and associated materials (see

ADDRESS).

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

controlling 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,

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

Sotirrellis at 410–786–0532.)


William N. Parham, III,

Director, Paperwork Reduction Staff, Office

of Strategic Operations and Regulatory

Affairs.

[FR Doc. 2018–06052 Filed 3–23–18; 8:45 am]

BILLING CODE 4120–01–P

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 docket, 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, Rockville, MD 20852.

I. Background


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.

[FR Doc. 2018–06046 Filed 3–23–18; 8:45 am]

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