained within this paragraph. Disclosure of any Form CMS-2567 that the State generates on a provider or supplier must comply specifically with 42 CFR 401.126(b)(1), 42 CFR 401.130 (b)(17), 42 CFR 401.133(a), SOM § 3308A, and SOM § 3314. This means that, <u>when requested</u>:

1. Prior to release, the provider must have had an opportunity to review the report (not exceeding 60 days) and offer comments within the overall time frames cited below.
2. Prior to release, the report must have been provided to CMS (via upload to the ASPEN system), and the disclosure made within 30 days of CMS's receipt of the report. The disclosure must be made within 90 days following completion of the survey by the SA.
3. Pertinent written comments, if received from the surveyed provider within the time frames above, must be disclosed with the report.
4. Individual identifiers within the report (of patients, health care practitioners, or others) must be deleted (this does not include alphanumeric patient/resident or staff identifiers).

Releasable Information on SNFs and NFs:

Per 42 CFR 488.325 and SOM §§ 7900 and 7903A disclosure of SNF and NF results is made within 14 calendar days after such information is made available to those facilities. Plans of corrections are made available when approved (42 CFR 488.325(a)(3)). Additional releasable information/records are set forth at §7900.

PROCEDURES FOR PROCESSING SUBPOENAS DUCES TECUM UNDER DHHS POLICY ESTABLISHED AT 45 C.F.R. PART 2

Section A: Requirements

1. A subpoena duces tecum is governed by 45 C.F.R. Part 2 and must be processed in accordance with these instructions if the subpoena:

   A. seeks records the SA has acquired in the course of performing official survey, certification or enforcement functions for CMS/DHHS only or for both CMS/DHHS and the State; and

   B. involves State, local and tribal judicial, administrative, and legislative proceedings, and Federal judicial and administrative proceedings, with the exception of such proceedings as listed at A.2.B.- D. below.

2. A subpoena duces tecum is not governed by 45 C.F.R. Part 2 if the subpoena:

   A. seeks records the SA has acquired in the course of performing official survey, certification or enforcement functions solely for State purposes;

   B. involves civil or criminal proceedings where the United States, the Department of Health and Human Services, or any agency thereof, or any other Federal agency is a party;

   C. involves civil or criminal proceedings in State court brought on behalf of the Department of Health and Human Services;

D. involves civil, criminal, or administrative proceedings where the SA is a party and seeks to use records obtained for joint Federal/State purposes to enforce its own laws or regulations.[2]

Section B: Initial Processing Actions

1. Upon receipt of a subpoena duces tecum, the SA should immediately consult with its own legal counsel and, as necessary, with its CMS program contact to determine whether the two 45 C.F.R. Part 2 requirements at A.1 of this guidance are met.

2. After consultation with its own legal counsel, the SA should immediately forward to its CMS RO FOIA Coordinator the following kinds of subpoenas duces tecum for Federal and/or joint Federal/State records:

   A. Federal court subpoena duces tecum.
   B. Subpoena duces tecum for proceedings in which DHHS and/or any of its agencies (including CMS), the United States, or any other Federal agency, is a named party.
   C. Subpoenas duces tecum for proceedings in State court brought on behalf of DHHS.
   D. Any subpoena whose status is unclear to the SA and its legal counsel.

   The SA should not provide to the RO documents responsive to the subpoena duces tecum at this point in the process.

3. Referrals listed at number 2 of this section must be made within 48 hours of service of the subpoena. Subsequent to CMS and/or OGC/DHHS review, the CMS RO FOIA Coordinator will provide any additional processing instructions to the SA.

[2]Because amended 45 C.F.R. Part 2 was never intended to impede the SA's ability to enforce State laws and regulations, CMS is authorizing the SA, where it is a party to civil, criminal, or administrative proceedings, to release records obtained for joint Federal/State purposes as necessary to enforce its own laws and regulations.

Section C:	Routine Processing Procedures for Subpoenas Duces Tecum Involving State, Local or Tribal Judicial, Administrative and Legislative Proceedings

1. The SA should automatically process, in accordance with instructions in this section, all subpoenas duces tecum for Federal or joint Federal/State survey, certification and enforcement documents when the subpoenas do not fall within any of the categories mentioned at section A.2.B. – D. and B.2 of this guidance.[3]

2. Follow instructions A through D immediately below if the subpoena only seeks the following records that SOM §§ 3308, 3308A, 3314, 7900, or 7903A authorize the SA to disclose:

   - Form CMS-2567 for surveyed providers and suppliers;[4]

   - Whether a facility does or does not participate in the Medicare/Medicaid/CLIA program;

   - The Official Medicare/Medicaid/CLIA report of a survey **except** to the extent that it contains:

     --The name of any patient;
     --Medical information about any identifiable patient;
     --The identity of a complainant;
     --The address of anyone other than an owner of the facility; or
     --Information which could be defamatory toward any identifiable person.

   NOTE: The SA reviews the report of survey (Form CMS-2567), and if it contains any of the above elements, it deletes the information from the report by blocking it out fully prior to release of the report. (See 42 C.F.R. 401.118)

   - Citations of deficiencies that have been conveyed to the provider following a survey, except to the extent the report contains any of the identifiable information listed above. The SA blocks this information out prior to release of the statement of deficiencies;

   - Plan of Correction (PoC) and pertinent comments submitted by the provider relating to Medicare/Medicaid/CLIA deficiencies cited following a survey, except to the extent the PoC or comments contain any of the identifiable information listed above. The SA blocks this information out prior to release of the PoC;

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[3] Case law holds that absent a waiver, the doctrine of "sovereign immunity" precludes state or tribal court jurisdiction over a federal agency or official. Based on this case law, CMS's position is that the State, tribal and local court subpoena duces tecum is from a tribunal not having jurisdiction over the Department, and such a subpoena must be processed as a FOIA request.

[4] For surveyed providers and suppliers, other than SNFs or NFs, disclosures must be consistent with the provisions contained in 42 C.F.R. 401.126(b)(1), 42 C.F.R. 401.133(a), SOM § 3308A and SOM § 3314. For SNFs and NFs, disclosures must be consistent with 42 C.F.R. 488.325 and SOM §§ 7900 and 7903A.

- Official notices of involuntary provider termination (including alternative remedies);

- Reports and information about a laboratory's performance in proficiency testing programs (Note: information about any individual person's performance may not be released);

- Information contained within the CMS manuals distributed to the SAs, intermediaries, carriers, providers, or suppliers;

- Statistical data on provider characteristics that do not identify any specific provider or individual;

- CMS-116, CLIA Application for Certification; however, the name of the laboratory director must be blocked prior to the release of the application;

- Statistical data on facility characteristics that does not identify any specific individual, e.g., Standard OSCAR/CASPER Reports;

- Decisions issued by the Departmental Appeals Board or its Administrative Law Judges;

- Medicare and Medicaid cost reports; and

- Names of individuals with direct or indirect ownership interest in a skilled nursing facility or nursing facility, as defined in 42 C.F.R. 420.201, who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law.

A. Fully comply with the subpoena by releasing the requested records in compliance with any conditions specified in the SOM.

B. Notify the requester in writing of the decision to release the requested records within 20 workings days of receipt of the subpoena/request in the SA's disclosure unit[5]

   [Note that for subpoena duces tecum processed under 45 C.F.R. § 2.5(b), the SA does not have to adhere to the deadlines imposed by the subpoena but rather to FOIA's response deadline of 20 working days.]

C. Release the requested records with this decision letter, if possible.

D. If release within 20 working days is not possible because a voluminous amount of records must be collected and duplicated, the SA should advise the requester of this unusual circumstance in the decision letter and release the responsive records *as shortly thereafter as practicable.*

[5] FOIA requires that Federal agencies provide a substantive response (i.e., a decision to release or withhold the requested records) to requesters within 20 working days of receipt of the request in the appropriate component of the agency.

3. If the subpoena seeks some records that SOM §§ 3308, 3308A, 3314, 7900, and 7903A authorize the SA to disclose and other records that the SA is not authorized to disclose:

   A. Partially comply with the subpoena by releasing the records the SOM authorizes the SA to release in compliance with any conditions specified in the SOM;

   B. Advise the requester, in writing, that the remaining records are not within the SA's authority to release, and that they have been forwarded to the applicable CMS RO FOIA Coordinator for disposition. Specifically explain that under 45 C.F.R. Part 2 the records at issue are Federal records under the control of DHHS, and that Federal law and governmental privileges affect their release. Attach a copy of 45 C.F.R. Part 2 to this notification.

   C. Direct the requester to contact the applicable CMS RO FOIA Coordinator for follow-up inquiries. Include the name, address and telephone number of the CMS RO FOIA Coordinator in the notification.

   D. Forward a copy of the incoming subpoena and the documents that the SA is not authorized to release to the SA's CMS RO FOIA Coordinator **(Attachment E)**. If the subpoena seeks several categories/items of records, bundle the records according to the specific category/item to which they respond and clearly identify the category/item associated with each bundle.[6] Include in the SA's cover letter/ transmittal to the CMS RO FOIA Coordinator any concerns or recommendations the SA has regarding release of the requested records.

   E. For any surveyor worksheets and notes that are responsive to the subpoena that are forwarded to the CMS RO, indicate whether the SA believes that release of these records would be a deterrent to future free exchanges of information within the SA because survey personnel will fear public disclosure of their opinions, advice, analyses, and recommendations, and such fear would impinge upon the ability of the surveyor to do his/her job. (Note that if the SA does not communicate disclosure concerns regarding the release of surveyor worksheets and notes, the CMS FOIA Officer may exercise his discretionary authority to release such documents even if they are protected by a FOIA exemption). If the SA recommends release of surveyor worksheets and notes, this should also be noted in the SA's transmittal letter.

      CMS solicits SA input regarding the effect of release of the surveyor worksheets in order to facilitate CMS's analysis of the worksheets in light of the deliberative process privilege of FOIA Exemption 5 (5 U.S.C. § 552(b)(5)). This exemption permits the withholding of "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." The deliberative process privilege of Exemption 5 protects internal communications that are both pre-decisional and deliberative. However, CMS's analysis is not limited to Exemption 5. Portions of the worksheets may also be subject to withholding under Exemptions 6 and 7(C) (5 U.S.C. § 552 (b)(6) and (b)(7)(C)) of FOIA.

[6] The CMS Regional Office FOIA Coordinator, at his/her discretion, may return documents to the SA if they are not bundled properly.

