The Substance Abuse and Mental Health Services Administration (SAMHSA)

Drug and Alcohol Warning Network (DAWN)

Supporting Statement A - Justification

Check off which applies:
☐ New
☐ Revision
☒ Reinstatement with Change
☐ Reinstatement without Change
☐ Extension
☐ Emergency
☐ Existing

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Service Administration (SAMHSA) seeks OMB approval for a reinstatement with change for the Drug Abuse Warning Network (DAWN) (referred to as "legacy DAWN"; OMB No. 0930-0078).

Legacy DAWN was initiated in 1972 by the White House Special Action Office for Drug Abuse Prevention (SAODAP) and the Drug Enforcement Administration (DEA). The National Institute on Drug Abuse (NIDA) assumed responsibility for the continued operation of DAWN in 1981. SAMHSA administered the legacy DAWN data collection system from 1992 through 2011. At the end of 2011, the legacy DAWN was discontinued.

Under the Public Health Service Act (42 U.S.C. §290aa-4), SAMHSA is authorized to collect data on the number of individuals admitted to hospital emergency rooms as a result of the abuse of alcohol or other drugs. The reinstatement of DAWN stemmed from HHS's 2017 Five-Point Opioid Strategy to strengthen public health data reporting and collection, which was developed to respond to the opioid crisis. SAMHSA's authority to protect DAWN data from unauthorized disclosures resides in 42 U.S.C. §290aa(p).

The proposed reinstated DAWN with changes (hereafter referred to as the "Drug and Alcohol Warning Network" or the "DAWN") is a nationwide public health surveillance system to improve hospital emergency department (ED) monitoring of substance use-related visits. It captures data on ED visits related to recent substance use and misuse directly from the electronic health records (EHR) of participating hospitals. The new DAWN also helps SAMHSA and public health professionals, clinicians, and policymakers respond effectively to the overdose crisis in the United States.

2. Purpose and Use of Information

<u>Purpose of the new DAWN</u>

The guiding principle for the reinstatement of DAWN was to meet the criteria of a public health surveillance system: "…the systematic, ongoing collection, management, analysis, and interpretation of data followed by the dissemination of these data to public health programs to stimulate public health action." The surveillance objectives most important for DAWN include the ability to quickly detect a substance use "outbreak," to estimate the magnitude of the health effects from substance use (as reflected in ED visits), to document the geographic, temporal, and demographic distribution of the problem, and to yield data to inform planning and policy.

The new DAWN provides current data on an on-going basis to identify adverse drug reactions as well as the health consequences of drug use, misuse, and use disorders. The key objectives are to:

Monitor demographic and geographic distribution, and identify trends of substance-related ED visits;

Provide an early warning system that identifies emerging and novel psychoactive substances and/or combinations of substances; and

Provide national estimates of substance-related ED visits to key stakeholders and the public.

Use of Information

A key goal of the new DAWN is to strengthen public health data reporting, providing a true "early warning" system that can inform public health response efforts in local areas.

The new DAWN data are available to participating hospital staff through an online dashboard that provides dynamic real-time visualizations on sentinel event findings, new drug mentions, and trends of interest over time for their hospital. Hospitals can use this information internally to improve quality of care, allocate resources for treating patients, and potentially apply for grants for prevention activities in their local service areas. The dashboard will be enhanced and tailored for additional data users (e.g., local, state, and national public health users) with specific data access rights and strong confidentiality protections.

The new DAWN data will also provide information on potential public health problems to state and local public health agencies and community groups. The new DAWN data can help local agencies assess the need for public health resources and detect emerging drug problems before they become widespread.

Planned Changes

The new DAWN shares the uniqueness of legacy DAWN and builds upon it in several ways, allowing the new DAWN to function as a true "early warning" system and inform public health response efforts in local areas (see Table A1 for a summarized comparison between the legacy DAWN and the new DAWN).

This information collection request proposes to make the following changes from the legacy DAWN:

Revise the data collection title to "Drug and Alcohol Warning Network", replacing existing "abuse" term with a clinically accurate, non-stigmatizing language for substance use to help reduce stigma and support treatment for substance use disorders. This revision aligns with the current edition of *The Diagnostic and Statistical Manual of Mental Disorders* (5th ed., American Psychiatric Association, 2013), where "abuse" has been replaced by "use." This revision also aligns with the White House Office of National Drug Control Policy 2017 Memo on "Changing Federal Terminology regarding Substance Use and Substance Use Disorders." Including "alcohol" in the title explicitly and effectively communicates with stakeholders and data users that the new DAWN collects all alcohol cases regardless of age, which is a significant update of the legacy DAWN.

Remove the drug-related death investigation records review component administered by state medical examiners (MEs) and individual medical examiners/coroners (ME/Cs).

Revise data collection procedures (see section B2 for details) and corresponding estimated burden hours (see section A12 for details). DAWN Medical Record Abstractors (hereafter referred to as "abstractor"), employed and supplied by the contractor, will review all the ED records and abstract DAWN eligible data if participating hospitals choose the direct chart review option. In this option, the hospital grants abstractors access to EHR records, either at the contractor's operation center or at the hospital. Hospitals will also have the choice to select a home-based abstraction approach. In this option, the abstractor will work from a secure home environment using contractor-issued equipment. This option provides the benefit of a larger national recruitment pool of qualified abstractors and increased abstractor retention. Hospitals will also have the opportunity to select the machine learning with natural language processing (ML with NLP) option. This option involves the hospital securely sending a data extract from the EHR that contains the clinical information needed for DAWN data collection to the SAMHSA cloud environment. ML with NLP models will then review the file and identify drug-related visits for further review by an evaluator. For ED visits flagged by the models for review as potential DAWN cases, the abstractor will review the data, decide if the ED visit is a DAWN case, and then, construct the DAWN case so that it is formatted in the same manner as the cases obtained through direct chart review. The option for hospitals to use their own staff to abstract DAWN data as they did in the legacy DAWN is no longer offered.

Revise the hospital ED selection design (See section B2 for details) to a hybrid system that combines sentinel hospitals and probability-based selection of hospitals from high priority suburban/rural areas and remaining areas in the United States.

Change the reporting and publication schedule to further increase the timeliness of the new DAWN data availability and delivery to SAMHSA. The new DAWN data are collected on an ongoing basis and could be available to SAMHSA on demand. The new DAWN data are delivered to SAMHSA and available for analysis at more frequent intervals than the legacy DAWN (see section A16 for details on time schedule).

Table A1: Legacy DAWN (2008) and New DAWN (2024) differences

System Design	Legacy DAWN (2008-2011)	New DAWN (2024-2026)
Drug-related visits collected	All drugs and alcohol for patients < 21 years of age	All drugs and alcohol for all ages
Data collection method	Direct chart review	Direct chart review or ML with NLP
ED charts reviewed	100% of visits reviewed or a sample of visits reviewed	100% of visits reviewed at all hospitals
Number of sampled hospitals	61	128
Data availability to SAMHSA	Quarterly	Ongoing
Medical Examiner/Coroner data collection	Yes	No
Sample Design	National sample and oversample in select metropolitan areas	Hybrid sentinel and probability-based surveillance design
Abstractor Options	Contractor-based abstractor or hospital-staff abstractor	Contractor-based abstractor
Data report releases	Annually and ad hoc	Annually and quarterly (ad hoc)
Data stakeholder access	• Web-based query system available to participating hospitals • Web-based query system aggregated to metro area data available to stakeholders	• Web-based visualizations available to participating hospitals • Web based query system aggregated at national level available to stakeholders

Propose changes to the ED Case Report Form (Attachment A)

Add "Center for Behavioral Health Statistics and Quality" to specify the center responsible for DAWN data collection.

Revise the data collection title to "Drug and Alcohol Warning Network" from "Drug Abuse Warning Network" to explicitly and effectively communicates with stakeholders and data users that the reinstated DAWN collects all alcohol cases regardless of age, which is a significant change from the prior system. Replace prior "Facility" data field title with "Hospital Emergency Department ID" to provide more precise description and ID number of the DAWN participating hospitals.

Q3 "Age": replace prior option of "less than 1 year" with two detailed options

of “4 weeks (28 days) or younger” and “Between 4 weeks and one year old (>4 weeks, <1 year)” to enable new identification of neonatal substance issues.

Q4 “County of Residence”: revise data field title from “patient’s home zip code” to “Patient’s County of Residence” and add more accurate description on what data to be collected and clarify the purpose of data collection. Add new “Unable to determine county” option to improve data accuracy and account for geographical variation.

Q6 “Gender Identity” and Q7 “Sexual Orientation” (SOGI): added to provide inclusive measures and to align with SAMHSA’s efforts in enhancing behavioral health equities among diverse populations. With limited standards in implementation and SOGI data spans multiple EHR systems of participating hospitals with inherent variations in format and structure, standard abstraction methodology is inadequate to the unstructured SOGI data elements. SAMHSA proposes a free text data abstraction method to improve SOGI data abstraction inclusiveness and reliability. Free text abstraction also provides greater flexibility in SOGI data re-coding, secondary analysis, and meeting various existing and new guidance and standards, such as the SOGI measurement strategies recommended by the National Academies of Sciences, Engineering, and Medicine in 2022.

Q8 “Ethnicity” and Q9 “Race”: revise prior data field “Race/Ethnicity” to align with OMB 1997 Standards for Maintaining, Collecting, And Presenting Federal Data on Race and Ethnicity (Statistical Policy Directive No. 15) and to improve data accuracy and comprehensiveness.

Q10 “Case Description”: replace the word “drug(s)” with “substance(s)” to clarify that the DAWN collects data on all substances including alcohol. Add new instruction language of “Do not include information that could identify the patient or hospital” to provide clear instruction and specify the importance of patient and hospital privacy protection.

