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Dissemination of Patient-Specific Information from Devices by Device Manufacturers

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document, contact Mr. Sugato De at (301) 796-6270.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

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Dissemination of Patient-Specific Information from Devices by Device Manufacturers

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I. Introduction

The Food and Drug Administration (FDA) developed this draft guidance to facilitate the appropriate and responsible dissemination of patient-specific information recorded, stored, processed, retrieved, and/or derived from medical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 This draft guidance provides recommendations to industry, healthcare providers, and FDA staff about the mechanisms and considerations for device manufacturers sharing such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 when they request it.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Increasingly, patients seek to play an active role in their own healthcare. FDA is issuing this guidance to clarify that manufacturers may share patient-specific information recorded, stored, processed, retrieved, and/or derived from a medical device with the patient who is either treated or diagnosed with that specific device. FDA believes that providing patients with access to accurate, useable information about their healthcare when they request it (including the medical products they use and patient-specific information these products generate) will empower patients to be more engaged with their healthcare providers in making sound medical decisions. This draft guidance document also outlines considerations for the form in which this information is communicated to help to ensure clarity of content and appropriate context.

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, consistent with the intended use of a medical device, may be recorded, stored, processed, retrieved, and/or derived from that 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. This information does not include any interpretations of data aside from those interpretations of data normally reported by the device to the patient or the patient's healthcare provider. Generally, categories for patient-specific information may include, but are not limited to: (1) data a healthcare provider inputs to record the status and ongoing treatment of an individual patient or (2) information stored by the device to record usage, alarms, or outputs (e.g., pulse oximetry data, heart electrical activity, and rhythms as monitored by a pacemaker). Patient-specific case logs entered into a medical device by a healthcare provider may be included under this definition. Cumulatively, this information may be used to facilitate continuity of care, to create an adequate patient treatment history and current treatment profile, and to record information relating to medical device functionality.

III. Patient-Specific Information Dissemination Policy

Although not generally required under the Federal Food, Drug, and Cosmetic Act (FD&C Act), manufacturers may share patient-specific information (recorded, stored, processed, retrieved, and/or derived from a legally marketed medical device, consistent with the intended use of that medical device) with patients at the patient's request, without obtaining additional premarket review before doing so. It should be noted, however, that any labeling, as that term is defined in section 201(m) of 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.

In many cases, patient-specific information from a medical device is accessible by the patient's healthcare provider and patients can contact their healthcare provider to obtain such information. Alternatively, patients may contact the manufacturer directly and request access to their patient-specific information.

The Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C. § 300gg; 29 U.S.C. 1811 *et seq.*; 42 U.S.C. § 1320d *et seq.*) and the associated HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) mandated the adoption of federal privacy protections for individually identifiable health information. These protections are intended to prevent manufacturers from sharing this information with covered entities (e.g., health plans, healthcare providers that electronically transmit health information) without the patient's consent. However, these protections are not intended to prevent a device manufacturer from sharing patient-specific information with the affected patient.

FDA believes that device manufacturers should take certain considerations into account when sharing patient-specific information to help to ensure it is useable by patients and to avoid the disclosure of confusing or unclear information that could be misinterpreted. These considerations relate to the content of information provided, the context in which patient information from medical devices should be understood, and the need for access to additional, follow-up information from the manufacturer or a healthcare provider.

A. Content

Patient-specific information derived from a medical device that can be shared by a device manufacturer with an individual patient may include any information from the device that is pertinent to that specific patient.

FDA recommends that a manufacturer take appropriate measures to ensure that the information provided is interpretable and useful to the patient and to prevent the disclosure of confusing or unclear information that could be misinterpreted. When communicating patient-specific information, the manufacturer should take into consideration the characteristics of the intended audience that may affect interpretability. Depending on the type and scope of information being shared, the manufacturer may choose to provide supplementary instructions, materials or references to aid patient understanding. If this supplemental material meets the definition of labeling, it would be subject to regulation by the FDA and the relevant requirements and restrictions would apply.

Generally, patient-specific information provided to patients should be comprehensive and contemporary. For example, if a patient requests a history of his own blood pressure measurements from a device, the data should include all available data up through the most recent measurement.

B. Context

When providing patient-specific information to the affected patient, it may be appropriate for the device manufacturer to include relevant context to avoid circumstances where this information may be misinterpreted, thus leading to incorrect or invalid conclusions. For example, when providing data regarding a measured physiological parameter over time, it may be useful to a patient to include information regarding how that parameter was measured and recorded by the medical device. In another example, if information is being provided regarding the activity of a pacemaker, information regarding the circumstances under which an electrical impulse is delivered by the device may provide helpful context.

Manufacturers who make patient-specific information available to patients should consider what, if any, information they should include about whom to contact for follow-up information. FDA recommends, at a minimum, that such manufacturers advise patients to contact their healthcare providers should they have any questions about their patient-specific information and may also wish to provide contact information for the manufacturer to answer questions from patients about the device at issue.