Exemption 6 protects information about individuals contained in "personnel and medical files and similar files" when the disclosure of such information "would constitute a clearly unwarranted invasion of personal privacy." Exemption 7(C) protects information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information . . . could reasonably be expected to constitute an unwarranted invasion of personal privacy." Under these exemptions, CMS withholds the identities of residents, witnesses, complainants and other individuals, as well as information that could lead to the identification of the same. If the SA believes that these or any other exemptions apply, the SA should point this out when forwarding the records to the RO].

F. Complete the attached Form CMS 632-FOIA **(Attachment G)** so that CMS can track costs for processing the subpoena. The Form 632-FOIA is used to capture all actual costs associated with responding to a FOIA request. (In lieu of completion of this form, it is acceptable for the SA to inform the CMS RO FOIA Coordinator of the number of pages forwarded to CMS for disposition; the number of hours SA personnel searched to locate the responsive pages; and the hourly wage of the SA personnel who performed the search.)

G. Complete the above processing actions within 20 working days of receipt of the subpoena within the SA's disclosure unit.

4. If the subpoena only seeks records that the SA is not authorized to release, complete the following actions.

A. Advise the requester, in writing, that the requested records are not within the SA's authority to release, and that they have been forwarded to the applicable CMS RO FOIA Coordinator for disposition. Specifically explain that under 45 C.F.R. Part 2 the records at issue are Federal records under the control of DHHS, and that Federal law and governmental privileges affect their release. Attach a copy of 45 C.F.R. Part 2 to this notification.

B. Direct the requester to contact the applicable CMS RO FOIA Coordinator for follow-up inquiries. Include the name, address and telephone number of the CMS RO FOIA Coordinator in the notification.

C. Follow the instructions set forth at numbers 3.D through G of this section.

5. Immediately notify the CMS RO FOIA Coordinator of a party's resistance to treating its subpoena as a FOIA request and/or if the party obtains an order from a state or tribal court judge compelling the SA's compliance with a subpoena on pain of contempt. The CMS RO FOIA Coordinator, in turn, will promptly notify DHHS RO OGC.

Section D: Certification of Records

1. If the subpoena requests that the SA certify responsive records, any records that the SA determines can be released in accordance with section C.2 and C.3.A of this guidance should not be released to the requester but forwarded to the applicable CMS RO FOIA Coordinator for certification. Enclose with the documents a copy of the incoming subpoena duces tecum and the notification to the requester discussed at item 2 below.

2. The SA should advise the requester that the responsive records have been forwarded to the CMS RO FOIA Coordinator for certification under the authority of 45 C.F.R. Part § 2.6.

Section E: Fees for Processing FOIA Requests

Fees for processing subpoenas must be assessed in accordance with FOIA and DHHS' FOIA regulations. Instructions will be provided under separate cover. In the interim, SAs are allowed to collect any fees that they have collected in the past (for the release of documents that the SA is authorized to release.)

Questions concerning these instructions should be directed to your CMS RO FOIA Coordinator or to CMS Disclosure Policy Advisor, Freedom of Information Group (FIG), Centers for Medicare & Medicaid Services (CMS) at (410) 786-5358 or Deborah Peters, Assistant Disclosure Policy Advisor, FIG, CMS at (410) 786-3677.

_____/s/_____ _____/s/_____

Thomas E. Hamilton Michael S. Marquis

Attachments

A -- 45 C.F.R. Part 2
B -- *45 C.F.R. Part 2 As Amended By 73 FR 53148, dated September 15, 2008*
C -- *Freedom of Information Act Briefing Document on 45 C.F.R. Part 2 As Amended*
D -- Sample Response Letter and Transmittal to CMS Regional Office FOIA Coordinator
E -- List of CMS Regional Office FOIA Contacts
F -- Summary of FOIA Exemptions Most Often Applicable to CMS Records
G -- Form CMS 632-FOI
H-- Questions Raised by SAs in Response to Draft Guidance and CMS's Responses

cc: CMS RO FOIA Coordinators
CO and RO Survey and Certification Management
Freedom of Information Group

SUBCHAPTER A—GENERAL ADMINISTRATION

PART 1—HHS'S REGULATIONS

Sec.

§ 1.1 Location of HHS regulations.

Regulations for HHS's programs and activities are located in several different titles of the Code of Federal Regulations:

- Regulations having HHS-wide application or which the Office of the Secretary administers are located in Parts 1–99 of Title 45.
- Health regulations are located at Parts 1–399 of Title 42.
- Health care financing regulations are located at Parts 400–499 of Title 42. These include regulations for Medicare and Medicaid.
- Human development services regulations are located at Parts 200–299 and 1300–1399 of Title 45. These include regulations for Head Start, social services, social and nutrition services for older persons, rehabilitative services, developmental disabilities services, Native American programs, and various programs relating to families and children.
- Social Security regulations are located at Parts 400–499 of Title 20.
- Food and Drug regulations are located at Parts 1–1299 of Title 21.
- Procurement (contract) regulations are located at Chapter 3 of Title 41.

Each volume of the Code contains an index of its parts.

(5 U.S.C. 301)

[44 FR 61598, Oct. 26, 1979, as amended at 48 FR 35099, Aug. 3, 1983]

§ 1.2 Subject matter of Office of the Secretary regulations in parts 1–99.

This subject matter of the regulations in Parts 1–99 of this title includes:

- *Civil rights/nondiscrimination:* Parts 80, 81, 83, 84, 86, 90.
- *Protection of human subjects:* Part 46.
- *Day care requirements:* Part 71.
- *Information, privacy, advisory committees:* Parts 5, 5a, 5b, 11, 17, 99.
- *Personnel:* Parts 50, 57, 73, 73a.
- *Grants and letter of credit administration, property, hearing rights:* Parts 10, 12, 15, 16, 74, 75, 77, 95.
- *Claims:* Parts 30, 35.
- *Inventions and patents:* Parts 6, 7, 8.
- *Miscellaneous:* Parts 3, 4, 9, 67.

(5 U.S.C. 301)

[50 FR 781, Jan. 7, 1985, as amended at 52 FR 28658, July 31, 1987]

PART 2—TESTIMONY BY EMPLOYEES AND PRODUCTION OF DOCUMENTS IN PROCEEDINGS WHERE THE UNITED STATES IS NOT A PARTY

Sec.

AUTHORITY: 5 U.S.C. 301, 5 U.S.C. 552.

SOURCE: 52 FR 37146, Oct. 5, 1987, unless otherwise noted.

§ 2.1 Scope, purpose, and applicability.

(a) This part sets forth rules to be followed when an employee or former employee of the Department of Health and Human Services (''DHHS'' or ''Department''), other than an employee of the Food and Drug Administration, is requested or subpoenaed to provide testimony in a deposition, trial, or other similar proceeding concerning information acquired in the course of performing official duties or because of such person's official capacity with DHHS. This part also sets forth procedures for the handling of subpoenas duces tecum and other requests for any document in the possession of DHHS, other than the Food and Drug Administration, and for the processing of requests for certification of copies of documents. Separate regulations, 21 CFR part 20, govern the Food and Drug Administration, and those regulations are not affected by this part.

(b) It is the policy of the DHHS to provide information, data, and records to non-federal litigants to the same extent and in the same manner that they

are *made* available to the general public *and,* when subject to the jurisdiction of a court or other tribunal presiding over non-federal party litigation, to follow all applicable procedural and substantive rules relating to the production of information, data, and records by a non-party. The availability of Department employees to testify in litigation not involving federal parties is governed by the Department's policy to maintain strict impartiality with respect to private litigants and to minimize the disruption of official duties.

(c) This part applies to state, local and tribal judicial, administrative, and legislative proceedings, and to federal judicial and administrative proceedings.

(d) This part does not apply to:

(1) Any civil or criminal proceedings where the United States, the Department of Health and Human Services, and any agency thereof, or any other Federal agency is a party.

(2) Congressional requests or subpoenas for testimony or documents.

(3) Consultative services and technical assistance provided by the Department of Health and Human Services, or any agency thereof, in carrying out its normal program activities.

(4) Employees serving as expert witnesses in connection with professional and consultative services as approved outside activities in accordance with 5 CFR 2635.805 and 5 CFR 5501.106. (In cases where employees are providing such outside services, they must state for the record that the testimony represents their own views and does not necessarily represent the official position of the DHHS.)

(5) Employees making appearances in their private capacity in legal or administrative proceedings that do not relate to the Department of Health and Human Services (such as cases arising out of traffic accidents, crimes, domestic relations, etc.) and not involving professional and consultative services.

(6) Any matters covered in 21 CFR part 20-,involving the Food and Drug Administration.

(7) Any civil or criminal proceedings in State court brought on behalf of the Department of Health and Human Services.

Example (1): While on duty, an employee of the Department witnesses an incident in which a fellow employee trips on a loose piece of carpeting and sustains an injury. The injured employee brings a private tort action against the contractor installing the carpeting and the private landlord maintaining the building. The employee/witness is served with a subpoena to appear at a deposition to testify about the incident. The person seeking the testimony would not be required to obtain Agency head approval prior to requesting the testimony, because the subject of the testimony does not ''relate to'' the Department, within the meaning of §2.1(d)(5).

Example (2): While on duty, an employee of the Department witnesses a mugging while looking out the window to check the weather, and then notifies the local police of what she observed. She is subsequently subpoenaed to testify in a criminal proceeding. The local prosecutor would not be required to obtain Agency head approval prior to requiring the employee to testify, because the subject of the testimony does not ''relate to'' the Department, within the meaning of §2.1(d)(5).

Example (3): A nurse on duty at an Indian Health Service hospital emergency room treats a child who is brought in following a report of domestic violence. The nurse is subsequently served with a subpoena to testify in a criminal proceeding against one of the child's parents concerning the injuries to the child which he observed. The local prosecutor would be required to obtain Agency head approval prior to requiring the nurse to testify, because the subject of the testimony involves ''information acquired in the course of performing official duties or because of the person's official capacity,'' within the meaning of §2.1(a).

Example (4): A personnel specialist working for the Department is subpoenaed to testify concerning the meaning of entries on time and attendance records of an employee, which the requesting party received from the employee pursuant to discovery in a personal injury action brought by the employee. The party requesting the personnel specialist to appear would be required to obtain Agency head approval prior to compelling the personnel specialist to testify, because the testimony sought involves ''information acquired in the course of performing official duties or because of the person's official capacity,'' within the meaning of §2.1(a).

