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 and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Songe Baek, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22., Silver Spring, MD 20993–0002, 240–402–6117.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Symptomatic Nonerosive Gastroesophageal Reflux Disease: Developing Drugs for Treatment.''

The draft guidance provides FDA's current recommendations on clinical trials for drugs being developed for the treatment of sGERD in adults, including considerations for eligibility criteria, trial design features, efficacy evaluations, and safety assessments. This draft guidance details endpoint assessments and analyses of collected data to support a determination of efficacy for the indication of the treatment of sGERD, to promote consistency and interpretability in the assessment of efficacy within and across development programs. This draft guidance does not address the development of drugs for the treatment of erosive esophagitis, Barrett's esophagus, pathological hypersecretory conditions (*e.g.,* Zollinger-Ellison syndrome), peptic ulcer disease, or sGERD in pediatric patients.

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 ''Symptomatic Nonerosive Gastroesophageal Reflux Disease: Developing Drugs for Treatment.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

This draft guidance refers to collections of information from ''individuals under treatment or clinical examination in connection with research,'' which are not subject to review by the Office of Management and Budget (OMB) under 5 CFR 1320.3(h)(5). This draft guidance also refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 50 pertaining to protection of human subjects have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 312 pertaining to the investigational new drug application pathway, which includes clinical trials and clinical trial design, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologic license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Teaching Health Center Graduate Medical Education Program Reconciliation Tool, OMB No. 0915–0342—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than October 17, 2025.

ADDRESSES: Written comments and recommendations for the proposed 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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Reconciliation Tool OMB No. 0915–0342—Revision.

Abstract: The THCGME program, authorized by Section 340H of the Public Health Service Act, was established by Section 5508 of Public Law 111–148. The Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4) provides continued funding for the THCGME program. THCGME payments support training for primary care residents in community-based ambulatory patient care settings. HRSA collects information from THCGME program award recipients using an OMB-approved reconciliation tool. HRSA seeks to renew this approved information collection. The only changes to the information collection are increases in the number of respondents due to an increase in the number of program award recipients from 83 to 87, as well as an increase in the average burden per response based on feedback received during the 60-day comment period (see below for more detail).

A 60-day notice was published in the **Federal Register** on May 16, 2025, vol. 90, No. 94; pp. 21051–52. There were nine public comments. Below is a summary of key themes raised in the comments and HRSA's response:

- All commenters expressed strong support of HRSA's use of the THCGME Program Reconciliation Tool to collect data from participating teaching health centers (THCs). They state that this data collection is essential for ensuring proper reconciliation of payments which promotes accountability across THCGME program-supported THCs.
- Commenters stated that the burden hour estimate does not correctly reflect the time required to complete the reconciliation tool and urged HRSA to revise the burden hours.
- Commenters encouraged HRSA to explore potential refinements to the tool to reduce unnecessary manual steps while maintaining program integrity and accountability.
- Commenters leveraged the **Federal Register** notice comment period as an opportunity to express support for program expansion, changes to recoupment methodology, or other program policies.
- Some commenters proposed a collaboration with other federal graduate medical education funding agencies to standardize funding frameworks to ease administrative burden and ensure compliance with funding regulations.

HRSA directly responded to each stakeholder who submitted comments, acknowledging the considerations raised. HRSA recognizes and appreciates the amount of work that existing grant recipients put into completing the Reconciliation Tool annually. HRSA provides the average burden hours based on grant recipients' responses. Grant recipient burden hours can vary greatly based on the number of their awarded resident Full-Time Equivalents (FTEs). Given the comment, HRSA will adjust the burden hours to reflect grant recipients with smallest and largest awarded resident FTEs within the calculated average. Due to the significant differences among the THCs, HRSA will consider providing a range of burden hours on future OMB documents to reflect this marked difference. Determining the appropriate burden range will require additional inquiries from grant recipients of varying sizes. For items outside the scope of this notice, such as a standardized funding framework across federal graduate medical education funding agencies, program expansion, recoupment methodology or other program policies, HRSA will take these comments into consideration for future policy development.

Need and Proposed Use of the Information: THCGME program payments are prospective payments, and the statute provides for a reconciliation process, through which overpayments may be recouped, and adjustments made, at the end of the fiscal year. This data collection instrument will gather information relating to the number of resident FTEs in THC training programs to reconcile payments.

Likely Respondents: The likely respondents to the THCGME Reconciliation Tool are THCGME program award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
THCGME Reconciliation Tool	87	1	87	5	435
Total	87		87		435

Maria G. Button,

Director, Executive Secretariat.

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