

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]

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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.

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Dated: August 28, 2008.

Michael O. Leavitt,
Secretary.

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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)”;
 - 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]

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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;