Example (5): A National Institutes of Health physician is subpoenaed in a private medical malpractice action to provide expert testimony in her specialty. The party requesting her testimony would be required to obtain Agency head approval prior to her testifying in response to the subpoena, because the expert testimony sought involves

''information acquired in the course of performing official duties or because of the person's official capacity,'' within the meaning of §2.1(a).

[52 FR 37146, Oct. 5, 1987, as amended at 55 FR 4611, Feb. 9, 1990; 68 FR 25838, May 14, 2003]

§2.2 Definitions.

Agency head refers to the head of the relevant operating division or other major component of the DHHS, or his or her delegatee. *Agency head* for the purposes of this part means the following officials for the components indicated:

(1) Office of the Secretary—Assistant Secretary for Administration and Management;

(2) Administration on Aging—Assistant Secretary for Aging;

(3) Administration for Children and Families—Assistant Secretary for Children and Families;

(4) Agency for Healthcare Research and Quality—Administrator;

(5) Agency for Toxic Substances and Disease Registry—Administrator;

(6) Centers for Disease Control and Prevention—Director;

(7) Centers for Medicare and Medicaid Services—Administrator;

(8) Health Resources and Services Administration—Administrator;

(9) Indian Health Service—Director;

(10) National Institutes of Health—Director;

(11) Substance Abuse and Mental Health Services Administration—Administrator;

(12) Office of Inspector General—Inspector General.

Employee includes:

(1) Commissioned officers in the Public Health Service Commissioned Corps, as well as regular and special DHHS employees (except employees of the Food and Drug Administration), when they are performing the duties of their regular positions, as well as when they are performing duties in a temporary assignment at DHHS or another organization.

(2) Any employees of health insurance intermediaries and carriers performing functions under agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h, 1395u; *and*

(3) Current and former employees and contractors of entities covered under the Federally Supported Health Centers Assistance Act of 1992, as amended, 42 U.S.C §233 (FSHCAA), provided that the requested testimony or information relates to the performance of medical, surgical, dental or related functions which were performed at a time when the DHHS deemed the entity to be covered by the FSHCAA.

Certify means to authenticate under seal, pursuant to 42 U.S.C 3505, official documents of the Department.

Testify and testimony includes both in-person, oral statements before a court, legislative or administrative body and statements made pursuant to depositions, interrogatories, declarations, affidavits, or other formal participation.

[68 FR 25839, May 14, 2003]

§2.3 Policy on Presentation of testimony and production of documents.

No employee or former employee of the DHHS may provide testimony or produce documents in any proceedings to which this part applies concerning information acquired in the course of performing official duties or because of the person's official relationship with the Department unless authorized by the Agency head pursuant to this part based on a determination by the Agency head, after consultation with the Office of the General Counsel, that compliance with the request would promote the objectives of the Department.

[68 FR 25839, May 14, 2003]

§2.4 Procedures when voluntary testimony is requested or when an employee is subpoenaed.

(a) All requests for testimony by an employee or former employee of the DHHS in his or her official capacity and not subject to the exceptions set forth in §2.1(d) of this part must be addressed to the Agency head in writing and must state the nature of the requested testimony, why the information sought is unavailable by any other means, and the reasons why the testimony would be in the interest of the DHHS or the federal government.

(b) If the Agency head denies approval to comply with a subpoena for testimony, or if the Agency head has

not acted by the return date, the employee will be directed to appear at the stated time and place, unless advised by the Office of the General Counsel that responding to the subpoena would be inappropriate (in such circumstances as, for example, an instance where the subpoena was not validly issued or served, where the subpoena has been withdrawn, or where discovery has been stayed), produce a copy of these regulations, and respectfully decline to testify or produce any documents on the basis of these regulations.

[68 FR 25840, May 14, 2003]

§ 2.5 Subpoenas duces tecum.

(a) Whenever a subpoena duces tecum has been served upon a DHHS employee or former employee commanding the production of any record, such person shall refer the subpoena to the Office of the General Counsel (including regional chief counsels) for a determination of the legal sufficiency of the subpoena, whether the subpoena was properly served, and whether the issuing court or other tribunal has jurisdiction over the Department.) If the General Counsel or his designee determines that the subpoena is legally sufficient, the subpoena was properly served, and the tribunal has jurisdiction, the terms of the subpoena shall be complied with unless affirmative action is taken by the Department to modify or quash the subpoena in accordance with Fed. R. Civ. P. 45 (c).

(b) If a subpoena duces tecum served upon a DHHS employee or former employee commanding the production of any record is determined by the Office of the General Counsel to be legally insufficient, improperly served, or from a tribunal not having jurisdiction, such subpoena shall be deemed a request for records under the Freedom of Information Act and shall be handled pursuant to the rules governing public disclosure established in 45 CFR part 5.

[68 FR 25840, May 14, 2003]

§ 2.6 Certification and authentication of records.

Upon request, DHHS agencies will certify, pursuant to 42 U.S.C. 3505, the authenticity of copies of records that are to be disclosed. Fees for copying and certification are set forth in 45 CFR 5.43.

[68 FR 25840, May 14, 2003]

PART 3—CONDUCT OF PERSONS AND TRAFFIC ON THE NATIONAL INSTITUTES OF HEALTH FEDERAL ENCLAVE

Subpart A—General

Subpart B—Traffic Regulations

Subpart C—Facilities and Grounds

Subpart D—Penalties

AUTHORITY: 40 U.S.C. 318–318d. 486; Delegation of Authority, 33 FR 604.

SOURCE: 55 FR 2068, Jan. 22, 1990, unless otherwise noted.

Subpart A—General

§ 3.1 Definitions.

Director means the Director or Acting Director of the National Institutes of Health (NIH), or other officer or employee of NIH to whom the authority involved has been delegated.

Enclave means, unless the context requires a different meaning, the area, containing about 318 acres, acquired by the United States in several parcels in the years 1935 through 1983, and any further future acquisitions, comprising

A deed dated March 18, 2005 contains the appropriate use restrictions for the 11-acre portion of Parcel B. The restrictions listed in the deed include restrictions on groundwater use, restrictions limiting the use of the property, restrictions on land disturbance, and limitations on activities to protect the remedy. The deed with the use restrictions are institutional controls.

For Parcel C the current owner of the 11-acre portion of Parcel B also bought Parcel C to maintain the property as open space. Parcels B and C are adjacent to one another. A deed dated July 10, 2006 contains restrictions on the use of the parcel consistent with the UAO. The restrictions listed in the deed include restrictions on groundwater use, restrictions limiting the use of the property, restrictions on land disturbance, and limitations on activities to protect the remedy. The deed with the use restrictions are institutional controls.

Regarding Parcel D, the owner of Parcel D signed a letter agreement dated August 14, 2002 with the UAO Respondents granting the Respondents access to install a sentinel well and to collect groundwater samples. The letter agreement also provides for groundwater use restrictions and prohibitions on interfering with the well. The letter agreement is an institutional control.

Five-Year Review

Since the remedy for the Site utilized containment of the hazardous materials as a method to reduce risk, EPA will conduct five-year reviews to insure that the remedy is functioning as designed and preventing exposure to human health and the environment. EPA completed the first statutory Five-Year Review on August 2, 2005 and has determined that the remedy for Berks Landfill remains protective of human health and the environment. EPA plans to complete the next five-year review by August, 2010.

Community Involvement

To ensure that the community was well informed about activities at the Site, a series of outreach activities were performed. Public meetings at key points in the remedial process were held such as a meeting on the proposed remedy in 1997 and the construction of the remedy in 2000. Since then, in 2005 as part of the five-year review, EPA placed an advertisement in the Reading Eagle and mailed a fact sheet notifying residents of the five-year review. In addition, residents whose water is tested receive annual information on their well water test results. As part of the deletion, EPA will place an advertisement in the local paper notifying the community of the public comment period, the process for submitting comments, and location of the deletion docket.

Determination That the Site Meets the Criteria for Deletion in the NCP

This Site meets all the requirements in the NCP and the criteria specified in OSWER Directive 9320.2–09–A–P, *Close Out Procedures for National Priorities List Sites.* Specifically, sampling performed during operation, maintenance, and monitoring verifies the Site has achieved the ROD remedial action objective that no site-related contaminants exceed MCLs off-site and that all components of the remedy selected by EPA in the ROD have been implemented. Operation, maintenance, and monitoring are, and will continue to be, performed by the Respondents pursuant to the 1998 UAO.

V. Deletion Action

The EPA, with concurrence of the Commonwealth through the PADEP, has determined that all appropriate response actions under CERCLA, other than operation, maintenance, and monitoring and five-year reviews, have been completed. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective November 14, 2008 unless EPA receives adverse comments by October 15, 2008. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion, and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: September 5, 2008.

Donald S. Welsh,

Regional Administrator, Region III.

■ For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by removing the entry under Pennsylvania for ''Berks Landfill'', ''Spring Township''.

[FR Doc. E8–21305 Filed 9–12–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 2

Testimony by Employees and the Production of Documents in Proceedings Where the United States Is Not a Party

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This rule amends Part 2 of Title 45 of the Code of Federal Regulations, which provides that employees and former employees of the Department of Health and Human Services (HHS or Department) may not provide testimony as part of their official duties in litigation where the United States or a federal agency is not a party, without the approval of the head of the agency. The purpose of these amendments is to modify the definition of ''employee'' contained in 45 CFR part 2. Under these amendments, the definition of employee will be revised to reflect changes in Medicare contracting, including changes brought about by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). In addition, the definition of employee will be modified to include employees of a state agency performing survey, certification, or enforcement functions under Title XVIII of the Social Security Act or Section 353 of the Public Health Service Act. Further, the definition of employee with respect to employees of entities covered by the

Federally Supported Health Centers Assistance Act, as amended, 42 U.S.C. 233(g)–(n) (FSHCAA), will be limited to testimony requested in medical malpractice tort litigation which relates to medical functions performed at a time when the center was covered under FSHCAA.

DATES: *Effective Date:* October 15, 2008.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Davis, Associate General Counsel, General Law Division, Office of the General Counsel, Department of Health and Human Services, 330 Independence Ave., SW., Room 4760 Cohen Bldg., Washington, DC 20201, Telephone Number 202–619–0150.

SUPPLEMENTARY INFORMATION: In 1987, the Department of Health and Human Services published regulations addressing the issue of the increasing number of requests for the testimony of Department employees in litigation involving only private parties and not the United States. The regulations generally prohibit an employee or former employee of the Department from giving testimony concerning information acquired in the course of performing official duties or because of such person's official capacity, except where the relevant agency head determines that the appearance would promote the objectives of the Department.

