Information Collections

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* 13th SOW Quality Innovation Network—Quality Improvement Organization (QIN–QIO) and American Indian Alaskan Native (AIAN) Measure Data Collection; *Use:* The Quality Innovation Network—Quality Improvement Organization (QIN–QIO) program and American Indian Alaskan Native (AIAN) program assists providers/practices with high-quality, hands-on quality improvement assistance toward meeting their needs, and the healthcare quality and safety goals for beneficiaries. The purpose of this new information collection within these programs is to quantify performance and improvement in a broad set of quality measures that are not currently available from other sources. Selected measures are derived from the Merit Based Incentive Payment System (MIPS), the Hospital Inpatient Quality Reporting Program (HIQR), the Hospital Outpatient Quality Reporting Program (HOQR), and the CDC National Healthcare Safety Network (NHSN).

Measure data collection is an integral part of the quality improvement process. It is the primary source of knowledge about quality of care, allowing Quality Improvement (QI) practitioners to understand current state and quantitatively measure progress and effectiveness. There are three primary user categories for this data collection:

- Participants in the QIO program will use measure data from their facilities/practices to implement their own quality improvement efforts, and benefit from the collection and analysis of data from other facilities and practices to contextualize progress towards QI goals.
- QI contractors (both QIOs and the AIAN contractor) will use measure data to direct their efforts and understand the effectiveness of interventions, to measure progress towards their contractual objectives, and to report on progress to CMS.
- CMS will use the collected measure data along with derived analytic products to track the success of the program, to inform strategic decisions and priorities, and to calculate return on investment.

Form Number: CMS–10934 (OMB control number: 0938–NEW); *Frequency:* Quarterly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 16,735; *Total Annual Responses:* 66,940; *Total Annual Hours:* 1,471,284. (For policy questions regarding this collection contact Geoffrey Berryman at (410) 786–8766.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Provider Directory Data for Medicare Plan Finder; *Use:* Medicare Plan Finder (MPF) is an online tool where current and prospective beneficiaries can explore their Medicare coverage options. On MPF, individuals can shop for Medicare coverage options and make choices based on a variety of search criteria, such as plan benefits, premiums, deductibles, and star ratings. Previously, MPF had not included search capability or information on MA organizations' contracted provider networks.

To simplify and streamline the Medicare beneficiary shopping experience, CMS is expanding the existing requirements applicable to MA organizations regarding their provider directories that requires MA organizations to: (1) make the information described in 42 CFR 422.111(b)(3)(i) available to CMS/HHS for publication online in accordance with guidance from CMS/HHS; (2) submit or otherwise make available their plan provider directory data, that is the requirements found under § 422.111(b)(3)(i), available to CMS/HHS in a format, manner, and timeframe determined by CMS/HHS; (3) update the information subject to § 422.111(m) within 30 days of the date an MA organization becomes aware of a change; and (4) attest, in a format and manner and at times determined by CMS/HHS, that all information submitted or otherwise made available to CMS/HHS under paragraph (m) is accurate. *Form Number:* CMS–10906 (OMB 0938–TBD); *Frequency:* Once and yearly; *Affected Public:* Private sector; *Number of Respondents:* 700; *Total Annual Responses:* 1,400; *Total Annual Hours:* 6,300. (For questions regarding this collection contact Jim Canavan at 410–786–5223.)

3. *Type of Information Collection Request:* Revision; *Title of Information Collection:* CMS Electronic Data Interchange (EDI) Enrollment Registration, CMS EDI Enrollment Form, and CMS EDI Enrollment Attestation Form; *Use:* The collection consists of three forms used by Medicare providers and suppliers to register for EDI services with Medicare contractors. The updated collection includes the revised CMS EDI Registration Form (10164A) and CMS EDI Enrollment Agreement Form (10164B), both serving as model forms. The collection also introduces the CMS EDI Enrollment Attestation Form (10164C), a new mandatory attestation form requiring formal compliance verification from all participating entities.

