DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

[Document Identifier CMS–10508, CMS–10507 and CMS–855A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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.

DATES: Comments must be received by January 14, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send 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) that are 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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:


2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see ADDRESSES).

CMS–10508 Evaluation of the Rural Community Hospital Demonstration (RCHD)

CMS–10507 State-based Marketplace Annual Report (SMAR)

CMS–855A Medicare Enrollment Application: Medicare Part A Institutional Providers

Under the Paperwork Reduction Act (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. The term “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 requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. Type of Information Collection Request: New collection (Request for a new OMB control number);

Title of Information Collection: Evaluation of the Rural Community Hospital Demonstration (RCHD); Use: Section 10313 of the Affordable Care Act of 2010 (ACA) extended and expanded the Rural Community Hospital Demonstration (RCHD). Originally authorized under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the RCHD provides enhanced reimbursement for inpatient services to small rural hospitals that do not qualify as critical access hospitals (CAHs). The RCHD is intended to increase the capability of these hospitals to meet the health care needs of rural beneficiaries in their service areas. As a demonstration, the RCHD aims to provide information that can be used to assess the feasibility and advisability of establishing a new category of rural community hospitals for reimbursement policy. As of January 2013, 23 hospitals from 11 states are participating in the RCHD. This number includes seven hospitals continuing from the original demonstration as authorized under the MMA and 15 new hospitals that joined under the expansion authorized under the ACA.

For the original demonstration, the MMA required a Report to Congress six months after the end of the demonstration, a requirement unchanged by the ACA. An initial evaluation was conducted between 2007 and 2011 toward preparing for a Report to Congress and focused on the 17 hospitals that had participated at some point between October 2004 and March 2011. Findings from this evaluation were reported to the Centers for Medicare and Medicaid Services (CMS) in the Interim Evaluation Report of the Rural Community Hospital Demonstration (an unpublished report).

The current five-year evaluation of the RCHD will extend and build on the prior evaluation and produce the Report to Congress required by the MMA. It will assess the impact of the RCHD in meeting its goals: To enable hospitals to...
achieve community benefits such as improved services for their communities (especially Medicare beneficiaries), meet their individual strategic goals, and improve the financial solvency and viability of the participating hospitals. In addition, the evaluation will determine if it is feasible and advisable to create a new payment category of rural hospitals. To achieve this objective, the evaluation will examine how RCHD hospitals responded to payment options and assess how the costs to Medicare under RCHD compare to existing alternative payment options. The evaluation will also summarize the characteristics of the markets served by RCHD hospitals, including beneficiaries’ proximity to inpatient providers and competition among providers in the area. The information will be used to assess the implications of expanding the RCHD payment system to hospitals in various market environments. In addition, the evaluation will examine the potential costs of expanding the RCHD payment methodology, accounting for alternative approaches to targeting rural hospitals.

Form Number: CMS–10508 (OCN: 0938–NEW); Frequency: Annually; Affected Public: State, Local or Tribal Governments, Private sector—Business or other for-profit and Not-for-profit organizations; Number of Respondents: 57; Total Annual Responses: 101; Total Annual Hours: 245. (For policy questions regarding this collection contact Woolton Lee at 410–786–4942.)

2. Title of Information Collection: State, Local, or Tribal Marketplace A5A Annual Report (SMAR); Type of Information Collection Request: New collection (Request for a new OMB control number); Use: The annual report is the primary vehicle to insure comprehensive compliance with all reporting requirements contained in the Affordable Care Act. It is specifically called for in section 1313(a)(1) of the Act which requires an State-based Marketplace (SBM) to keep an accurate accounting of all activities, receipts, and expenditures, and to submit a report annually to the Secretary concerning such accounting. We will use the information collected from states to assist in determining if a state is maintaining a compliant operational Exchange. It will also provide a mechanism to collect innovative approaches to meeting challenges encountered by the SBMs during the preceding year. Additionally, it will provide information to us regarding potential changes in priorities and approaches for the upcoming year. Form Number: CMS–10508 (OCN: 0938–NEW); Frequency: Annually; Affected Public: State, Local, or Tribal governments; Number of Respondents: 19; Number of Responses: 19; Total Annual Hours: 1,482. (For policy questions regarding this collection, contact Shelley Bain at 301–492–4453.)

3. Title of Information Collection: Medicare Enrollment Application: Medicare Part A Institutional Providers; Type of Information Collection Request: Revision of a currently approved collection; Use: We are revising the CMS–855 Medicare Enrollment Applications information collection request to remove the CMS–855I, CMS–855B and CMS–855R applications from its collection. We have found that the regulations governing the enrollment requirements for health care facilities occur at intervals separate from the other provider and supplier types reimbursed by Medicare. Consequently, we may need to revise and submit the CMS–855A enrollment application for OMB approval at intervals separate from the other enrollment applications which include the CMS–855B, CMS–855I and CMS–855R enrollment applications. The ability to revise the CMS–855A separately from the other CMS–855 enrollment applications will lessen the burden on us and OMB as well as the public during the Federal Register notice period, as only one subset of provider or suppliers will be affected by CMS–855A revisions. We intend to maintain the continuity of the CMS–855 enrollment applications by using the same formats and lay-out of the current CMS–855 enrollment applications, regardless of the separation of the CMS–855A from other CMS–855 enrollment applications. At this time we are also using this opportunity to make editorial and clerical corrections to the CMS–855A to simplify and clarify the current data collection and to remove obsolete requirements and data collection. The sections and sub-sections within the form are also being re-numbered and re-sequenced to create a more logical flow of the data collection. In addition, we are adding a data collection for an address to mail the periodic request for the revalidation of enrollment information (only if it differs from other addresses currently collected). More specific information regarding types of Home Health Agency sub-units will also be collected. Other than the information above, new data being collected in this revision package is information on, if applicable, where the supplier stores its patient records electronically.

Form Number: CMS–855A (OCN: 0938–0685); Frequency: Annually; Affected Public: State, Local, or Tribal governments; Number of Respondents: 18,000; Number of Responses: 18,000; Total Annual Hours: 78,000. (For policy questions regarding this collection, contact Kim McPhillips at 410–786–5374.)

Dated: November 8, 2013.

Martique Jones,
Deputy 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–2013–D–0715]

Draft Guidance for Industry on Acrylamide in Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled “Guidance for Industry: Acrylamide in Foods.” The draft guidance is intended to provide information that may help growers, manufacturers, and food service operators reduce acrylamide in certain foods. Acrylamide is a chemical that can form in some foods during certain types of high-temperature cooking. The draft guidance is intended to suggest a range of possible approaches to acrylamide reduction and not to identify specific recommended approaches.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 14, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.