These amendments are designed to address changes in Medicare contracting, including changes brought about by the MMA. The amendments also address involvement of the Department in matters in which parties request testimony or documents from employees of state survey agencies or contractors that carry out survey, certification, or enforcement activities for the Medicare and CLIA programs. Finally, these amendments address the involvement of the Department in cases other than medical malpractice matters where parties request testimony from any current or former employee or contractor of an entity covered by the FSHCAA.

Section 911 of the MMA added section 1874A to the Social Security Act (SSA) and took the separate authorities under which the Centers for Medicare & Medicaid Services (CMS) contracted with intermediaries and carriers and consolidated them into a single authority for a new type of contractor, the Medicare Administrative Contractor (MAC). See MMA section 911. Under section 911, the Secretary may enter into contracts with any eligible entity to serve as a MAC with respect to the performance of the core Medicare administrative functions listed at SSA section 1874A(a)(4). Thus, in the contracting environment created by the MMA, MACs perform functions once performed solely by intermediaries and carriers. Currently, CMS has agreements with intermediaries, carriers and MACs to make Medicare payments for health care items and services. Furthermore, under section 911(e) of the MMA, any reference to a carrier or intermediary under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out these titles) shall be deemed a reference to a MAC.

Furthermore, historically, carriers and intermediaries also carried out all Medicare program integrity activities, such as cost report audits and medical, utilization, and fraud reviews. However, CMS has begun contracting with Program Safeguard Contractors (PSCs) and Recovery Audit Contractors (RACs) to perform program integrity activities, *see* SSA section 1893, although intermediaries and carriers continue to carry out many program integrity functions. There is substantial functional overlap between the functions that are performed by PSCs and RACs and the program integrity activities that are now, or were once, carried out by carriers and intermediaries.

Accordingly, we are amending the definition of ''employee'' in these regulations to include the employees of contractors that perform the core Medicare administrative functions listed at SSA sections 1874A(a)(4) and 1893. Under such definition, these regulations cover intermediaries, carriers, MACs, PSCs and RACs, and any successor entities that perform the functions listed in the amended definition. Not only does this definition reflect the more flexible contracting procedures created by the MMA, but a functional definition of ''employee'' also limits the need to amend these regulations again in the event Congress further modifies the Medicare contracting nomenclature through future legislation.

The second amendment concerns requests for testimony and documents of employees of contractors, subcontractors, and state survey agencies that carry out many of the Department's survey, certification, and enforcement activities. Section 1864 of the Social Security Act provides that the Secretary shall enter into agreements with states under which appropriate state or local survey agencies determine whether providers meet Medicare conditions of participation, suppliers meet Medicare conditions of coverage, and rural health clinics meet Medicare conditions of certification. Furthermore, under section 353(o) of the Public Health Service Act, the Secretary is permitted to use the services of state agencies to carry out his responsibilities under the Clinical Laboratory Improvement Act Amendments of 1988 (CLIA). Thus, employees of state survey agencies carry out federal functions for both the Medicare and CLIA programs. In addition, contractors of the Department under certain circumstances survey and certify providers and suppliers. Contractors of the Department also perform validation surveys to ensure that state survey agencies and deeming authorities satisfactorily perform their survey, certification, and enforcement responsibilities.

Parties in private litigation frequently request testimony and documents from employees of contractors, subcontractors, and state survey agencies that perform survey, certification, and enforcement functions under the Medicare and CLIA programs. These requests are especially prevalent in medical malpractice litigation. Although any specific request for testimony or documents may not be unduly burdensome, the requests divert employees from their federal survey, certification, and enforcement responsibilities. The cumulative effect of these requests can impede these activities. Moreover, we believe that information gathered during these federal activities is federal information and may be protected by governmental privileges. Therefore, we are amending the definition of ''employee'' in these regulations to include employees of contractors, subcontractors, and state survey agencies that perform survey, certification, or enforcement activities under the Medicare and CLIA programs.

We recognize that employees of state survey agencies may have dual roles. These employees perform activities for the Medicare and CLIA programs, but also have survey, certification, and enforcement responsibilities with respect to state requirements. For example, it is our understanding that state survey agencies commonly survey skilled nursing facilities for compliance with both federal and state requirements during a single visit. Under 45 CFR 2.1(a), the Department's regulations apply only to information acquired in the course of performing official duties or because of the employee's official capacity with the Department. Therefore, these regulations will apply to requests for testimony or documents from an employee of a contractor, subcontractor, or state agency only to the extent the information was acquired in the course of performing survey,

certification, or enforcement functions under Title XVIII of the Social Security Act or section 353 of the Public Health Service Act and regardless of whether documents are also relevant to the state's activities.

The third amendment addresses the increasing frequency of requests to the Department in cases other than medical malpractice matters for employees and qualified contractors of entities covered under the FSHCAA to provide testimony. The FSHCAA provides that, for the purposes of the Federal Tort Claims Act (FTCA), employees and certain qualified health care practitioner contractors acting within the scope of their employment with an entity covered under the FSHCAA are deemed to be employees of the Public Health Service. 42 U.S.C. 233(g)(1)(A). As such, these employees or qualified contractors are deemed to be employees solely for the purpose of securing coverage under the FTCA in medical malpractice cases brought against them. The current definition of ''employee'' in the Department's regulations includes employees and contractors of a covered entity when the requested testimony relates to their performance of medical, surgical, dental or related functions which were performed at a time when HHS deemed the entity to be covered by the FSHCAA, even in matters that do not relate to medical malpractice litigation.

The interests of the United States are implicated in state court actions that may impact upon liability under the FTCA. By amending the definition to require application of these regulations in medical malpractice cases only, the number of requests to the Department for testimony of federally supported health center employees and qualified contractors will be significantly reduced. Thus, the burden on the Department to respond to these time-consuming requests will be lessened.

Further, the current definition of ''employee'' under subpart (3) of section 2.2 refers to ''the requested testimony or information.'' Because FSHCAA entities and records are normally subject to state law and are beyond the control of the Department, we have only applied the Department's regulations in matters involving the FSHCAA to requests for testimony in FTCA matters, not to record requests. Therefore, we have limited this subpart to requests for testimony.

Public Participation: This rule is published as a final rule. It is exempt from public comment, pursuant to 5 U.S.C. 553(b)(A), as a rule of ''agency organization, procedure, or practice.''

Paperwork Reduction Act: This regulation is not subject to the Paperwork Reduction Act because it deals solely with the Department's internal rules of organization, procedure or practice.

Cost/Regulatory Analysis: We have examined the impact of this rule as required by Executive Order (EO) 12866 (Regulatory Planning and Review), as amended, the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*); the Unfunded Mandated Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*); and EO 13132 (Federalism). EO 12866, as amended, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize the benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in 1 year). We have determined that the rule is consistent with the principals set forth in the EO, and we find that the rule would not have an effect on the economy that exceeds $100 million in any one year. Under the RFA, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities and determine it will not have any effect. The agency has considered the effect that this rule would have on small entities. I hereby certify, under 5 U.S.C. 605(b), that the rule will not have a significant economic impact on a substantial number of small entities, including small businesses, small organizations and small local governments. Therefore, a regulatory flexibility analysis is not required. The UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribunal governments, in the aggregate, or by the private sector of $100 million. As noted above, we find that the rule would not have an effect of this magnitude on the economy. Therefore, no further analysis is required under the UMRA. EO 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed the rule under the threshold criteria of EO 13132 and have determined that this rule would not have substantial direct impact on States, or on the distribution of power and responsibilities among the various levels of government. As there are no federalism implications, a federalism impact statement is not required.

List of Subjects in 45 CFR Part 2

Administrative practice and procedure, Freedom of Information, Government employees.

■ Accordingly, for the reasons set forth in the preamble, 45 CFR part 2 is amended as follows:

PART 2—[AMENDED]

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 5 U.S.C. 301, 5 U.S.C. 552.

■ 2. The definition of ''Employee'' in 45 CFR 2.2 is amended by revising the introductory text and paragraphs (2) and (3), adding paragraph (4), and placing the definition in alphabetical order to read as follows:

§ 2.2 Definitions.

* * * * *

Employee of the Department includes current and former:

* * * * *

(2) Employees of intermediaries, carriers, Medicare Administrative Contractors, Program Safeguard Contractors, and Recovery Audit Contractors, and any successor entities, that perform one or more of the following functions described in section 1874A or 1893 of the Social Security Act relating to the administration of the Medicare program:

(i) Determination of payment amounts; making payments; beneficiary education and assistance; providing consultative services; communication with providers; or, provider education and technical assistance; or,

(ii) Other such functions as are necessary to carry out the Medicare program, including any of the following program integrity functions under section 1893 of the Social Security Act:

(A) Review of activities of providers or suppliers, including medical and utilization review and fraud review;

(B) Auditing of cost reports;

(C) Determinations as to whether payment should not be, or should not have been, made because Medicare is the secondary payer, and recovery of payments that should not have been made;

(D) Education of providers, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues; or,

(E) Developing (and periodically updating) a list of items of durable medical equipment which are subject to prior authorization.

(3) Employees of a contractor, subcontractor, or state agency performing survey, certification, or enforcement functions under title XVIII of the Social Security Act or Section 353 of the Public Health Service Act but only to the extent the requested information was acquired in the course of performing those functions and regardless of whether documents are also relevant to the state's activities.

(4) Employees and qualified contractors of an entity covered under the Federally Supported Health Centers Assistance Act of 1992, as amended, 42 U.S.C. 233(g)–(n), (FSHCAA), provided that the testimony is requested in medical malpractice tort litigation and relates to the performance of medical, surgical, dental or related functions which were performed by the entity, its employees and qualified contractors at a time when the DHHS deemed the entity and its employees and qualified contractors to be covered by the FSHCAA.

* * * * *

Dated: August 28, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–21113 Filed 9–12–08; 8:45 am]

BILLING CODE 4150–26–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 202 and 252

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is making technical amendments to the Defense Federal Acquisition Regulation Supplement (DFARS) to update the list of DoD contracting activities and to correct a reference in a contract clause.

DATES: *Effective Date:* September 15, 2008.

FOR FURTHER INFORMATION CONTACT: Ms. Michele Peterson, Defense Acquisition Regulations System, OUSD (AT&L) DPAP (DARS), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone 703–602–0311; facsimile 703–602–7887.

