

Dated: November 2, 2020.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020-24611 Filed 11-4-20; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; OCSE Stafford Act Flexibilities Request Form (New Collection)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.
ACTION: Request for Public Comment.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), seeks approval of a standardized request form to collect information from state and tribal title IV-D child support agencies requesting

administrative flexibilities under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the “Stafford Act”), due to the COVID-19 pandemic.

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: Due to the exceptional impact of the COVID-19 pandemic, state and tribal agencies operating child support programs under title IV-D of the Social Security Act have faced significant operational and other challenges in providing critical child

support services to families. Section 301 of the Stafford Act, 42 U.S.C. 5141, provides that “Any Federal agency charged with the administration of a Federal assistance program may, if so requested by the applicant State [or Indian tribal government] or local authorities, modify or waive, for a major disaster, such administrative conditions for assistance as would otherwise prevent the giving of assistance under such programs if the inability to meet such conditions is a result of the major disaster.” To communicate that child support agencies may request relief under the Stafford Act, on May 28, 2020, OCSE published Dear Colleague Letter 20-04: Flexibilities for State and Tribal Child Support Agencies during COVID-19 Pandemic. OCSE seeks approval of a standardized request form to collect information from state and tribal IV-D agencies requesting Stafford Act administrative flexibilities, due to the COVID-19 pandemic and according to OCSE Dear Colleague Letter 20-04.

Respondents: State and tribal agencies administering a child support program under title IV-D of the Social Security Act.

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
OCSE Stafford Act Flexibilities Request Form	114	3	1	342	114

Estimated Total Annual Burden Hours: 114

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: 42 U.S.C. 5141.

Mary B. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5569]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in

response to the notice. This notice solicits comments on information collection requirements for the tracking of medical devices.

DATES: Submit either electronic or written comments on the collection of information by January 4, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 4, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 4, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-5569 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including

the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites

comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Device Tracking—21 CFR Part 821

OMB Control Number 0910-0442—Extension

Section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)), as amended by Food and Drug Administration Modernization Act (Pub. L. 105-115), provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a "tracked implant"), or (3) the device is life-sustaining or life-supporting (referred to as a "tracked l/s-l/s device") and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, e.g., distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements.

Respondents for this collection of information are medical device

manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The annual hourly burden for respondents involved with medical device tracking is estimated to be 615,380 hours per year. The burden estimates cited in tables 1 through 3 are based on the approximate number of device tracking orders, 12 annually. FDA estimates that approximately 22,000 respondents may be subject to tracking reporting requirements.

Under § 821.25(a) (21 CFR 821.25(a)), device manufacturers subject to FDA tracking orders must adopt a tracking method that can provide certain device, patient, and distributor information to FDA within 3 to 10 working days.

Assuming one occurrence per year, FDA estimates it would take a firm 20 hours to provide FDA with location data for all tracked devices and 56 hours to identify all patients and/or multiple distributors possessing tracked devices.

Under § 821.25(d) manufacturers must notify FDA of distributor noncompliance with reporting requirements. Based on the number of audits manufacturers conduct annually, FDA estimates it would receive no more than one notice in any year, and that it would take 1 hour per incident.

Under § 821.30(c)(2) (21 CFR 821.30(c)(2)), multiple distributors must provide data on current users of tracked devices, current device locations, and other information, upon request from a manufacturer or FDA. FDA has not made such a request and is not aware of any manufacturer making a request.

Assuming one multiple distributor receives one request in a year from either a manufacturer or FDA, and that lists may be generated electronically, the Agency estimates a burden of 1 hour to comply.

Under § 821.30(d) distributors must verify data or make required records available for auditing, if a manufacturer provides a written request. FDA's estimate of the burden for distributor audit responses assumes that manufacturers audit database entries for 5 percent of tracked devices distributed. Each audited database entry prompts one distributor audit response. Because lists may be generated electronically, FDA estimates a burden of 1 hour to comply.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity; 21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Discontinuation of business—821.1(d)	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e)	1	1	1	1	1
Notification of failure to comply—821.25(d)	1	1	1	1	1
Multiple distributor data—821.30(c)(2)	1	1	1	1	1
Total					4

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity; 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a)	12	1	12	76	912
Record of tracking data—821.25(b)	12	46,260	555,120	1	555,120
Standard operating procedures—821.25(c) ²	12	1	12	63	756
Manufacturer data audit—821.25(c)(3)	12	1,124	13,488	1	13,488
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity; 21 CFR part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this information collection has not changed since the last OMB approval.

Dated: October 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-24541 Filed 11-4-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1561]

Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes—Exploring the Path Forward for Assessment; Public Workshop; Issues Paper; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: As part of the work by the Federal Government to address the opioid crisis, the Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled “Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes—Exploring the Path Forward for Assessment.” The purpose of the public workshop is to obtain scientific input on methods to evaluate the Opioid Analgesics Risk Evaluation and Mitigation Strategy (OA REMS) education program. To assist in the workshop discussion, FDA is making available an issues paper that provides a brief overview of the REMS background and challenges with evaluating the REMS education intervention.

DATES: The public workshop will be held virtually and broadcast via webcast only on December 11, 2020, from 9 a.m. to 5 p.m., Eastern Time. Submit either electronic or written comments on this public workshop by February 11, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this public workshop via an online teleconferencing platform.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 11, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 11, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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Instructions: All submissions received must include the Docket No. FDA-2020-N-1561 for “Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing

Behaviors and Patient Outcomes—Exploring the Path Forward for Assessment; Public Workshop; Issues Paper; Request for Comments.” Received comments, those filed in a timely manner (see *ADDRESSES*), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

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Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4462, Silver Spring, MD 20993-0002, 301-796-9029, OAREMS@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: