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Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the Office of the Center Director at (301) 796-6900.

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

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Preface

Public Comment

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or "we") 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, healthcare providers, and FDA staff about the mechanisms and considerations for device manufacturers sharing such information with individual 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 guidance 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 aware that sometimes a patient will request that a manufacturer share with her information about herself that has been recorded, stored, processed, retrieved, and/or derived from a legally marketed medical device. FDA is issuing 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. FDA believes that sharing "patient-specific information" with patients upon their request may assist them in being more engaged with their healthcare providers in making sound medical decisions.

III. Scope

For purposes of this guidance, "patient-specific information" is 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. 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. For the purposes of this guidance, patient-specific information does not include any interpretations of data by the manufacturer aside from those interpretations of data normally reported by the device to the patient or the patient's healthcare provider. For example, results of individual component tests for specific analytes that comprise or are utilized in a cleared assay but have not been individually approved or cleared to test for those specific analytes are not "patient-specific information" for purposes of this guidance and so fall outside the scope of the guidance.

Generally, categories of patient-specific information may include, but are not limited to: (1) data a healthcare provider inputs in the device 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. 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.

IV. Patient-Specific Information Sharing Policy

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. In general, although not required under the Federal Food, Drug, and Cosmetic Act (FD&C Act), manufacturers may share patient-specific information about a patient with that patient at that patient's request. In general, manufacturers may do so without undergoing additional premarket review in advance. FDA generally would not consider patient-specific information to be "labeling," as defined in section 201(m) of the FD&C Act. FDA is aware that when manufacturers share patient-specific information with patients, manufacuters also may provide them with supplemental information or other materials (e.g., descriptions of intended use, benefit and risk information, instructions for use) that may be considered labeling. Any labeling is subject to applicable requirements in the FD&C Act and FDA regulations.

We are aware that some devices are designed to record or transmit information in a format that is not easily provided to the patient. Other devices record and retain information in a closed system that is not accessible by the manufacturer. In such circumstances, it may not be feasible for manufacturers to share patient-specific information with patients as doing so would require manufacturers to redesign devices or gain access to information they do not have.

Generally, if patient-specific information is shared with patients by manufacturers, it should be comprehensive and contemporary. For example, if a patient requests from a manufacturer a history of her own blood pressure measurements from a device, the data should include all available data up through the most recent measurement. Manufacturers may also format the patient-specific information to facilitate its usability by the patient.

FDA recognizes the important role healthcare providers play in providing interpretation of and context to patient-specific information. FDA recommends that manufacturers advise patients to contact their healthcare providers should they have any questions about their patient-specific information.

Finally, this guidance does not affect any federal, state or local laws or regulations, such as 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), which may otherwise be applicable to the provision of patient-specific information. Moreover, the guidance does not change FDA's policy and is not intended to supersede any other relevant policies and guidances regarding manufacturers' communications about their devices.