Q11 “Substance(s) Involved and Route of Administration”: add two new options of “transdermal” and “vaped” to improve the comprehensiveness of the list on how substance is administered by the patient. Remove “Mark if confirmed by toxicology test” and “alcohol involved?”

Q12 “Diagnosis”: change the question order and move the data field after Q11. Revise prior instruction of “list up to 4 diagnoses” to “list all diagnoses” to enhances new DAWN’s ability to identify novel drug, drug trends, and drug outbreaks.

Q13 “Type of Case”: remove instruction language of “using the decision tree.” Revise the existing option of “seeking detox” to “seeking detox and/or

substance abuse treatment only" and remove age restriction for "Alcohol only" option to include cases involving alcohol as the only substance of all ages.

Q14, Q15 and Q16 "Was naloxone/buprenorphine/methadone administered to the patient in the ED": added to capture new data on the implementation of medication-assisted treatment for opioid use disorder in the emergency department setting and understand why buprenorphine and methadone is administered.

Q17 "Disposition": add new options and re-categorize disposition to improve data accuracy and comprehensiveness and better understand where the patient went after their ED visit.

Activity Report Form (Attachment B): SAMHSA proposes a new Activity Report From to be submitted by the abstractors to collect information on the date of ED visits the abstractor has reviewed, counts of ED visits for that date, number of records reviewed, and number of "left without being seen" (LWBS) visits for the ED visit date, if participating hospitals choose the direct chart review option.

3. Use of Information Technology

The abstraction and dissemination of DAWN data involves the use of web-based technologies that reside and operate within SAMHSA's AWS Cloud. All DAWN data are submitted electronically through a web-based system called the Case Reporting System (CRS). DAWN data are available to authorized users at participating hospitals through the same platform. DAWN data is collected by contractor-employed abstractors only. Participating hospitals grant access to their EHR system in one of two ways. Either hospitals provide direct access to abstractors, enabling them to identify DAWN cases within their EHR system, or hospitals choose to securely transmit extracts from the EHR system to the SAMHSA cloud environment. These extracts will be evaluated by ML and NLP techniques that flag potential DAWN cases, which are then routed to abstractors for review and adjudication. Hospitals authorize access by signing a Data Access Agreement (DAA).

Regardless of the option selected above (i.e., direct chart review or ML with NLP), once a DAWN case is identified, abstractors collect key data elements from the medical record and enter that data into the web-based case form (see Attachment A). The CRS provides error and consistency checks throughout the data abstraction process. For tracking and analysis purposes, DAWN abstractors enter activity reports that document the total number of ED records for each day and the number of records reviewed each day (see Attachment B).

DAWN abstractors will access the CRS via a secure web browser and perform their work either in the hospital or remotely from a secure location (contractor-based or home-based). Responding DAWN hospitals have specified which option – in-hospital or

remote – is agreed to in their DAA. DAWN abstractors working within the hospital enter data into the CRS using either a contractor-provided laptop or a workstation at the hospital.

The same web application used for DAWN data collection is used for DAWN data dissemination. This part of the application, called DAWN Data Highlights, shares data visualizations with authorized users at SAMHSA and authorized users at participating hospitals. It provides users with data visualization tools to run or download analytic reports containing DAWN data. Each user type has a role assigned to limit the information seen. For example, SAMHSA has access to data at the individual case level, the hospital user only has access to aggregated monthly totals of their own hospital's data.

Users connect to the CRS using standard web browsers, using Hyper Text Transfer Protocol Secure (HTTPS). HTTPS provides enhanced security by encrypting and decrypting user web page requests and pages returned by the web server. Access to the DAWN system requires user login credentials that restrict the user to a predefined role and specific data. The DAWN website incorporates design principles to comply with Section 508 mandates as prescribed by the Americans with Disabilities Act (ADA), including providing dynamically generated data in downloadable table form.

4. Efforts to Identify Duplication

SAMHSA is aware of a number of other ED data collection initiatives, noted below, that are surveillance-based systems or surveys administered or funded by HHS. The new DAWN is designed to augment, not duplicate, these other activities.

Existing ED data systems primarily rely on ICD-10 diagnostic coding systems, which provide information about *categories* of drugs but not about specific drugs. Existing ED data systems are often not equipped to identify new psychoactive substances or substance outbreaks. The proposed new DAWN data provides information over and beyond diagnostic codes. It captures ED visits involving both substance misuse and use disorders. The new DAWN employs:

A case finding method—direct record review—that enables the identification of ED visits related to recent drug use, rather than relying on diagnostic codes which paradoxically can yield a high percentage of false positives while also resulting in a high percentage of false negatives.

The collection of specific drug information (brand name of pharmaceuticals when available; slang terms for illegal drugs and pharmaceuticals) that enabled a more granular understanding of drug use patterns. It also collects detailed drug information on illicit drugs, prescription medications, over-the-counter medications, dietary supplements, alcohol, and non-pharmaceutical inhalants with some restrictions.

