

supplies (other than commercially available off-the-shelf (COTS) items) to be acquired outside the United States, or the services to be performed, outside the United States has an estimated value that exceeds \$500,000. These protections include the following: (a) The contractor is required to implement and maintain a compliance plan during the performance of the contract that includes an awareness program, a process for employees to report activity inconsistent with the zero-tolerance policy, a recruitment and wage plan, a housing plan, and procedures to prevent subcontractors from engaging in trafficking in persons; and (b) The contractor is required to submit a certification to the contracting officer prior to receiving an award, and annually thereafter, asserting that it has the required compliance plan in place and that there have been no abuses, or that appropriate actions have been taken if abuses have been found. The compliance plan must be provided to the contracting officer upon request, and relevant portions of it must be posted at the workplace and on the contractor's website. Additionally, contractors are required to flow these requirements down to any subcontracts where the estimated value of the supplies acquired or the services required to be performed outside the United States exceeds \$500,000.

## B. Annual Reporting Burden

*Title, Associated Form, and OMB Number:* Ending Trafficking in Persons, FAR 22.1705 and FAR 52.222-50 and 52.222-56; OMB Control Number 9000-0188.

*Adjustment:* This information collection is revised to include appropriate burden hours for reporting that was initially published in FAR Case 2013-001 (78 FR 59317 and 80 FR 4967) for FAR clause 52.222-50, Combating Trafficking in Persons, and provision 52.222-56, Certification Regarding Trafficking in Persons Compliance Plan. The full burden associated with this FAR Case was inadvertently omitted in the Paperwork Reduction Act notice published on August 20, 2014 (78 FR 59317). The following represents current burdens associated with the FAR clause and provision that were published in the proposed and final rules.

*Affected Public:* Businesses and other for-profit entities.

*Respondent's Obligation:* Required to obtain or retain benefits.

*Type of Request:* Revision of a currently approved collection.

*Reporting Frequency:* On occasion.

*Respondents:* 5,909.

*Responses per Respondent:* 3.

*Annual Responses:* 17,727.

*Hours per Response:* 12.

*Total Burden Hours:* 212,724.

## C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

*Obtaining Copies of Proposals:* Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202-501-4755.

Please cite OMB Control No. 9000-0188, Combating Trafficking in Persons, in all correspondence.

Dated: March 20, 2018.

**Lorin S. Curit,**

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10249 and CMS-10261]

### 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 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 May 25, 2018.

**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' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

### 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–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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**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