

Biotech nuclear pharmacy locations and closed its Cardinal facilities. The Order requires that within six months of the date on which the Order is accepted for public comment, Cardinal must reconstitute each of the three former Cardinal nuclear pharmacies and divest each of the pharmacies to a Commission-approved acquirer.

In connection with the divestiture of the three nuclear pharmacies, Cardinal is also required to divest to each acquirer the intellectual property related to the nuclear pharmacies owned by Biotech prior to the Acquisition. Cardinal must also obtain, maintain, and transfer to the acquirer(s) all regulatory approvals, licenses, qualifications, permits, or clearances that are necessary to operate a nuclear pharmacy. Finally, although, as stated above, the Commission must approve each acquirer, the Order specifically requires that Cardinal demonstrate that each acquirer has a supply of the two vital low energy radiopharmaceutical inputs, the radioisotope technetium 99 and a heart perfusion agent.

#### *B. Customer Rights To Terminate Contracts With Cardinal*

To ensure that the acquirer(s) have the opportunity to compete for sufficient business to obtain viable scale and restore competition, the Order requires that Cardinal grant each of its customers in Las Vegas, Albuquerque, and El Paso the right to terminate, without penalty or charge, its existing contract with Cardinal for the purchase of radiopharmaceuticals. Specifically, any customer that purchased radiopharmaceuticals from either Cardinal's or Biotech's nuclear pharmacy in Las Vegas, Albuquerque, or El Paso, at any time between July 1, 2009 (30 days prior to the Acquisition) and the relevant closing date (*i.e.*, the day on which Cardinal divests the reconstituted pharmacy in the customer's market), has the right to terminate its existing contract for radiopharmaceuticals with Cardinal. However, the Order does not grant customers the right to terminate radiopharmaceutical contracts with Cardinal that relate solely to the purchase of Positron Emission Tomography radiopharmaceuticals (also referred to as high energy radiopharmaceuticals).

Pursuant to the Order, Cardinal is required to notify each relevant customer within five days after the relevant closing date of the customer's right to terminate its existing contract. The Order further requires that Cardinal will terminate any relevant customer's existing contract within 30 days upon

receiving that customer's request to terminate. Relevant customers will have the option to terminate their existing contract with Cardinal for a period of 24 months from the relevant closing date.

#### *C. Facilitating the Acquirer's Employment of Certain Cardinal and Former Biotech Employees*

To provide the acquirer(s) with access to any necessary employees, the Order requires Cardinal to facilitate and not interfere with the recruitment of certain former Biotech employees and current Cardinal nuclear pharmacy employees in Las Vegas, Albuquerque, and El Paso. Such employees also are released from any restrictions on their ability to work for the acquirer(s).

#### *D. A Monitor Will Help Ensure Compliance*

The Order provides for the appointment by the Commission of an independent monitor with fiduciary responsibilities to the Commission, to help ensure that Cardinal carries out all of its responsibilities and obligations under the Order. The Order provides that Katherine L. Seifert, a person with significant experience in the radiopharmaceutical industry, shall serve as monitor. Ms. Seifert, currently of Seifert and Associates, Inc., provides consulting services for various clients in the radiopharmaceutical industry. In the event Cardinal fails to comply with its divestiture obligations, the Order also provides that the Commission may appoint a divestiture trustee to fulfill those requirements.

#### **VII. Purpose of the Analysis To Aid Public Comment**

The purpose of this analysis is to facilitate public comment on the proposed Decision and Order. This analysis is not intended to constitute an official interpretation of the Consent Agreement and Order.

By direction of the Commission, Commissioner Kovacic recused.

**Richard C. Donohue,**

*Acting Secretary.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Office of the Secretary**

#### **Renewal of Declaration Regarding Emergency Use of Doxycycline Hyclate Tablets Accompanied by Emergency Use Information and Amendment To Include All Oral Formulations of Doxycycline**

**AGENCY:** Office of the Secretary (OS), HHS.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Homeland Security determined on September 23, 2008 that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*. On the basis of this determination, the Secretary of Health and Human Services is renewing the October 1, 2008 declaration by former Secretary Michael O. Leavitt of an emergency justifying the authorization of emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued by the Commissioner of Food and Drugs under 21 U.S.C. 360bbb-3(a) and amending the declaration to include all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued by the Commissioner of Food and Drugs under 21 U.S.C. 360bbb-3(a). This notice is being issued in accordance with section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(4).

