Contains Nonbinding Recommendations

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

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on June 20, 2014.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH- regulated devices, contact Bakul Patel at 301-796-5528, or email at Bakul.Patel@fda.hhs.gov or contact the Office of the Center Director at 301-796-5900.

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

Preface

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Table of Contents

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance when finalized will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 draft 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).[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).

This document is also proposing edits to the Agency's guidance entitled "Mobile Medical Applications" (September 25, 2013) which would conform to the policy discussed in this draft guidance, when finalized. (See 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

Medical Device Data Systems (MDDS) are hardware or software products that transfer, store, convert formats, and display medical device data. A MDDS does not modify the data, and it does not control the functions or parameters of any connected medical device. MDDS are not intended to be used in connection with active patient monitoring.

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:

- 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.

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

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

- 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 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 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 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. However, even when subject to 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 MDDS intended to be used in

a system 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)).

IV. Edits to 2013 Mobile Medical Applications Guidance

The following are the conforming changes that FDA proposes to make to the Mobile Medical Applications guidance document:

Section V-A-1

- FDA would modify the Section V-A-1 heading by deleting the sentence after the word "or" and inserting "for use in active patient monitoring or analyzing medical device data." –

  Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or ~~displaying, storing, analyzing, or transmitting patient-specific medical device data~~ for use in active patient monitoring or analyzing medical device data.

  -- to read as follows:

  Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or for use in active patient monitoring or analyzing medical device data.

- FDA would modify the following example by inserting a period after "server" and deleting the rest of the sentence --

  Examples of displays of patient-specific medical device data include: remote display of data from bedside monitors, ~~display of previously stored EEG waveforms,~~ and display of medical images directly from a Picture Archiving and Communication System (PACS) server~~, or similar display functions that meet the definition of an MDDS~~. Mobile medical apps that display medical device data to perform active patient monitoring are subject to regulations associated with such devices.

  -- to read as follows:

  Examples of displays of patient-specific medical device data include: remote display of data from bedside monitors, and display of medical images directly from a Picture Archiving and Communication System (PACS) server. Mobile medical apps that display medical device data to perform active patient monitoring are subject to regulations associated with such devices.

- FDA would delete the following example in its entirety:

Examples of mobile apps that display, store, or transfer medical device data in its original format include: apps that are intended to display or store medical device data, without controlling or altering the functions or parameters of any connected medical device constitute a Medical Device Data System (MDDS) (21 CFR 880.6310) and are subject to class I requirements (general controls). Class I are the lowest risk devices with the fewest requirements and generally no premarket submission. Class I general controls include these basics: adequate design controls, registration, device listing, adverse event reporting, and corrections and removals. The FDA believes that requiring general controls sufficiently manages the risks for mobile medical apps that are used as a secondary display to a regulated medical device and are not intended to provide primary diagnosis or treatment decisions (i.e., mobile medical apps that meet the MDDS definition).

Section V-B

- In Section V-B-2, FDA would modify footnote 28 as indicated below—

  [28] We consider these mobile apps to be tools which are not intended to provide specific treatment recommendations and/or are ~~not part of diabetes management referred to in 21 CFR 862.9(c)(5)~~

  -- to read as follows:

  [28] We consider these mobile apps to be tools which are not intended to provide specific treatment recommendations and/or are NOT subject to limitations of exemptions referred in 21 CFR 880.9(c)(4) -- For assessing the risk of cardiovascular diseases; or in 21 CFR 880.9(c)(5) -- For use in diabetes management.

- FDA would add an example after Section V-B-6 to read as follows:

  7. **Mobile apps that meet the definition of Medical Device Data Systems** – These are apps that are intended to transfer, store, convert format, and display medical device data, without controlling or altering the functions or parameters of any connected medical device, as defined in the MDDS classification regulation (21 CFR 880.6310). These mobile apps include those that are used as a secondary display to a regulated medical device and are not intended to provide primary diagnosis, treatment decisions, or to be used in connection with active patient monitoring (i.e., mobile apps that meet the MDDS definition).

Appendix B

- FDA would add the following examples to Appendix B:

- Mobile apps that transfer, store, convert formats, and display medical device data without modifying the data and do not control or alter the functions or parameters of any connected medical device (i.e., mobile apps that meet the definition of MDDS under 21 CFR 880.6310).

- Mobile apps that connect to a nursing central station and display medical device data to a physician's mobile platform for review (i.e., a medical device data system or MDDS). Product code: OUG (21 CFR 880.6310).

Appendix C

- FDA would delete the following example in its entirety:

  - Mobile apps that connect to a nursing central station and display medical device data to a physician's mobile platform for review. (i.e., a medical device data system or MDDS). Product code: OUG (21 CFR 880.6310).

Appendix D

- FDA would remove the row for regulation 880.6310 from the Table.

~~880.6310~~	~~Medical device data systems~~	~~Medical device data system (OUG)~~	~~1~~	~~510(k) exempt~~