

Dated: July 2, 2010.

Carol Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB Clearance No. 0915-0193—Revision)

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by the Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and other grantees under Section 330. The authorizing statute is section 330 of

the Public Health Service Act, as amended.

HRSA collects data in the UDS which are used to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of data collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The UDS will be revised in several ways. Certain data elements are added for staffing and utilization and for diagnoses, services, and tests. Specifications for current clinical measures are revised to align with those of national standard setting organizations. Revenue sources are updated to include new federal revenue sources. A limited number of clinical measures will be added consistent with identified national priorities.

These new measures are included in the UDS data collection request in order to allow advance time for health centers to change data collection systems. These changes reflect an increase in burden of 18,224 hours over the previous information collection request in 2009. The burden is increased due to a greater number of respondents and reporting of the new measures.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Universal report	1,181	1	68	80,308
Grant report	328	1	18	5,904
Total	1,181	86,212

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 2, 2010.

Sahira Rafiullah,

Director, Division of Policy Information and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0316]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Pilot Program for Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register**

concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the continuation of a pilot project to evaluate the electronic collection of the 3500A Form for adverse events related to the use of medical products to obtain data from user facilities participating in the Medical Product Safety Network (MedSun). Additionally, the electronic form will include hospital profile information and several other questions related to the use of medical products. It will no longer contain the page called Device-Safety Exchange (DS-X) (formerly called M-Den), which was a moderated site where MedSun members shared information with each other. This will be replaced by a page where questions about possible emerging

signals will be asked of the MedSun sites.

DATES: Submit either electronic or written comments on the collection of information by September 7, 2010.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleman, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance

of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adverse Event Pilot Program for Medical Products—21 U.S.C. 360(i) (OMB Control Number 0910-0471)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)), FDA is authorized to require: Manufacturers to report medical device related deaths, serious injuries, and malfunctions; and user facilities to report device-related deaths directly to manufacturers and FDA, and to report serious injuries to the manufacturer. Section 213 of the FDA Modernization Act of 1997 (FDAMA), amended section 519(b) of the act relating to mandatory reporting by user facilities of deaths and serious injuries and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a " * * * subset of user facilities that constitutes a representative profile of user reports" for device related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the act. The current universal reporting system remains in place during the pilot stages of the new program, and until FDA implements the new national system by regulation. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high quality data on medical devices in

clinical use. This system is called MedSun.

FDA is continuing to conduct a pilot of the MedSun system before the agency issues a regulation to change from universal mandatory reporting for medical device user facilities to reporting by a representative sample of facilities. This data collection has been ongoing since February 20, 2002, and this notice is for continuation of this data collection.

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on the 3500A Form related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and to pilot additional questions which will permit FDA to better understand the cause of reported adverse events. During the pilot program, participants will be asked to complete an annual outcome measures form, as a Customer/Partner Service Survey (approved under OMB control number 0910-0360) to aid FDA in evaluating the effectiveness of the program. Participation in this pilot is voluntary and currently includes 400 facilities. The use of an interactive electronic data collection system is easier and more efficient for the participating user facilities to use than the alternative paper system.

In addition to collecting data on the electronic adverse event report form, MedSun also is proposing to collect additional information from participating sites about reported problems emerging from the MedSun Network hospitals. This data collection is also voluntary, and will be collected on the same Web site as the report information. This will replace the Device-Safety Exchange (DS-X). The burden to respond to these questions will take the same time as that used for DS-X, 30 minutes.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total
Facilities participating in the electronic reporting of adverse events programs	400	15	6,000	.75	4,500
Facilities responding to emerging signal questions (not used by all sites)	300	10	3,000	.50	1,500
Total					6,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The total burden hours for MedSun and emerging signal questions equals 6,000 hours (4,500 for MedSun and 1,500 for emerging signals).

The burden estimate for the electronic reporting of adverse events is based on the number of facilities currently participating in MedSun (400). FDA estimates an average of 15 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, electrophysiology laboratories, and the hospital laboratories.

The burden estimate for the emerging signal portion of MedSun is based on the assumption that not all sites will use this part of the software each time questions are asked, because not all sites will use the device in question.

Dated: July 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0101]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 3356; Eligibility Determination for Donors; and Current Good Tissue Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 9, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to

oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0543. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 3356; Eligibility Determination for Donors; and Current Good Tissue Practice—(OMB Control Number 0910-0543)—Extension

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States. As derivatives of the human body, all human cells, tissues, and cellular and tissue-based products (HCT/Ps) pose some risk of carrying pathogens that could potentially infect recipients or handlers. FDA has issued regulations related to HCT/Ps involving establishment registration and listing using Form FDA 3356, eligibility determination for donors, and current good tissue practice (CGTP).

A. Establishment Registration and Listing; Form FDA 3356

The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute an HCT/P described in § 1271.10(a), or that perform screening or testing of the cell or tissue donor to register with FDA (§ 1271.10(b)(1)) and submit a list of each HCT/P manufactured (§ 1271.10(b)). Section 1271.21(a) requires an establishment to follow certain procedures for initial registration and listing of HCT/Ps, and § 1271.25(a) and (b) identifies the required initial registration and HCT/P listing information.

Section 1271.21(b), in brief, requires an annual update of the establishment registration. Section 1271.21(c)(ii) requires establishments to submit

HCT/P listing updates when an HCT/P is changed as described in § 1271.25(c). Section 1271.25(c) identifies the required HCT/P listing update information. Section 1271.26 requires establishments to submit an amendment if ownership or location of the establishment changes. FDA requires the use of a registration and listing form (Form FDA 3356: Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)) to submit the required information (§§ 1271.10, 1271.21, 1271.25, and 1271.26). To further facilitate the ease and speed of submissions, electronic submission is accepted (<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm>).

B. Eligibility Determination for Donors

In brief, FDA requires certain HCT/P establishments described in § 1271.1(b) to determine donor eligibility based on donor screening and testing for relevant communicable diseases agents and diseases, except as provided under § 1271.90. The documented determination of a donor's eligibility is made by a responsible person defined in § 1271.3(t) and is based on the results of required donor screening, which includes a donor medical history interview (defined in § 1271.3(n)) and testing (§ 1271.50(a)). Certain records must accompany an HCT/P once the donor-eligibility determination has been made (§ 1271.55(a)). This requirement applies both to an HCT/P from a donor who is determined to be eligible as well as to an HCT/P from a donor who is determined to be ineligible or where the donor-eligibility determination is not complete if there is a documented urgent medical need (§ 1271.60). Once the donor-eligibility determination has been made, the HCT/P must be accompanied by a summary of records used to make the donor-eligibility determination (§ 1271.55(b)) and a statement whether, based on the results of the screening and testing, the donor is determined to be eligible or ineligible (§ 1271.55(a)(2)).

Records used in determining the eligibility of a donor, i.e., results and interpretations of testing for relevant communicable disease agents, the donor-eligibility determination, the name and address of the testing laboratory or laboratories, and the name of the responsible person (defined in § 1271.3(t)) who made the donor-eligibility determination and the date of the determination, must be maintained (§ 1271.55(d)(1)). If any information on