

“suppliers” for purposes of this agreement. *Form Number:* CMS–460 (OMB control number: 0938–0373); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 14,029; *Number of Responses:* 14,029; *Total Annual Hours:* 3,507. (For questions regarding this collection contact Mark G. Baldwin at 410–786–8139.)

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–10749 and CMS–8550]**

#### 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 (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 September 2, 2025.

**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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**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**).

**CMS–10749** National Plan and Provider Enumeration System Supplemental Data Collection  
**CMS–8550** Registration for Eligible Ordering and Referring Physicians and Non-Physician Practitioners

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 Collections

1. *Type of Information Collection*  
*Request:* Reinstatement without change of a previously approved collection;  
*Title of Information Collection:* National Plan and Provider Enumeration System (NPPES) Supplemental Data Collection;  
*Use:* The adoption by the Secretary of HHS of the standard unique health identifier for health care providers is a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The unique identifier is to be used on standard transactions and may be used for other lawful purposes in the health care system. The CMS Final Rule published on January 23, 2004 adopts the National Provider Identifier (NPI) as the standard unique health identifier for health care providers. Health care providers that are covered entities under HIPAA must apply for and use NPIs in standard transactions. The law requires that data collection standards for these measures be used, to the extent that it is practical, in all national population health surveys. It applies to self-reported optional information only. The law also requires any data standards published by HHS to comply with standards created by the Office of Management and Budget (OMB).

The web based optional data fields can be seen in Appendix A1: Data Collected for the Office of Minority and Appendix A2: Data collected for the 21st Century Cures Act, interoperability. The standards apply to population health surveys sponsored by HHS, where respondents either self-report information or a knowledgeable person responds for all members of a household. HHS is implementing these data standards in all new surveys. *Form Number:* CMS–10749 (OMB control number: 0938–1427); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 545,648; *Total Annual Responses:* 545,648; *Total Annual Hours:* 92,760. (For policy questions regarding this collection contact Nora Simmons at 410–786–1981.)

2. *Type of Information Collection*  
*Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Registration Application; *Use:* Various sections of the Social Security Act (Act), the United States Code (U.S.C.), Internal Revenue Service Code (Code) and the Code of Federal Regulations (CFR) require providers and suppliers to furnish information concerning the

amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before allowing payment. The principal function of the CMS–855O is to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications to enroll in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services. The CMS–855O allows a physician or other eligible professional to enroll in Medicare without approval for billing privileges.

The collection and verification of this information protects our beneficiaries from illegitimate providers/suppliers. These procedures also protect the Medicare Trust Funds against fraud. The CMS–855O gathers information that allow Medicare contractors to ensure that the physician or eligible professional is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. Furthermore, the data collected also ensures that the applicant has the necessary credentials to order and certify health care services. This is the sole instrument implemented for this purpose.

*Form Number:* CMS–855O (OMB control number 0938–1135); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits), State, Local, or Tribal Governments; *Number of Respondents:* 2,250; *Number of Responses:* 2,250; *Total Annual Hours:* 1,125. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302).

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2025–N–1108]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; 510(k) Third-Party Review Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is

announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the 510(k) Third-Party Review Program.

**DATES:** Either electronic or written comments on the collection of information must be submitted by September 2, 2025.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 2, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### 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–2025–N–1108] for “Agency Information Collection Activities; Proposed Collection; Comment Request; 510(k) Third-Party Review Program.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- **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.govinfo.gov/content/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