Services (CMS), and Bureau of the Census. Data collected through the NHDS are essential for evaluating health status of the population, for the planning of programs and policy to elevate the health status of the Nation, for studying morbidity trends, and for research activities in the health field. NHDS data have been used extensively in the development and monitoring of goals for the Year 2000 and 2010 Healthy People Objectives. In addition, NHDS data provide annual updates for numerous tables in the Congressionally-mandated NCHS report, *Health, United States*. Other users of these data include universities, research organizations, foundations, and a variety of users in the print media. There is no cost to respondents other than their time to participate. The total estimated annualized burden hours are 5,591.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS

Type of data collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Current NHDS Primary Procedure Hospitals Sample Listing Sheet	13	12	25/60
Current NHDS Primary Procedure Hospitals Medical Abstract Form	13	250	5/60
Current NHDS Primary Procedure Hospitals Transmittal Notice	13	12	1/60
Current NHDS Alternate Procedure Hospitals locating medical records	41	250	1/60
Current NHDS In-House Tape or Printout Hospital—computer programming and submission	29	12	13/60
Current NHDS Hospital Interview Questionnaire	10	1	2
Redesigned pretest Survey presentation to hospital	10	1	1
Redesigned pretest Facility questionnaire	10	1	4
Redesigned pretest Sample discharges within hospital, obtain UB–04 & payment data	10	10	14/60
Redesigned pretest Verify sampling & reabstract medical records	2	10	14/60
Redesign pretest Debrief hospital staff	10	1	1
Redesigned 2010–2011 Survey presentation to hospital	80	1	1
Redesigned 2010–2011 Facility questionnaire	80	1	4
Redesigned 2010–2011 Sample discharges within hospital, obtain UB–04 & payment data	160	120	14/60
Redesigned 2010–2011 Verify sampling & re-abstract medical records	3	25	14/60

Dated: July 24, 2008.

Maryam I. Daneshvar,

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

[FR Doc. E8–17605 Filed 7–31–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10265]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Mandatory Insurer Reporting Requirements of Section 111 of the Medicare, Medicaid and SCHIP Act of 2007 (MMSEA) (Pub. L. 110–173); *Use:* Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (Pub. L. 110–173) amends the Medicare Secondary Payer (MSP) provisions of the Social Security Act (42 U.S.C. 1395y(b)) to provide for mandatory reporting by group health plan arrangements and by liability insurance (including self-insurance), no-fault insurance, and workers' compensation laws and plans. The law provides that, not withstanding any other provision of law, the Secretary of Health and Human Services may implement this provision by program instruction or otherwise. The Secretary has elected not to implement the provision through rulemaking and will implement by publishing instructions on a publicly available Web site and submitting an information collection request to OMB for review and approval of the associated information collection requirements.

Effective January 1, 2009, as required by the MMSEA, an entity serving as an insurer or third party administrator for a group health plan and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary must: (1) Secure from the plan sponsor and plan participants such information as the Secretary may specify to identify situations where the group health plan is a primary plan to Medicare; and (2) report such information to the Secretary in the form and manner (including frequency) specified by the Secretary.

Effective July 1, 2009, as required by the MMSEA, ''applicable plans,'' must: (1) Determine whether a claimant is entitled to Medicare benefits; and, if so, (2) report the identity of such claimant and provide such other information as the Secretary may require to properly coordinate Medicare benefits with respect to such insurance arrangements in the form and manner (including frequency) as the Secretary may specify after the claim is resolved through a settlement, judgment, award or other payment (regardless of whether or not there is a determination or admission of liability). Applicable plan refers to the following laws, plans or other arrangements, including the fiduciary or administrator for such law, plan or arrangement: (1) Liability insurance (including self-insurance); (2) No-fault

insurance; and (3) Workers' compensation laws or plans.

As indicated, the Secretary has elected to implement this provision by publishing instructions at a Web site established for such purpose. The Web site is *http://www.cms.hhs.gov/MandatoryInsRep/*. CMS shall use this Web site to publish preliminary guidance as well as the final instructions. The Web site also advises interested parties how to comment on the preliminary guidance. *Form Number:* CMS–10265 (OMB# 0938–New); *Frequency:* Yearly; *Affected Public:* Business or other for-profits, Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 290,404; *Total Annual Responses:* 6,920,504; *Total Annual Hours:* 2,120,478.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by September 30, 2008:

1. *Electronically*. You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail*. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number___, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 2, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0420]

Medical Device User Fee Rates for Fiscal Year 2009

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2009. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA)), authorizes FDA to collect user fees for certain medical device submissions, and annual fees both for certain periodic reports and for certain establishments subject to registration. The FY 2009 fee rates are provided in this notice. These fees apply from October 1, 2008, through September 30, 2009. To avoid delay in the review of your application, you should pay the fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is received. If you want to pay a reduced small business fee, you must qualify as a small business before you make your submission to FDA; if you do not qualify as a small business before you make your submission to FDA, you will have to pay the higher standard fee. This notice provides information on how the fees for FY 2009 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT: *For information on MDUFMA*: Visit FDA's Web site, *http://www.fda.gov/cdrh/mdufma*.

For questions relating to this notice: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3917.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, and notices (for simplicity, this notice refers to these collectively as ''submissions''); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily-defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see 21 U.S.C. 379j(d) and (e)).

Under the act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics licensing application (BLA)). The act specifies the standard fee for a premarket application for each year from FY 2008 through FY 2012; the standard fee for a premarket application received by FDA during FY 2009 is $200,725. From this starting point, this notice establishes FY 2009 fee rates for other types of submissions, and for periodic reporting, by applying criteria specified in the act.

The act specifies the annual fee for establishment registration for each year from FY 2008 through FY 2012; the registration fee for FY 2009 is $1,851. There is no reduction in the registration fee for small businesses. An establishment must pay the registration fee if it is any of the following types of establishments:

- *Manufacturer*. An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.
- *Single-Use Device Reprocessor*. An establishment that performs manufacturing operations on a single-use device that has previously been used on a patient.
- *Specification Developer*. An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

The fees for FY 2009 go into effect on October 1, 2008, and will remain in effect through September 30, 2009.

II. Fees for FY 2009

Under the act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see 21 U.S.C. 379j(a)(2)(A)), and the act sets the