3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations; *Use:* There are a number of information users of Part C reporting data, including our central and regional office staff that use this information to monitor health plans and to hold them accountable for their performance, researchers, and other government agencies such as the Government Accounting Office. Health plans can use this information to measure and benchmark their performance.

Based on internal review, this notice withdraws a portion of a prior notice (August 24, 2015) concerning the same subject matter and corrects that notice by adding a new requirement which was inadvertently omitted from that notice. Specifically, we propose to add a new Payments to Providers reporting section to capture data related to MA organizations' value-based payments. Upon OMB approval, the Payments to Providers section would add 10 data elements.

HHS has developed four categories of value based payment: (1) Fee-for-service with no link to quality; (2) fee-for-service with a link to quality; (30 alternative payment models built on fee-for-service architecture; and (4) population-based payment. To compliment HHS' action, CMS is seeking to collect data from MA organizations about the proportion of their payments to providers made based on these four categories. The collected information would help us understand the extent and use of alternate payment models in the MA industry.

Form Number: CMS–10261 (OMB Control Number 0938–1054); *Frequency:* Yearly and semi-annually; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 561; *Total Annual Responses:* 3,508; *Total Annual Hours:* 182,023. (For policy questions regarding this collection contact Terry Lied at 410–786–8973).

Partial Withdrawal of Previous Notice

This document also withdraws a portion of a prior notice concerning the same CMS–10261-specific subject matter.

Specifically, on page 51276, in the second column, in the second paragraph, information collection CMS–10261 (OMB Control Number 0938–1054) that published in the **Federal Register** on August 24, 2015 (80 FR 51275) is hereby withdrawn.

Dated: September 15, 2015.

William N. Parham, III,

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

[FR Doc. 2015–23482 Filed 9–17–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3230]

Consumer Comments—Public Posting and Availability of Comments Submitted to Food and Drug Administration Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is changing the Agency's long standing practice of not publically posting on *http://www.regulations.gov* comments submitted by individuals in their individual capacity. These are generally comments from people who self-identify as an ''individual consumer'' under the field titled ''Category (Required)'' on the ''Your Information'' page on *http://www.regulations.gov.* Changing FDA's practice to routinely post these comments, as we do other comments, will increase the transparency and public utility of FDA's public dockets. It will better enable our public dockets to function as intended: To share information and encourage an open exchange of ideas.

DATES: All comments submitted to any FDA docket on or after October 15, 2015, will be publically posted, unless otherwise determined not to be subject to posting as described in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Cohen, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3324, Silver Spring, MD 20993–0002, 301–796–7001.

SUPPLEMENTARY INFORMATION:

I. Background

Historically, FDA generally has not publicly posted on *http://www.regulations.gov* comments submitted by individuals in their individual capacity (and not on behalf of an organization, corporation, or other entity). For comments submitted through *http://www.regulations.gov,* for example, such comments are identified as ''Individual Consumer'' under the field titled ''Category (Required) '' on the ''Your Information'' page. This non-posting practice has applied only to individual consumer comments which otherwise would be displayed on *http://www.regulations.gov.* These comments have been placed in the official FDA docket and are publicly available in FDA's Reading Room or through Freedom of Information Act requests and have been considered by the Agency in finalizing its regulatory actions.

FDA is changing this practice and will post such consumer comments on *http://www.regulations.gov,* as it posts other comments. FDA has made this change so that its public dockets better serve their purpose of promoting transparency and the sharing of information.

In 1995, FDA explained that it routinely reviewed all comments for obvious confidential information before placing the comments in the docket (60 FR 66982), but this practice is no longer feasible given factors such as the volume of comments FDA receives and the adoption of a government-wide electronic portal system for submitting and posting comments at *http://www.regulations.gov.* FDA developed the practice of not posting individual consumer comments largely because of concerns about disclosing personal information of individuals who may not have realized, when submitting their comments, that their name, address, and other identifying information would be publicly viewable. This public viewability became more obvious as the Internet gained popularity and particularly when FDA dockets system was merged with the government-wide portal system for submission of all public comments on government regulatory actions at *http://www.regulations.gov* in 2007. This practice has been precautionary because, as FDA has stated previously, ''there can be no reasonable expectation of confidentiality for information submitted to a public docket in a rulemaking proceeding.'' [1] With the advent of *http://www.regulations.gov,*

[1] 60 FR 66981, at 66982 (December 27, 1995).

