

implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and Tribal governments, in the aggregate, or by the private sector, of \$136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act of 1995

This action does not impose a collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Executive Order 13175

This rule is not a policy that has Tribal implications under Executive Order 13175. It will not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

List of Subjects in 21 CFR Part 1308

Drug traffic control, Controlled substances.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

2. Section 1308.11 is amended by adding new paragraph (d)(36) to read as follows:

§ 1308.11 Schedule I.

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(d) * * *

(36) Marijuana Extract 7350

Meaning extracts that have been derived from any plant of the genus cannabis and which contain cannabinoids and cannabidiols.

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Dated: June 14, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011–16800 Filed 7–1–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

RIN 1218–AC46

Infectious Diseases

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of stakeholder meetings.

SUMMARY: OSHA invites interested parties to participate in informal stakeholder meetings concerning occupational exposure to infectious diseases. OSHA plans to use the information gathered at these meetings to explore the possible development of a proposed rule to protect workers from occupational exposure to infectious agents in settings, either where workers provide direct patient care or where workers perform tasks other than direct patient care that also have occupational exposure. These other work tasks include: Providing patient support services (e.g., housekeeping, facility maintenance); handling, transporting, receiving or processing infectious items or wastes (e.g., transporting medical specimens, disposing of medical waste); conducting autopsies or performing mortuary services; and performing tasks in laboratories.

DATES: Dates and locations for the stakeholder meetings are:

July 29, 2011, 9 a.m.–noon in Washington, DC.

July 29, 2011, 1:30 p.m.–4:30 p.m. in Washington, DC.

The deadline for confirmed registration at the meeting is: July 22, 2011. However, if space remains after this deadline, OSHA may accept additional participants until the meetings are full. Those who submit their registration after July 22, 2011 may not receive confirmation of their attendance from OSHA.

ADDRESSES:

Registration: Submit your notice of intent to participate in a stakeholder meeting through one of the methods below. Specify which meeting (morning or afternoon) you would like to attend.

Electronic: Register at: <https://www2.ergweb.com/projects/conferences/osha/register-osha-stakeholder.htm> (follow the instructions online).

Facsimile: Fax your request to: (781) 674–7200, and label it “*Attention:* OSHA Infectious Diseases Stakeholder Meeting Registration.”

Regular mail, express delivery, hand (courier) delivery, and messenger

service: Send your request to: OSHA Infectious Diseases Stakeholder Meeting Registration, *Attention:* Thomas Nerad, OSHA, Room N–3718, 200 Constitution Avenue, NW., Washington, DC 20210.

Meetings: The July 29, 2011 meetings will be held in the Francis Perkins Building, Room N–4437 at 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Frank Meilinger, Acting Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; *telephone:* (202) 693–1999.

General and technical information: Contact Andrew Levinson, Director, Office of Biological Hazards, OSHA Directorate of Standards and Guidance, Room N–3718, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; *telephone:* (202) 693–2048.

Copies of this Federal Register notice: Electronic copies are available at <http://www.regulations.gov>. This **Federal Register** notice, as well as news releases and other relevant information, also are available on the OSHA Web page at <http://www.osha.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

On May 6, 2010, OSHA published a Request for Information, entitled “Infectious Diseases” (Docket Number: OSHA–2010–0003). The Agency was interested in more accurately characterizing the nature and extent of occupationally-acquired infectious diseases and the strategies that are currently being used to mitigate the risk of occupational exposure to infectious agents. More than 200 comments were received in response to the RFI. Based upon these responses and an ongoing review of current literature on this subject, OSHA is considering what action, if any, the Agency should take to limit the spread of occupationally-acquired infectious diseases.

One action the Agency is considering is the development of a program standard to control workers’ exposure to infectious agents in settings, either where workers provide direct patient care or where workers perform tasks other than direct patient care which also have occupational exposure. These other tasks might include such tasks as: Providing patient support services (e.g., housekeeping, food delivery, facility maintenance); handling, transporting, receiving or processing infectious items

or wastes (e.g., laundering healthcare linens, transporting medical specimens, disposing of medical waste, reprocessing medical equipment); maintaining, servicing or repairing medical equipment that is contaminated with infectious agents; conducting autopsies (e.g., in medical examiners' offices); performing mortuary services; and performing tasks in laboratories (e.g., clinical, biomedical research, production laboratories) that result in occupational exposure.

A typical OSHA program standard affords employers substantial flexibility in determining the best way to tailor protective measures to their workplaces. Program standards generally involve: A hazard assessment; a written exposure control plan; methods of compliance (e.g., engineering controls, work practice controls, administrative controls, and personal protective equipment); medical surveillance; worker training; signage and labeling; and recordkeeping. A program standard to control occupational exposure to infectious diseases would likely incorporate all these elements.