The collection of all drug-related ED visits. This approach allows DAWN to capture ED visits that involve drug misuse, but also capture adverse reactions to prescription and over-the-counter medications, ED visits resulting from the accidental use of drugs, and intentional drug poisonings with malicious intent. Essentially, the inclusive case definition enables the capture of ED visits that involved substance misuse but do not meet the classic criteria of "abuse" (drug use for psychoactive effects, dependence, or suicide).

Table A2 summarizes some major differences between DAWN and existing ED data systems.

CDC funds and operates the National Syndromic Surveillance Program (NSSP), a collaboration between the CDC and state and local health departments for the timely exchange of syndromic data for situation awareness and responsiveness to hazardous events and disease outbreaks. Public health officials submit data to the cloud based BioSense Platform. Data are collected in near real time. ED data submitted include chief complaint, ICD-10 diagnostic codes, patient characteristics, and location. State and local health departments using NSSP have access to their own detailed data and aggregated national and regional data, and can share their data with any other jurisdiction and CDC. CDC can run queries against a subset of data elements and generate and report regional and national results. CDC can only access the detailed data in collaboration with the jurisdictions. Data are not nationally representative.

CDC's National Center for Health Statistics administers the National Hospital Care Survey (NHCS), with a nationally representative sample of hospitals. NCHS collects data on patient care to describe patterns of health care delivery and utilization in the United States. Hospital settings include inpatient, emergency departments, and outpatient departments. Drugs are identified by ICD-10 diagnostic codes. Nationally representative data are not yet available. Restricted data are available through the CDC's Research Data Centers.

The Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project Nationwide Emergency Department Sample (HCUP-NEDS) samples inpatient and ED claims data submitted by 40 participating states and the District of Columbia to produce nationwide estimates. Drugs are identified by ICD-10 diagnostic codes. Data become available 2-3 years following each data year. There is an online query system; public use datasets and restricted data are available upon request. Another component of HCUP, the State Emergency Department Databases (SEDD), captures discharge information on ED visits that did not result in admission to the hospital. Data organizations in 42 states participate in SEDD. There are several important differences between DAWN and SEDD: DAWN is able to produce estimates for the Nation. Because SEDD does not sample hospitals, it is unable to provide national estimates. The SEDD databases do not have the detailed drug information that DAWN provides. In SEDD, case descriptions that could be used to make the link between a drug (if reported) and the ED visit are not available.

CDC has partnered with the Consumer Product Safety Commission (CPSC) on the National Electronic Injury Surveillance System Cooperative Adverse Drug Event Surveillance (NEISS-CADES). NEISS-CADES collects data on adverse drug events (ADEs) from a nationally representative sample of U.S. hospital emergency departments; NEISS-CADES uses a subsample of these EDs for its data collection. Trained abstractors review ED records at participating hospitals to identify clinician diagnosed ADEs and the medications implicated in each adverse event. Data are nationally representative and available within two years; restricted data are available upon request.

NIH's National Institute on Drug Abuse (NIDA) funds the National Drug Early Warning System (NDEWS). The second iteration of NDEWS incorporates real-time surveillance to detect early signals of potential drug epidemics. A coordinating center collects and harmonizes data from 18 urban, suburban, and rural areas in the US, comprising the Early Warning Network. The sites regularly provide a standardized set of community-level indicators including drug availability, use and consequences of emerging drugs, morbidity, and mortality to compare sites. Reports are produced for the sentinel community sites.

CDC's Overdose Data to Action program supports surveillance of nonfatal overdoses through the Drug Overdose Surveillance and Epidemiology (DOSE) system. Partnering state and local health departments collect data through syndromic and ED discharge data to identify outbreaks or changes in overdose trends. Estimates are not nationally representative and subject to ED discharge data limitations.

Table A2: Comparison of New DAWN with other ED data collection initiatives.

Characteristics	NSSP	NHCS	HCUP-NEDS	NEISS-CADES	NDEWS	DOSE	New DAWN
Type	Syndromic, passive	Survey	Population, passive	Population, passive	Sentinel	Integrative (syndromic & discharge), passive	Integrative (sentinel & population), active
Focus	ED outcomes, early warning	ED outcomes	ED outcomes	Adverse drug events	Drug (not alcohol)	Overdose	Substance (Alcohol and drugs)
Timeliness of data availability	Near real-time (submitted within 24 hours)	>1 year	2-3 years	1-2 years	>2 years for site annual reports	Quarterly	Monthly
Time period of data	Near real-time, continuous collection	Year	Year	Year	Annual	Month, Annual	Continuous abstraction
Substance detail	Clinical symptoms or ICD-10-CM	ICD-10-CM	ICD-10-CM	ICD-10-CM, clinical notes	ICD-10-CM (ED)	ICD-10-CM	Detailed drug information, specific combinations, novel substances,

							and alcohol.
Reporting level geography	Jurisdiction-level response	Nation	Nation, region	Nation	Sentinel site	State, Jurisdiction-level response	Nation, Hospital-level
Data available to the public	Aggregated dashboard(s)	Yes	Yes	Yes	Aggregated reports	Aggregated dashboard(s)	Aggregated dashboards and reports

Other drug abuse data collection efforts operated by SAMHSA and other agencies typically provide information by general categories rather than by specific drugs of abuse or, if specific drug information is available, it typically involves only the most frequent such drugs; on a periodic rather than a continual basis; and/or in insufficient quantity to produce valid estimates or extrapolations.

