actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, Empaveli (pegcetacoplan) indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria. Subsequent to this approval, the USPTO received patent term restoration applications for Empaveli (U.S. Patent Nos. 10,035,822; 10,125,171; and 10,875,893) from Apellis Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 21, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Empaveli represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Empaveli is 2,501 days. Of this time, 2,258 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 11, 2014. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 11, 2014.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 14, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for Empaveli (NDA 215014) was initially submitted on September 14, 2020.

3. *The date the application was approved:* May 14, 2021. FDA has verified the applicant's claim that NDA 215014 was approved on May 14, 2021.

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 applications for patent extension, this applicant seeks 137 days, 545 days, or 579 days 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: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26255 Filed 11–28–23; 8:45 am]

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; Evidence Based Telehealth Network Program Measures

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 December 29, 2023.

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 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 Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Evidence Based Telehealth Network Program Measures, OMB No. 0906–0043—Revision.

Abstract: This ICR is for a revision of a currently approved information collection of measures for the Office for the Advancement of Telehealth's (OAT) Evidence Based Telehealth Network Program, under which OAT administers cooperative agreements in accordance with section 330I of the Public Health Service Act (42 U.S.C. 254c–14), as amended. The purpose of this program is to fund evidence-based projects that utilize telehealth technologies through telehealth networks to expand access to, and improve access to and the quality of, health care services. This program will work to help assess the effectiveness of evidence-based practices with the use of telehealth for patients, providers, and payers.

In the Evidence-Based Telehealth Network Program Report, the adjusted data collection instrument includes the addition, removal, and revision of measures, with 27 total data elements addressing patient encounter information. The current measures focus on behavioral health and the proposed adjusted measures allow for the inclusion of broader health care services and expanded outcome measures. Five data elements were updated to specify data collection that allows for deeper understanding of outcomes related to socioeconomic indicators. The estimated burden for the Evidence-Based Telehealth Network Program

Report has decreased since the data collection frequency is changing from monthly to quarterly. In addition, the information collected from grantees in the Performance Improvement and Measurement System more closely aligns measures with the Notice of Funding Opportunity and will assist in clarifying program measures and impact. These adjustments allow OAT to gain a more thorough understanding of how to utilize telehealth technologies through telehealth to improve access to, and improve the quality of, health care services.

A 60-day notice published in the **Federal Register** on August 18, 2023, 88 FR 56640–41. There were no public comments, but OAT made minor adjustments to the numbering, wording, and some categories on the Rural Telehealth Research Center Data Dictionary and accompanying Direct-to-Consumer Telehealth Evidence Collection tool to increase ease of use.

Need and Proposed Use of the Information: The measures will enable HRSA and OAT to capture data that illustrate the impact and scope of federal funding along with assessing these efforts. The measures cover the principal topic areas of interest to OAT, including: (1) population demographics, (2) access to health care, (3) cost savings and cost-effectiveness, and (4) clinical outcomes.

Likely Respondents: The likely respondents are award recipients of the Evidence Based Telehealth Network Program.

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: instrument name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Evidence-Based Telehealth Network Program Report	11	4	44	31	1,364
Telehealth Performance Measurement Report	11	1	11	5	55
Total	*11	.....	55	.....	1,419

*HRSA estimates 11 unique respondents, each completing the two forms.

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–26248 Filed 11–28–23; 8:45 am]

BILLING CODE 4165–15–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; Rural Health Network Development Program Performance Improvement Measurement System, OMB No. 0906–0010–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 December 29, 2023.

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 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 Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Health Network Development Program Performance Improvement Measurement System, OMB No. 0906–0010–Revision.

Abstract: The Rural Health Network Development (RHND) program is authorized under section 330A(f) of the Public Health Service Act (42 U.S.C. 254c(f)). The purpose of this program is to support integrated health care networks that collaborate to achieve efficiencies; expand access to, coordinate, and improve the quality of basic health care services and associated health outcomes; and strengthen the rural health care system as a whole. The program supports networks as they address gaps in service, enhance systems of care, and expand capacity of the local health care system.

RHND-funded programs promote population health management and the transition towards value-based care through diverse network participants that include traditional and nontraditional network partners. Evidence of program impact demonstrated by outcome data and program sustainability are integral components of the program. This is a 4-year competitive program for networks composed of at least three participants that are existing health care providers. At least 66 percent of network