notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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 Parham at (410) 786–4669.

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:

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Patient Access through Application Programming Interfaces (API); *Use:* This final rule is the first phase of policies centrally focused on advancing interoperability and patient access to health information using the authority available to the Centers for Medicare & Medicaid Services (CMS). We believe this is an important step in advancing interoperability, putting patients at the center of their health care, and ensuring they have electronic access to their health information. We are committed to working with stakeholders to solve the issue of interoperability and getting patients access to information about their health care, and we are taking an active approach to move participants in the health care market toward interoperability and the secure and timely exchange of electronic health information by adopting policies for the Medicare and Medicaid programs, the Children's Health Insurance Program (CHIP), and qualified health plan (QHP) issuers on the individual market Federally-facilitated Exchanges (FFEs). For purposes of this rule, references to QHP issuers on the FFEs excludes issuers offering only stand-alone dental plans (SADPs). Likewise, we are also excluding QHP issuers only offering QHPs in the Federally-facilitated Small Business Health Options Program Exchanges (FF–SHOPs) from the provisions of this rule. This rule requires these impacted payers to maintain and use standards-based APIs to make certain information available to enrollees. CMS regulations at 42 CFR 417.414, 417.416, 422.112(a)(1)(i), and 422.114(a)(3)(ii) require that all Medicare Advantage organizations (MAOs) offering coordinated care plans, network-based private fee-for-service (PFFS) plans, and as well as section 1876 cost organizations, maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. To enforce this requirement, CMS regulations at § 422.116 outline network adequacy criteria which set forth the minimum number of providers and maximum travel time and distance from enrollees to providers, for required provider specialty types in each county in the United States and its territories. Organizations must be in compliance with the current CMS network adequacy criteria guidance, which is updated and published annually on CMS's website. This collection of information is essential to appropriate and timely compliance monitoring by CMS, in order to ensure that all active contracts offering network-based plans maintain an adequate network.

This notice originally published on August 22, 2024 (89 FR 67943), but CMS was delayed in submitting it to OMB. For that reason, we are republishing this notice and the associated information collection request will be submitted upon to OMB upon publication of this notice. *Form Number:* CMS–10767 (OMB control number: 0938–1412); *Frequency:* Occasionally; *Affected Public:* Private sector; *Number of Respondents:* 345; *Number of Responses:* 345; *Total Annual Hours:* 589,950. (For policy questions regarding this collection contact Lorraine Doo at 410–786–6597.)

William N. Parham, III,

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

[FR Doc. 2024–28515 Filed 12–5–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Healthy Marriage and Responsible Fatherhood Local Evaluation Final Report (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) in the Administration for Children and Families (ACF), U.S. Department of Health and Human Services is requesting approval of the Healthy Marriage and Responsible Fatherhood (HMRF) Final Report Templates. HMRF grant programs are required to submit a final report describing their local evaluation analyses and findings. This request includes guidance for grant recipients in the form of templates. Information will inform technical assistance to support grantees in developing and submitting the final reports to ACF to fulfill a grant requirement.

DATES: *Comments due* January 6, 2025. OMB must decide about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.*

Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Since 2005, Congress has authorized dedicated funding for discretionary awards from ACF's Office of Family Assistance to support HMRF programs. Per the 2020 HMRF Notice of Funding Opportunities issued by ACF, HMRF grant recipients that are carrying out local evaluations are required to submit a final evaluation report to ACF at the end of their grant. The final reports must document the research questions, measures, study design, planned and actual implementation of the program, analytic methods for their evaluation, and evaluation findings.

OPRE is conducting the HMRF Local Evaluation Technical Assistance (LETA) projects, jointly referred to as the HMRF–LETA projects, to support federally funded programs in evaluating their healthy relationship and family stability services to adult couples, adult individuals, fathers, and youth. As part of the HMRF–LETA project, grant recipients receive technical assistance to support planning and executing a local evaluation and analyzing and reporting local evaluation findings.

The purpose of the current information collection request is to provide standardized report templates and table shells to grant recipients to document their evaluation's analysis and findings. A structured final report template will facilitate grant recipients' efficient and consistent reporting of evaluation findings in their final reports. The completed draft reports will be reviewed by the HMRF–LETA teams to determine whether the analysis and reports meet standards set by ACF, and to develop recommendations for grant recipients to improve the analysis and reports before final submission to ACF. Grant recipients will finalize and submit their final reports to ACF, as required. This request includes the time to develop and submit the reports.

Respondents: The respondents are HMRF grant recipients conducting a local evaluation. There are currently 79 grant recipients conducting local evaluations: 50 evaluations using descriptive designs (''descriptive evaluations'') and 29 evaluations using impact designs (''impact evaluations'').

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Descriptive Evaluation Final Report Template	50	1	40	2,000
Impact Evaluation Final Report Template	29	1	30	870
Impact Evaluation Final Report Table Shells	29	1	10	290

Estimated Total Annual Burden Hours: 3,160.

Authority: 42 U.S.C. 603(a)(2).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–28555 Filed 12–5–24; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2033]

Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' Accelerated approval is one of FDA's expedited programs intended to facilitate and expedite development and review of certain drugs and biological products for serious or life-threatening conditions. This guidance provides information on FDA's policies and procedures for the accelerated approval program, including discussions of which products may be candidates for accelerated approval, the standards for granting accelerated approval, and the procedures for withdrawing accelerated approval. When finalized, this draft guidance will replace the accelerated approval-related content in the final guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' issued on May 30, 2014 (the 2014 final guidance). Additional programs to expedite product development are covered in the 2014 final guidance as well as other guidances.

DATES: Submit either electronic or written comments on the draft guidance by February 4, 2025. to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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