**DATES:** This Notice and referenced HHS declaration are effective as of July 20, 2011.

**FOR FURTHER INFORMATION CONTACT:** Nicole Lurie, MD MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

**SUPPLEMENTARY INFORMATION:** On September 23, 2008, former Secretary of Homeland Security, Michael Chertoff, determined that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*—although there is no current

domestic emergency involving anthrax, no current heightened risk of an anthrax attack, and no credible information indicating an imminent threat of an attack involving *Bacillus anthracis*. Pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b), and on the basis of such determination, on October 1, 2008, former Secretary of Health and Human Services, Michael O. Leavitt, declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a).<sup>1</sup>

Pursuant to section 564(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b), and on the basis of Secretary Chertoff's September 23, 2008 determination, I hereby renew former Secretary Leavitt's October 1, 2008 declaration of an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a) and amend the declaration to justify the authorization of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). I previously renewed the declaration on October 1, 2009 and October 1, 2010.<sup>2</sup> I am issuing this notice in accordance with section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(4).

Dated: July 20, 2011.

**Kathleen Sebelius,**

Secretary.

[FR Doc. 2011-18937 Filed 7-26-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Pre-test of an Assisted Living Consensus Instrument." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on May 11, 2011 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

**DATES:** Comments on this notice must be received by August 26, 2011.

**ADDRESSES:** Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by e-mail at [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

#### FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Proposed Project

##### *Pre-Test of an Assisted Living Consensus Instrument*

Using a consensus-based process and in partnership with the Center for Excellence in Assisted Living (CEAL), AHRQ has developed a data collection tool that will collect uniform information about individual assisted living facilities (ALFs) in the United States to increase the value of healthcare for consumers by helping them make informed choices when selecting an ALF. Included in the development process were a voluntary committee of

national representatives of Assisted Living Facilities, consumers, and researchers.

Assisted living (AL) is a relatively new long-term care option that currently serves approximately one million older and dependent Americans. Unlike skilled nursing facilities which are federally regulated and relatively uniform from state to state, ALFs vary from state to state, as well as within each state, reflecting various core values that embrace consumer choice and provider diversity.

Most states mandate a set of basic services that an ALF must offer, such as meals and housekeeping. The upper limits of allowable services are also often prescribed. However, within the range of services required and allowed, ALFs in most states are given some latitude as to who they choose to serve and what services they choose to provide. Further, the choice of services is not always confined by geography; that is, given the widespread dispersion of families, potential AL residents may be looking to choose among assisted living properties in different states, thereby widening the choices available.

While some ALFs are equipped to serve a wide range of resident needs, it is more common that an assisted living property will address a particular "market niche." There are many ways in which ALFs offer diversity — in the religious or cultural affiliations of its target market; in the house rules that influence expectations about dress and behavior in the dining room; in the admission and discharge criteria in place; as well as in the range of services provided. Major variation is found in the extent to which a particular ALF is able and willing to serve those with dementia. While most ALFs admit and retain residents with mild cognitive impairment, those without a specialized dementia program may have difficulty serving residents with common symptoms such as a lack of safety awareness, wandering, sleep disturbances and agitation.

To some extent, admission and discharge criteria are dictated by the laws and regulations of the state in which a particular ALP operates. Beyond this, ALFs have considerable latitude in assessing individuals whom they will admit and retain in their facilities.

In addition to the assessment of needed services in relation to the services that are available, the ability to pay for AL services is a critical factor for both the consumer and ALF decision-making about whether and when an individual moves into and out of a particular ALF. Approximately ten

<sup>1</sup> Pursuant to section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, notice of the determination by the Secretary of Homeland Security and the declaration by the Secretary of Health and Human Services was provided at 73 FR 58242 (October 6, 2008).

<sup>2</sup> Pursuant to section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, notices of the renewal of the declaration of the Secretary of Health and Human Services were provided at 74 FR 51,279 (Oct. 6, 2009) and 75 FR 61,489 (Oct. 5, 2010).