5. Involvement of Small Entities

The information requested from all participants (both small entities and otherwise) has been kept to the absolute minimum required to meet DAWN's objectives. SAMHSA contractors will provide abstractors to collect and submit all DAWN data for participating hospitals. Hospital staff provides support to abstractor for their continuous access to the hospitals' EHR systems and automated process is used to minimize burden to all participating hospitals. There is minimal impact on small entities.

6. Consequences If Information Collected Less Frequently

When legacy DAWN was discontinued in 2011, it left a critical gap where no other system was able to identify and track trends in ED visits for specific drugs across the country. The proposed new DAWN adheres to Section 505 of the Public Health Service Act by collecting DAWN data on a continuous basis as soon after the ED visit as possible. It goes beyond the legacy DAWN by proposing to release weighted national estimates on an annual basis and to produce quarterly (ad-hoc) reports on targeted DAWN data topics. This will ensure critical information about outbreaks, the appearance, and the emergence of substances can be disseminated to local public health authorities, frequently. Receiving information that is more frequent will allow public health authorities to take action on emergent activity. More frequent data collection will also provide SAMHSA and other HHS agencies with a broad picture of what is happening across the country, in rural areas as well as the suburbs and cities. Less frequent collection and reporting would therefore significantly diminish DAWN's effectiveness and could adversely affect the federal government's drug use monitoring and prevention efforts.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

SAMHSA is requesting an exemption of revisions of race and ethnicity data classification related to the revised Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), effective March 28, 2024.

In the "Revisions to OMB's Statistical Policy Directive No. 15" Federal Register Notice (FRN) published on March 29, 2024 (89 FR 22182), OMB acknowledges that "*certain programs that involve interconnected data across multiple agencies or offices, or that rely on data collected and provided by non-Federal entities, may take longer to implement than programs like statistical surveys"*.

DAWN abstracts data directly from the existing Electronic Health Records (EHR) system of participating hospitals. All DAWN participating hospitals are non-federal entities and the hospital EHRs follow the standard and implementation specification identified in the Interoperability Standards Advisory (ISA). ISA is recommended, reviewed and updated by the Office of the National Coordinator for Health Information Technology (ONC) on a regular basis. As of July 29, 2024, ISA references its race and ethnicity standard and implementation specification to the prior SPD 15 (1997). In addition, DAWN data analysis and reporting involves interconnected data across federal agencies. DAWN utilizes U.S. Resident Population Estimates, provided by the Census Bureau, to generate nationally representative weighted estimates by demographic characteristic. Updates to hospital EHR systems and Census Bureau U.S. Resident Population Estimates require additional time. Therefore, it will take longer for DAWN to implement changes in race and ethnicity per SPD 15.

OMB also acknowledges that "w*hen data are collected through visual observation, agencies are not required to collect detailed categories and are encouraged to instead use the minimum categories*." The *method* of how race and/or ethnicity data are collected (either self-reported, proxy reporting, record matching, or observer identification) varies from hospital to hospital. With mixed data collection methods utilized for DAWN data, DAWN requests approval to use the minimal categories identified in SPD 15 (1997) until the full revision is implemented.

DAWN will adopt revisions to race and ethnicity data collection in a timely manner and come into compliance with the revised SPD 15 not later than March 28, 2029.

8. Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on March 14, 2024 (89 FR 18655). No comments were received.

In addition, SAMSHA has consulted with stakeholders and experts outside of the agency to obtain their views on the proposed information collection. The following experts have been consulted for their technical and subject matter expert inputs on DAWN:

Keith Burkhart, M.D., Senior Advisor for Medical Toxicology, Center for Drug Evaluation and Research (CDER)/ Food and Drug Administration (FDA)

Phillip Coffin, M.D., M.I.A., Director, Substance Use Research, Center for Public Health Research, San Francisco Department of Public Health

MeLisa Creamer, Ph.D., Deputy Branch Chief, Epidemiology Research Branch, National Institute on Drug Abuse (NIDA)

Rick Dart, Ph.D., Director, Rocky Mountain Poison and Drug Safety (RMPDS)
Brian J. Dew, Ph.D., Chair and Associate Professor, Department of Counseling and Psychological Services, Georgia State University

