

EXHIBIT 3—ESTIMATED TOTAL AND ANNUAL COST—Continued

Cost component	Total cost	Annual cost
Coordination	38,003	7,601
Stakeholder Feedback	201,637	40,327
Technical Expert Panel	359,276	71,855
Evaluation Design & Implementation	3,981,390	796,278
Technical Assistance Plan	934,440	186,888
Data Collection Instruments	138,997	27,799
OMB Clearance	35,617	17,808
Section 508 Compliance	13,883	2,777
Data and Analysis Reports	735,426	147,085
Interim Evaluation Reports	408,803	81,761
Dissemination	736,149	184,037
Final Report	103,269	103,269
Total	8,258,311	1,651,662

Request for Comments

In accordance with the Paperwork Reduction Act, 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: September 26, 2011.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-11-0576]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. (0920-0576) Exp. 12/31/2011—Revision—Office of Public Health Preparedness and Response (OPHPR), Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107-188 (42 U.S.C. 262a)*, requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins (*i.e.*, select agents and toxins) that could pose a severe threat to public health and safety. The *Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107-188 (7 U.S.C. 8401)*, requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins (*i.e.*, select agents and toxins) that could pose a severe threat to animal or plant health, or animal or plant products. In accordance with these Acts, HHS and USDA promulgated regulations requiring entities to register with the CDC or the Animal and Plant Health Inspection Service (APHIS) if they possess, use, or transfer a select agent or toxin (42 CFR part 73, 7 CFR part 331, and 9 CFR part 121).

CDC is requesting continued OMB approval to collect this information through the use of five forms: (1) Application for Registration, (2) Request

to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin, and (5) Request for Exemption. Revision will be made to (2) Request to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin. There will be no revisions made to the Application for Registration and Request for Exemption. The total estimated annualized burden for all data collection is 8,878 hours. Information will be collected via fax, e-mail and mail from respondents of the 320 entities registered with the Select Agent Program. Annualized burden hours were calculated by multiplying the average number of hours used to complete the: (1) Application for Registration; (2) Request to Transfer Select Agent or Toxin; (3) Report of Theft, Loss, or Release of Select Agent or Toxin; (4) Report of Identification of Select Agent or Toxin; and (5) Request for Exemption. The estimated annualized burden for the 2008 Possession, Use, and Transfer of Select Agents and Toxins submission was 9,656.5 hours. The 2011 estimated annualized burden hours are 8,878. Burden has been reduced by 778.5 hours due to the removal of similar questions on the Request to Transfer Select Agent or Toxin (Form 2), Report of Theft, Loss, or Release of Select Agent or Toxin (Form 3) and the Report of Identification of Select Agent or Toxin (Form 4). Therefore respondents are not required to answer as many questions as requested in the previous data collection tool.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) will be used by entities requesting transfer of a select agent or toxin to their facility. CDC in conjunction with APHIS has revised the Request to Transfer Select Agent or Toxin form by requiring the recipient to submit the initial request, be notified by the sender of the expected shipment date, and verify if the shipment did not occur. Estimated average time to complete this form is 1 hour, 30 minutes. Based on data regarding the transfer requests received since the last submission, CDC estimates 1 transfer requests submitted per registered entity on an annual basis.

The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a)(b)) must be completed by entities whenever there is theft, loss, or release of a select agent or toxin.

Estimated average time to complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 1 report

per respondent will be received on an annual basis.

The Report of Identification of Select Agent or Toxin form 42 CFR 73.5(a)(b) and 73.6(a)(b) will be used by clinical and diagnostic laboratories to notify CDC that select agents or toxins identified as the result of diagnostic or proficiency testing have been disposed of in a proper manner. In addition, the form will be used by Federal law

enforcement agencies to report the seizure and final disposition of select agents and toxins. CDC in conjunction with APHIS has revised the Report of Identification of Select Agent or Toxin form to ensure duplicate reports are not submitted by requesting the entity making the final identification report the select agents or toxins identified as the result of diagnostic or verification testing. Estimated average time to

complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 9 reports per respondent will be received on an annual basis.

There is no cost to the respondents other than their time. The total estimated annualized burden hours are 8,878, which is a reduction of 778.5 hours from the previously approved ICR.

ESTIMATED ANNUALIZED BURDEN HOURS

CFR	Form name	Number of respondents	Number responses per respondent	Average burden per response
73.3(d)	Application for Registration	5	1	4.5
73.7(h)(1)	Amendment to Registration Application	320	8	1
73.16	Request to Transfer Select Agents or Toxins	320	1	1.5
73.19(a)(b)	Notification of Theft, Loss or Release	180	1	1
73.5 & 73.6(a)(b)	Report of Identification of Select Agent	320	9	1
73.5 & 73.6(d-e)	Request of Exemption	3	1	1
73.3 & 73.4(e)(1)	Request for Exclusions/Restricted	71	1	1
73.10(e)	Request for Expedited Review	1	1	1
73.20	Administrative Review	30	1	4
73.18	Inspections	320	1	8

Dated: September 30, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10268 and CMS-1696]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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:* Extension of a currently approved collection; *Title of Information Collection:* Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-party Submission Authorization Form; *Use:* The Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-Party Submission Authorization form is to be completed by "Facility Administrators" (administrators of CMS-certified dialysis facilities) if they intend to authorize a third party (a business with which the facility is associated, or an independent vendor) to submit data to CMS to comply with the recently-revised Conditions for Coverage of dialysis facilities. The CROWNWeb system is the system used as the collection point of data necessary for entitlement of ESRD patients to Medicare benefits and for Federal Government monitoring and assessing of the quality and types of care provided to renal patients. The information collected through the CWTPSA form will allow CMS and its contractors to receive data from authorized parties acting on behalf of CMS-certified dialysis facilities. Since February 2009, CMS has received 4,160 CWTPSA forms and anticipates that they will continue to receive no more than 400 new CWTPSA forms annually to address the

creation of new facilities under the current participating "third party submitters." *Form Number:* CMS-10268 (OCN: 0938-1052); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours:* 34. (For policy questions regarding this collection contact Michelle Tucker at 410-786-0736. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Appointment of Representative; *Use:* This information collection requests re-approval of an information collection associated with regulations that permit individuals or entities to appoint representatives to exercise their rights to appeal an initial determination. The Appointment of Representative form will be completed by beneficiaries, providers and suppliers who wish to appoint representatives to assist them with obtaining initial determinations and filing appeals. The appointment of representative form must be signed by the party making the appointment and the individual agreeing to accept the appointment. *Form Number:* CMS-1696 (OCN: 0938-0950); *Frequency:* Occasionally; *Affected Public:* Individuals or households and Business or other for-profits; *Number of Respondents:* 265,481; *Total Annual Responses:* 265,481; *Total Annual*