DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10148]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by September 27, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 OR Email: OIRA_submission@omb.eop.gov

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. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT:
Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 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:

Information Collection
1. Type of Information Collection Request: Revision of the currently approved collection.; HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form; Use: The authority for administering and enforcing compliance with the non-privacy/security Health Insurance Portability and Accountability Act (HIPAA) rules has been delegated to the Centers for Medicare & Medicaid Services (CMS). At present, CMS’ compliance and enforcement activities are primarily complaint-based. Although our enforcement efforts are focused on investigating complaints, they may also include conducting compliance reviews to determine if a covered entity is in compliance. Potential violations can come through a complaint form or a compliance review.

This standard form collects identifying and contact information of the complainant, as well as, the identifying and contact information of the filed against entity (FAE). This information enables CMS to respond to the complainant and gather more information if necessary, and to contact the FAE to discuss the complaint and CMS’ findings.

In addition to the identifying and contact information, the standard form collects a summary which outlines the nature of the complaint. This summary is used to determine the validity of the complaint, and to categorize the complaint as related to transactions, standards, code sets, unique identifiers, and/or operating rules. This ensures the appropriate direction of the complaint process and enables CMS to produce accurate reports regarding complaint activity.

The revision form associated with this submission adds an option for filing complaints under Unique Identifier and Operating Rules. It also requests an email address for filed against entities, if available.

The 60-day notice published on March 29, 2018. It must be noted that the files CMS posted on its PRA website were the incorrect files. CMS acknowledges and apologizes for this oversight. To allow the public extra time to review the correct form, CMS is extending the 30-day comment period to a 45-day comment period. It should be noted that where possible and practical, CMS reviewed and responded to commenters concerns that would still be present in the corrected version of the document. Form Number: CMS–10148 (OMB Control number: 0938–0949); Frequency: Occasionally; Affected Public: Individuals; Number of Respondents: 125; Total Annual Responses: 125; Total Annual Hours: 125. (For policy questions regarding this collections contact Kevin Stewart at 410–786–6149.)
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9110–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April through June 2018

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other Federal Register notices that were published from April through June 2018, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda | Contact | Phone Number
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I CMS Manual Instructions | Ismael Torres | (410) 786-1864
II Regulation Documents Published in the Federal Register | Terri Plumb | (410) 786-4481
III CMS Rulings | Tiffany LaFerry | (410) 786-7548
IV Medicare National Coverage Determinations | Wanda Belle, MPA | (410) 786-7491
V FDA-Approved Category B IDEs | John Manlove | (410) 786-6877
VI Collections of Information | William Parham | (410) 786-4669
VII Medicare Approved Carotid Stent Facilities | Sarah Fulton, MHS | (410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites | Sarah Fulton, MHS | (410) 786-2749
IX Medicare’s Active Coverage-Related Guidance Documents | JoAnna Baldwin, MS | (410) 786-7205
X One-time Notices Regarding National Coverage Provisions | Jo Anna Baldwin, MS | (410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites | Stuart Caplan, RN, MAS | (410) 786-8564
XII Medicare Approved Ventricular Assist Device (Destination Therapy) Facilities | Linda Gousis, JD | (410) 786-8616
XIII Medicare Approved Lung Volume Reduction Surgery Facilities | Sarah Fulton, MHS | (410) 786-2749
XIV Medicare Approved Bariatric Surgery Facilities | Sarah Fulton, MHS | (410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials | Stuart Caplan, RN, MAS | (410) 786-8564
All Other Information | Annette Brewer | (410) 786-6580

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the Federal Register.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at http://www.cms.gov/manuals.


Olen D. Clybourn,
Deputy Director, Office of Strategic Operations and Regulatory Affairs.