Zachary Dezman, M.D., Medical Officer. FDA/CDER Jim Hall, Epidemiologist, Center for Applied Research on Substance Use and Health Disparities, Nova Southeastern University

Stephen Liu, Ph.D., Health Scientist, ESB/DOP/NCIPC/CDC

Jana Mcaninch, M.D., MPH, M.S., Acting Associate Director for Public Health Initiatives, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration

Desiree Mustaquim, Ph.D., Overdose Morbidity Team, Epidemiology and Surveillance Branch (ESB), Division of Overdose Prevention (DOP), National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC)

Scott Oulton, Associate Deputy Assistant Administrator, Office of Forensic Sciences, Drug Enforcement Administration (DEA)

Rob Poirier, M.D., Clinical Chief, Department of Emergency Medicine at Barnes-Jewish Hospital, Associate Professor at Washington University School of Medicine in St. Louis

Sheila Sjolander, Deputy Director, Public Health Services, Arizona Department of Health Services

Erin Stokes, Overdose Morbidity Team, ESB/DOP/NCIPC/CDC

Nimalie Stone, M.D., Director, Medication Safety Program, Division of Healthcare Quality Promotion, CDC

9. Payment to Respondents

SAMHSA understands the challenges in recruiting and retaining hospitals. Hospitals have found it inconvenient to have abstractors in their facility and difficult to find the time, space, and staff support needed to allow access to ED records for the data

abstraction. Large hospitals are inundated with numerous data requests and may be reluctant to accommodate any additional data requests. Based on its extensive experience managing the legacy DAWN, SAMSHA recognizes the necessity of providing incentives to participating hospitals and the importance of retaining the statistical sample of selected participants to maintain the validity of the DAWN estimates. SAMHSA offers hospitals data access payment to: (a) encourage selected hospitals to join DAWN, (b) retain the hospital once they join DAWN and (c) ensure timely access to ED records and receive support for ongoing data collection. SAMHSA also recognizes that data access payment has to be part of a comprehensive outreach and marketing strategy and recruitment plan that include both monetary and non-monetary incentives to encourage hospitals' DAWN participation.

10. Assurance of Confidentiality

Data will be kept private to the extent allowable by law. Health information privacy regulations issued pursuant to the Health Insurance Portability and Accountability Act (HIPPA) of 1996 affect all hospital participants in DAWN. Hospitals were required to comply with these rules dated April 14, 2003. Under the HIPAA Privacy Rule, hospitals may disclose individually identifiable data to DAWN under disclosures for public health activities authorized by law, 45 CFR 164.512(b)(1). These disclosures are permitted without individual consent or authorization. SAMHSA is a public health authority required by law Section 505 of the Public Health Service Act (42 U.S.C. 290 aa-4) to collect data on: the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs.

In accordance with the HIPAA Privacy Rule, SAMHSA requests only the minimum amount of information necessary to fulfill DAWN's purpose. SAMHSA has developed and will follow the following policies and procedures that govern DAWN data abstraction and prevent misuse or disclosure of DAWN data:

DAWN does not abstract direct identifiers (e.g., names, Social Security number, and medical record number) for patients.

Hospital DAAs, the document executed with DAWN hospitals, contain specific clauses regarding the confidentiality of DAWN data and the obligations of each party with respect to confidentiality.

Data collected electronically are encrypted and transmitted via secure connections to the SAMHSA's AWS Cloud DAWN System.

Employees of Center for Behavioral Health Statistics and Quality (CBHSQ at SAMHSA and its contractor sign confidentiality agreements that spell out the confidentiality requirements, how those requirements affect employees' behavior and use of data, and the penalties associated with violations.

Every individual affiliated with DAWN at SAMHSA and its contractor receives specific annual training on the confidentiality and data protection rules that apply to DAWN.

DAWN data are viewed and processed only by individuals who require access. Access to DAWN electronic data abstraction systems is limited to authorized DAWN staff and hospital abstractors with a valid user id and password. The central database is maintained on a secure server to which access is limited to authorized project staff only.

An ED's own data, located in the SAMHSA's AWS Cloud DAWN System, are accessible only to individuals authorized by the hospital and accessed using a unique user id and password.

All data produced in tabular format are reviewed for confidentiality risks before release. Published reports suppress data where necessary if the publication of such data could potentially identify an individual hospital and/or patient.

11. Questions of a Sensitive Nature

Information of a sensitive nature shall not be solicited directly from individuals. The data collection form does not record direct identifiers for patients. No PHI or PII is collected. DAWN's data abstraction procedures involve abstraction of information from existing records. Information contained on DAWN forms will be a subset of the information available in medical records. The race and ethnicity questions follow the Office of Management and Budget (OMB) 1997 Standards for Maintaining, Collecting, And Presenting Federal Data on Race and Ethnicity (Statistical Policy Directive No. 15).

