

new drug application became effective was on October 20, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* April 17, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for TAVALISSE (NDA 209299) was initially submitted on April 17, 2017.

3. *The date the application was approved:* April 17, 2018. FDA has verified the applicant's claim that NDA 209299 was approved on April 17, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19993 Filed 9–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Health Center Program Scope of Project and Telehealth Policy Information Notice

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

ACTION: Request for public comment on Draft Health Center Program Scope of Project and Telehealth Policy Information Notice.

SUMMARY: HRSA is inviting public comment on the Draft Health Center Program Scope of Project and Telehealth Policy Information Notice (Telehealth PIN). The purpose of the Telehealth PIN is to establish policy for health centers that provide services via telehealth within the HRSA-approved scope of project. The Telehealth PIN also describes considerations and criteria health centers must meet for providing services via telehealth within the Health Center Program scope of project.

The Health Center Program is authorized by section 330 of the Public Health Service Act, 42 U.S.C. 254b. HRSA provides federal award funding to health centers to deliver required primary care and additional health services to medically underserved areas and populations. HRSA also certifies entities that it has determined to meet section 330 requirements as Health Center Program look-alikes. Health centers provide required primary care and additional health services to residents of the area served by the health center.

Each health center is responsible for maintaining its operations, including developing and implementing its own operating procedures for providing health services through telehealth, in compliance with all Health Center Program requirements and all other applicable federal, state, and local laws and regulations.¹

Health centers are increasingly using telehealth as a means of delivering required and additional services to health center patients. Providing health care via telehealth² can increase patient access and improve clinical outcomes, quality of care, continuity of care, and reduce the need for hospitalization.

¹ 42 CFR 51c.304(d)(3)(v).

² HRSA defines telehealth as the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, health administration, and public health.

Within the context of the Health Center Program scope of project, telehealth is not a service or a service delivery method requiring specific HRSA approval; rather, telehealth is a mechanism or means for delivering a health service(s) to health center patients using telecommunications technology or equipment.

DATES: Submit comments no later than November 14, 2022.

ADDRESSES: The PIN is available at the Scope of Project and Telehealth PIN Public Comments web page. Written comments should be submitted through the HRSA Bureau of Primary Health Care Contact Form (<https://hrsa.force.com/feedback/s/policy-information-notice>), by November 14, 2022.

FOR FURTHER INFORMATION CONTACT:

Jennifer Joseph, Director, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; email: jjoseph@hrsa.gov; telephone: 301–594–4300; fax: 301–594–4997.

SUPPLEMENTARY INFORMATION: HRSA provides grants to eligible applicants under section 330 of the PHS Act, as amended (42 U.S.C. 254b), to support the delivery of preventive and primary care services to the nation's underserved individuals and families. HRSA also certifies eligible applicants under the Health Center Look-Alike Program (see sections 1861(aa)(4)(B) and 1905(l)(2)(B) of the Social Security Act). Look-alikes do not receive Health Center Program funding but must meet the Health Center Program statutory and regulatory requirements. Nearly 1,400 Health Center Program-funded health centers and approximately 100 Health Center Program look-alike organizations collectively operate over 14,000 service delivery sites that provide care to over 30 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. Note that for the purposes of this document, the term “health center” refers to entities that receive a federal award under section 330 of the PHS Act, as amended, as well as subrecipients and organizations designated as look-alikes, unless otherwise stated.

Section A of the Telehealth PIN includes considerations for health centers delivering services via telehealth within the HRSA-approved scope of project. Each health center is responsible for maintaining its operations, including developing and implementing its own operating procedures for telehealth, in compliance with all Health Center Program

requirements and all other applicable federal, state, and local laws and regulations. Among other considerations, health centers using telehealth to deliver in-scope services to health center patients are responsible for addressing the considerations described in the policy.

Section B of the Telehealth PIN includes criteria for health centers delivering services via telehealth within the HRSA-approved scope of project. PIN 2008–01: Defining Scope of Project and Policy for Requesting Changes provides the parameters of what may be included in a health center's scope of project and how to accurately document a health center's scope of project. Health centers may deliver in-scope services via telehealth to individuals who have previously presented for care at a health center site and to individuals who have not previously presented for care at a health center site. Services delivered via telehealth generally would be within the scope of the health center project if all of the criteria are met as described in the policy.

Diana Espinosa,
Deputy Administrator.

[FR Doc. 2022–19933 Filed 9–14–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information
Collection Request Title: The Teaching Health Center Graduate Medical Education Program Eligible Resident/Fellow FTE Chart, OMB No. 0915–0367—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and

Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 17, 2022.

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 more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Eligible Resident/Fellow FTE Chart OMB No. 0915–0367—Revision

Abstract: The THCGME Program, section 340H of the Public Health Service Act, was established by section 5508 of Public Law 111–148. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) and the American Rescue Plan Act of 2021 (Pub. L. 117–2) provided continued funding for the THCGME Program. The THCGME Program awards payment for both direct and indirect expenses to support training for primary care residents in community-based ambulatory patient care settings. The THCGME Program Eligible Resident/Fellow FTE Chart, published in the THCGME Notice of Funding Opportunity (NOFO), is a means for determining the number of eligible resident/fellow full-time equivalents (FTEs) in an applicant's primary care residency program. The FTE Chart revisions will now collect the number of resident/fellow FTEs from previous academic years and will further clarify the number of resident/fellow FTEs positions requested with the NOFO application.

A 60-day notice published in the **Federal Register** on June 24, 2022, vol. 87, No. 121; pp. 37876. There were no public comments.

Need and Proposed Use of the Information: The THCGME Program Eligible Resident/Fellow FTE Chart requires applicants to provide: (a) data related to the size and/or growth of the residency program over previous academic years, (b) the number of residents enrolled in the program during the baseline academic year, and (c) a projection of the program's proposed expansion over the next 5 academic years. It is imperative that applicants complete this chart to quantify the total supported residents. THCGME funding is used to support expanded numbers of residents in existing residency programs, to establish new residency training programs, or to maintain filled positions at existing residency training programs. Utilization of a chart to gather this important information has decreased the number of errors in the eligibility review process resulting in a more accurate review and funding process, and this ICR comports with the regulatory requirement imposed by 45 CFR 75.206(a) “*Standard application requirements, including forms for applying for HHS financial assistance, and state plans*”.

Likely Respondents: Teaching Health Centers applying for THCGME funding through a THCGME NOFO process, which may include new applicants and existing awardees.

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: