

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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DDM

[Docket No. 2007N-0218]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Pilot Program for Medical Products (Formally Medical Device Adverse Event Reporting Program)

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 continuing 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 Device Safety Network (MedSun). Additionally, the electronic form will include hospital profile information and several other questions related to the use of medical products. A portion of the MedSun software, called Device-Safety Exchange (DS-X) (formerly called M-Den), is a moderated site where MedSun members may share information with each other.

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DATES: Submit written comments on the collection of information by *[insert date 60 days after publication in the Federal Register.]*

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Dockets Management Branch (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: Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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 continuing collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (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 (21 U.S.C. 360i(b)) 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 a few additional questions which will permit FDA to better understand the cause of the reported adverse event. During the pilot program, participants will be asked to complete an annual outcome measures form to aid FDA in evaluating the effectiveness of the program. Participation in this pilot is voluntary and currently includes 400 facilities and over 100 beds. 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. The paper form takes approximately 1 hour to complete and the electronic version takes approximately 45 minutes, or less, to complete. Much of the data which must be filled in by hand on the paper system is automatically filled in by the electronic version.

In addition to collecting data on the electronic adverse event report form, MedSun also collects data electronically in DS-X. This data collection is also voluntary, and is an FDA moderated site. MedSun sites may send in “success stories” describing quality improvement initiatives they have implemented to improve patient safety with medical products and also may send in medical product related questions to which other sites may respond. The maximum time it takes to enter a story or write or respond to a question is 30 minutes.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
519(b) Facilities participating in the electronic reporting of adverse events program	400	15	6,000	.75	4,500
519 (b) Facilities participating in DS-X (not used by all sites)	200	5	1,000	.50	500
Total					5,000

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

The burden estimate for the electronic reporting of adverse events is based on the number of facilities currently participating in MedSun (400) and the number of sites (50) expected to be added to the program over the next 3 years. The current average number of reports per site is 7 reports annually. For purposes of this renewed data collection, we are estimating an average of 15 reports per site annually. This increase is expected since MedSun is 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.

Therefore, this yields a total annual responses of 6,000 (400 facilities x 15 data entries = 6,000.) The participating MedSun reporters tell FDA that it typically takes 20 to 45 minutes to fill out the online form. Using the high end of that timeframe, the overall annual burden hours will be 4,500 hours (6,000 report entries x 0.75 hours = 4,500 hours).

Determining burden for the DS-X portion of MedSun: Not all sites use this part of the software. To determine the total annual responses for DS-X: 200 participants multiplied by the number of times each will access DS-X yields annual responses of 1,000 reports.

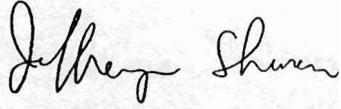
It typically takes an average of 30 minutes to enter data into DS-X, given that there are various types of data entries which are possible, some of which are lengthier than others. The number of burden hours for DS-X is determined

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by multiplying the expected 1,000 times the site will be accessed by the average amount of time it takes to make a DS-X data entry (30 minutes). This equals a burden of 500 hours ($1,000 \times 0.50 = 500$).

The total burden hours for MedSun and DS-X data entry equals 8,000 hours (7,500 for MedSun and 500 for DS-X).

Dated: 6/7/07
June 7, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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