12. Estimates of Hour Burden

DAWN participating hospitals do not perform any data collection for DAWN. Instead, hospitals select one of the abstraction options to collect DAWN data. The direct chart review option provides abstractors with read-only access to EHR records to review all ED visits and identify DAWN cases. For the direct chart review method, the majority of abstractor time (approximately 90 percent) is spent reviewing ED records that do not meet the DAWN case definition. The ML with NLP option will reduce burden of data collection and cost and HHS/SAMHSA to enhance timely reporting of data for early warning. SAMHSA will offer the ML with NLP option as the first option to participating hospitals with an objective of all hospital data to be abstracted through ML with NLP eventually, making exceptions for hospitals lacking infrastructure to support the option.

Under either data abstraction option, participating hospital staff spend time and effort required to set up the provision of DAWN information and provide ongoing assistance to maintain the DAWN information collection. Table A3 details the burden estimate for each activity and Table A4 summarizes the Total Burden Hours.

Table A3: Estimated annualized burden for the DAWN 2024 - 2026:

Information Collection Title	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response (in hours)	Total Burden Hours	Average Hourly Wage[1]	Total Annual Cost
Setting Up Activities*							
Initial outreach and recruitment (all hospitals)	143	1	143	81.50	11,655	$48.72	$567,807
ED record provision setting up (direct chart review)	58	1	58	5.25	305	$26.71	$8,133
ED record provision setting up (ML with NLP)	85	1	85	36.00	3,060	$26.71	$81,733
Ongoing Maintenance Activities							
Ongoing Maintenance (direct chart review)	58	1	58	1.50	87	$26.71	$2,324
Ongoing Maintenance (ML with NLP)	85	1	85	6.00	510	$26.71	$13,622
Totals					**15,616**		**$673,619**

Table A4: Proportional burden hours per response

SAMHSA Tool	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Burden Hours
DAWN Case Report Form	143	1	143	81.5	11,655
DAWN Activity Report Form	143	1	143	27.7	3,961
Totals			**286**		**15,616**

<u>Basis for Burden Hour Estimates</u>:

DAWN Case Report Form

While DAWN participating hospitals do not perform any data collection for DAWN, they spent time responding to DAWN initial outreach and recruitment. Based on initial hospital recruitment outreach experience, SAMHSA estimates that it takes a hospital 81.5 hours at the initial outreach and recruitment stage. This includes:

40 hours of reviewing DAWN outreach and recruitment materials;

[1] Average hourly wage is based on Bureau of Labor Statistic's latest data on national median wages of health information technologists. Further information on hourly rate calculations is summarized under "Basis for Hour Costs Estimates" below.

0.5 hours of establishing initial contact between the contractor and an executive assistant to the Chief Executive Officer and engaging in conversations with stakeholders, influencers, or decision makers;

40 hours of reviewing and executing the DAA; and
attending a one-hour conference call with the contractor once the DAA is signed.

DAWN Activity Report Form

Based on initial hospital recruitment outreach and experience from prior DAWN data abstraction experience, SAMHSA anticipates that 58 hospitals choose "direct chart review" option and 85 hospitals choose "ML with NLP" option for data abstraction. Both options require participating hospitals' ED record provision setting up and ongoing system maintenance activities (basis for each activity's burden hour estimate is explained respectively below and is summarized in Table A3). The proportional Burden Hour per Response is estimated to be 27.7 hours per response (Table A4).

ED record provision setting up (direst chart review): SAMHSA estimates that hospital staff on average spend 5.25 hours to set up electronic health record access for the contracted abstractors. This includes a one-hour EHR training for the abstractors and the DAWN supervisors; and 4.25 hours to work with DAWN's IT staff to facilitate the process of gaining access to the hospital's EHR system.

ED record provision setting up (ML with NLP): SAMHSA estimates 36 hours of hospital employee time to establish ongoing data feeds to send electronic records to abstractors for hospitals choosing the ML with NPL option. The estimated breakdown of tasks is:

6 hours for discussion of requirements (2 hour each, average of 3 hospital attendees);
22 hours for hospital staff to engage with their EHR vendor and complete documentation needed for a DAWN-specific report or for internal hospital staff to develop and test a DAWN-specific report;
2 hours to establish, test, and validate the data transfer connection between the hospital and DAWN; and
6 hours to allow for refining and remediating any validating any issues found during the test transmission phase.

Ongoing maintenance (direct chart review): SAMHSA estimates that participating hospitals allocate 1.5 hours for ongoing maintenance activities, including 0.5 hours annually to conduct EHR audits to track appropriate HIPAA related activities and 1 hour annually to undergo ongoing data access maintenance.

Ongoing Maintenance (ML with NLP): SAMHSA estimates 6 hours of hospital staff time in post-setup years for technical support and maintenance for the automated data transfer routine and user accounts for hospitals choosing the ML with NPL option.

