

Oncology Care Model (OCM) beginning in 2016. The new deadline for receipt of online applications from payers and practices is 5:00 p.m. Eastern Daylight Time (EDT) on June 30, 2015. Only those payers and practices that submitted timely, complete Letters of Intent (LOIs) are eligible to apply to participate in OCM, and only the submission of web-based applications will be accepted.

DATES: Application Submission Deadline: Applications for payers and practices must be received by 5:00 p.m. Eastern Daylight Time (EDT) on June 30, 2015. Application materials and instructions are available at <http://innovation.cms.gov/initiatives/Oncology-Care/>.

FOR FURTHER INFORMATION CONTACT: OncologyCareModel@cms.hhs.gov for questions regarding the application process of OCM.

SUPPLEMENTARY INFORMATION:

I. Background

The Oncology Care Model (OCM) aims to improve health outcomes for people with cancer, improve the quality of cancer care, and reduce spending for cancer treatment. We expect that physician practices selected for participation in the model will be able to transform care delivery for their patients undergoing chemotherapy, leading to improved quality of care for beneficiaries at a decreased cost to payers. Through this care transformation, practices participating in OCM can reduce Medicare expenditures while improving cancer care for Medicare Fee-for-Service beneficiaries. Beneficiaries can experience improved health outcomes when health care providers work in a coordinated and person-centered manner. We are interested in partnering with payers and practitioners who are working to redesign care to deliver these aims.

The Request for Applications (RFA) requests applications to test the model, which is centered around a chemotherapy episode of care. For more details, see the RFA and related informational materials available on the Center for Medicare and Medicaid Innovation (Innovation Center) Web site at <http://innovation.cms.gov/initiatives/Oncology-Care/>.

On February 17, 2015, we published a notice in the **Federal Register** announcing the RFA for payers and practices to apply to participate in the testing of OCM for a 5-year performance period beginning in 2016 (80 FR 8323). In that notice, we stated that payers and practices interested in applying to

participate in the testing of OCM must submit non-binding letters of intent (LOIs) by March 19, 2015 and April 23, 2015, respectively; and that all applications from payers and practices must be received by 5:00 p.m. EDT on June 18, 2015. We subsequently extended the deadlines for the submission of LOIs to April 9, 2015 (payers) and May 7, 2015 (practices), as announced on the Innovation Center Web site at (<http://innovation.cms.gov/initiatives/Oncology-Care/>), in updates to the RFA and related informational materials, and in emails to stakeholders.

II. Provisions of the Notice

Since the publication of the February 17, 2015 notice, several stakeholders have requested additional time to prepare their applications and form partnerships in order to participate in the OCM beginning in 2016. Therefore, the Innovation Center is extending the deadline for receipt of payer and practice applications from June 18, 2015 at 5:00 p.m. Eastern Daylight Time (EDT) to June 30, 2015 at 5:00 p.m. EDT. Only those payers and practices that submitted timely, complete LOIs are eligible to apply to participate in OCM, and only the submission of web-based applications will be accepted. The extended application deadline has already been announced on the Innovation Center Web site at (<http://innovation.cms.gov/initiatives/Oncology-Care/>), in updates to the RFA and related informational materials, and in emails to stakeholders.

In the **DATES** section of this notice, we are including the new submission deadline. For additional information on the OCM and how to apply, we refer readers to click on the RFA and related informational materials located on the Innovation Center Web site at <http://innovation.cms.gov/initiatives/Oncology-Care/>.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirement. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Dated: June 12, 2015.

Andrew M. Slavitt,
Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015-15129 Filed 6-18-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-643]

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: 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 August 18, 2015.

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-643 Hospice Survey and Deficiencies Report Form and Supporting Regulations

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 without change of a currently approved collection; *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations; *Use:* We use the information collected as the basis for certification decisions for hospices that wish to obtain or retain participation in the Medicare and Medicaid programs. The information is used by CMS regional offices, which have the delegated authority to certify Medicare

facilities for participation, and by State Medicaid agencies, which have comparable authority under Medicaid. The information on the Hospice Survey and Deficiencies Report Form is coded for entry into the OSCAR system. The data is analyzed by the CMS regional offices and by the CMS central office components for program evaluation and monitoring purposes. The information is also available to the public upon request. *Form Number:* CMS-643 (OMB control number: 0938-0379); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 3,976; *Total Annual Responses:* 1,325; *Total Annual Hours:* 1,325. (For policy questions regarding this collection contact Annette Snyder at 410-786-0807.)

Dated: June 16, 2015.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015-15126 Filed 6-18-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1434]

Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules." This guidance discusses FDA recommendations for the size, shape, and other physical attributes of generic tablets and capsules intended to be swallowed intact. FDA is concerned that differences in these physical characteristics between generic drugs and the originator drug could affect patient outcomes.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-

0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Debra Catterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-3861; or Vilayat Sayeed, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-9077.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules." FDA is concerned that the differences in size, shape, and other physical characteristics between a generic drug and the originator drug may affect patient compliance and acceptability of medication regimens or could lead to medication errors. For example, studies show that tablet size and shape can affect ease of swallowing; generic tablets that are significantly larger than their corresponding reference drug product may be more difficult to swallow, leading to potential adverse events as well as noncompliance with treatment regimens. FDA is recommending that generic manufacturers consider the size, shape, and other physical characteristics of the originator drug when developing a generic version.

In the **Federal Register** of December 10, 2013 (78 FR 74154), this guidance was published as a draft guidance. We have carefully reviewed and considered the comments that were received on the draft guidance and have made editorial changes primarily for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the size, shape, and other physical attributes of generic tablets and capsules. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.