



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Dissemination of Patient-Specific Information from Devices by Device Manufacturers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Dissemination of Patient-Specific Information from Devices by Device Manufacturers." The FDA developed this draft guidance to facilitate the appropriate and responsible dissemination of patient-specific information recorded, stored, processed, retrieved, and/or derived from medical devices from manufacturers to patients. This draft guidance provides recommendations to industry, healthcare providers, and FDA staff about the mechanisms and considerations for device manufacturers sharing such information with patients. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 "Dissemination of Patient-Specific Information from Devices by Device Manufacturers." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 draft guidance document entitled "Dissemination of Patient-Specific Information from Devices by Device Manufacturers" 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: Sugato De, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5435, Silver Spring, MD 20993-0002, 301-796-6270, Sugato.De@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Increasingly, patients seek to play an active role in their own healthcare. FDA believes that manufacturers providing patients with accurate, useable information about their healthcare (including the medical products they use and patient-specific information these products generate) will improve healthcare by empowering patients to participate fully with their healthcare providers in making sound medical decisions. For purposes of this guidance, patient-

specific information is defined as any information unique to an individual patient or unique to that patient's treatment or diagnosis that may be recorded, stored, processed, retrieved, and/or derived from a medical device. This information may include, but is not limited to, recorded patient data, device usage/output statistics, healthcare provider inputs, incidence of alarms, and/or records of device malfunctions or failures.

FDA developed this draft guidance to convey FDA's policy regarding the dissemination of patient-specific information recorded, stored, processed, retrieved, and/or derived from a medical device and provided by the manufacturer to the patient who is either treated or diagnosed with that specific device. This draft guidance document also outlines considerations for the form in which this information is communicated to help to ensure clarity of content and appropriate context.

Manufacturers may share patient-specific information (recorded, stored, processed, retrieved, and/or derived from a medical device, consistent with the intended use of that medical device) with patients either on their own initiative or at the patient's request, without obtaining additional premarket review before doing so. Any labeling, as that term is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), that is provided to the patient by the manufacturer is subject to applicable requirements in the FD&C Act and FDA regulations.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance when finalized will represent the current thinking of FDA on "Dissemination of Patient-Specific Information from Devices by Device Manufacturers." It does not establish any rights for any person and is not binding on FDA or the

public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Dissemination of Patient-Specific Information from Devices by Device Manufacturers" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500067 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 801 and 809, regarding device labeling, are approved under OMB control number 0910-0485.

Dated: June 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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