SUPPLEMENTARY INFORMATION: This final rule amends DFARS text as follows:

- *202.101.* Adds the U.S. Transportation Command to the list of DoD contracting activities.
- *252.212–7001.* Amends the reference to the clause at 252.219–7004 in paragraph (b)(3) to reflect the current clause date.

List of Subjects in 48 CFR Parts 202 and 252

Government procurement.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

■ Therefore, 48 CFR parts 202 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 202 and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 202—DEFINITIONS OF WORDS AND TERMS

202.101 [Amended]

■ 2. Section 202.101 is amended in the definition of ''Contracting activity'' by adding at the end ''United States Transportation Command, Directorate of Acquisition''.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.212–7001 [Amended]

■ 3. Section 252.212–7001 is amended as follows:

■ a. By revising the clause date to read ''(SEP 2008)''; and

■ b. In paragraph (b)(3) by removing ''(APR 2007)'' and adding in its place ''(AUG 2008)''.

[FR Doc. E8–21375 Filed 9–12–08; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 206, 225, and 252

RIN 0750–AG02

Defense Federal Acquisition Regulation Supplement; Acquisitions in Support of Operations in Iraq or Afghanistan (DFARS Case 2008–D002)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule with request for comments.

SUMMARY: DoD has issued an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement Sections 886 and 892 of the National Defense Authorization Act for Fiscal Year 2008. Section 886 provides authority for DoD to limit competition when acquiring products or services in support of operations in Iraq or Afghanistan. Section 892 addresses competition requirements for the procurement of small arms for assistance to Iraq or Afghanistan.

DATES: *Effective date:* September 15, 2008.

Comment date: Comments on the interim rule should be submitted in writing to the address shown below on or before November 14, 2008, to be considered in the formation of the final rule.

ADDRESSES: You may submit comments, identified by DFARS Case 2008–D002, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: dfars@osd.mil.* Include DFARS Case 2008–D002 in the subject line of the message.
- *Fax:* 703–602–7887.
- *Mail:* Defense Acquisition Regulations System, Attn: Ms. Amy Williams, OUSD (AT&L) DPAP (DARS), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062.
- *Hand Delivery/Courier:* Defense Acquisition Regulations System, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202–3402.

Comments received generally will be posted without change to *http://www.regulations.gov*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, 703–602–0328.

SUPPLEMENTARY INFORMATION:

A. Background

Section 886 of the National Defense Authorization Act for Fiscal Year 2008 (Pub. L. 110–181) provides authority for DoD to limit competition when acquiring products or services in support of military operations or stability operations in Iraq or Afghanistan (including security, transition, reconstruction, and humanitarian relief activities) under certain circumstances. In those circumstances, and when the required determination is made, Section 886 authorizes DoD to—

- Limit competition to products or services from Iraq or Afghanistan;

Attachment C

Freedom of Information Act Briefing Document on 45 CFR Part 2 –
As Amended By 73FR 53148, dated September 15, 2008

1. 45 CFR Part 2.2(3) / Definition of Employee of DHHS / Effective 10/15/2008

- The definition of "Employee of the Department" is modified to include current and former "[*e]mployees of a contractor, subcontractor, or state survey agency performing survey, certification, or enforcement functions under title XVIII of the Social Security Act or Section 353 of the Public Health Service Act but only to the extent that the requested information was acquired in the course of performing those functions and regardless of whether documents are also relevant to the state's activities."*

Impact: This definition brings within the governance of 45 C.F.R. Part 2 those situations in which the State Survey Agency (SA) acquires, generates, and maintains survey, certification or enforcement records for Federal and joint Federal/State purposes. It does not apply to those situations in which the SA acquires, generates, and maintains such records *exclusively* for State purposes.

2. 45 C.F.R. § 2.1 / Scope, Purpose and Applicability

- The policy applies to State, local and tribal judicial, administrative, and legislative proceedings, and to Federal judicial and administrative proceedings. 45 C.F.R. § 2.1(c).

- The policy does not apply to civil or criminal proceedings where the United States, the Department of Health and Human Services, or any agency thereof, or any other Federal agency is a party. 45 C.F.R. § 2.1(d)(1).

- The policy does not apply to any civil or criminal proceedings in State court brought on behalf of the Department of Health and Human Services. 45 C.F.R. § 2.1(d)(7).

Impact: 45 CFR Part 2 applies to any subpoena duces tecum that the SA receives for Federal and joint Federal/State records, except for subpoenas related to the proceedings specifically referenced in bullets two and three above. In addition, since these regulations were never intended to impede the SA's ability to enforce State laws and regulations, as a matter of policy, CMS is authorizing the SA, where it is a party to civil or criminal or administrative proceedings, to release records obtained for joint Federal/State purposes as necessary to enforce its own laws or regulations.

3. 45 C.F.R. § 2.5 / Subpoenas Duces Tecum

- Requires referral of any subpoena duces tecum (served upon a DHHS employee or former employee for the production of any record acquired in the course of that employee performing official duties) to the Office of the General Counsel (OGC), DHHS for a determination of the legal sufficiency of the subpoena, whether the subpoena was properly served, and whether the issuing court or other tribunal has jurisdiction over the Department. 45 C.F.R. § 2.5(a).

- *If OGC determines that the subpoena is legally sufficient, the subpoena was properly served, and the tribunal has jurisdiction*, requires that the Department comply with the subpoena unless affirmative action is taken by the Department to modify or quash the subpoena in accordance with Fed. R. Civ. P. 45(c). 45 C.F.R. § 2.5(a).

- *If OGC determines the subpoena to be legally insufficient, improperly served, or from tribunal not having jurisdiction over the Department*, requires that the subpoena be deemed a request for records under the Freedom of Information Act and handled pursuant to the FOIA rules established at 45 CFR Part 5. 45 C.F.R. § 2.5(b).

Impact: Based upon current CMS practices, the only subpoenas that the SA will need to forward to the CMS Regional Office FOIA Coordinator for review, consultation and further referral to OGC, DHHS (if appropriate), are:

- Federal court subpoenas duces tecum;
- Subpoenas duces tecum in civil and criminal proceedings in which DHHS and/or any of its agencies (including CMS) is a named party; and
- Subpoenas in civil and criminal proceedings in State court brought on behalf of DHHS.

The SA will be authorized to automatically process as FOIA requests, in accordance with instructions in Section C of this memorandum,Treatment of Subpoenas Duces Tecum for Federal and Joint Federal/State Documents," all State, local and tribal judicial, administrative and legislative court subpoenas which do not fall within the categories mentioned above. This is because case law holds that absent a waiver, the doctrine of "sovereign immunity" precludes state or tribal court jurisdiction over a Federal agency or official. Based on this case law, CMS's position is that the State, tribal, and local court subpoena duces tecum is from a tribunal not having jurisdiction over the Department, and such a subpoena must be processed as a FOIA request.

DHHS' FOIA regulations provide that the CMS Freedom of Information Officer is vested with sole authority to release and deny agency records. He will, however, in some instances, authorize SAs to make certain releases in response to receipt of State, tribal and local court subpoenas duces tecum. Specifically, *if a subpoena seeks records that SOM §§ 3308, 3308A, 3314, 7900 and 7903A authorize SAs to disclose, SAs will be authorized to release those records in response to the subpoena*. SAs, however, must forward any and all records the SOM does not authorize them to release to their respective CMS Regional Office FOIA Coordinator for disposition under FOIA.[1]

FOIA requires that Federal agencies provide a substantive response to requesters (i.e., a decision to release or withhold the requested records (in full or in part) within 20 working

[1] The CMS Regional Office FOIA Coordinators will continue to serve as the principal FOIA contacts for SAs, and, therefore, will be responsible for receiving those subpoenas and responsive records that must be processed in CMS under FOIA rules. CMS Regional Office FOIA Coordinators also will be responsible for receiving records for certification purposes.

days of receipt of the request by the appropriate component of the agency. SAs must comply with this 20 working day time frame. In addition, SAs will need to follow HHS's fee schedule when assessing fees for processing subpoenas subject to this rule.

4. 45 CFR § 2.6 / Certification and Authentication of Records

- Requires that, upon request, DHHS agencies certify, pursuant to 42 U.S.C. 3505, the authenticity of copies of records that are to be disclosed.

Impact: Based upon CMS delegations of authority, the Associate Regional Administrator is the lowest level delegate authorized to certify true copies of records maintained by SAs for CMS. Therefore, SAs must forward records covered by 45 CFR Part 2 to their applicable CMS Regional Office FOIA Coordinator for certification, when a subpoena requests such certification.

By definition at 45 CFR § 2.2(3), this applies to subpoenas for information acquired in the course of performing functions under title XVIII of the Social Security Act or section 353 of the Public Health Service Act, regardless of whether documents are also relevant to the State's activities.

Prepared By:
The Freedom of Information Group
Office of Strategic Operations
and Regulatory Affairs
Centers for Medicare & Medicaid Services
December 8, 2008

ATTACHMENT D -- 45 CFR PART 2 SAMPLE RESPONSE LETTER TO REQUESTER

Dear _____:

This is in response to the subpoena duces tecum dated _____ initiated by your firm for certain records in the possession of [insert name of State Survey Agency].

You are advised that the processing of your firm's subpoena duces tecum is governed by the Department of Health and Human Services (DHHS) regulation at 45 C.F.R. Part 2 (attached). This is because your subpoena seeks records that [insert name of State Survey Agency] acquired and maintains as a result of performing Federal or joint Federal/State survey, certification or enforcement functions. 45 C.F.R. Part 2 states, among other things, that a subpoena served upon an employee of DHHS shall be deemed a request for records under the Freedom of Information Act (5 U.S.C. 552), and handled pursuant to federal rules governing public disclosure established in 45 C.F.R. Part 5. It includes within the definition of employee of DHHS current or former "employees of a state agency performing survey, certification, or enforcement functions under title XVIII of the Social Security Act or Section 353 of the Public Health Service Act but only to the extent the requested information was acquired in the course of performing those functions and regardless of whether documents are also relevant to the state's activities."

In light of the above, we have processed/are processing your firm's subpoena duces tecum as a FOIA request. In accord with instructions provided by the Centers for Medicare & Medicaid Services (CMS), DHHS, the disposition of your request is as follows:

[ ] ***We will release all responsive records to you.*** However, because you seek a voluminous amount of records that must be gathered and copied, the records are not enclosed with this decision. We will release the records to you as soon as practicable.

[ ] ***We have gathered the responsive records, and they will be released to you.*** However, because you have requested a certified copy of the records, we have forwarded the records to CMS, DHHS for certification. This action is required by 45 C.F.R. § 2.6. CMS will directly release the certified records to you. For status inquiries, please contact to: [Insert Name, Address and Phone Number of CMS Regional Office FOIA Coordinator].