The Agency has determined that informal discussion with stakeholders would be beneficial to its further deliberations on how to proceed with respect to occupational exposure to infectious diseases. To this end, OSHA will conduct stakeholder meetings, as announced in this notice.

II. Stakeholder Meetings

The stakeholder meetings announced in this notice will be conducted as group discussions on views, concerns, and issues surrounding the hazards of occupational exposure to infectious agents and how best to control them. To facilitate as much group interaction as possible, formal presentations by stakeholders will not be permitted. The stakeholder meeting discussions will center on such major issues as:

- Whether and to what extent an OSHA standard on occupational exposure to infectious diseases should apply in settings where workers provide direct patient care, as well as, settings where workers have occupational exposure even though they don't provide direct patient care. Whether and to what extent there are any other settings where an OSHA standard should apply.

- The advantages and disadvantages of using a program standard to limit occupational exposure to infectious diseases, and the advantages and disadvantages of taking other approaches to organizing a prospective standard.

- Whether and to what extent an OSHA standard should require each employer to develop a written worker infection control plan (WICP) that documents how the employer will implement the infection control measures it will use to protect the workers in its facility. Some of the elements that might be appropriate to include in such a worker infection control plan are: Designation of the plan administrator responsible for WICP implementation and oversight; designation of the individual(s) responsible for conducting infectious agent hazard analyses in the work setting; and written standard operating procedures (SOPs) to minimize or prevent exposure to infectious agents (e.g., SOPs for early identification of potentially infectious individuals and for implementation of standard and transmission-based precautions).

- Whether and to what extent SOP development should be based upon consideration of applicable regulations/guidance issued by the Centers for Disease Control and Prevention, the National Institutes of Health, and other authoritative agencies/organizations.

- Whether and to what extent an OSHA standard should require each employer to implement its WICP through a section addressing methods of compliance. OSHA envisions that this section would require, among other control measures, that an employer conduct an infectious agent hazard analysis, follow appropriate SOPs, institute appropriate engineering, work practice, and administrative controls, provide and ensure the use of appropriate personal protective equipment, clean and decontaminate the worksite, and conduct prompt exposure investigations.

- Whether and to what extent an OSHA standard should require each employer to make available routine medical screening and surveillance, vaccinations to prevent infection, and post-exposure evaluation and follow-up to all workers who have been exposed to a suspected or confirmed source of an infectious agent(s) without the benefit of appropriate infection control measures.

- Whether and to what extent an OSHA standard should contain signage, labeling, and worker training requirements to ensure the effectiveness of infection control measures.

- Whether and to what extent an OSHA standard should require the employer to establish and maintain medical records, exposure incident records, and records of reviews of its worker infection control program, and whether and to what extent an OSHA

standard should contain other recordkeeping requirements.

- The economic impacts of a prospective standard.

- Whether and to what extent OSHA should take alternative approaches to rulemaking to improve adherence to current infection control guidelines issued by the Centers for Disease Control and Prevention, the National Institutes of Health, and other authoritative agencies/organizations.

- Additional topics as time permits.

III. Public Participation

Approximately 30 participants will be accommodated in each meeting, and three hours will be allotted for each meeting. Members of the general public may observe, but not participate in, the meetings as space permits. The morning and afternoon meetings will cover identical information and participants may attend only one session to allow greater stakeholder participation. OSHA staff will be present to take part in the discussions. Eastern Research Group (ERG), Inc., (110 Hartwell Avenue, Lexington, MA 02421) will manage logistics for the meetings, provide a facilitator, and compile notes summarizing the discussion; these notes will not identify individual speakers. ERG also will make an audio recording of each session to ensure that the summary notes are accurate; these recordings will not be transcribed. The summary notes will be posted on the docket for the Infectious Diseases Request for Information, Docket ID: OSHA-2010-0003, available at the Web site <http://www.regulations.gov>.

To participate in one of the July 29, 2011 stakeholder meetings, or be a nonparticipating observer, you must submit a notice of intent electronically, by facsimile, or by hard copy. OSHA will confirm participants, as necessary, to ensure a fair representation of interests and to facilitate gathering diverse viewpoints. To receive a confirmation of your participation as soon as possible before the meeting, register by the date listed in the **DATES** section of this notice. However, registration will remain open until the meetings are full. Additional nonparticipating observers that do not register for the meetings will be accommodated as space permits. See the **ADDRESSES** section of this notice for the registration Web site, facsimile number, and address. To register electronically, follow the instructions provided on the Web site. To register by mail or facsimile, please indicate the following:

Name, address, phone, fax, and e-mail.

First and second preferences of meeting time.

