

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-based Marketplace 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-10507 (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 effected 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 the collective enrollment application package.

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.

FOR FURTHER INFORMATION CONTACT:

Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1639.

SUPPLEMENTARY INFORMATION:**I. Background**

We are announcing the availability of a draft guidance entitled "Guidance for Industry: Acrylamide in Foods." We are issuing this draft guidance as a Level 1 draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on acrylamide in foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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, and is a concern because it can cause cancer in laboratory animals at high doses, and is reasonably anticipated to be a human carcinogen. Reducing acrylamide in foods may mitigate potential human health risks from exposure to acrylamide. The draft guidance is intended to suggest a range of possible approaches to acrylamide reduction and not to identify specific recommended approaches.

In particular, the draft guidance is intended to give information to manufacturers on selecting and handling raw materials, modifying processing practices, and choosing ingredients, so as to reduce acrylamide in potato-based foods (such as fries, sliced potato chips, and fabricated potato chips) and cereal-based foods (such as cookies, crackers, and breads). The draft guidance also discusses acrylamide reduction in coffee. The draft guidance also is intended to give information to manufacturers for placing preparation and cooking instructions on frozen French fry packages. Lastly, the draft guidance is intended to give information for food service operations on preparation of potato-based and cereal-based foods.

II. Paperwork Reduction Act of 1995

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995

(the PRA) (44 U.S.C. 3501-3520). "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. Federal law at 44 U.S.C. 3506(c)(2)(A) requires Federal Agencies to publish a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice of the proposed collection of information in a future issue of the **Federal Register**.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

Dated: November 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2013-N-1306]

International Medical Device Regulators Forum; Medical Device Single Audit Program International Coalition Pilot Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing participation in the Medical Device Single Audit Program International Coalition Pilot Program. The Medical

Device Single Audit Program (MDSAP) was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the diverse international regulatory requirements of medical devices quality management systems and other specific regulatory requirements of the regulatory authorities participating in the pilot program. FDA will be participating in the MDSAP and will accept the resulting audit reports as a substitute for routine Agency inspections.

ADDRESSES: Submit electronic comments on the MDSAP International Coalition Pilot Program to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Kimberly A. Trautman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5400, Silver Spring, MD 20993-0002, 301-796-5515, Kimberly.Trautman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The International Medical Device Regulators Forum (IMDRF) was conceived in 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world, which includes FDA, who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices. The purpose of the IMDRF is to accelerate international medical device regulatory harmonization and convergence. See <http://www.imdrf.org/>.

The IMDRF recognizes the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices. The IMDRF, at its inaugural meeting in Singapore in 2012, identified a Work Group (WG) to develop specific documents for advancing the concept of the MDSAP. See <http://www.imdrf.org/>.

This global approach opens possibilities and pathways to support the development of an international initiative of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an