Basis for Hour Costs Estimates:

The hospital staff that spend time during the initial outreach and recruitment stage (reviewing the outreach material, engage in discussion with DAWN contractor, review and execute the agreement) are generally mid- to senior-level staff. Based on latest data from the Bureau of Labor Statistics' *Occupational Outlook Handbook (2021),* the median wage for this level (medical and health service managers) is $48.72 per hour.

The hospital staff that spend time on setting up ED record provision and ongoing maintenance activities for DAWN data collection are usually junior staff (health information technologist). Based on latest data from the Bureau of Labor Statistics' *Occupational Outlook Handbook (2021),* the median wage for health information technologist is $26.71 per hour.

13. Estimates of Annualized Cost Burden to Respondents

Respondent (participating hospitals) will not incur capital or start-up costs such as purchasing computers or software, monitoring, sampling, equipment, or record storage when participating in DAWN. Office space and computer equipment used by abstractors are already in place for participating hospitals' general operational purposes and are not resulting from participating in DAWN. Where necessary, DAWN contractor provides laptop computers and internet connections so data can be collected and submitted electronically by abstractors.

14. Estimates of Annualized Cost to the Government

Contract Cost: The annualized cost to the Government for the DAWN contract is approximately $14,000,000.

SAMHSA Staff: The cost for multiple federal staff's time spent on monitoring the contract, overseeing DAWN data collection and operation, reviewing and drafting analytic reports, conducting quality control of all reports, designing and implementing ad hoc analysis and assessment is estimated to be approximately $750,000 annually. The cost estimate is based on proportionate annual rates of two GS 11 staff (spending 75% of their time), one GS 12 staff (75% of its time), two GS 13 staff (75% of their time), two GS 14 staff (75% and 15% of their time respectively), and two GS 15 staff (75% and 50% of their time respectively). The 2023 mid-point grade level annual rates for GS 11 to GS 15 (Step 5) are $89,069, $106,759, $126,949, $150,016, and $176,458 for SAMHSA headquarter federal staff in Maryland.

Total annualized cost to the government is $14,750,000.

15. Program or Burden Changes

In 2008, the annualized burden hours were estimated at 72,227 hours compared to 15,616 hours in this submission. Program changes from the legacy DAWN to this proposed new version of DAWN result in a decrease of 56,611 hours.

Several program changes led to the decrease in DAWN's burden on respondent hospitals.

The new DAWN removes the mortality component from the legacy DAWN. Thus, data collection and the related burden of 8,025 hours associated with drug-related deaths information collected by State Medical Examiners and individual Medical Examiner and Coroner (ME/C) in the legacy DAWN is eliminated in this proposed new DAWN burden estimate.

Under legacy DAWN, participating hospitals used their own staff to perform data collection activities. The new DAWN does not offer an option for the hospitals to perform data collection activities themselves. Hospitals are offered to use direct chart review data abstraction option or ML with NLP option, both of which are implemented by the contractor. Participating hospital staff spend time and efforts setting up record provision and providing ongoing maintenance for DAWN data collection. Thus, estimated annualized burden hours of 64,202 hours associated with hospital staff performing ED data collection in the legacy DAWN is now decreased to 15,616 hours in this new DAWN.

16. Publication and Tabulation Dates

DAWN data are abstracted in participating hospital EDs on a continuous basis. Data are stored on a secure Cloud site with access given to authorized SAMHSA team and contractor staff. All reports will be stored on the SAMHSA website. The following describes the schedule and information for each planned DAWN report:

Findings from Drug-Related Emergency Department Visits: the annual report may present information on (1) nationally representative weighted estimates, including percent and unadjusted rates per 100,000, for all drug-related emergency department visits, (2) nationally representative weighted estimates for the top five drugs in drug-related ED visits, (3) weighted national estimates of all drug related ED visits with percentage and rates per 100,000 by age, sex, race, ethnicity, region and quarter , and (4) the identification of drugs new to DAWN's Drug Reference Vocabulary.

Quarterly reports on sentinel event reporting related to an early warning system and/or emerging trends: these reports may include drug advisories, visualizations, demographics analyses, and/or geographical analysis of at-risk population.

Dashboards with both internal and public facing components based customized requirements and disclosure requirements to protect confidentiality. Different profiles will be built to accommodate different levels of access from SAMHSA super-users and stakeholders associated with participating DAWN hospitals and those in the local public health/epidemiology community.

Special topic short reports with infographics: these reports will target timely topics by including descriptive statistics with visualizations for communication to general audiences.

DAWN data presented to the public includes counts and/or associated rates of specific drugs involved in ED visits or other such information as determined by SAMHSA.

In addition to the reports, the data produced by the DAWN is continuously monitored and examined to identify meaningful trends, changes, and events that may be of reporting interest. Statistical process control (SPC) is currently used to identify anomalies in incoming data for dissemination through DAWN Data Highlights portal (DDH) for hospitals to monitor early warning.

17. Display of Expiration Date

All DAWN data will be collected via the web. The OMB expiration date will be included and displayed on all web instruments.

18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act submissions.