The forms collect essential information necessary to identify Medicare providers and suppliers during electronic transactions, authorize requested EDI functions, and establish appropriate access privileges for healthcare entities. These forms ensure compliance with HIPAA transaction standards while implementing strengthened security requirements for billing vendors and clearing houses that handle Medicare data. The information collected by the forms will be uploaded into Medicare contractor computer systems. Medicare contractors will store this information in a database accessed at the time of provider connection to the Medicare Data Contractor Network (MDCN). When authentication is successful and connectivity is established, transactions may be exchanged. *Form Number:* CMS–10164 (OMB 0938–0983); *Frequency:* Yearly; *Affected Public:* Business or other-for-profits and not-for-profits; *Number of Respondents:* 229,767; *Total Annual Responses:* 229,767; *Total Annual Hours:* 153,178. (For questions regarding this collection contact Charlene Parks at 410–786–8684.)

William N. Parham, III

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #: 0970–0467]

Submission for Office of Management and Budget Review; Trafficking Victim Assistance Program Data

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 requesting an extension of approval with revisions of an Office of Management and Budget (OMB) approved information collection: Trafficking Victim Assistance Program

(TVAP) Data (OMB #0970–0467; expiration date February 28, 2026).

DATES: *Comments due* December 24, 2025.

ADDRESSES: The public may view and comment on this information collection request at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0970-005.* 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. 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 Trafficking Victims Protection Act of 2000 (TVPA), as amended, authorizes the Secretary of HHS to expand benefits and services to victims of severe forms of trafficking in persons in the U.S. Through TVAP, grant recipients provide time-limited comprehensive case management services to confirmed and potential victims of a severe form of human trafficking, as defined by TVPA, as amended, who are seeking or have received HHS certification. Case management services must be provided to qualified persons directly by full-time case managers that are staffed by the prime recipient and may also be provided through a network of per capita service providers.

OTIP proposes to continue 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 captures information on participant demographics (*e.g.,* age, sex, type of trafficking experienced, service location) and services provided, along with aggregate information on outreach activities conducted, subrecipients enrolled, and dollars spent per service. Minor nonsubstantive updates have been made to performance indicators under this collection to simplify response options or to bring the collection into alignment with OTIP's grant recipient reporting database, the Anti-Trafficking Information Management System (ATIMS).

Respondents: TVAP grant recipients and clients of those programs, specifically: TVAP and the Aspire: Child Trafficking Victim Assistance Demonstration Program funding recipients.

Annual Burden Estimates

Based on review of performance data received pertaining to the number of clients served through TVAP programs and funding levels, the total number of respondents for each form has been lowered. The time to complete each form remains the same.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Client Characteristics and Program Entry	5300	1	0.75	3975	1325
Client Case Closure	5300	1	0.167	885	295
Barriers to Service Delivery and Monitoring	120	4	0.167	80	27
Client Service Use and Delivery	5300	1	0.25	1325	442
Client Outreach	120	4	0.3	144	48
Subrecipient Enrollment	60	3	0.167	30	10
Client Service Costs	60	1	0.5	30	10

Estimated Total Annual Burden Hours: 2,157.

Authority: 22 U.S.C. 7105

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2976]

Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Improving Anaphylaxis Outcomes: Approaches for Enhancing Access to Epinephrine.'' The purpose of the public workshop is to initiate a discussion on expanding epinephrine accessibility and use, including in community settings, to reduce anaphylaxis-related morbidity and mortality. This public workshop will be convened and supported by a cooperative agreement between FDA and the Duke-Margolis Institute for Health Policy.

DATES: The public workshop will be held virtually and in person on December 16, 2025, from 9 a.m. to 4:30 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by January 16, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom Platform and in person at the Duke in DC Office, 1201 Pennsylvania Ave. NW, Suite 500, Washington, DC 20004 with limited seat availability. Parking is available through a number of area garages including one located at 1201 Pennsylvania Ave. with entrance off of E Street. Names of in-person attendees will be provided to building security. Upon entering the building, please walk toward the front desk. The security staff at the front desk will have a list of all confirmed in-person attendees and will provide access to the elevators. Upon exiting the elevator on the 5th floor, turn right and you will find the entrance to the Duke offices.

You may submit comments as follows: Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.