[ ] ***We hereby release [all records responsive to your request or records responsive to that portion of your request for _____.]*** These records (i.e., ___ pages) are released to you in their entirety and without redaction.

[ ] ***We have forwarded [all records responsive to your request or records responsive to the remainder of your request] to CMS, DHHS for further processing under Federal law.*** For status inquiries, please contact [Insert Name, Address and Phone Number of CMS Regional Office FOIA Coordinator].

[ ] Other:

Questions concerning this response can be directed to _____.

Sincerely yours,

Signature of Authorized Official

Attachment: 45 CFR Part 2

cc: CMS Regional Office FOIA Coordinator

ATTACHMENT D -- 45 CFR PART 2 SAMPLE TRANSMITTAL

DATE:

TO: Freedom of Information Coordinator, Region ___, CMS

FROM:

SUBJECT: Subpoena Duces Tecum Issued in the Matter _____
(Requester's Name: _____)

In line with 45 C.F.R. Part 2 as amended, we refer the subject subpoena duces tecum and responsive records to RO ____, Centers for Medicare & Medicaid Services (CMS) for disposition.

We have determined that this subpoena duces tecum (check all blocks that apply):

[ ] Seeks records we maintain for Federal survey, certification or enforcement activities, only.
[ ] Seeks records we maintain for joint Federal/State survey, certification or enforcement activities.
[ ] Involves a State, tribal or local judicial, administrative or legislative proceeding.
[ ] Involves State, tribal or local proceeding in which the SA is a named party.

A hearing in this matter is scheduled for _____.

We have completed the following actions with respect to this subpoena duces tecum (check all blocks that apply):

[ ] Determined that [all/some] of the responsive records are within our authority to release. However, the requester has asked that the records be certified. Therefore, we have enclosed the records at Tab --- for CMS certification. We have notified the requester of this action. See Tab ---.
[ ] Partially complied with the subpoena by releasing to the requester those records the SOM authorizes SAs to release. Our response letter is enclosed at Tab ----.
[ ] Enclosed at Tab -- responsive records **(indicate the # of pages)** that we are not authorized to release. We have notified the requester of this action. See Tab ---.

We request that CMS consider the following in making the disclosure decision regarding the enclosed responsive surveyor worksheets and notes:

[ ] We believe that release of the responsive surveyor worksheets and notes would be a deterrent to future free exchanges of information within the SA because survey personnel will fear the public disclosure of their opinions, advice, analyses and recommendations and such fear would impinge upon the ability of the surveyor to do his/her job.
[ ] We recommend that the enclosed surveyor worksheets and notes be released to the requester because these particular worksheets and notes are factual in content and fully support the SA's findings.
[ ] Other:

We expended (insert # of hours) in searching for records responsive to this subpoena duces tecum. The hourly pay of our searcher was:

[ ] up to $28.53/hr [ ] $28.54--$64.20/hr [ ] $64.21 or more/hr

CENTERS FOR MEDICARE & MEDICAID SERVICES
REGIONAL OFFICE FREEDOM OF INFORMATION ACT COORDINATORS

Nora Morris (REGION I)
CMS, Boston Regional Office
JFK Federal Building, Rm. 2375
Boston, MA 02203
(617) 565-1183
(617) 565-1339 (Fax)
(CT, ME, MA, NH, RI, VT)

Lisa Maldonado (REGION II)
CMS, New York Regional Office
26 Federal Plaza, Room 38-130
New York, NY 10278
(212) 616-2220
(212) 264-2790 (Fax)
(NJ, NY, PR, VI)

Constance Smalls (REGION III)
CMS, Philadelphia Regional Office
150 South Independence Mall West
Philadelphia, PA 19106
(215) 861-4347
(215) 861-4240 (Fax)
(DE, DC, MD, PA, VA, WV)

Prescious Boudouin (REGION IV)
CMS, Atlanta Regional Office
Atlanta Federal Center, 4th Floor
61 Forsythe Street, SW Suite 4T20
Atlanta, GA 30303-8909
(404) 562-7358
(404) 562-7186 (Fax)
(AL, NC, SC, FL, GA, KY, MS, TN)

Susan Hahn Reizner (REGION V)
CMS, Chicago Regional Office
233 N. Michigan Avenue, Suite 600
Chicago, IL 60601
(312) 353-1504
(312) 353-5887 (Fax)
(IL, IN, MN, OH, WI)

Mary Jane Collard (REGION VI)
CMS, Dallas Regional Office
1301 Young Street, Rm. 714
Dallas, TX 752-02
(214) 767-6428
(214) 767-6400 (Fax)
(AR, LA, NM, OK, TX)

Anita Groves (REGION VII)
CMS, Kansas City Regional Office
601 East 12th Street
Kansas City, MO 64106
(816) 426-6540
(816) 426-3548 (Fax)
(IA, KS, MO, NE)

Lisa Hughes (REGION VIII)
CMS, Denver Regional Office
1600 Broadway, Suite 700
Denver, Colorado 80202
(303) 844-7035
(303) 844-3753 (Fax)
(CO, MT, ND, SD, UT, WY)

Daniel Hersh* (REGION IX)
CMS, San Francisco Regional Office
90 7th Street, Suite 5-300
San Francisco, CA 94103
(415) 744-3731
(415) 744-2692 (Fax)
(AM, Samoa, AZ, CA, GU, HI, NV

Debbie Hinckley (REGION X)
CMS, Seattle Regional Office
2201 6th Avenue, RX 41
Seattle, WA 98121
(206) 615-2415
(206) 615-2325 (Fax)
(AK, ID, OR, WA)

* Mr. Hersh serves as the FOIA contact for Region IX State Survey Agencies

Attachment F

The Freedom of Information Act, 5 U.S.C.§ 552
Subsection (b) - The FOIA Exemptions

Exemptions - The exemptions most often applicable to CMS records are exemptions 2, 4, 5, 6 and 7. They are discussed below.

A. Exemption 2 (internal personnel rules and practices of agency).

1. Internal matters of a relatively trivial nature are exempt - but only if there is no significant public interest. Examples: leave practices, timekeeping records and forms, computer codes.

2. Substantial internal matters, the disclosure of which would risk circumvention of a legal requirement. Examples: law enforcement manuals, prison alarm procedures, auditing guidelines.

B. Exemption 4 (trade secrets and confidential commercial information).

1. To be exempt, commercial information must have been obtained "from a person"- provided by a non-governmental entity.

2. Commercial information is considered confidential, in general, only if

a. it was submitted voluntarily (i.e., not under any compulsion) and the submitter does not customarily release it to the general public; or

b. it was submitted involuntarily, and its release would:
1) impair the Government's ability to obtain necessary information in the future,
2) cause substantial harm to the competitive position of the submitter, or
3) harm compliance and program effectiveness.

3. Confidential commercial information is protected by a criminal statute that prohibits disclosure - Thus, in general, if commercial information may be withheld under the FOIA, it must be withheld.

C. Exemption 5 (intra-governmental records that would be subject to a generally-recognized discovery privilege)

1. Records must have originated with HHS or another Executive Branch agency. However, a memo from a non-employee consultant would qualify since the consultant is functionally part of the agency.

2. The discovery privilege most often used is the "deliberative process" privilege. This protects documents (or parts of documents) that are "predecisional" -- are written before some decision that is anticipated in the agency -- and “deliberative” are in the nature of recommendations, advice, or opinion. In particular, draft documents are protected, in full, because the draft consists of the drafter's recommendations as to what the final document should say, and the draft is written before the final.

3. Other privileges that are incorporated in Exemption 5 include the following:

   a. Attorney-client communications

   b. Work product -- records created by the party or by its attorney, for purposes of actual or anticipated litigation.

D. Exemption 6 (clearly unwarranted invasion of personal privacy)

1. An invasion of privacy is "warranted" only if it is outweighed by the "public interest" in disclosure. However, the only "public interest" that counts is the interest in shedding light on the agency's performance of its duties. It is irrelevant that disclosure could cause other results that would, in someone's opinion, be of immense public good.

2. The following information on a Federal employee is not exempt: current and past position titles, work addresses and phones, grades, and base salaries (though deductions and withholdings are exempt).

E. Exemption 7 (law enforcement records)

1. This protects civil or criminal law enforcement records, but only to the extent that disclosure would tend to cause one of the results listed in the statute. The three primary ones for our purposes are the following:

2. 7(A): Interference with enforcement proceedings. For example, disclosing the contents of a file on an ongoing investigation could reveal the scope of the investigation or the strengths and weaknesses of the agency's case.

3. 7(C): Unwarranted invasion of personal privacy. This is very similar to Exemption 6, but the test is somewhat more favorable to the agency, since the invasion need only be "unwarranted," not "clearly unwarranted."

4. 7(D): Disclose the identity of a confidential source, or, in the case of information compiled by a criminal law enforcement authority (e.g., OIG) in a criminal investigation, disclose any information furnished by a confidential source.

