

specified by OPA (instructions forthcoming). Such reports should detail data on purchases provided through rebates, information related to claim delays and denials, and other information that may evaluate the effectiveness of the rebate model.

Rebates

11. Plan should specify if rebates are paid at the package level, or at the unit level.

12. Plan should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission.

13. Plan should ensure that 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts, pursuant to sections 340B(a)(5)(A) and (B) of the Public Health Service Act and should provide for rationale and specific documentation for reasons claims are denied (*e.g.*, deduplication for MFP or 340B rebate provided to another covered entity on the same claim). If a manufacturer has concerns regarding diversion or Medicaid duplicate discounts, the manufacturer should raise those concerns directly with OPA or utilize the 340B statutory mechanisms, such as audits and administrative dispute resolution (ADR), for addressing such issues. Covered entities are also afforded opportunities to raise concerns with OPA if there are issues with rebate delays and denials, or any other administrative or logistical issues emerging through implementation of the rebate model.

14. Plan should ensure that 340B rebates are only paid on sales of drugs selected under the MDPNP, regardless of payer.

Data

15. All data requested as part of the Plan should be limited to only the following readily available pharmacy claim fields:

- a. Date of Service
- b. Date Prescribed
- c. RX number
- d. Fill Number
- e. 11 Digit National Drug Code (NDC)
- f. Quantity Dispensed
- g. Prescriber ID
- h. Service Provider ID
- i. 340B ID
- j. Rx Bank Identification Number (BIN)
- k. Rx Processor Control Number (PCN)

Thomas J. Engels,
Administrator.

[FR Doc. 2025–14619 Filed 7–31–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Proposed Project: 988 Suicide and Crisis Lifeline and Crisis Services Program Evaluation—New Package

The Substance Abuse and Mental Health Services Administration (SAMHSA) 988 & Behavioral Health Crisis Coordinating Office (BHCCO) is requesting clearance for the new data collection associated with the evaluation of the SAMHSA 988 Suicide and Crisis Lifeline and Crisis Services Program Evaluation (988 Suicide and Crisis Lifeline Evaluation). The collection of this information is critical to successfully oversee the operational response and quality of service through the 988 Suicide and Crisis Lifeline to ensure connections to care for individuals in suicidal crisis or emotional distress contacting in for 988 phone, chat, and text support for connecting local, state/territory, and national outcomes and monitoring contractual obligations for current and future 988 grant programs.

In 2020, Congress designated the three-digit number 9–8–8 for the Suicide and Crisis Lifeline, and the Suicide and Crisis Lifeline transitioned to the 3-digit number in July 2022. As a part of the federal government's commitment to addressing the mental health and opioid crises in America, unprecedented federal resources have been invested to expand crisis centers in support of 988. Since its launch in July 2022, the 988 Suicide & Crisis Lifeline has answered over 10 million contacts (SAMHSA, 2024). Progress recognized in 2023 continues in all areas including crisis line features, crisis center supports, and funding. In FY2024, nearly \$500 million was allocated for new funding opportunities to support the 988 Lifeline Administrator and other grantees at the state, territorial, Tribal, and center levels, as part of the commitment to strengthen crisis care nationally. In Section 1103(a)(2)(B) of

the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), Congress called for enhanced program evaluation, including performance measures to assess program response and improve readiness and performance of the service, including review of each contact to ensure timely connection of service and quality provision in line with evidence-based care. To meet the standards and requirements set forth in the statute, ongoing communication of key outcomes within this OMB request must be received and reviewed to ensure connection and quality of care through the 988 Suicide and Crisis Lifeline.

The information collected will be used by SAMHSA to conduct an evaluation of the 988 Suicide and Crisis Lifeline and Crisis Services, to ensure individuals in suicidal, mental health, and/or substance use crisis can contact 988 Suicide and Crisis Lifeline and are connected to crisis centers providing evidence-based care and receiving critical resource referral and linkage, including opportunities for mobile crisis support, crisis receiving and stabilizing facilities, peer respite centers, and withdrawal management services. The purpose of the 988 Lifeline and Crisis Services Program Evaluation is to assess the implementation and expansion of the 988 Lifeline in the U.S. The evaluation will provide SAMHSA, grantees, and other interested parties with the information needed to strengthen the Behavioral Health Crisis Services Continuum (BHCSC) for all people in crisis. The evaluation utilizes multiple studies to conduct the evaluation of the 988 Lifeline and Crisis Services across a 5-year period. The 988 Lifeline and Crisis Services Program Evaluation includes three levels: system-level, client-level, and impact. Embedded within each of the three evaluation levels are inquiries into differences in utilization of 988 Lifeline and BHCSC services and outcomes.

