Contains Nonbinding Recommendations

Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-7800.

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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Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) recognizes that the progression to digital health offers the potential for better, more efficient patient care and improved health outcomes. To achieve this goal requires that many medical devices be interoperable with other types of medical devices and with various types of health information technology. The foundation for such inter-communication is hardware and software that transfer, store, convert formats, and display medical device data or medical imaging data.

The FDA is issuing this guidance document to inform manufacturers, distributors, and other entities that the Agency does not intend to enforce compliance with the regulatory controls that apply to MDDS, medical image storage devices, and medical image communications devices, due to the low risk they pose to patients and the importance they play in advancing digital health.

On February 15, 2011, the FDA issued a regulation down-classifying MDDS from Class III (high-risk) to Class I (low-risk) ("MDDS regulation").[1] Class I devices are subject to general controls under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Since down-classifying MDDS, the FDA has gained additional experience with these types of technologies, and has determined that these devices pose a low risk to the public. Therefore, the FDA does not intend to enforce compliance with the regulatory controls that apply to MDDS devices, medical image storage devices, and medical image communications devices.

[1] See Medical Devices; Medical Device Data Systems Final Rule (76 FR 8637) (Feb. 15, 2011).

The policy described in this guidance document is also consistent with the Agency's updated guidance entitled "Mobile Medical Applications" (February 9, 2015). (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)

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

A Medical Device Data System (MDDS) is a hardware or software product that transfers, stores, converts formats, and displays medical device data. 21 CFR 880.6310 defines MDDS as follows:

§ 880.6310 Medical device data system. (a) Identification.

(1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

(i) The electronic transfer of medical device data;

(ii) The electronic storage of medical device data;

(iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

(iv) The electronic display of medical device data.

(2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

An MDDS is a medical device[2] intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

[2] For additional information about whether a product is a medical device, see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm

- The electronic transfer or exchange of medical device data. For example, this would include software that collects output from a ventilator about a patient's CO2 level and transmits the information to a central patient data repository.

- The electronic storage and retrieval of medical device data. For example, software that stores historical blood pressure information for later review by a healthcare provider.

- The electronic conversion of medical device data from one format to another in accordance with a preset specification. For example, software that converts digital data generated by a pulse oximeter into a digital format that can be printed.

- The electronic display of medical device data. For example, software that displays a previously stored electrocardiogram for a particular patient.

An MDDS may include the following, provided the intended use is consistent with the MDDS regulation:

- Any assemblage or arrangement of network components that includes specialized software or hardware expressly created for a purpose consistent with the intended use in the MDDS regulation.

- Products specifically labeled (per 21 CFR part 801) by the manufacturer as an MDDS, provided such products do not provide additional functionality.

- Custom software that is written by entities other than the original medical device manufacturer (for example, hospitals, third party vendors) that directly connects to a medical device, to obtain medical device information.

- Modified portions of software or hardware that are part of an Information Technology (IT) infrastructure created and/or modified (writing and compiling software) for specific MDDS functionality. For example, when modifying software for MDDS functionality, only the modified portion is considered MDDS; the original software is not.

An MDDS does not modify the data, and it does not control the functions or parameters of any connected medical device. An MDDS does not include devices intended for active patient monitoring.[3] Devices intended for active patient monitoring include the following characteristics:

- The clinical context requires a timely response (e.g. in-hospital patient monitoring).

[3] As noted in the preamble of the MDDS regulation, the word *"active"* represents *"any device that is intended to be relied upon in deciding to take immediate clinical action*" (21 CFR 8637 at 8644). FDA further noted that there are existing classifications for patient monitoring devices (See, e.g., 21 CFR part 880, subpart C (general hospital and personal use monitoring devices); 21 CFR part 868, subpart C (anesthesiology monitoring devices); 21 CFR part 884, subpart C (obstetrical and gynecological monitoring devices); and 21 CFR part 870, subpart C (cardiovascular monitoring devices)).

- The clinical condition (disease or diagnosis) requires a timely response (e.g. a monitor that is intended to detect life-threatening arrhythmias such as ventricular fibrillation or a device used to actively monitor diabetes for time-sensitive intervention).

Examples of devices that provide active patient monitoring include:

- A nurse telemetry station that receives and displays information from a bedside hospital monitor in an ICU.
- A device that receives and/or displays information, alarms, or alerts from a monitoring device in a home setting and is intended to alert a caregiver to take an immediate clinical action.

Examples of devices that perform monitoring but are not considered to perform "active patient monitoring" based on the characteristics described above include:

- An application that transmits a child's temperature to a parent/guardian while the child is in the nurse/health room of a school.
- An application that facilitates the remote display of information from a blood glucose meter, where the user of the meter can independently review their glucose and glucose levels, and which is not intended to be used for taking immediate clinical action. In these cases, remotely displaying information such as the most recent blood glucose value or time-lapse between blood glucose measurements is not considered active patient monitoring.

This guidance also provides the policy for medical image storage and medical image communications devices. These devices are defined as follows:

A medical image storage device, defined under 21 CFR 892.2010, is a device that provides electronic storage and retrieval functions for medical images.

A medical image communications device, defined under 21 CFR 892.2020, is a device that provides electronic transfer of medical image data between medical devices.

III. Policy for Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

The FDA does not intend to enforce compliance with the regulatory controls that apply to the following devices:

a) MDDS subject to 21 CFR 880.6310,
b) Medical image storage devices subject to 21 CFR 892.2010, and
c) Medical image communications devices subject to 21 CFR 892.2020.

This means that for devices that meet the definitions in the regulations listed above, the FDA does not intend to enforce compliance with the regulatory controls, including registration and listing, premarket review, postmarket reporting, and quality system regulation for manufacturers of these types of devices.

MDDS (21 CFR 880.6310), medical image storage devices (21 CFR 892.2010), and medical image communications devices (21 CFR 892.2020) are exempt from premarket notification; however, limitations to this exemption identified under 21 CFR 880.9 and 21 CFR 892.9 would require a premarket notification. Even when exceeding these limitations, FDA does not intend to enforce compliance with the regulatory controls for devices that meet the definitions identified by the above regulations. For example, to the extent that these limitations apply, FDA does not intend to enforce compliance with regulatory controls for a MDDS that is an in vitro device that is intended for assessing the risk of cardiovascular diseases (21 CFR 880.9(c)(4)) or for use in diabetes management (21 CFR 880.9(c)(5)).