

Dated: August 15, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Medical Devices 101: An Educational Forum; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in cosponsorship with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Medical Devices 101: An Educational Forum." This public workshop, presented previously on February 9, 2007, is intended to provide an overview on FDA's medical device requirements to entrepreneurs, startup companies, and small businesses.

**Date and Time:** The public workshop will be held on October 26, 2007, from 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at the FDA SWRO, 4040 North Central Expressway, 9th floor conference room, Dallas, TX.

**Contact Person:** David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, e-mail: [oraswrsbr@fda.hhs.gov](mailto:oraswrsbr@fda.hhs.gov).

**Registration:** FMDIC has a \$75 early registration fee. The early registration fee for government officials is \$50 and for students is \$25 with positive identification. Early registration ends October 12, 2007. After October 12, 2007, registration is \$100 for the public at large, \$75 for government officials, and \$50 for students with positive identification. To register online, please visit <http://www.fmdic.org/>. As an alternative, you may mail your registration information including name, title, organization or company name, physical address, telephone and fax numbers, and e-mail address, along with a check or money order for the appropriate amount payable to the FMDIC, to William Hyman, Texas A&M University, Department of Biomedical Engineering, 3120 TAMU, College Station, TX 75843-3120. The available space will be filled in order of receipt

of registration with appropriate fees. Seats are very limited; please submit registration as soon as possible. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site may be available based on space availability on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$99 payable to FMDIC. The registration fee will be used to offset expenses associated with this event including lunch, refreshments, and course materials.

If you require special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 21 days in advance.

**Transcripts:** Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at an estimated cost of 10 cents per page.

**SUPPLEMENTARY INFORMATION:** The workshop, previously presented on February 9, 2007 (72 FR 968, January 9, 2007), is being held in response to the interest in the topics discussed from small medical device entrepreneurs and startup manufacturers in the Dallas District area. FDA presents this workshop in cosponsorship with FMDIC to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the Medical Device Quality System Regulation. The following topics will be broadly covered at the workshop: (1) Medical device

classification; (2) establishment registration; (3) device listing; (4) premarket notification; (5) premarket approval; (6) quality system regulation; (7) labeling; (8) recalls, removals, and corrections; (9) medical device reporting; (10) tracking; and (11) postmarket surveillance.

Dated: August 15, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### Proposed Project: Data Collection Tool for the Black Lung Clinics Program: (OMB No. 0915-0292) Revision

The Office of Rural Health Policy (ORHP), Health Resources and Services Administration, conducts an annual data collection of user information for the Black Lung Clinics Program. The purpose of the Black Lung Clinics Program is to improve the health status of coal workers by providing services to minimize the effects of respiratory and pulmonary impairments of coal miners. Grantees provide specific diagnostic and treatment procedures required in the management of problems associated with black lung disease which improves the quality of life of the miner and reduces economic costs associated with morbidity and mortality arising from pulmonary diseases. The purpose of collecting this data is to provide HRSA with information on how well each grantee is meeting the needs of active and retired miners in the funded communities.

Data from the annual report will provide quantitative information about

the programs, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, occupation type); (b) the characteristics of services provided (medical, non-medical, or counseling); (c) number of patients served and visits conducted

(encounters); and (d) the improvement in pulmonary function of patients (pulmonary rehabilitation). This assessment will provide data useful to the program and will enable HRSA to provide data required by Congress under the Government Performance and

Results Act of 1993. It will also ensure that the organizations funded have demonstrated a need for services in their communities and that funds are being effectively used to provide services to meet those needs.

The estimated burden is as follows:

Form name	Number of respondents	Hours per response	Total burden hours
Database .....	15	20	300

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: August 15, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Correction of total burden hours.

**SUMMARY:** The Health Resources and Services Administration published an Agency Information Collection document in the **Federal Register** of July 31, 2007 (FR Doc. E7-14680), on page 41759, regarding Bureau of Primary Health Care (BPHC) Uniform Data System (OMB No. 0915-0193). In the burden table, the total burden hours published are incorrect.

**Correction**

In the **Federal Register** issue of July 31, 2007, FR Doc. E7-14680), on page

41759, correct the Total Burden Hours as follows:

Type of report	Total burden hours
Universal report .....	58,104
Grant report .....	2,700
<b>Total .....</b>	<b>60,804</b>

Dated: August 15, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: National Practitioner Data Bank and Healthcare Integrity and Protection Data Bank Market Surveys and Survey of Use of Data Bank Information by Queriers: NEW**

The purpose of these surveys is to conduct a follow-up study to the National Practitioner Data Bank (NPDB) User and Non-User Surveys of 2001. In addition, Healthcare Integrity and Protection Data Bank (HIPDB) users and non-users will be included in this study. The study will evaluate the effectiveness of the NPDB and the HIPDB as flagging systems, sources of information, and decisionmaking tools. It will also determine user satisfaction with the process, use, and information provided by the NPDB and HIPDB.

Surveys will be administered to entities that report to and/or query the NPDB and HIPDB, including users who query either the NPDB and/or HIPDB and who receive a "match", i.e. copies of adverse actions concerning a queried practitioner. A sample of Queriers who received a matched response will be surveyed about the information received. NPDB and HIPDB non-users will also be surveyed. Eligible NPDB and HIPDB users will be asked to complete a Web-based Internet survey or a computer-assisted telephone interview (CATI). NPDB and HIPDB non-users will complete either a Web or CATI, or will be transferred to an interactive voice response (IVR) system during the CATI to complete the survey.

Data gathered from the survey will be compared with similar information from previous surveys of users and non-users and will provide HRSA with the information necessary to improve the usability of the NPDB and HIPDB.

The estimate of burden is as follows:

Respondents	Respondent description	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden (hours)
NPDB Users Group Survey	Malpractice Payers .....	228	1	228	.25	57
	Licensing Boards .....	90	1	90	.25	22.5
	Hospitals (Reporting) .....	466	1	466	.25	116.5
	Hospitals (Querying) .....	994	1	994	.25	248.5
	MCOs .....	900	1	900	.25	225