

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*

Hours: 66,370. (For policy questions regarding this collection contact Katherine Hosna at 410-786-4993. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address 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](mailto: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 must be received by December 6, 2011, and submitted in one of the following ways:

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: October 4, 2011.

**Martique Jones,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10340, CMS-10237, CMS-10137, and CMS-265-11 and CMS-265-94]

**Agency Information Collection Activities: Submission for OMB Review; 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), Department of Health and Human Services, 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 function; (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:* Collection of Encounter Data from Medicare Advantage Organizations; *Use:* The Centers for Medicare and Medicaid Services (CMS) intends to collect encounter data, or data on each item or service delivered to an enrollee, from Medicare Advantage Organizations. Medicare Advantage organizations will obtain this data from providers. CMS would collect the data electronically from Medicare Advantage Organizations via the Health Insurance Portability and Accountability Act (HIPAA) compliant standard Health Care Claims transactions for professional data and institutional data. The information is used to submit health care claims or equivalent health encounter information, carry out health plan enrollments and disenrollments, determine health plan eligibility, send and receive health care payment and remittance advices, transmit health plan premium payments, determine health care claim status, provide referral certifications and authorizations, and coordinate the benefits for individuals who have more than one health plan. *Form Number:* CMS-10340 (OMB#: 0938-New); *Frequency:* Weekly; *Affected Public:* Private Sector; Businesses or other for-profits; *Number of Respondents:* 827; *Total Annual Responses:* 517,793,438; *Total Annual Hours:* 34,520. (For policy questions regarding this collection contact Sean Creighton at 410-786-9302 or Deondra Moseley at 410-786-4577. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection;

*Title of Information Collection:* Part C Medicare Advantage and 1876 Cost Plan Expansion Application; *Use:* Collection of this information is mandated in Part C of the Medicare Prescription Drug, Improvement and Modernization Act of

2003 (MMA) in Subpart K of 42 CFR part 422 entitled *Contracts with Medicare Advantage Organizations*. In addition, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended titles XVII and XIX of the Social Security Act to improve the Medicare program.

In general, coverage for the prescription drug benefit is provided through prescription drug plans (PDPs) that offer drug-only coverage or through Medicare Advantage (MA) organizations that offer integrated prescription drug and health care products (MA-PD plans). PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans (MA-CCPs) either must offer a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans (MA-PFFS) may choose to offer enrollees a Part D benefit. Employer Group Plans may also provide Part D benefits. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

Organizations wishing to provide healthcare services under MA and/or MA-PD plans must complete an application, file a bid, and receive final approval from CMS. Existing MA plans may request to expand their contracted service area by completing the Service Area Expansion (SAE) application. Applicants may offer a local MA plan in a county, a portion of a county (*i.e.*, a partial county) or multiple counties. Applicants may offer a MA regional plan in one or more of the 26 MA regions.

This clearance request is for the information collected to ensure applicant compliance with CMS requirements and to gather data used to support determination of contract awards. The information will be collected under the solicitation of Part C application from MA, EGWP Plan, and Cost Plan applicants. The collection information will be used by CMS to: (1) Ensure that applicants meet CMS requirements, (2) support the determination of contract awards. Participation in all Programs is voluntary in nature. Only organizations that are interested in participating in the program will respond to the solicitation. MA-PDs that voluntarily participate in the Part C program must submit a Part D application and successful bid. *Form Number:* CMS-10237 (OMB # 0938-0935); *Frequency:* Yearly; *Affected Public:* Private Sector; *Number of Respondents:* 378; *Total Annual Responses:* 378; *Total Annual Hours:*