CENTERS FOR MEDICARE & MEDICAID SERVICES
FREEDOM OF INFORMATION ACT REQUEST

1. Case #: _____
2. Date Received: _____ 3. Due Date: _____ 4. Response Date: _____ 5. Processing Days: _____
6. Requester: _____
7. Affiliation/Address: _____
8. Subject: _____
9. Referred To: _____ _____ _____ _____ _____
10. Category of Requester _____ Commercial
_____ Educational/Scientific or News Media
_____ Other

11. **IS THERE PROGRAM CONCERN ABOUT DISCLOSING THESE RECORDS?** _____ **Yes** _____ **No**

_____ Ongoing Deliberations _____ Invasion of Privacy _____ Circumvention of Agency Rules
_____ Decision-making Process _____ Pending Litigation
_____ Proprietary Information _____ Open Investigation
_____ Other (Specify) _____

12. **ACTIONS:** _____ Direct Reply _____ No Records Found _____ Request Withdrawn
_____ Not FOIA _____ Records Not Reasonably Described _____ Subpoena Denial
_____ Fee Related Closure _____ Referral to Next Review Level _____ Other

ACTUAL COSTS OF RESPONDING TO REQUEST

13. **ACTUAL PROCESSING COSTS:**	**Hours**	**Hourly Wage**	**Total**	17. **Invoiceable Fees**
Reading/Interpreting/Logging				xxxxxxxxxxxxxxx
Clarifying/Negotiating/Consultation				xxxxxxxxxxxxxxx
Searching for Records				$
Review/Edit/Delete (DFOI Only)				$
Compose/Type Response				xxxxxxxxxxxxxxx
Other (specify)				$

14. **COPYING COSTS – @ $.10 per page:**	**No. of Pages**	**No. of Sets**	**Total**	
Pages Located/Copied		1 x $.10 per page		xxxxxxxxxxxxxxx
No. of Pages Released to Requester		1 x $.10 per page	xxxxxxxxxxxx	$_____
No. of Pages Sent to Next Review Level		1	xxxxxxxxxxxx	xxxxxxxxxxxxxxx

15. **MAILING COSTS:**		
Postage	_____	xxxxxxxxxxxxxxx
Special Handling	_____	_____

16. Total Actual Cost: _____

18. Total Invoiceable Fees: _____

19. Fees Charged: _____
20. Fee Waived: _____

21. **Name(s), Phone Number(s) and Component(s) of Person(s) Who Searched For and Compiled These Records:**

See reverse side for instructions on completing this form. If you have questions, call the Freedom of Information Group at (410) 786-5353.
Form CMS-632-FOI (01/08) (Formerly HCFA-632-FOI)

INSTRUCTIONS FOR COMPLETING FORM CMS-632-FOI

Completion of this form is mandatory. It must be attached to and remain with every Freedom of Information Act (FOIA) request for control and tracking. Every CMS employee involved in processing the request must add to a given Form CMS-632-FOI data accounting for that involvement. This data will be the base for the Annual Report.

Item

1. **Case #**: number assigned in accordance with FIG instructions.
2. **Date Received**: date request was received in the FOIA unit.
3. **Due Date**: date 20 working days from receipt of request in the FOIA unit.
4. **Response Date**: actual date case was completed and response sent.
5. **Processing Days**: the number of work days it took to process the request.
6. **Requester**: last name, first name, initial of person who signed the request.
7. **Affiliation/Address**: name of company, law firm etc., and complete address of requester.
8. **Subject**: explain briefly the nature of the request by subject or records requested.
9. **Referred To**: where the request was sent for records search(es).
10. **Category of Requester**: check appropriate category based upon number seven above.
11. **Program Concern**: check appropriate item(s) to show concern about release of these records.
12. **Actions**: check all appropriate items that show the disposition of the request.
13. **Actual Processing Costs**: actual costs of time spent by each person involved in processing this request. Complete all items. Include computer-based data costs in the block entitled "other."
14. **Copying Costs**: cost for photocopying the responsive records. Complete all applicable items. Copying costs are $.10 per page.
15. **Mailing Costs**: input postage and special handling, such as certification of records.
16. **Total Actual Costs**: summation of totals for actual processing, copying and mailing costs.
17. **Invoiceable Fees**: different from actual costs. They are based upon the HHS fee schedule for search, review and copying activities.
18. **Total Invoiceable Fees**: summation of search, review and copying fees.
19. **Fees charged**: responding office tallies. If invoiceable fee is $25.00 or more, invoice the requester.
20. **Fees waived**: If invoiceable fee is less than $25.00, do not invoice requester. Insert amount waived in this block.
21. **Name, Phone Number and Component of Person Who Searched For/Compiled Records**: be specific; give name and title of person who searched, their component, address and phone number.

ATTACHMENT H

CMS RESPONSES to
Questions/Issues Submitted to CMS from State Survey Agency Directors
Re: CMS Instructions for Implementing 45 CFR Part 2, as Amended

1. State courts can be expected in most instances to accept the proposition that certain documents in SA files are, as a matter of law, Federal records that are subject to production pursuant to the Federal Freedom of Information Act, 5 U.S.C. § 552, and not state court subpoenas. However, if a State court subpoena is directed to the SA Director, personally, and the State court does not accept this proposition, will CMS or HHS serve as the SA Director's counsel should he/she be held in contempt of court?

   CMS RESPONSE*:* DHHS's Office of the General Counsel (OGC) does not represent CMS in court except under the aegis of the U.S. Department of Justice (DOJ). Therefore, if a State court determined to compel a SA, or a SA official, personally, to produce in response to a subpoena documents that are federal records, it would be up to DOJ to determine whether it could represent either the SA or the SA official.

   In the circumstances described by this query, CMS recommends that SA employees immediately confer with SA legal counsel to resolve any issue of potential personal liability. CMS notes at least two strategies SAs could pursue. First, it is often possible to obtain State court judges' cooperation simply by explaining the process under the FOIA for providing Federal records to requesters. This approach would likely be effective whenever the requested documents are not subject to FOIA exemptions and CMS is able to expedite the FOIA staff's pre-release review. SA lawyers could convey assurances to the court that allowing the FOIA process to play out would lead to essentially the same result as attempting to enforce the subpoena.

   Second, in circumstances where this is not an option because, for example, certain of the requested records are exempt from disclosure under the FOIA, SA attorneys could themselves remove the subpoena enforcement case to Federal court on the ground that the dispute over production of documents in response to the subpoena duces tecum arises under the FOIA, a federal statute. Pursuant to 28 U.S.C. § 1442(a)(1), a civil action can be removed by any person acting under any officer of any agency of the United States "sued...for any act under color of such office....." This procedure was followed recently by the Kentucky SA in Campbell v. EPI Healthcare, LLC, Civil Action No. 08-401 (E.D. Ky.). We caution that the SA *must* remove a case within 30 days of the date that it has notice of the Federal issue that makes the case removable. 28 U.S.C. § 1446(b). Untimely removal is grounds for remand to state court, which is exactly what happened in Campbell. See Civil Action No. 08-401, Memorandum Opinion and Order (Document 17) (E.D. Ky. Feb. 18, 2009).

2. What is the legal authority for the Touhy regulation amendments? Will all CMS Regional Offices (ROs) handle this matter consistently?

   CMS RESPONSE*:* The authority for these regulations is recited in 73 Fed. Reg. 3148 (Sept. 15, 2008), and the Code of Federal Regulations, 45 C.F.R. Part 2, as 5 U.S.C. § 301 (general authority for Federal agencies to issue regulations) and 5 U.S.C. § 552 (FOIA). The authority for SA compliance with these regulations is Article III and Article XIII of the 1864 contract between DHHS and the SA.

All RO FOIA staff have already participated in a training conference call regarding the draft instructions and will receive additional training when final instructions are issued. The provision of timely support to SAs will be emphasized.

3. Is CMS willing to lend legal support in any hearings or Mandamus actions? What is CMS's position when SAs are court ordered to release this information?

   CMS RESPONSE: As noted in response to question 1, above, CMS could not provide representation to the SA except under the aegis of the U.S. DOJ. If a SA is under a court order to release Federal survey documents and the judge will not acknowledge the SA's obligations under its 1864 contract with CMS, the SA should consider asking its attorneys to remove the mandamus action or court order to federal court pursuant to 28 U.S.C. § 1442(a)(1).

4. This guidance is instructing the SA to treat a subpoena duces tecum (which is a specific type of legal instrument) as if it were a FOIA request (which is a different type of legal instrument) based upon the nature of the documents requested. How can the nature of the documents requested change the very nature of the legal instrument used to make the request?

   CMS RESPONSE*:* The principle underlying the instruction to process a state court subpoena for SA documents that relate to SA functions under its 1864 Agreement as if the subpoena were a FOIA request is that the SA documents are federal records. Federal records are not subject to State process, but treating the subpoena like a FOIA request provides a legal means for responding to the subpoena and releasing the requested records, except in cases where one of the enumerated exemptions applies. It is emphasized that FOIA is a statute that, much like a subpoena, mandates release of documents (unless, as noted, the documents or portions thereof are protected from release by a statutory exemption). The point is that although federal agencies do not respond to a state court subpoena duces tecum, they must respond to a FOIA request.

5. How does this guidance affect requests for information under the State's Public Information Act (PIA)? Are PIA requests now considered FOIA requests?

   CMS RESPONSE: This guidance only affects subpoenas duces tecum received by the SA for Federal and joint Federal/State survey, certification and enforcement records. Processing of routine requests, including PIAs, for the aforementioned records is governed by Sections 3300-3320 and 7900-7907 of the State Operations Manual (SOM). S&C-09-34 (April 30, 2009) and before that Administrative Information Letter 07-06 was distributed to SAs in January 2007 to provide guidance and clarification on the processing of such requests.

6. Does this guidance provide incentive to third party litigators to merely make a FOIA request and then call the custodian of records (which from this guidance apparently would be a CMS employee) to testify to prove up the records?

   CMS RESPONSE*:* Third parties should be encouraged to use FOIA to request Federal records. Any request for the testimony of a CMS employee to "prove up" Federal records would itself be subject to the Touhy regulations. Moreover, CMS can certify documents as true copies, which in most courts would likely obviate the need for a prove-up.

7. Does this guidance affect subpoenas from sister agencies (such as the State nursing board or medical board)?

   CMS RESPONSE: 45 CFR Part 2, as amended is applicable to subpoenas duces tecum issued from sister agencies, including State nursing boards and medical boards. CMS notes, however, that SOM §3318 states that confidential certification information may be released by the SA to another State component, or to a county or other local entity which performs survey functions for the SA if the SA obtains an agreement by the component or other entity to use the information for certification or licensure purposes with the understanding that such information may not be released to another party. Therefore, if the SA has such an agreement with State nursing boards and medical boards, the SA can comply with the subpoenas duces tecum that seek confidential certification information. If the SA does not have such agreements, subpoenas duces tecum from State nursing boards and medical boards must be processed in accordance with CMS instructions that implement 45 CFR Part 2.

8. Should all subpoenas duces tecum in the State's administrative or civil enforcement cases be processed in accordance with 45 C.F.R. Part 2, as amended?

   CMS RESPONSE: Amended 45 C.F.R. Part 2 was never intended to impede the SA's ability to enforce State laws and regulations. Therefore, when a subpoena duces tecum involves civil or criminal or administrative proceedings where the SA is a party and seeks to use records obtained for joint Federal/State purposes to enforce its own laws and regulations, CMS is authorizing the SA to release such records as necessary to enforce its own laws and regulations.

9. The guidance at page 3, Section C.1 authorizes SA's to automatically process as FOIA requests all State, local, and tribal judicial, administrative and legislative court subpoenas which do not fall within certain excepted categories. Does this instruction make the State the custodian of records?

