

and associated materials (see **ADDRESSES**).

CMS–10249 Administrative

Requirements for Section 6071 of the Deficit Reduction Act

CMS–10261 Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a)

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:** Administrative Requirements for Section 6071 of the Deficit Reduction Act; **Use:** State Operational Protocols should provide enough information such that: The CMS Project Officer and other federal officials may use it to understand the operation of the demonstration, prepare for potential site visits without needing additional information, or both; the State Project Director can use it as the manual for program implementation; and external stakeholders may use it to understand the operation of the demonstration. The financial information collection is used in our financial statements and shared with the auditors who validate CMS’ financial position. The Money Follows the Person Rebalancing Demonstration (MFP) Finders File, MFP Program Participation Data file, and MFP Services File are used by the national evaluation contractor to assess program outcomes while we use the information to monitor program implementation. The MFP Quality of Life data is used by the national evaluation contractor to assess program outcomes. The evaluation is used to determine how participants’ quality of life changes after transitioning to the community. The semi-annual

progress report is used by the national evaluation contractor and CMS to monitor program implementation at the grantee level. **Form Number:** CMS–10249 (OMB control number: 0938–1053); **Frequency:** Yearly, quarterly, and semi-annually; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 45; **Total Annual Responses:** 28,590; **Total Annual Hours:** 14,225. (For policy questions regarding this collection contact Effie George at 410–786–8639.)

2. Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a); **Use:** Medicare Advantage Organizations (MAOs) must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to: The cost of its operations; the patterns of service utilization; the availability, accessibility, and acceptability of its services; to the extent practical, developments in the health status of its enrollees; information demonstrating that the MAO has a fiscally sound operation; and other matters that CMS may require. CMS also has oversight authority over cost plans which includes establishment of reporting requirements. The changes for the 2019 reporting requirements under Organization Determinations and Reconsiderations (ODR) will add 18 new data elements to the reporting section. The new data elements will allow CMS to obtain more information about who is submitting requests for ODR and whether the service or claim is being provided by a contract or non-contract provider. The timeliness requirement for ODR will also be eliminated to be consistent with Part D reporting. In addition, the number of data reporting elements of grievances is reduced from 23 to 19. The reporting sections for Private Fee For Service (PFFS) Payment Dispute Resolution Process and Mid-Year Network Changes will also be suspended. **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:** 432; **Total Annual Responses:** 3,024; **Total Annual Hours:** 127,329. (For policy questions

regarding this collection contact Maria Sotirelis at 410–786–0552.)

Dated: March 21, 2018.

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–2018–D–1067]

Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled “Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” This draft guidance describes policies that FDA proposes to use in evaluating bulk drug substances nominated for use in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for inclusion on the list of bulk drug substances that can be used in compounding under section 503B.

DATES: Submit either electronic or written comments on the draft guidance by May 25, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2018-D-1067 for "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20903, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Section 503B (21 U.S.C. 353b), added to the FD&C Act by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and section 582 (21 U.S.C. 360eee-1) (concerning drug

supply chain security requirements). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound drug products using a bulk drug substance unless either: (1) It appears on a list established by the Secretary of Health and Human Services identifying bulk drug substances for which there is a clinical need (see section 503B(a)(2)(A)(i) of the FD&C Act) (503B Bulks List) or (2) the drug compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing (see section 503B(a)(2)(A)(ii) of the FD&C Act).

This draft guidance addresses FDA policies for developing the 503B Bulks List, including the Agency's interpretation of the phrase "bulk drug substances for which there is a clinical need," as it is used in section 503B of the FD&C Act. The draft guidance also addresses the factors and processes by which the Agency intends to evaluate and list bulk drug substances.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act." 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. This draft guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: March 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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