DATES: Comments must be received by November 25, 2019.

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, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

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–855 Medicare Enrollment Application for Clinics/Group Practices and Other Suppliers

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 Collection

1. Type of Information Collection Request: New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Enrollment Application for Clinics/Group Practices and Other Suppliers Revision; *Use:* The primary function of the CMS–855B Medicare enrollment application for suppliers, also known as Health Diagnosing and Treating Practitioners, is to gather information from the supplier that tells CMS who the supplier is, whether the supplier meets certain qualifications to be a Medicare health care provider or supplier, where the supplier practices or renders services, and other information necessary to establish correct claims payments.

The CMS–855B form includes an attachment for Opioid Treatment Programs (OTPs). This attachment is only used to capture the OTP personnel and consists of limited data fields (name, Social Security Number, National Provider Identifier, and license number) in response to the ''SUPPORT for Patients and Communities Act'' that was signed into law on October 24, 2018. This legislation was designed to alleviate the nationwide opioid crisis by: (1) Reducing the abuse and supply of opioids; (2) helping individuals recover from opioid addiction and supporting the families of these persons; and (3) establishing innovative and long-term solutions to the crisis. Section 2005 of the SUPPORT Act establishes a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) beginning on or after January 1, 2020. *Form Number:* CMS–855B (OMB control number: 0938–New); *Frequency:* Annually; *Affected Public:* Individuals and households; *Number of Respondents:* 327,696; *Total Annual Responses:* 327,696; *Total Annual Hours:* 522,041. For questions regarding this collection contact Kim McPhillips at 410–786–5374.

Dated: September 20, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–20871 Filed 9–25–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; State Court Improvement Program (OMB #0970–0307)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a three-year extension of the Court Improvement Program (CIP) Program Instruction, Strategic Plan Template, and Annual CIP Self-Assessment (OMB #0970–0307, expiration 9/30/2019). There are minimal updates to the form to reflect new legislation. The collections are necessary to continue operating the program in compliance with congressional reauthorization.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning 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 directly to the following:

Office of Management and Budget Paperwork Reduction Project.

Email: OIRA_SUBMISSION@OMB.EOP.GOV.

Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed collection is a continuation of the current collection and comprised of two components: An application including a strategic plan that is due once every five years, and an annual self-assessment. The next collection (annual self-assessment) will be due June 30, 2020. The next five-year application will be due in 2021.

Respondents: We anticipate the highest state court of every state, Puerto Rico and the US Virgin Islands to respond. All 52 jurisdictions currently participate in the program.

ANNUAL BURDEN ESTIMATES

Collection	Year	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Complete Application	2021	52	1	92	4784
Complete Program Assessment Report	2020	52	1	77	4004
	2021	52	1	77	4004
	2022	52	1	77	4004
Total					16,796

Estimated Total Annual Burden Hours: 4004 hours in 2020 and 2022; 8788 hours in 2021 (when both the self-assessment and the 5-year application are due within the year)

Authority: Sec. 50761, P.L. 115–123.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–20890 Filed 9–25–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3935]

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Global Meeting on E8(R1) Guideline on General Considerations for Clinical Trials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting entitled ''International Council on Harmonisation (ICH) Global Meeting on E8(R1) Guideline on General Considerations for Clinical Trials.'' The purpose of the public meeting is to provide information on the draft revised E8(R1) Guideline ''General Considerations for Clinical Trials'' (ICH E8 Guideline) following the closing of the FDA comment period and closing of the regional consultations conducted in other ICH regions. The ICH E8 Guideline is being revised to provide updated guidance that is both appropriate and flexible enough to address the increasing diversity of clinical trial designs and data sources being employed to support regulatory and other health policy decisions, while retaining the underlying principles of human subject protection and data quality.

DATES: The public meeting will be held on Thursday, October 31, 2019, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. The meeting will also be broadcast on the web, allowing participants to join in person or via the web. For those who will attend in person, the entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* For those who register to attend the public meeting remotely via the webcast, a link to access the webcast will be emailed in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–4548, Amanda.Roache@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory requirements for safety and effectiveness. One of the goals of harmonization is to identify and then reduce regional differences in technical regulatory requirements for pharmaceutical products while preserving a consistently high standard for drug efficacy, safety, and quality. This is accomplished through the development of internationally harmonized guidelines developed through a process of scientific consensus with regulatory and industry experts. FDA participates in ICH as a founding member and implements all ICH guidelines as FDA guidance.

In 2015, ICH was reformed to establish it as a true global initiative and to expand beyond the previous ICH members. More involvement from regulators around the world is expected, as they join counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH regulatory members and observers. Expanded involvement is also anticipated from global regulated pharmaceutical industry parties, joining as ICH industry members and observers. The reforms built on a 25-year track record and have allowed ICH to continue its successful delivery of harmonized guidelines for global pharmaceutical development and their regulation.

The ICH E8 Guideline sets out general principles on the conduct of clinical trials, was adopted in 1997, and has not undergone revision. Since its adoption, clinical trial design and conduct have become more complex, impacting the time and cost required to develop drugs. A wide range of both trial designs and data sources play a role in drug development and are not adequately addressed in the original ICH E8 Guideline. Approaches are needed for