

**Leroy A. Richardson,**  
Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

#### Proposed Projects

*Title:* Multistate Financial Institution  
Data Match and Federally Assisted State  
Transmitted Levy (MSFIDM/FAST  
Levy).

*OMB No.:* 0970-0196.

*Description:* Section 466(a)(17) of the  
Social Security Act (the Act) requires  
states to establish procedures for their  
child support agencies to enter into  
agreements with financial institutions  
doing business in their state for the  
purpose of securing information leading  
to the enforcement of child support  
orders. Under 452(m) and  
466(a)(17)(A)(i) of the Act, the Secretary  
may aid state agencies conducting data  
matches with financial institutions  
doing business in two or more states by  
establishing a centralized and  
standardized matching program through  
the Federal Parent Locator Service.

To further assist states collect child  
support, the federal Office of Child  
Support Enforcement (OCSE) worked  
with child support agencies and  
financial institutions to develop the  
Federally Assisted State Transmitted  
(FAST) Levy system.

FAST Levy is a central, standardized,  
and secure electronic process for child  
support agencies and financial  
institutions to exchange information  
about levying financial accounts to  
collect past-due support. OCSE picks up  
files created by child support agencies  
that contain FAST Levy requests and  
distributes them to financial institutions  
that use the FAST Levy system. Those  
financial institutions create response  
files that OCSE picks up and distributes  
to the child support agencies.

The MSFIDM/FAST-Levy information  
collection activities are authorized by:  
42 U.S.C. 652(m), which authorizes  
OCSE, through the Federal Parent  
Locator Service, to aid state child  
support agencies and financial  
institutions doing business in two or  
more states reach agreements regarding  
the receipt from financial institutions,  
and the transfer to the state child  
support agencies, of information  
pertaining to the location of accounts  
held by obligors who owe past-due  
support; 42 U.S.C. 666(a)(2) and  
(c)(1)(G)(ii), which require state child  
support agencies in cases in which there  
is an arrearage to establish procedures to  
secure assets to satisfy any current  
support obligation and the arrearage by  
attaching and seizing assets of the

obligor held in financial institutions; 42  
U.S.C. 666(a)(17)(A), which requires  
state child support agencies to establish  
procedures under which the state child  
support agencies shall enter into  
agreements with financial institutions  
doing business in the State to develop  
and operate, in coordination with  
financial institutions, and the Federal  
Parent Locator Service (in the case of  
financial institutions doing business in  
two or more States), a data match  
system, using automated data exchanges  
to the maximum extent feasible, in  
which a financial institution is required  
to quarterly provide information  
pertaining to a noncustodial parent  
owing past-due support who maintains  
an account at the institution and, in  
response to a notice of lien or levy,  
encumber or surrender, assets held; 42  
U.S.C. 652(a)(7), which requires OCSE  
to provide technical assistance to state  
child support enforcement agencies to  
help them establish effective systems for  
collecting child and spousal support;  
and, 45 CFR 303.7(a)(5), which requires  
state child support agencies to transmit  
requests for information and provide  
requested information electronically to  
the greatest extent possible. To facilitate  
this requirement for states, OCSE  
developed the FAST Levy system that  
supports the electronic exchange of lien  
and levy information between child  
support agencies and financial  
institutions.

*Respondents:* Multistate Financial  
Institutions and State Child Support  
Agencies.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Financial Data Match Result File-Portal .....	192	4	5 minutes <sup>1</sup>	64
Election Form .....	30	1	0.5	15
FAST-Levy Record Specifications: Current Financial Institutions Users to Program New Codes .....	1	1	65 <sup>2</sup>	65
FAST-Levy Record Specifications: Current State Child Support Agencies to Program New Codes .....	3	1	65	195
FAST-Levy Response Withhold Record Specifications: Financial Institutions FAST-Levy Request Withhold Record Specifications: State Child Support Agencies .....	1	1	1,716	1,716
	2	1	1,610	3,220

<sup>1</sup> Estimate is approximately 5 minutes per response. For calculation, use 5/60.

<sup>2</sup> Estimate is an average based on input from OCSE's matching partners.

*Estimated Total Annual Burden  
Hours:* 5,275.

*Additional Information:* Copies of the  
proposed collection may be obtained by  
writing to the Administration for  
Children and Families, Office of  
Planning, Research and Evaluation, 330  
C Street SW., Washington, DC 20201,  
Attention Reports Clearance Officer. All  
requests should be identified by the

information collection. Email address:  
[infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov)

*OMB Comment:* OMB is required to  
make a decision concerning 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. Written

comments and recommendations for the  
proposed information collection should  
be sent directly to the following: Office  
of Management and Budget, Paperwork  
Reduction Project, Email: [OIRA\\_](mailto:OIRA_SUBMISSION@OMB.EOP.GOV)  
[SUBMISSION@OMB.EOP.GOV](mailto:SUBMISSION@OMB.EOP.GOV), Attn:

Desk Officer for the Administration for Children and Families.

**Bob Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-D-1264]

#### Manufacturers Sharing Patient-Specific Information From Medical Devices With Patients Upon Request; 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 guidance entitled “Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request.” FDA developed this guidance to clarify our position regarding manufacturers appropriately and responsibly sharing “patient-specific information”—information unique to an individual patient or unique to that patient’s treatment or diagnosis that has been recorded, stored, processed, retrieved, and/or derived from a legally marketed medical device—with that patient at that patient’s request. This guidance provides information and recommendations to industry, health care providers, and FDA staff about the mechanisms and considerations for device manufacturers sharing such information with individual patients when they request it.

**DATES:** The announcement of the guidance is published in the **Federal Register** on October 30, 2017.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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 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-2016-D-1264 for “Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request.” Received comments 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.

- **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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Esther Bleicher, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5424, Silver Spring, MD 20993-0002, 301-796-8547.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Increasingly, patients seek to play an active role in their own health care. FDA believes that sharing “patient-specific information” with patients upon their request may assist them in being more engaged with their health care providers in making sound medical decisions. For purposes of this guidance, “patient-specific information” is information unique to an individual