

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Immediate Disaster Case Management Intake Assessment	1,564	1	1	1,564	521

Estimated Total Annual Burden Hours: 521.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 426 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C.

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2020-06182 Filed 3-24-20; 8:45 am]

BILLING CODE 4184-PC-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Title V State Sexual Risk Avoidance Education (SRAE) Program (New Collection)

AGENCY: The Administration on Children, Youth and Families (ACYF);

Administration for Children and Families (ACF).

ACTION: Request for public comment.

SUMMARY: The Administration on Children, Youth and Families (ACYF), Family and Youth Services Bureau (FYSB) is accepting mandatory formula grant applications and State Plans from states and territories for the development of and implementation for Title V State Sexual Risk Avoidance Education (SRAE) Program. The Title V State SRAE Funding Opportunity Announcement sets forth the application requirements for the receipt of the following documents from applicants and awardees: Application, State Plan, and Performance Progress Report.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing infocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This Notice is to solicit comments from the public on ACYF's proposed information collection documents (application, State Plan, and Performance Progress Report).

Purpose and Use of the Information Collections: The application and State Plan will offer information about the proposed state project and it will be used as the primary basis to determine whether or not the project meets the minimum requirements for the award.

The Performance Progress Report will inform the monitoring of the grantees program design, program evaluation, management improvement, service quality, and compliance with agreed upon goals. ACYF/FYSB will use the information to assure effective service delivery. Finally, the data from this collection will be used to report outcomes and efficiencies and will provide valuable information to policy makers and key stakeholders in the development of program and research efforts.

Respondents: Fifty states and nine territories, to include the District of Columbia, Puerto Rico, Virgin Islands, Guam, American Samoa, Northern Mariana Islands, the Federated States of Micronesia, the Marshall Islands, and Palau.

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Information collection title	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Application	59	1	24	1,416	472
State Plan	59	3	40	7,080	2,360
Performance Progress Report	59	6	16	5,664	1,888

Estimated Annual Burden Total: 4,702.

Comments: The Department specifically requests comments on (a)

whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the

information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility,

and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

(Authority: Section 510 (42 U.S.C. 710), as amended by Section 50502 (Pub. L. 115–123))

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2020–06210 Filed 3–24–20; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1136, FDA–2020–D–1137, FDA–2020–D–1138, FDA–2020–D–1139, FDA–2020–D–1140, FDA–2020–D–1141, FDA–2020–D–1142, and FDA–2020–D–1143]

Process for Making Available Guidance Documents Related to Coronavirus Disease 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the process for making available FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA believes that this process will allow the Agency to rapidly disseminate essential Agency recommendations and policies related to COVID–19 to industry, FDA staff, and other stakeholders.

FOR FURTHER INFORMATION CONTACT:

Kimberly Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–796–2357; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911; Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353; Phil Chao, Center for Food Safety and Applied Nutrition, Food and Drug Administration, CPK1 Rm. 1C001, College Park, MD 20740, 240–402–2112;

Diane Heinz, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., MPN2 RME435, HFV–6, Rockville, MD 20855, 240–402–5692; May Nelson, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4420, Silver Spring, MD 20993–0002, 301–796–9241; John Weiner, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130; Silver Spring, MD 20993–0002, 301–796–8941; or Erik Mettler, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., ELEM Rm. 3008, Rockville, MD 20857, 301–796–9254.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID–19, and after consultation with public health officials as necessary, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), determined that a public health emergency exists and has existed since January 27, 2020, nationwide.¹ On March 13, 2020, President Donald J. Trump declared that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.² FDA is committed to providing timely recommendations, regulatory advice, guidance, and technical assistance on an Agency-wide basis on issues related to COVID–19, including to clarify our expectations regarding regulatory requirements to support response efforts to this emergency. To this end, FDA is announcing procedures for making available FDA guidance documents related to the COVID–19 public health emergency. FDA believes that these procedures, which operate within FDA's established good guidance practices regulations, will allow the Agency to rapidly disseminate Agency recommendations and policies related to COVID–19 to industry, FDA staff, and other stakeholders.

II. Procedures for Making COVID–19-Related Guidance Documents Available

To facilitate issuance of guidance on topics related to the COVID–19 public

¹ Determination that a Public Health Emergency Exists (January 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (March 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

health emergency, the Agency intends to use the following procedures:

- In light of the need to act quickly and efficiently to respond to the COVID–19 public health emergency, FDA anticipates that prior public participation will not be feasible or appropriate before FDA implements COVID–19-related guidance documents. FDA anticipates it will issue COVID–19-related guidance documents for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2) (§ 10.115(g)(2)).

- Although FDA expects that COVID–19-related guidances will be implemented without prior comment, FDA will solicit comment, review all comments received, and revise the guidance documents as appropriate (see § 10.115(g)(2)). Each guidance will specify the docket number(s) to which comments can be submitted.

- Guidance documents related to COVID–19 will be accessible on the internet from the FDA web page entitled “Coronavirus Disease 2019 (COVID–19),” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19>.

- Guidance documents related to COVID–19 may also be accessed from the FDA web page entitled “Search for FDA Guidance Documents” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

- Rather than publishing a separate Notice of Availability (NOA) for each COVID–19-related guidance document, FDA intends to publish periodically a consolidated NOA. This periodic NOA will announce the availability of all the COVID–19-related guidance documents that issued during the relevant period. The consolidated NOA will provide instructions to the public on submitting comments on COVID–19-related guidance documents, including the docket number(s) associated with each guidance document, information on how to view the dockets, and instructions for persons interested in obtaining a copy of a COVID–19-related guidance document. In addition, the guidance document will provide information to the public on submitting comments on the guidance document, including the docket number(s) associated with the guidance document and instructions for persons interested in obtaining a copy of a COVID–19-related guidance document.

- FDA intends to establish one docket for each Center or Office that may issue