Organization for which you work.
Organization you will represent (if different).

Stakeholder category: Government, industry, union, trade association, insurance, manufacturers, consultants, or other (if other, please specify).

Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available on the OSHA Web page at: <http://www.osha.gov>.

Authority and Signature

This document was prepared under the direction of David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. This action is taken pursuant to sections 4, 6, and 8, Public Law 91-596, 84 STAT. 1590 (29 U.S.C. 653, 655, 657), Secretary of Labor's Order No. 4-2010 (75 FR 55355 (Sept. 10, 2010)), and 29 CFR part 1911.

Signed at Washington, DC, on June 29, 2011.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2011-16742 Filed 7-1-11; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID DoD-2010-HA-0072; RIN 0720-AB41]

TRICARE; Reimbursement of Sole Community Hospitals and Adjustment to Reimbursement of Critical Access Hospitals

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: This proposed rule is to implement the statutory provision at 10 United States Code (U.S.C.) 1079(j)(2) that TRICARE payment methods for institutional care be determined, to the extent practicable, in accordance with the same reimbursement rules as those that apply to payments to providers of services of the same type under Medicare. This proposed rule implements a reimbursement methodology similar to that furnished to Medicare beneficiaries for inpatient services provided by Sole Community

Hospitals (SCHs). It will be phased in over a several-year period.

DATES: Written comments received at the address indicated below by September 6, 2011 will be accepted.

ADDRESSES: You may submit comments, identified by docket number or Regulatory Information Number (RIN) and title, by either of the following methods:

The Web site: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Federal Docket Management System Office, Room 3C843, 1160 Defense Pentagon, Washington, DC 20301-1160.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Martha M. Maxey, TRICARE Management Activity (TMA), Medical Benefits and Reimbursement Branch, telephone (303) 676-3627.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

Hospitals are authorized TRICARE institutional providers under 10 U.S.C. 1079(j)(2) and (4). Under 10 U.S.C. 1079(j)(2), the amount to be paid to hospitals, skilled nursing facilities, and other institutional providers under TRICARE, "shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under Medicare." Medicare reimburses SCHs for inpatient care the greatest of these aggregate amounts:

1. What the SCH would have been paid under the Medicare Diagnosis-Related Group (DRG) method for all of that hospital's Medicare discharges.
2. The amount that would have been paid if the SCH were paid the average "cost" per discharge at that hospital in Fiscal Year (FY) 1982, 1987, 1996, or 2006, updated to the current year, for all its Medicare discharges.

TRICARE currently pays SCHs for inpatient care in one of two ways:

Network Hospitals: Payment is an amount equal to billed charges less a negotiated discount. The discounted reimbursement is usually substantially greater than what would be paid using

the Diagnosis-Related Group (DRG) method.

Non-network Hospitals: Payment is equal to billed charges.

TRICARE's current method results in reimbursing SCHs substantially more than Medicare does for equivalent inpatient care. A change is needed to conform to the statute.

Under 32 CFR 199.14(a)(1)(ii)(D)(6), SCHs are exempt from the TRICARE DRG-based payment system. Based on the above statutory mandate, TRICARE is proposing to use an approach that approximates The Centers for Medicare and Medicaid Services' (CMS) method for SCHs.

II. SCH Reimbursement Methodology

Establishing a TRICARE SCH inpatient reimbursement method exactly matching that of Medicare is not practicable. While TRICARE can calculate the aggregate DRG reimbursement for all TRICARE discharges by a SCH during a year, using the Medicare cost per discharge would not be appropriate for TRICARE. Differences in the TRICARE and Medicare beneficiary case mix render the Medicare average cost per discharge not directly applicable for TRICARE purposes.

In addition, basing SCH reimbursement on annual updates to a TRICARE base-year average cost per discharge could result in inappropriate payments to some SCHs. At many SCHs, the number of TRICARE discharges per year is very low. Approximately half of the SCHs had fewer than 20 TRICARE discharges annually. The TRICARE average cost per discharge in 1 year may not be a good predictor of the average cost per discharge in a future year due to significant change in the case mix that can occur between two small sets of patients.

Alternatively, TRICARE could make payments equal to the SCH's specific cost-to-charge ratio (CCR) multiplied by the hospital's billed charges for services. This would avoid making payments unrelated to case mix and would be consistent with the Medicare principle of relating payments for SCHs to cost of services. This is the approach adopted in the proposed rule.

III. TRICARE's SCH Phase-in Period

In introducing its current SCH reimbursement method, Medicare used a 3-year phase-in period to provide the hospitals time for making business and clinical process adjustments. TRICARE is proposing a phase-in period with a maximum 15 percent per-year reduction from the starting point in TRICARE-allowed amounts for non-network