

## EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate**	Total cost burden
Total .....	190	722	NA	31,046

\*Wage rates were calculated using the mean hourly wage based on occupational employment and wage estimates from the Dept of Labor, Bureau of Labor Statistics' May 2008 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—located at [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).

\*\*Wage rate of \$43.00 is based on the mean hourly wages for Medical and Health Services Managers. Wage rate of \$42.67 is the weighted mean hourly wage for: Medical and Health Services Managers (\$42.67 × 2.6 hours = \$110.95), Lawyers (\$59.98 × .5 hours = \$29.99), Chief Executives (\$89.16 × .5 hours = \$44.58), and Computer programmer (\$35.32 × 4 hours = \$141.28) [Weighted mean = (\$110.95 + 29.99 + 44.58 + 141.28)/7.6 hours = \$326.80/7.6 hours = \$43.00/hour].

### Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated annualized cost to the government for developing, maintaining and managing the Health Plan Database and analyzing the data and reporting results. The cost is estimated to be \$260,000 annually. Annualized costs for collecting and processing the CAHPS Health Plan Database are based upon 10 years of historical project costs. Start-up costs were present in the early years of the database only.

#### EXHIBIT 3—ESTIMATED ANNUALIZED COST

Cost component	Annualized cost
Database Maintenance .....	\$50,000
Data Submission .....	100,000
Data Analysis and Reporting .....	110,000
Total .....	260,000

### Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All

comments will become a matter of public record.

Dated: March 19, 2010.

Carolyn M. Clancy,

Director.

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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 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: The Health Education Assistance Loan (HEAL) Program: Physician's Certification of Borrower's Total and Permanent Disability Form (OMB No. 0915-0204)—Extension

The Health Education Assistance Loan (HEAL) program provided federally-insured loans to students in schools of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, and graduate students in health administration or clinical psychology through September 30, 1998. Eligible lenders, such as banks, savings and loan associations, credit unions, pension funds, State agencies, HEAL schools, and insurance companies, made new refinanced HEAL loans which are insured by the Federal Government against loss due to borrower's death, disability, bankruptcy, and default. The basic purpose of the program was to assure the availability of funds for loans to eligible students who needed to borrow money to pay for their educational loans. Currently, the program monitors the federal liability, and assists in default prevention activities.

The HEAL borrower, the borrower's physician, and the holder of the loan completes the Physician's Certification form to certify that the HEAL borrower meets the total and permanent disability provisions. The Department uses this form to obtain detailed information about disability claims which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans, (2) pertinent information supplied by the certifying physician, (3) the physician's certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death, and (4) information from the

lender on the unpaid balance. Failure to submit the required documentation will result in disapproval of a disability

claim. No changes have been made to the current form.

The estimate of burden for the Physician's Certification form is as follows:

Type of respondent	Number of respondents	Responses per respondent	Number of responses	Minutes per response	Total burden hours
Borrower .....	75	1	75	5	6
Physician .....	75	1	75	30	38
Loan Holder .....	13	6	78	10	13
Total .....	163	.....	228	.....	57

E-mail comments to [paperwork@hrsa.gov](mailto: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: March 25, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010-7251 Filed 3-30-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0161]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates

**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 information collection requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA-regulated products, pharmaceuticals, biologics, and devices as indicated in the Federal Food, Drug, and Cosmetic Act (the act) as amended.

**DATES:** Submit written or electronic comments on the collection of information by June 1, 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:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, [Jonnalynn.Capezzuto@fda.hhs.gov](mailto:Jonnalynn.Capezzuto@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.

#### Export of Food and Drug Administration Regulated Products: Export Certificates (OMB Control Number 0910-0498)—Extension

In April 1996, a law entitled "The FDA Export Reform & Enhancement Act of 1996" (FDAERA) amended sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FDAERA provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of 801(e) and 802 or other requirements of the act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to \$175 for the certifications.

This new section of the act authorizes FDA to issue export certificates for regulated pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the act. FDA has developed five types of certificates that satisfy the requirements of section 801(e)(4)(B) of the act: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, (4) Non-Clinical Research Use Only Certificates, and (5) Certificates of Free Sale. Table 1 of this document lists the different certificates and details their use: