and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Forms (If necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response (hours)	Total burden hours
CRM Tool	Regional Extension Center	62	12	1.5	1080
Total					1080

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2014–04484 Filed 2–28–14; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10054]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by April 29, 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:

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 collection. More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**). CMS–10054 Recognition of Payment for New Technology Services for New Technology Ambulatory Payment Classification (APC) Groups Under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR part 419.

Under the Paperwork ReductionAct (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:* Recognition of Payment for New Technology Services for New Technology Ambulatory Payment Classification (APC) Groups Under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR part 419; *Use:* CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. It is necessary that we continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies and others that bring to our attention specific services that they wish us to evaluate for New Technology APC payment. *Form Number:* CMS–10054 (OCN: 0938–0860); *Frequency:* Once; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 160. (For policy questions regarding this collection contact Barry Levi at 410–786–4529).

Dated: February 26, 2014.

Martique Jones,

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

[FR Doc. 2014–04613 Filed 2–28–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0053]

Revised Draft Guidance for Industry on Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices.'' This draft guidance revises the final guidance titled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices'' published in January 2009. The revised draft guidance provides guidance on FDA's current thinking on recommended practices for drug or medical device manufacturers and their representatives to follow when distributing to health care professionals or health care entities scientific or medical journal articles, scientific or medical reference texts, or clinical practice guidelines ((CPGs); all three collectively referred to as ''scientific and medical publications'') that discuss unapproved new uses for approved drugs or approved or cleared medical devices marketed in the United States.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 2, 2014. Submit either electronic or written comments on the proposed collection of information by May 2, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448; or to the Division of Small Manufacturers, International and Consumer Assistance, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription drugs: Bryant Godfrey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, Rm. 3258, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding prescription biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

Regarding medical devices: Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993–0002, 301–796–5732.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices.'' This draft guidance describes recommended practices for drug or medical device manufacturers or their representatives to follow when distributing to health care professionals or health care entities scientific and medical publications that discuss unapproved new uses of approved drugs or approved or cleared medical devices.

In January 2009, FDA published a final guidance titled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices,'' which set forth the Agency's thinking as of that time regarding the dissemination by manufacturers of medical journal articles and scientific or medical reference publications that discuss unapproved or uncleared uses of medical products.[1] FDA received comments to the docket for the 2009 guidance, including submissions requesting clarification of how the principles set forth in the 2009 guidance would apply to medical textbooks and potential changes to those principles.

In July 2011 and September 2013, FDA received citizen petitions, filed on behalf of multiple prescription drug and medical device manufacturers, that include several requests related to FDA's approach to the distribution of scientific and medical information reflecting unapproved or uncleared uses, specifically including CPGs.[2] FDA continues to consider the specific requests made in the citizen petitions, which include requests for issuance or revision of regulations, and has not yet reached a final determination on those petitions.

At the same time, FDA continues actively to review, analyze, and develop approaches to a variety of topics of interest to industry and others, including issues raised in the petition. As part of this process, FDA is soliciting public comment on the draft guidance made available here. Similarly, as part of the Agency's ongoing efforts to address industry questions, FDA continues to solicit public input and consider approaches with respect to several related issues, including the following:

(1) *Further explaining ''scientific exchange.''* On December 28, 2011, FDA issued a **Federal Register** notice (76 FR 81508) opening a docket and requesting comments and information related to ''scientific exchange.'' Comments were submitted to Docket No. FDA–2011–N–0912. FDA is reviewing those comments and considering how that information may inform future Agency action related to its policies on communications and activities related to unapproved or uncleared uses of marketed drugs and devices, as well as communications and activities related to use of products that are not yet legally marketed for any use.

[1] Please visit *http://www.regulations.gov* and enter docket number FDA–2008–D–0053.

[2] Please visit *http://www.regulations.gov* and enter docket numbers FDA–2011–P–0512 and FDA–2013–P–1079.