The System-level Evaluation examines the characteristics, collaborations, and structures of the crisis services infrastructure within states, territories, and Tribal jurisdictions that support improved client outcomes. The Systems-level Evaluation includes two studies: the System Composition and Collaboration Study and the System-Level Service Utilization Study. The System Composition and Collaboration Study examines the structure of the 988 Lifeline and the BHCSC at the national, state, territory, and Tribal levels, and the extent to which crisis service agencies work together. The System-level Service Utilization Study

investigates whether the 988 Lifeline and BHCSC are successful in creating a behavioral-health-system-first response to crisis events and the resulting reduction in use of non-behavioral health crisis services (e.g., 911, law enforcement, emergency medical services).

The Client-level Evaluation provides critical information about the ways in which the 988 Lifeline and crisis services fulfill their mission to connect those in crisis with the services and supports needed to reduce crisis risk and improve overall behavioral health outcomes. The Client-level Evaluation consists of two studies: The Client-level Service Utilization and Outcome Study and the Client-level Risk Reduction Study. The Client-Level Service Utilization and Outcome Study explores the effectiveness of 988 Lifeline and BHCSCs in linking individuals to referral services following their contact with the crisis system and assess the relationship between engagement with crisis services and behavioral health outcomes. The Client-Level Risk Reduction Study assesses the efficacy of 988 Lifeline and BHCSCs contacts on immediate reductions in risks of suicide, violence toward others, and overdose.

The Impact Evaluation informs SAMHSA's efforts to continue to build

the evidence base for suicide prevention and crisis programming. Specifically, this evaluation will examine the impact of 988 Lifeline and BHCSC on suicide and overdose morbidity and mortality. A quasi-experimental interrupted time series (ITS) design using extant, secondary data sources (e.g., CDC mortality data, Medicaid claims data, data from Healthcare Cost and Utilization Project (HCUP), data from the NSDUH, and SAMHSA's Performance and Accountability Reporting System [SPARS] data) gathered across multiple years to establish longitudinal state-level trends before and after major milestones in the implementation of the 988 Lifeline and BHCSC.

The 988 Lifeline and Crisis Services Program Evaluation engages with the following SAMHSA grant-funded programs that make up the core of the crisis care continuum: 988 State/Territory; 988 Tribal nations; Community Crisis Response Program (CCRP); Crisis Center Follow-Up (CCFU); 988 Administrator; and Certified Community Behavioral Health Clinics (CCBHCs). Additional grant programs which are relevant to the BHCSC, such as the Mental Health Services Block Grant (MHBG), State Opioid Response (SOR), Tribal Opioid

Response (TOR), Substance Use Prevention, Treatment, and Recovery Services Block Grant (SUPTRS BG), will be included in portions of the evaluation as relevant. In addition, crisis-providing organizations that are not SAMHSA grantees, especially mobile crisis programs, crisis stabilization units, and CCBHCs will also be engaged to participate in the evaluation.

Ultimately, the purpose of the 988 Lifeline and Crisis Services Program Evaluation is to build the program's knowledge base of effectiveness by thoroughly describing the implementation, outcomes, and impact of a program meant to reduce deaths by suicide.

The total annualized burden is an estimated 16,724 respondents for the 988 Lifeline and Crisis Services Program Evaluation instruments, with a combined hourly estimate to be 8,006.10 hours. Burden estimates are based on the data collection requirements and the number of respondents. The estimated response burden to collect this information associated with the 988 Lifeline and Crisis Services Program Evaluation is as follows annualized over the requested 3-year clearance period is presented below:

TOTAL ANNUALIZED BURDEN HOURS AND COSTS
[Across the 3-year clearance period]

Type of respondent	Instrument	Number of respondents per year	Responses per respondent	Total number of responses	Burden per response (hours)	Annual burden (hours)	Hourly wage rate (\$)	Total annualized cost (\$)
System Composition and Collaboration Study								
Organizational Staff/Crisis System Administrator ¹ .	SIS	73	1	73	0.75	54.75	\$78.06	\$4,273.79
Organizational Staff/Crisis Agency Manager ² .	CCPS	1,034	1	1,034	1.00	1,034.00	58.80	60,799.20
Organizational Staff/Crisis Agency Staff ³ .	KII-CS	35	1	35	1.00	35.00	27.46	961.10
Organizational Staff/Crisis Agency Staff ³ .	KII-CS-CSS	13	1	13	0.50	6.50	27.46	178.49
Client-Level Service Utilization and Outcome Study								
Organizational Staff/Crisis Agency Staff ³ .	CCDF	6,000	1	6,000	0.15	900.00	27.46	24,714.00
Parents/Caregivers ⁴	CCDF Parent Supplement	⁵ 1,560	1	1,560	0.10	156.00	7.25	1,131.00
Client ⁴	CES—Baseline	6,000	1	6,000	0.75	4,500.00	7.25	32,625.00
Client ⁴	CES—3 months	1,500	1	1,500	0.65	975.00	7.25	7,068.75
Client ⁴	CES—6 months	375	1	375	0.65	243.75	7.25	1,767.19
Client ⁴	CES—12 months	94	1	94	0.65	61.10	7.25	442.98
Client-Level Risk Reduction Study								
Client ⁴	C-KII-DC	30	1	30	1.00	30.00	7.25	217.50
Client ⁴	C-KII-TPC	10	1	10	1.00	10.00	7.25	72.50
Total		16,724				8,006.10		134,251.49

¹ BLS OES May 2022 National Industry-Specific Occupation Employment and Wage Estimates mean hourly salary for General and Operations Managers (code 11-1021), <https://www.bls.gov/oes/current/oes111021.htm>.

