

System of Records Notice (SORN) published at 78 **Federal Register** (FR) 63211 (Oct. 23, 2013).

The OPM System of Records for this matching program is titled "General Personnel Records" (OPM/GOVT-1), published at 77 **Federal Register**, 73694 (December 11, 2012). OPM will submit to CMS a monthly Status File that is a full refresh of all Federal employee health care insurance information. OPM also will submit to CMS, on an annual basis, a Premium Spread Index File that provides information identifying the lowest self-only premium for an OPM FEHB plan available to a Federal employee in each State as well as national OPM FEHB plans.

Inclusive Dates of the Match

The CMP will become effective no sooner than 40 days after the report of the matching program is sent to OMB, 30 days after a copy of the matching agreement is transmitted to Congress, or 30 days after publication in the **Federal Register**, whichever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-138 and 10088]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 December 12, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. 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:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

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.

FOR 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-R-138 Medicare Geographic Classification Review Board Procedures and Criteria

CMS-10088 Notification of FIs and CMS of co-located Medicare providers

Under 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 Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Geographic Classification Review Board Procedures and Criteria; *Use:* During the first few years of IPPS, hospitals were paid strictly based on their physical geographic location concerning the wage index (Metropolitan Statistical Areas (MSAs)) and the standardized amount (rural, other urban, or large urban). However, a growing number of hospitals became concerned that their payment rates were not providing accurate compensation. The hospitals argued that they were not competing with the hospitals in their own geographic area, but instead that they were competing with hospitals in neighboring geographic areas. At that point, Congress enacted Section 1886(d)(10) of the Act which enabled hospitals to apply to be considered part of neighboring geographic areas for payment purposes based on certain criteria. The application and decision process is administered by the MGCRB which is not a part of CMS so that CMS could not be accused of any untoward action. However, CMS needs to remain apprised of any potential payment changes. Hospitals are required to provide CMS with copy of any applications that they made to the MGCRB. CMS also developed the guidelines for the MGCRB that were the interim final issue of the **Federal Register**, and must ensure that the MGCRB properly applied the guidelines. This check and balance process also contributes to limiting the

number of hospitals that ultimately need to appeal their MGCRB decisions to the CMS Administrator. *Form Number:* CMS-R-138 (OMB control number: 0938-0573); *Frequency:* Occasionally; *Affected Public:* Businesses or other for-profits and Not-for-profit institutions; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 300. (For policy questions regarding this collection contact Noel Manlove at 410-786-5161.)

2. Type of Information Collection Request: Reinstatement of a previously approved collection; **Title of Information Collection:** Notification of FIs and CMS of co-located Medicare providers; **Use:** Many long-term care hospitals (LTCHs) are co-located with other Medicare providers (acute care hospitals, IRFs, SNFs, psychiatric facilities), which leads to potential gaming of the Medicare system based on patient shifting. In regulations at 42 CFR 412.22(e)(3) and (h)(6) and 412.532(i), CMS is requiring LTCHs to notify Medicare Administrative Contractors (MACs) and CMS of co-located providers in order to establish policies to limit payment abuse that will be based on FIs tracking patient movement among these co-located providers. *Form Number:* CMS-10088 (OMB control number: 0938-0897); *Frequency:* Annually; *Affected Public:* Businesses or other for-profits and Not-for-profit institutions; *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 6. (For policy questions regarding this collection contact Emily Lipkin at 410-786-3633.)

Dated: October 4, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3990]

Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled

“Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process.” This guidance explains the process by which FDA intends to carry out the section of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Sunscreen Innovation Act (SIA), which governs the convening of advisory committees to provide recommendations on requests submitted under the SIA regarding nonprescription sunscreen active ingredients and the number of requests to be considered per meeting. The recommendations in this guidance apply to 586A requests submitted under the FD&C Act and to pending requests as defined by the SIA that seek a determination from FDA on whether a nonprescription sunscreen active ingredient, or a combination of nonprescription sunscreen active ingredients, is generally recognized as safe and effective (GRASE) for use under specified conditions and should be included in the over-the-counter (OTC) sunscreen drug monograph. The SIA describes specific circumstances under which FDA is not required to convene or submit requests to the Nonprescription Drugs Advisory Committee (NDAC). We are issuing this guidance pursuant to the SIA, which directs FDA to issue guidance on four topics, including the topic discussed in this guidance. This guidance finalizes the draft guidance on the same topic issued on November 23, 2015.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2015-D-3990 for “Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR