following areas where, as of the date of this final notice, ACHC has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Revising the compliant policies and processes to align with the State Operations Manual, Chapter 5 guidance. In particular, the Administrative Review Offsite Investigation process to align with the triage process to track and trend for potential focus areas during the next onsite survey or complete an onsite complaint investigation.

++ Clarifying the quantifying data surrounding equipment and maintenance logs, specifically the equipment review. The survey reports or notes need to identify the number of logs reviewed, date or timeframes.

++ Providing surveyor training on documentation reviews and the process for verifying the completeness of the facility request.

++ Reinforcing and providing education to facility surveyors to request Dialysis Facility Reports, the reports provide aggregate data regarding laboratory values, demographic information, mortality rates, hospitalizations, infections, etc., which may assist the surveyors during the review of patient medical records.

++ Developing additional surveyor training for verifying all elements required for the CMS emergency preparedness requirements.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve ACHC as a national accreditation organization for ESRD facilities that request participation in the Medicare program. The decision announced in this final notice is effective April 11, 2023 through April 11, 2029 (6 years). In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years.

While ACHC has taken actions based on the findings annotated in section V.A., of this final notice, (Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under § 488.8, we will continue ongoing review of ACHC's ESRD survey substance and processes. In keeping with CMS's initiative to increase AO oversight broadly, and ensure that our requested revisions by ACHC are completed, CMS expects more frequent review of ACHC's activities in the future.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J.Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: March 15, 2023.

Evell J. Barco Holland,

Federal Register Liaison, Center for Medicare & Medicaid Services.

[FR Doc. 2023–05761 Filed 3–20–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10847]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 22, 2023.

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, 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 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–10847 Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act

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:* Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act; *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program (the ''Negotiation Program''), codified in sections 1191 through 1198 of the Social Security Act (''the Act''). The Act establishes the Negotiation Program to negotiate maximum fair prices (''MFPs''), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the first year of the Negotiation Program, the Secretary of Health and Human Services (the ''Secretary'') will select 10 Part D high expenditure, single source drugs for negotiation.

The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. These data include the data required to calculate non-FAMP for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A), and the negotiation factors outlined in section 1194(e)(1) for the purpose of formulating offers and counteroffers process pursuant to section 1193(a)(4)(B). Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in section 1194(e)(1) and 1193(a)(4) must be submitted by the Primary Manufacturer.

Section 1194(e)(2) requires CMS to consider certain data on alternative treatments to the selected drug. Because the statute does not specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in 1194(e)(2) to ensure consideration of such factors. Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may optionally submit evidence about alternative treatments. *Form Number:* CMS–10847 (OMB control number: 0938–New); *Frequency:* Occasionally; *Affected Public Sector:* Individuals and Households, Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 3,300; *Total Annual Responses:* 3,300; *Total Annual Hours:* 17,000. (For policy questions regarding this collection contact Lara Strawbridge at 410–786–6880).

Dated: March 16, 2023.

William N. Parham, III,

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

[FR Doc. 2023–05784 Filed 3–20–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; SOAR (Stop, Observe, Ask, Respond) to Health and Wellness Training (SOAR) Demonstration Grant Program Data (NEW COLLECTION)

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new grant program: SOAR (Stop, Observe, Ask, Respond) to Health and Wellness Training (SOAR) Demonstration Grant Program Data.

DATES: *Comments due within 30 days of publication.* OMB must make a decision 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 *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The SOAR Demonstration Grant Program was developed in response to the Trafficking Victims Protection Act (TVPA) of 2000 (Pub. L. 106–386), § 106(b), as amended (22 U.S.C. 7104(b)(1)) and 22 U.S.C. 7105(b)(1)(B), which calls on agencies to ''increase public awareness of the dangers of trafficking and the protections that are available for victims of trafficking'' and provide ''services to assist potential victims of severe forms of trafficking in persons.'' The program's goal is to fund the implementation of SOAR trainings and capacity building efforts to identify, treat, and respond to patients or clients who have experienced severe forms of human trafficking as defined by the TVPA of 2000, as amended, among their patient or client population. SOAR is a nationally recognized, accredited training program delivered by OTIP's National Human Trafficking Training and Technical Assistance Center (NHTTAC) and designed to help target audiences identify and respond to those who are at risk of, are currently experiencing, or have experienced trafficking and connect them with needed resources. OTIP proposes to collect information to measure grant project performance, provide technical assistance to grant recipients, assess program outcomes, inform program evaluation, respond to congressional inquiries and mandated reports, and inform policy and program development that is responsive to the needs of victims.

The information collection will capture information on organizations enrolled in each grant recipient's multidisciplinary network of providers serving individuals who have experienced, or are at-risk of experiencing, a severe form of trafficking in persons, and clients served. Data elements are designed to capture information about organizational providers (*e.g.,* number of individuals trained to identify and respond to trafficking, types and number of trainings offered, types of services provided, number of clients enrolled in services, organizational barriers to service delivery and implementation, and total funds spent by category of assistance) and client