DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: Office of Child Care CCDF Onsite Monitoring.

Title: Child Care and Development Fund (CCDF) State Monitoring Compliance Demonstration Packet.

OMB No.: New.

Description: The proposed data collection form is designed as part of the evidence collection process of the Onsite Monitoring system and provides states with an opportunity to propose how they, as block-grant recipients, will choose to demonstrate compliance.

Respondents: 51 States and Territories triennially.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Compliance Demonstration Chart	17	1	16	272
Document Submission Chart	17	1	80	1,360

Estimated Total Annual Burden Hours: 1,632 hours.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3443]

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.'' As more medical devices are becoming interconnected, cybersecurity threats have become more numerous, more frequent, more severe, and more clinically impactful. There is a need to provide manufacturers with specific technical recommendations (*e.g.,* appropriate threat modeling and other premarket testing) to help ensure device cybersecurity. The updates to the existing ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices'' guidance is anticipated to better protect against risks, such as ransomware campaigns, that could disrupt clinical operations and delay patient care and risks, such as exploiting a vulnerability that enables attacks on multiple patients. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 18, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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 identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as