DEPARTMENT OF DEFENSE
GENERAL SERVICES ADMINISTRATION
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

OMB Control No. 9000–0011; Docket No. 2020–0053; Sequence No. 8

Submission for OMB Review: Preaward Survey Forms (Standard Forms 1403, 1404, 1405, 1406, 1407, and 1408).

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision and renewal of a previously approved information collection requirement regarding preaward survey forms.

DATES: Submit comments on or before December 10, 2020.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

Additionally submit a copy to GSA through http://www.regulations.gov and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite OMB Control No. 9000–0011, Preaward Survey Forms (Standard Forms 1403, 1404, 1405, 1406, 1407, and 1408). Comments received generally will be posted without change to http://www.regulations.gov, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or GSARegSec@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or zenaida.delgado@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0011, Preaward Survey Forms (Standard Forms 1403, 1404, 1405, 1406, 1407, and 1408).

B. Needs and Uses

Contracting officers, prior to award, must make an affirmative determination that the prospective contractor is responsible, i.e., capable of performing the contract. Before making such a determination, the contracting officer must have or obtain sufficient information to establish that the prospective contractor: Has adequate financial resources; or the ability to obtain such resources; is able to comply with required delivery schedule; has a satisfactory record of performance; has a satisfactory record of integrity; and is otherwise qualified and eligible to receive an award under appropriate laws and regulations. If such information is not readily available to the contracting officer, it is obtained through a preaward survey conducted by the contract administration office or another organization designated by the agency to conduct the surveys. The necessary data is collected from available data or through plant visits, phone calls, and correspondence in detail commensurate with the dollar value and complexity of the procurement. This clearance covers the information that prospective contractors must provide to ensure proper completion of the following preaward survey forms prescribed by the Federal Acquisition Regulation (FAR):

- Standard Form 1403 Preaward Survey of Prospective Contractor (General)
- Standard Form 1404 Preaward Survey of Prospective Contractor (Technical)
- Standard Form 1405 Preaward Survey of Prospective Contractor (Production)
- Standard Form 1406 Preaward Survey of Prospective Contractor (Quality Assurance)
- Standard Form 1407 Preaward Survey of Prospective Contractor (Financial Capability)
- Standard Form 1408 Preaward Survey of Prospective Contractor (Accounting System)

C. Common Form

This information collection is being converted into a common form. The General Services Administration is the sponsor agency of this common form. All executive agencies covered by the Federal Acquisition Regulation will use this common form. Each executive agency will report their agency burden separately, and the reported information will be available at Reginfo.gov.

D. Annual Burden

General Services Administration

Respondents: 107.
Total Annual Responses: 107.
Total Burden Hours: 2,568.

E. Public Comment

A 60-day notice was published in the Federal Register at 85 FR 55290 on September 4, 2020. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 9000–0011, Preaward Survey Forms (Standard Forms 1403, 1404, 1405, 1406, 1407, and 1408).

William F. Clark,
Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–2552–10]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 January 11, 2021.

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:

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. 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).

CM–2552–10 Hospital and Health Health Care Complex Cost Report

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: Revision of a currently approved collection; Title of Information Collection: Hospital and Health Care Complex Cost Report; Use: CMS requires the Form CMS–2552–10 to determine a hospital’s reasonable cost incurred in furnishing medical services to Medicare beneficiaries and calculate the hospital reimbursement. Hospitals paid under a prospective payment system (PPS) may receive reimbursement in addition to the PPS for hospital-specific adjustments such as Medicare reimbursable bad debts, disproportionate share, uncompensated care, direct and indirect medical education costs, and organ acquisition costs.

CMS uses the Form CMS–2552–10 for rate setting; payment refinement activities, including developing a hospital market basket; and Medicare Trust Fund projections; and to support program operations. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the hospital cost report data to calculate Medicare margins (a measure of the relationship between Medicare’s payments and providers’ Medicare costs) and analyze data to formulate Medicare Program recommendations to Congress.

We welcome comments on our burden estimates for the information collection request. Form Number: CMS–2552–10 (OMB control number: 0938–0050); Frequency: Occasionally; Affected Public: Private Sector; Business or other for-profit and not-for-profit institutions; Number of Respondents: 6,013; Total Annual Responses: 6,013; Total Annual Hours: 4,173,022. (For policy questions regarding this collection contact Gail Duncan at 410–786–7278.)


William N. Parham, III, Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–24948 Filed 11–9–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1264]

Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs.” This guidance recommends approaches that sponsors of clinical trials intended to support a new drug application or a biologics license application can take to increase enrollment of underrepresented populations in their clinical trials. This guidance is being issued, in part, to satisfy the mandates of the FDA Reauthorization Act of 2017 (FDARA). This guidance finalizes the draft guidance of the same title issued on June 7, 2019.


ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows: Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: https://www.regulations.gov. Follow the