

and contribute to billions of dollars in medical and lost productivity costs every year, the FASTER initiative was funded to improve the availability and timeliness of nonfatal firearm injury data. As the 3-year FASTER initiative was implemented, the utility of syndromic surveillance data for monitoring other forms of nonfatal violence and mental health conditions (which may increase risk for or be a negative outcome associated with violence victimization) became clear. Timely state- and local-level data on ED visits for firearm injuries, other nonfatal injuries (e.g., intimate partner violence, sexual violence, child abuse and neglect), and mental health conditions are currently limited; thus, the collection of near real-time data on ED visits for these conditions at the state- and local-level could improve the ability to identify, respond to, and prevent violence. These data can also be used to identify, track, and address

disparities in ED visits for firearm injuries, other violence-related injuries, and mental health conditions. The Advancing Violence Epidemiology in Real Time (AVERT) initiative, funded by CDC in FY2023, intends to integrate, expand, and enhance previous data sharing efforts with public health departments initiated under the FASTER program. The goal of AVERT is to build on the FASTER program and provide funding to a minimum of 10 jurisdictions to share timely ED data for all firearm injuries (regardless of intent), other violence-related injuries, and mental health conditions. AVERT will support states to conduct routine monitoring of electronic health record data via syndromic surveillance to identify ED visits related to these conditions, as well as to analyze these data in a timely manner and share these data with CDC. To do this, AVERT will leverage ED syndromic surveillance data already

routinely collected by state health departments and the District of Columbia health department through CDC’s National Syndromic Surveillance Program (NSSP), which receives near real-time ED data from health departments. Descriptive analyses, such as frequencies and changes in the rate of ED visits involving a firearm injury, other violence-related injury, or mental health condition by region, state, and local jurisdiction, will be conducted. Longitudinal statistical analyses will be used to describe trends. Understanding the full extent of the problem of firearm violence, other forms of nonfatal violence, and mental health conditions treated in EDs is crucial to informing prevention and response strategies and reducing future incidents. CDC requests OMB approval for an estimated 30 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Total number of responses per respondent	Average burden per response (hours)
Participating health departments sharing case-level ED data with CDC.	Emergency Department Form (ED Violence Data Form).	10	6	30/60

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[FR Doc. 2023–17378 Filed 8–11–23; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Administration for Children and
Families

Submission for OMB Review;
Replication of Recovery and
Reunification Interventions for
Families-Impact Study (New
Collection)

AGENCY: Office of Planning, Research,
and Evaluation, Administration for
Children and Families, Department of
Health and Human Services.
ACTION: Request for public comments.

SUMMARY: The Administration for
Children and Families (ACF) is
proposing a data collection activity as
part of the Replication of Recovery and
Reunification Interventions for
Families-Impact Study (R3-Impact). The
R3-Impact Study aims to satisfy the

legislative requirements called for by
the 2018 SUPPORT for Patients and
Communities Act by replicating and
testing the efficacy of two recovery
coaching interventions for families
engaged in the child welfare system due
to parental substance use disorders.
DATES: Comments due within 30 days of
publication. The Office of Management
and Budget (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
OPREinfocollection@acf.hhs.gov.
Identify all requests by the title of the
information collection.

SUPPLEMENTARY INFORMATION:
Description: The R3-Impact study will
use experimental and quasi-
experimental designs to test the
effectiveness of the recovery coaching
interventions on key child welfare and
parent well-being outcomes. The
implementation study will document
the fidelity of program implementation,
describe the services participants
receive under each approach, and
provide operational lessons gathered
directly from practitioners. These goals
represent ACF’s interest in
understanding whether recovery
coaching interventions yield successful
parental recovery and child welfare
outcomes, and if so, whether the
potential exists to scale the
interventions for the benefit of more
affected families. The proposed
information collection activity consists
of (1) Baseline data collection:
collection of baseline demographic and
parent well-being data from study
participants; (2) Contact form: short
form sent to study participants quarterly
for one year after study enrollment to
keep contact information current and
generally maintain the participant’s
connection to the study; (3) Validation
interviews: short interviews with a

subset of study participants to monitor the quality of data collection interviews and to validate that the interviewer spoke with the participant; (4) Implementation study interviews: using topic guides, collect information from program supervisors and frontline staff, community providers, child welfare

staff, and parents enrolled in the programs to assess the fidelity of implementation, document program services, and gather operational lessons; and (5) Parent Interview Information Form: demographic information to support analysis of parent perspectives by personal characteristics and history.

Future information collection requests will be submitted to collect follow-up data.

Respondents: Parents enrolled in the R3-Impact Study, and program and agency staff involved in implementing the R3 interventions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Baseline Parent Survey	2,750	1	.75	2063	688
Contact Form	1,843	4	.17	1,253	418
Validation Interviews	275	1	.08	22	7
Topic Guide—Child Welfare Lead Staff.	60	1	1	60	20
Topic Guide—Child Welfare Frontline Staff.	60	1	1	60	20
Topic Guide—Partners	120	1	1	120	40
Topic Guide—Program Managers	60	1	1.5	90	30
Topic Guide—Mentor Supervisors	60	1	1.5	90	30
Topic Guide—Parent/Family Mentors	60	1	1.5	90	30
Topic Guide—Parents	30	1	1	30	10
Parent Interview Information Form ..	30	1	.1	3	1

Estimated Total Annual Burden Hours: 1,294.

Authority: The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act; Pub. L. 115–271)

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2023–17364 Filed 8–11–23; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2483]

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee (the Committee). The general function of the Committee as a medical device panel is to provide advice and

recommendations to FDA. In addition, the Committee will meet to discuss and provide advice to FDA on in vitro diagnostic devices used in pandemic preparedness and response to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA). The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on September 7, 2023, from 9 a.m. to 5:15 p.m. Eastern Time and September 8, 2023, from 9:30 a.m. to 3:45 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–2483. Please note that late, untimely filed comments will not be considered. The docket will close on October 10, 2023. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 10, 2023. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before August 30, 2023, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that