FDA selected ''individual consumer'' comments for non-posting because of previous concerns raised by individuals and the conclusion that such commenters may not be as familiar with the regulatory process and the public nature of dockets as are other entities, such as regulated industry.

In recent years, FDA has occasionally made exceptions to this non-posting practice, typically using the COMMENTS section in a particular **Federal Register** document to alert the public that all comments were subject to public posting. FDA **Federal Register** documents, requesting or providing for the submission of comments, published subsequent to this notice will contain new instructions and information concerning the posting of comments submitted to that particular docket.

This change fulfills a recommendation from the 2010 FDA Transparency Initiative [2] and aligns with a 2013 recommendation from the Administrative Conference of the United States that ''[a]gencies should manage their public rulemaking dockets to achieve maximum public disclosure'' consistent with legal limitations and other claims of privilege.[3] It also furthers an objective in Executive Order 13563,[4] which directs Agencies to base their regulations on ''public participation and an open exchange of ideas.''

II. Consumer Comments and Confidential Information

The commenter is solely responsible for ensuring that the submitted comment does not include any confidential information that the commenter or a third party may not wish to be posted, such as private medical information, the commenter's or anyone else's Social Security number, or confidential business information, such as a manufacturing process. If a name, contact information, or other information that identifies the commenter is included in the body of the submitted comment, that information will be posted on *http://www.regulations.gov.* FDA will post comments, as well as any attachments submitted electronically, on *http://www.regulations.gov,* along with the State/Province and country (if provided), the name of the commenter's representative (if any), and the category selected to identify the commenter (*e.g.,* individual, consumer, academic, industry).

The Agency expects that only in exceptional instances would a comment need to include private, personal, or confidential information. If a comment is submitted with confidential information that the commenter does not wish to be made available to the public, the comment would be submitted as a written/paper submission and in the manner detailed in the applicable **Federal Register** document. For written/paper comments submitted containing confidential information, FDA will post the redacted/blacked out version of the comment including any attachments submitted by the commenter. The unredacted copy will not be posted, assuming the commenter follows the instructions in the applicable **Federal Register** document. Any information marked as confidential will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law.

FDA will include new information and standard instructions for submitting comments in all **Federal Register** documents requesting or providing for the submission of comments. The instructions will explain how to submit comments to the docket on that particular document via electronic means and also will explain the process for submission of comments, in written/paper format, that the commenter wishes to mark as confidential.

III. Date of Implementation

All comments submitted electronically through *http://www.regulations.gov* to any FDA docket, existing or new, after October 15, 2015, will be posted to the applicable docket and publicly viewable on *http://www.regulations.gov.* All comments submitted by mail or delivery to the Division of Dockets Management in written/paper format to any FDA docket, existing or new, after October 15, 2015, will be posted to the applicable docket and publicly viewable on *http://www.regulations.gov* unless submitted under the following conditions: (1) The written/paper submission is marked as confidential, and (2) the submitter provides an unredacted and a redacted version; the redacted version must have the information claimed as confidential redacted/blacked out. If submitted under these conditions, only the redacted/blacked out written/paper submission will be posted publicly on *http://www.regulations.gov,* except as otherwise provided by § 10.20 or other law.

Dated: September 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23389 Filed 9–17–15; 8:45 am]

BILLING CODE 4164–01–P

[2] ''FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration,'' May 2010, available at *www.fda.gov/AboutFDA/Transparency/PublicDisclosure* (p. 4).

[3] Recommendation No. 2013–4, available at *http://www.acus.gov/recommendation/administrative-record-informal-rulemaking.*

[4] Executive Order 13563, available at *http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–0279–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990–0279, scheduled to expire on September 30, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before October 19, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990–0279 and document identifier HHS–OS–30D for reference.

Information Collection Request Title: Institutional Review Board Form—OMB No. 0990–0279, Assistant Secretary for Health, Office for Human Research Protections.

Abstract: Section 491(a) of Public Law 99–158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (*e.g.,* a grant, contract, or cooperative