² BLS OES May 2022 National Industry-Specific Occupation Employment and Wage Estimates mean hourly salary for Social and Community Service Managers (code 11-9151), <https://www.bls.gov/oes/current/oes119151.htm>.

³ BLS OES May 2022 National Industry-Specific Occupation Employment and Wage Estimates mean hourly salary for Counselors, Social Workers, and Other Community and Social Service Specialists (code 21-1000), https://www.bls.gov/oes/current/naics5_541720.htm#29-0000.

⁴ <https://www.usa.gov/minimum-wage>.

⁵ This number represents an estimate based on the average distribution of monthly contacts by modality, cited in Lifeline Performance Metrics (SAMHSA, April 2024), and assumes that 40% of all individuals who contact 988 through chat or text (as cited in Gould et al., 2021 and Pisani et al., 2022) and 20% of those who contact 988 through phone call are below the age of 18.

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.

Krishna Palipudi,

Social Science Analyst.

[FR Doc. 2025–14624 Filed 7–31–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2025–0047; OMB No. 1660–0152]

Agency Information Collection Activities: Proposed Collection; Comment Request; FEMA Administered Disaster Case Management

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 60-Day notice of reinstatement and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a reinstatement, without change, of a previously approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning information collected for a FEMA-Administered Disaster Case Management (DCM) program implemented following a major disaster declaration.

DATES: Comments must be submitted on or before September 30, 2025.

ADDRESSES: To avoid duplicate submissions to the docket, please submit comments at www.regulations.gov under Docket ID FEMA–2025–0047. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID. Regardless of the method used for

submitting comments or material, all submissions will be posted, without change, to the Federal Rulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Heather Spadaro, Section Chief, Community Services Section, Individual Assistance Division, 202–646–3642, and fema-hq-css@fema.dhs.gov. You may contact the Information Management Division for copies of the proposed collection of information at email address: FEMA-Information-Collections-Management@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Executive Order (E.O.) 12148, as amended by E.O. 12673 and E.O. 13286, the President of the United States has delegated to the Department of Homeland Security (DHS), including FEMA, the authority to provide case management services pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5189d. Under the Stafford Act, FEMA may provide DCM services directly to survivors through financial assistance to State, Tribal, or local government agencies or qualified private organizations. DCM services include identifying and addressing disaster-caused unmet needs of survivors through identification of, and referrals to, available resources. A disaster-caused unmet need is an un-resourced item, support, or assistance that has been assessed and verified as necessary for a survivor to recover from a disaster. This may include food, clothing, shelter, first aid, emotional and spiritual care, household items, home repair, or rebuilding. When a case manager speaks to a survivor, they will ask the survivor to provide information through a series of questions (data elements), as outlined within the intake form. This will allow the case manager to better understand the survivor's disaster-caused unmet needs, to identify what types of referrals the case manager may provide, and to decide whether there is a need to meet again to address continuing disaster-caused unmet needs. Case managers then type the responses to the data elements into their

proprietary electronic secured case management database.

Collection of Information

Title: FEMA-Administered Disaster Case Management.

Type of Information Collection: Reinstatement, without change, of a previously approved information collection.

OMB Number: 1660–0152.

FEMA Forms: FF–104–FY–21–146 and FF–104–FY–21–147.

Abstract: This collection tool will primarily be used as a guide to support FEMA-administered DCM case managers by outlining the allowable data elements they can collect from survivors on behalf of FEMA. While there will be a paper collection tool, the case managers will primarily be using the tool as a reference for data elements they can collect and using their own case management database systems to guide the order in which the elements are collected. The elements within the tool are used to assess, screen, and refer disaster survivors to available resources that address their specific disaster-related unmet needs. Case managers then take the information from the intake form and manually upload the data into their secured case management database. Prior to any data collection, survivors will complete and sign a FEMA administered DCM Consent Form, authorizing FEMA, or its agent, to collect data from the survivor in order to effectively provide case management services.

Affected Public: Individuals and Households.

Estimated Number of Respondents: 30,750.

Estimated Number of Responses: 30,750.

Estimated Total Annual Burden Hours: 19,680.

Estimated Total Annual Respondent Cost: \$932,045.

Estimated Respondents' Operation and Maintenance Costs: \$0.

Estimated Respondents' Capital and Start-Up Costs: \$0.

Estimated Total Annual Cost to the Federal Government: \$51,693,869.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including