

regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR Parts 160 and 164, 65 Fed. Reg. 82462 (12-28-00), Subparts A and E. The protected health information is collected from the Plan during the enrollment process and passed onto the Medicare Beneficiary Database. These elements include the Beneficiary Name, Sex, Date of Birth, and Health Insurance Claim Number. Disclosures of Protected Health Information authorized by these routine uses may only be made if, and as, permitted or required by the "Standards for Privacy of Individually Identifiable Health Information."

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if CMS determines there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Magnetic storage media.

RETRIEVABILITY:

Information can be retrieved by name and health insurance claim number of the beneficiary.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the

Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 6 years and 3 months. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER AND ADDRESS:

Director, Division of MA & Part D Application Analysis, Information Services Design and Development Group, Office of Information Services, CMS.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the systems manager who will require the system name, SSN, address, date of birth, sex, and for verification purposes, the subject individual's name (woman's maiden name, if applicable). Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Data for this system is collected from MAs, MA-PDs, and PDPs (which obtained the data from the individuals concerned); Social Security Administration; and the Medicare Beneficiary Database, 1-800 Medicare Choice, and Health Plan Management System.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Request for Assistance for Child Victims of Human Trafficking
OMB No.: 0970-0362.

Description: The William Wilberforce Trafficking Victims Protection Reauthorization Act (TVPRA) of 2008, Public Law 110-457, directs the U.S. Secretary of Health and Human Service (HHS), upon receipt of credible information that a non-U.S. citizen, non-Lawful Permanent Resident (alien) child may have been subjected to a severe form of trafficking in persons and is seeking Federal assistance available to victims of trafficking, to promptly determine if the child is eligible for interim assistance. The law further directs the Secretary of HHS to determine if a child receiving interim assistance is eligible for assistance as a victim of a severe form of trafficking in persons after consultation with the Attorney General, the Secretary of Homeland Security, and nongovernmental organizations with expertise on victims of severe form of trafficking.

In developing procedures for collecting the necessary information from potential child victims of trafficking, their case managers, attorneys, or other representatives to allow HHS to grant interim eligibility, HHS devised a form. HHS has determined that the use of a standard form to collect information is the best way to ensure requestors are notified of their option to request assistance for child victims of trafficking and to make prompt and consistent determinations about the child's eligibility for assistance.

Specifically, the form asks the requestor for his/her identifying

information, for information on the child, information describing the type of trafficking and circumstances surrounding the situation, and the strengths and needs of the child. The form also asks the requestor to verify the information contained in the form because the information could be the basis for a determination of an alien child's eligibility for federally funded benefits. Finally, the form takes into consideration the need to compile information regarding a child's

circumstances and experiences in a non-directive, child-friendly way, and assists the potential requestor in assessing whether the child may have been subjected to trafficking in persons.

The information provided through the completion of a Request for Assistance for Child Victims of Human Trafficking form will enable HHS to make prompt determinations regarding the eligibility of an alien child for interim assistance, inform HHS' determination regarding the child's eligibility for assistance as a

victim of a severe form of trafficking in persons, facilitate the required consultation process, and enable HHS to assess and address potential child protection issues.

Respondents: Representatives of governmental and nongovernmental entities providing social, legal, or protective services to alien persons under the age of 18 (children) in the United States who may have been subjected to severe forms of trafficking in persons.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Request for Assistance for Child Victims of Human Trafficking | 200 | 1 | 1 | 200 |

Estimated Total Annual Burden Hours: 200.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget,
Paperwork Reduction Project, Fax:
202-395-7285, E-mail:
OIRA_SUBMISSION@OMB.eop.gov,
Attn: Desk Officer for the
Administration for Children and
Families.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0543]

Authorization of Emergency Use of Oral Formulations of Doxycycline; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for oral formulations of doxycycline for the post-exposure prophylaxis of inhalational anthrax during a public health emergency involving aerosolized *Bacillus anthracis* (*B. anthracis*). FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized doxycycline products. The Authorization follows the determination by the Secretary of the Department of Homeland Security (DHS) 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, *B. anthracis*. On the basis of such determination, the Secretary of the Department of Health and Human Services (HHS) declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets, accompanied by emergency use information, and later

renewed that declaration. The Secretary of HHS then renewed and amended that declaration so that it applies to all doxycycline products covered by this authorization. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of July 21, 2011.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4121, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Luciana Borio, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4280, Silver Spring, MD 20993, 301-796-8510.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Pub. L. 108-276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects,