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 [1]	64
Election Form	30	1	0.5	15
FAST-Levy Record Specifications: Current Financial Institutions Users to Program New Codes	1	1	65 [2]	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	1	1	1,716	1,716
FAST-Levy Request Withhold Record Specifications: State Child Support Agencies	2	1	1,610	3,220

[1] Estimate is approximately 5 minutes per response. For calculation, use 5/60.
[2] 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*

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_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