

and fiscal year 2010 (FY10) (OMB No. 0920-0776, exp. 03/31/2011). Respondents are the 68 programs participating in the NBCCEDP. Information is collected through a web-based Cost Assessment Tool (CAT) and includes: Staff and consultant salaries, screening costs, contracts and material costs, provider payments, in-kind contributions, administrative costs, allocation of funds and staff time devoted to specific program activities.

CDC requests OMB approval for a six-month extension of the current approval period in order to complete the third year of data collection. Based on our experience with previous data collection cycles, 20 grantees (30% of the total 68 grantees) will not be able to meet the current data collection deadline of 3/31/2011. These programs will complete their fiscal year (FY) closeout process in April or May 2011.

As a result, these programs will not be prepared to submit data to CDC until their FY is complete and records have been reconciled. The requested six-month extension period will provide the time they need to complete their closeout process and conduct data quality checks before submitting information to CDC. The requested six-month extension will improve the quality and completeness of information used for planned data analysis, and ensure CDC's authority to receive late submissions.

The activity-based cost data will be used to evaluate grantees to ensure the most appropriate use of limited program resources in delivering program services such as screening, diagnostic services, case management and outreach. The detailed cost data will allow CDC to determine the costs of various program components, identify factors that impact

average cost, perform cost-effectiveness analysis and budget impact analysis of the program, and allocate program resources more effectively and efficiently. The collection of economic cost information complements the measures of NBCCEDP effectiveness collected as Minimum Data Elements (0920-0571, exp. 11/30/2012).

In this Revision request, there are no proposed changes to the data collection instrument, data collection methodology, or the estimated burden per response. The only changes are a decrease in the estimated number of respondents (the number of late responders) and a six-month extension of the data collection period. All information is collected electronically. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden (in hrs)	Total burden (in hrs)
NBCCEDP grantee .....	20	1	22	440

Dated: October 6, 2010.

Carol E. 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: 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, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or 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: Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners (45 CFR 61)—OMB No. 0915-0239—Revision**

This is a request for revision and extension of OMB approval of the information collections contained in regulations found in 45 CFR Part 61 governing the Healthcare Integrity and Protection Data Bank (HIPDB) and the forms to be used in reporting information to and requesting information from the HIPDB cleared under OMB No. 0915-0239. An additional form entitled, "Instructions for Registering as an NPDB-HIPDB Self-Querier," has been included to meet identity proofing and e-authentication requirements stipulated in the *E-Authentication Guidance for Federal Agencies* (OMB M-04-04) and National Institutes of Standards and Technology's (NIST) Draft Special Publication 800-63-1, *Electronic Authentication Guidelines*. The burden estimate for self-queriers has been adjusted from the original OMB approval to reflect this new registration process. The HIPDB is authorized by section 1128E of the Social Security Act (hereinafter referred to as section 1128E), as added by section 221(a) of the Health Insurance Portability and

Accountability Act of 1996. Section 1128E directs the Secretary of Health and Human Services (the Secretary) to establish a national health care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions (excluding settlements in which no findings of liability have been made) taken against health care providers, suppliers, or practitioners. It also directs the Secretary to maintain a database of final adverse actions taken against health care providers, suppliers, or practitioners. The regulations implementing section 1128E governing the operation of the HIPDB are codified at 45 CFR Part 61. The HIPDB became operational November 22, 1999.

Approval is requested to continue the following reporting data collection and disclosure requirements and the ensuing HIPDB forms along with the instructions. The recordkeeping, reporting, and disclosure requirements are specified in the regulations to implement the HIPDB. Numbers in the table may not add up exactly due to rounding. *Please note* the burden for Administrative Forms has been accounted for in the NPDB OMB clearance renewal submission.

The annual estimate of burden is as follows:

## DISTRIBUTION OF BURDEN BY REGULATORY CITATION

Regulation citation	Number of respondents	Responses per respondent	Total responses	Hours per response (in minutes)	Total burden hours	Wage rate	Total cost
§ 61.6(a), (b) Errors & Omissions .....	188	4.4	817	15	204.25	\$25	\$5,106
§ 61.6 Revisions/Appeal Status .....	130	26.9	3,492	30	1,746	25	43,650
§ 61.7 Reporting By State Licensure Boards .....	305	80.8	24,640	45	18,480	25	462,000
§ 61.8 Reporting of State Criminal Convictions .....	45	56	2,518	45	1,888.5	43	81,205
§ 61.9 Reporting of Civil Judgments .....	4	2.5	10	45	7.5	43	322
§ 61.10(b) Reporting Exclusions from participation in Federal and State Health Care Programs .....	9	320.3	2,883	20	961.0	38	36,518
§ 61.11 Reporting of Adjudicated Actions/Decisions .....	92	17	1,562	45	1,171.5	43	50,375
§ 61.12 Request for Information: State and Federal Agencies .....	855	279.3	238,814	5	19,901.26	25	497,531.50
§ 61.12 Request for Information Health Plans .....	1,239	532.4	659,617	5	54,968.1	30	1,649,043
§ 61.12 Request for Information Health Care Providers, Suppliers and Practitioners (self-query) ...	50,416	1	50,416	55	46,214.7	45	2,079,661.50
§ 61.12(a)(4) Requests by Researchers for Aggregate Data .....	1	1	1	30	.5	38	19
§ 61.15 Dispute Report .....	300	1	300	5	25	45	1,125
§ 61.15 Add Report Statement .....	669	1	669	45	501.8	100	50,180
§ 61.15 Request for Secretarial Review ...	15	1	15	480	120	200	24,000
Administrative Forms ...	0	0	0	0	0	0	0
<b>Total .....</b>	<b>54,268</b>	<b>.....</b>	<b>985,754</b>	<b>.....</b>	<b>146,190.11</b>	<b>.....</b>	<b>4,980,736</b>

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](mailto: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: October 6, 2010.

**Wendy Ponton,**

*Director, Office of Management.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0499]

#### Cooperative Agreement To Support Building Global Capacity for the Surveillance and Monitoring of Counterfeit/Falsified Medicines and Supply Chain Threats

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single source application for award of a

cooperative agreement to the World Health Organization (WHO) in support of building a global surveillance and monitoring system for combating counterfeit/falsified medicines and risks and breaches in the supply.

#### FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

*Program Contact:* Deborah Autor, or Ilisa Bernstein, Office of Compliance, Center for Drugs Evaluation and Research, Food and Drug Administration, White Oak Bldg. 51, rm. 5270, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3100, *e-mail:*

*Deborah.Autor@fda.hhs.gov* or *Ilisa.Bernstein@fda.hhs.gov.*

*Management Contact:* Katherine C. Bond, Office of the Commissioner,