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 CDRH-regulated devices, contact the Division of Digital Health by e-mail at digitalhealth@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Identify all comments with the docket number FDA-2014-D-0798. Comments may not be acted upon by the Agency until the document is next revised or updated.

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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) 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, typically referred to as medical device data systems (MDDS) that transfer, store, convert formats, and display medical device data or medical imaging data.

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] 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. On February 9, 2015, the FDA issued a 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.

Since the issuance of the guidance document in 2015, section 3060(a) of the 21st Century Cures Act (Cures Act) amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on December 13, 2016, removing certain software functions from the definition

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

of device in section 201(h) of the FD&C Act. Pursuant to section 520(o)(1)(D) of the FD&C Act, *software functions* that are *solely intended* to transfer, store, convert formats, and display medical device data or medical imaging data, unless the software function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings, are not devices and are not subject to FDA laws and regulations applicable to devices. The definition of MDDS in 21 CFR 880.6310 is currently inconsistent with the definition of device as amended pursuant to the Cures Act. FDA intends to amend the regulation to be consistent with the amended device definiton. FDA's current thinking on the definition of MDDS is reflected in this guidance.

Hardware products that are intended to transfer, store, convert formats, and display medical device data and results remain devices under section 201(h) of the FD&C Act. FDA does not intend to enforce compliance with the regulatory controls for such devices, provided that the hardware function is limited to assisting the following software functions: electronic transfer, storage, conversion of formats, or display of medical device data.

The policy described in this guidance document is also consistent with the Agency's updated guidance entitled "Policy for Device Software Functions and Mobile Medical Applications," originally issued on February 9, 2015, with the title "Mobile Medical Applications.[2]"

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

FDA uses the following terms in this guidance:

> **Non-Device-MDDS:** *Software functions* that are *solely intended* to transfer, store, convert formats, and display medical device data or results.
>
> **Device-MDDS:** *Hardware functions* that are *solely intended* to transfer, store, convert formats, and display medical device data or results.

FDA further defines Non-Device-MDDS and Device-MDDS through the following examples:

[2] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.

A Non-Device-MDDS is a software function solely intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices, which may or may not be intended for active patient monitoring[3]:

- 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 CO_2 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 health care 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.

Other examples of Non-Device-MDDS include:

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

- Software functions specifically labeled (per 21 CFR Part 801) by the manufacturer as a 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 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.

A MDDS does not modify the data, and it does not control the functions or parameters of any connected medical device. Software functions intended to generate alarms or alerts or

[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)).

prioritize patient-related information on multi-patient displays, which are typically used for active patient monitoring, are considered device software functions because these functions involve analysis or interpretation of laboratory test or other device data and results. As noted above, a Non-Device-MDDS may include software functions that transfer, store, convert formats, or display medical device data that may or may not be intended for active patient monitoring.

Software functions that are device functions intended for active patient monitoring include the following characteristics:

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

- 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 products that transfer, store, convert formats, or display medical device data and are Non-Device-MDDS:

  - 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

A. Policy for Non-Device-MDDS

Software functions that meet the definition of Non-Device-MDDS, medical image storage devices, or medical image communications devices are not devices under section 201(h) of the FD&C Act. As such, software functions that are *solely intended* to transfer, store, convert formats, and display medical device data and results, including medical images, waveforms, signals, or other clinical information, are not devices and thus are not subject to FDA regulatory requirements applicable to devices. However, software functions that analyze or interpret medical device data in addition to transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results remain subject to FDA's regulatory oversight, unless they meet the criteria outlined in section 520(o)(1)(E) of the FD&C Act.

B. Policy for Device-MDDS

Hardware functions that are intended to transfer, store, convert formats, and display medical device data and results remain devices under section 201(h) of the FD&C Act. FDA does not intend to enforce the requirements under the FD&C Act for hardware products that are considered to be Device-MDDS, medical image storage, or medical image communications devices, provided that the hardware function is limited to assisting the following software functions: electronic transfer, storage, conversion of formats, or display of medical device data. These hardware functions may include the following regulations:

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 hardware functions 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.

Each Device-MDDS regulation listed above contains an exemption from premarket notification; however, limitations to this exemption identified under 21 CFR 880.9 and 21 CFR 892.9 require a premarket notification in the listed circumstances. Even when exceeding these limitations, FDA does not intend to enforce compliance with the regulatory controls for for hardware functions 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 Device-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)).

Specialized medical display hardware devices for digital mammography, radiology, pathology, and ophthalmology (see, for example, 21 CFR 892.2050) and other specialized medical display hardware integral to the safe and effective use of a medical device hardware product (such as integral 3D displays in robotic surgery systems and displays built into ICU bedside monitors) have not been considered MDDS, medical image storage, or medical image communications devices. Such medical display hardware devices and other specialized medical display hardware integral to a medical device are not excluded from the device definition by the Cures Act and are not considered to be Device-MDDS.

In some cases, software functions that transfer, store, convert formats, or display medical device data and results are utilized on hardware that is not intended by the hardware manufacturer for a device function under section 201(h) of the FD&C Act. For example, general-purpose hardware IT infrastructure intended for data transfer (e.g., network router), data storage (e.g., network attached storage (NAS)), conversion of data (e.g., PDF software), and display of data (computer monitor) are not device functions. Such products do not meet the definition of a device in section 201(h) of the FD&C Act for either the software or hardware function and are therefore not regulated as devices.

C. Multiple Function Device Products that contain Non-Device-MDDS or Device-MDDS

Consistent with section 520(o)(2) of the FD&C Act, which describes the regulation of a product with multiple functions, including at least one device function and at least one software function that is not a device, FDA does not regulate the Non-Device-MDDS functions contained in a multiple function device product. If a multiple function device product contains Device-MDDS functions, FDA does not, at this time and based our current understanding of the risks of these devices, intend to enforce the requirements under the FD&C Act. However, FDA may assess the impact that such Non-Device-MDDS and Device-MDDS functions have on the safety and effectiveness of the device function(s) in the multiple function device product. FDA intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.