   CMS RESPONSE: No. Articles III and XIII of the § 1864 Agreement require SA: (1) compliance with regulations and general instructions as the Secretary may prescribe for the administration of the Agreement, and (2) adoption of policies and procedures to ensure that information contained in its records and obtained from the Secretary or from any provider or supplier of services will be disclosed only as provided in the [Social Security] Act or regulations. 45 CFR Part 2 constitutes such regulations. The cited rule sets forth the procedures for the handling of subpoenas duces tecum for documents in the possession of DHHS. It specifically provides that any subpoena duces tecum served upon a DHHS employee which the Office of the General Counsel determines to be insufficient, improperly served or from a tribunal not having jurisdiction shall be deemed a request for records under the Freedom of Information Act and handled pursuant to the rules governing public disclosure established in 45 CFR Part 5.

   Per footnote 3, page 4 of the guidance, case law holds that absent a waiver, the doctrine of "sovereign immunity" precludes State or tribal court jurisdiction over a Federal agency or official. Therefore, CMS' position is that the State, tribal and local court subpoena duces tecum is from a tribunal not having jurisdiction over DHHS, and such a subpoena must be processed as a FOIA request. Accordingly, the draft instructions authorize SAs to deem State, tribal and local subpoenas duces tecum for Federal or joint Federal/State documents as FOIA requests and process them under FOIA rules.

Note that under Federal disclosure law, certain categories of documents which the SA acquires as a result of performing its § 1864 functions have already been determined to be releasable to members of the public, and CMS has authorized the SA to release these documents, per SOM §§ 3300-3320 and 7900-7907. The guidance authorizes SAs to continue to release these types of records in response to subpoenas duces tecum that are deemed FOIA requests. SAs, however, must forward subpoenas duces tecum/requests for documents that are not within the SA's authority to CMS for further processing under Federal law, i.e., the FOIA.

10. Why is it necessary for the SA to provide concerns regarding the release of surveyor notes? Any information of relevance in the surveyor notes is transcribed onto the CMS 2567 and the information is releasable in that format. Therefore, release of the surveyor notes is not necessary.

    CMS RESPONSE*:* CMS performs the FOIA analysis on a case-by-case basis. It is based upon whether the document under review is releasable in whole or in part or not at all. It is not and cannot be based upon whether relevant portions of the requested document are contained within another (releasable) document. While some SAs may make the argument that disclosure of surveyor notes would discourage open, frank discussions on matters of policy, other SAs contend that release of the surveyor notes supports the agency's findings and argue for their release. Therefore, on a case-by-case basis, CMS is asking that SAs' provide their disclosure concerns or recommendations.

11. What specific documents does this guidance apply to (whether the documents are releasable or not releasable)? Does the nature of the instrument used to make the request affect that distinction and, if so, how?

    CMS RESPONSE: The draft guidance applies when the SA receives a subpoena duces tecum for documents that the SA has acquired as a result of implementation of its Agreement with the Secretary, DHHS under § 1864 of the Social Security Act, (i.e., it applies to those records that the SA has acquired in the course of performing survey, certification, or enforcement functions under Title XVIII of the Social Security Act or § 353 of the Public Health Service Act.)

    The disposition of the subpoenaed records (whether the SA can release or not release the records) is outlined in the guidance. Specifically, Sections C.2 and C.3 refer to the sections of the SOM that lists the documents the SA is authorized to release. If a subpoena duces tecum seeks a record that does not appear in these SOM listings, the SA must refer the subpoena and the responsive records to its CMS RO for further processing under FOIA.

    The nature of the instrument used to make the request does affect how the SA processes the request, and may affect whether a document is released or withheld. For example, a non-legal request for records that is submitted to the SA must be processed in accordance with instructions found at SOM §§ 3300-3320 and 7900-7907. Additional guidance is available in CMS Administrative Information Memo 07-06. When the SA receives a non-legal request for records maintained for joint Federal/State use, SOM § 3304 requires that the disclosure decision be based upon application of the most restrictive confidentiality policies of all programs to which the information relates. In any instance in which State law is more restrictive than Federal law, the State would apply State law to make the disclosure decision. However, when a subpoena duces tecum is received for records maintained for joint

Federal/State use, 45 CFR Part 2 requires that the decision be based upon Federal (FOIA) law - irrespective of State law.

12. Will there be additional guidance for how to address subpoenas for testimony, including requests for depositions on written questions?

    ***CMS RESPONSE**:* This guidance pertains only to subpoenas duces tecum that the SA receives for the production of records. It does not apply to requests for depositions on written questions. CMS will issue separate guidance on subpoenas for testimony.

13. What is the impact (if any) of 45 CFR Part 2 on records generated as a result of the State's Medicaid activities?

    CMS RESPONSE: 45 CFR Part 2 does not apply to records which the SA acquires, generates and maintains exclusively for State purposes. Therefore, it would not impact records generated as a result of the State's Medicaid activities.

14. The guidance states in Section B 1 that upon receipt of a subpoena duces tecum, the SA should immediately consult with its own legal counsel and, as necessary, with its CMS Regional Office (RO) program contact to determine whether 45 CFR Part 2 requirements at A.l of this guidance are met. However, Attachment C, Section 3 requires referral of any subpoena duces tecum (served upon a DHHS employee or former employee for the production of any record acquired in the course of that employee performing official duties) to the Office of the General Counsel (OGC), DHHS for a determination of the legal sufficiency of the subpoena, whether the subpoena was properly served, and whether the issuing court or other tribunal has jurisdiction over the Department. Who has authority to make a determination about the subpoena, the SA legal counsel or DHHS OGC?

    CMS RESPONSE: Attachment C, Section 3 presents those provisions of 45 CFR Part 2, as amended that affect the processing of subpoenas duces tecum and the impact of those provisions.

    While the regulations require referral of subpoenas duces tecum to OGC, DHHS for a determination of the subpoena's sufficiency, the impact statement advises that based upon current CMS practices, the only subpoenas duces tecum that require OGC, DHHS review are: (l) Federal court subpoenas duces tecum; (2) subpoenas duces tecum in civil and criminal proceedings in which DHHS and/or any of its agencies (including CMS) is a named party; and (3) subpoenas in civil and criminal proceedings in State court brought on behalf of DHHS. OGC determinations regarding the sufficiency of all other subpoenas duces tecum have already been made.

    The consultation with SA legal counsel called for at Section B.1 is to determine whether the subpoena duces tecum is one which is subject to 45 CFR Part 2, but which does not need to be referred to OGC for a determination of sufficiency. The guidance in the draft specifically addresses how SAs are to process subpoenas duces tecum that meet both requirements found at A.1.

15. In Section B.3 the guidance states: Referrals listed at number 2 of this section must be made within 48 hours of service of the subpoena. Does "referral" mean that just the subpoena must be forwarded to CMS or the subpoena plus any responsive documents? Is there a required time frame for referring subpoenas to CMS other than those listed in B.2?

CMS RESPONSE: Section B.3 asks that the SA refer the subpoena to CMS. It does not require provision of the responsive documents.

Processing times for referring other subpoenas are found at sections C.3.G and C.4.C of the guidance.

Note that once the SA has determined that the subpoena duces tecum will be processed under 45 C.F.R. § 2.5(b), the SA does not have to adhere to the deadlines imposed by the subpoena but rather to the FOIA timeframe of 20 working days.

16. In Section 3 what are the time frames for this process? For example, are there specific deadlines by which the SA must submit the bundled documents to the CMS Regional Office FOIA Coordinator?

    CMS RESPONSE*:* Processing times are found at C.3.G and C.4.C of the guidance.

17. Section C.3.A & B state that the SA is instructed to "partially" comply with the subpoena, but then to withhold any documents not listed in the specific SOM sections and "advise the requestor" that the rest of their request is being treated as a FOIA request. How can the document be both a "subpoena" and "not a subpoena"?

    CMS RESPONSE: In compliance with 45 C.F.R. Part 2, as amended, the subpoena is being processed as a FOIA request - in its entirety. Section C.3.A & B allow the SA to continue to release those documents that CMS has authorized the SA to release per the SOM.

    The following explanation, provided in the sample response letter attached to the guidance, is informative:

    You are advised that the processing of your firm's subpoena duces tecum is governed by the Department of Health and Human Services (DHHS) regulation at 45 C.F.R. Part 2 (attached). This is because your subpoena seeks records that [insert name of State Survey Agency] acquired and maintains as a result of performing Federal or joint Federal/State survey, certification or enforcement functions. 45 C.F.R. Part 2 states, among other things, that a subpoena served upon an employee of DHHS shall be deemed a request for records under the Freedom of Information Act (5 U.S.C. 552), and handled pursuant to federal rules governing public disclosure established in 45 C.F.R. Part 5. It includes within the definition of employee of DHHS current or former "employees of a state agency performing survey, certification, or enforcement functions under title XVIII of the Social Security Act or Section 353 of the Public Health Service Act but only to the extent the requested information was acquired in the course of performing those functions and regardless of whether documents are also relevant to the state's activities."

18. Section C.3.F instructs the SA to track costs for processing the subpoena. If the SA is processing the paperwork, will the SA retain the fee charged to the requestor?

    CMS RESPONSE*:* Section E of the guidance states that instructions on fees will be issued under separate cover. In the meantime, SA's are allowed to collect any fees that they have collected in the past (for the release of documents that the SA is authorized to release).

The tracking requested at Section C.3.F and C.4.C. will facilitate CMS' assessment of FOIA fees for those subpoenas duces tecum that the SA refers to CMS for processing.

19. Does the State Survey Agency/Licensing Agency have to make a FOIA request to use records that State employees gathered themselves and already have in their files, or to respond to a facility's request for production in a license revocation proceeding?

    CMS RESPONSE*:* See the CMS response to question number 8 above.

20. Does this guidance impact requests for documents that are not "survey, certification, or enforcement documents" gathered, in whole or in part, pursuant to SA functions under the Medicare Act or CLIA?

    CMS RESPONSE: The documents described appear not to meet the definition of documents covered by 45 C.F.R. Part 2, as amended, and, accordingly, requests for such document should continue to be processed according to state law and procedures.

21. Does this guidance affect documentation regarding certified nurse aides or the nurse aide registry, or nursing facility administrators?

    CMS RESPONSE: The guidance affects documents that were gathered in connection with SA activities under the section 1864 contract with CMS, regardless of whether they were also gathered in connection with a purely state law function. Accordingly, documentation regarding certified nurse aides or the nurse aide registry, or nursing facility administrators, that was gathered by the SA in whole or in part in connection with survey, certification, or enforcement functions, such as a finding of noncompliance with a Medicare requirement, would be affected by this guidance.