Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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When final, the content of this guidance will be incorporated into the following guidance documents: General Wellness: Policy for Low Risk Devices, issued July 29, 2016; Mobile Medical Applications, issued February 9, 2015; Off-The-Shelf Software Use in Medical Devices, issued September 9, 1999; Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, issued February 9, 2015

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Preface

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

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 of device in section 201(h) of the FD&C Act. This draft guidance provides FDA's current thinking regarding the amended device definition and the resulting effect the amended definition has on FDA's guidances related to medical device software. Upon finalization, the concepts detailed in this draft guidance will also be made through Level 2 updates to the following guidance documents:

- General Wellness: Policy for Low Risk Devices, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm429674.pdf
- Mobile Medical Applications, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263366.pdf
- Off-The-Shelf Software Use in Medical Devices, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, available at

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm401996.pdf

The following guidance document will be withdrawn, for the reasons described in Section IV.D:

- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073720.htm

FDA's guidance documents, including this draft 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

On December 13, 2016, the Cures Act was enacted. Section 3060(a) of this legislation, titled "Clarifying Medical Software Regulation," amended the FD&C Act to add section 520(o), which describes software functions that are excluded from the definition of device in 201(h) of the FD&C Act. Section 3060(d) of the Cures Act amended section 201(h) of the FD&C Act to state that the term device does not include the software functions excluded pursuant to section 520(o). This draft guidance focuses on section 520(o)(1)(A)-(D) of the FD&C Act, reproduced below.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j)

(o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings…

III. Scope

This draft guidance details the changes to existing guidance documents that relate to the regulation of the software functions described in section 520(o)(1)(A)-(D) of the FD&C Act. These sections describe software functions that do not meet the device definition in 201(h) of the FD&C Act. Section 3060 also describes limited circumstances when software functions described in 520(o)(1)(A)-(D) would remain devices.[1, 2]

FDA intends to provide clarification of its interpretation of section 520(o)(1)(E) of the FD&C Act, which is for software functions intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of disease or other conditions (often referred to as clinical decision support software), in a separate guidance document. Section 520(o)(2) of the FD&C Act 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 also intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.

IV. Interpretation of the Cures Act and Modifications to Existing Guidance Documents

FDA's interpretation of each provision of Section 520(o)(1)(A) – 520(o)(1)(D) of the FD&C Act, as amended by the Cures Act, described in Sections A – D below will be added to the

[1] The Cures Act also provides that a software function described in section 520(o)(1)(A)-(D) of the FD&C Act will not be excluded from the device definition under section 201(h) of the FD&C Act if FDA makes a finding that the software function would be reasonably likely to have serious adverse health consequences and certain substantive and procedural criteria are met. Section 520(o)(3) of the FD&C Act.

[2] The Cures Act further provides that a software function described in section 520(o)(1)(A)-(D) of the FD&C Act will not be excluded from the device definition under section 201(h) of the FD&C Act if the software meets the criteria for class III classification under section 513(a)(1)(C) of the FD&C Act. (Section 520(o)(4)(C) of the FD&C Act). The Cures Act also states that this statutory provision shall not be construed to limit FDA's authority to regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans. (Section 520(o)(4)(B) of the FD&C Act).

Background sections of the indicated guidances that will be revised, after consideration of timely filed comments, through Level 2 updates to incorporate the changes detailed in this guidance. Similarly, FDA will make changes to the examples in the guidances, after consideration of comments, through level 2 updates, as described below.

Section 3060 of the Cures Act created a function-specific definition, and as such, the functions excluded from the device definition under section 520(o) of the FD&C Act are independent of the platform on which they might run. In order to clarify this, once this guidance is finalized, we will make changes to the relevant guidances, through Level 2 updates, to clarify, where appropriate, that the policies in the guidance documents are function-specific and apply across platforms. For example, as appropriate, instances of "mobile application" in the Mobile Medical Applications (MMA) guidance will be changed to "software function," and the title of the guidance will likely be revised to "Mobile Medical Applications and Software Functions."

A. Software Function Intended for Administrative Support of a Health Care Facility

Section 520(o)(1)(A) of the FD&C Act states that the term "device" does not include a software function that is intended "for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow." FDA has not historically considered most of these software functions to be devices; however, we propose the following modification in order to provide additional clarity.

Section 3.2.2 of the Guidance for Off-the-Shelf Software Use in Medical Devices, titled "Exemption of Laboratory Information Management Systems," will be removed from the guidance. As software with functions intended for administrative support of laboratories and/or for transferring, storing, converting formats, or displaying clinical laboratory test data and results, Laboratory Information Management Systems (LIMS) are not within the definition of the term device, according to 201(h) of the FD&C Act, as amended by the Cures Act (*see* section 520(o)(1)(A) and (D) of the FD&C Act). Therefore, these products are not subject to requirements under the FD&C Act.

B. Software Function Intended for Maintaining or Encouraging a Healthy Lifestyle

Section 520(o)(1)(B) of the FD&C Act states that the term device does not include a software function that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." FDA considers a product with an intended use for maintaining or encouraging a "healthy lifestyle" to

mean a product with an intended use that encourages or maintains a "general state of health or healthy activity," as defined in the FDA guidance General Wellness: Policy for Low Risk Devices ("General Wellness Guidance").[3] In that guidance CDRH defines a general wellness product as products that (1) are intended for only general wellness use, as defined in that guidance, and (2) present a low risk to the safety of users and other persons. That guidance defines two categories of general wellness intended uses: (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

If the intended use of the software function is related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, then the product is not excluded from the definition of the term "device" under section 520(o)(1)(B) of the FD&C Act. Since the second category of a general wellness intended uses, as defined in the General Wellness Guidance, relates to the mitigation or prevention of a disease or condition, these products are not excluded from the definition of device as modified by this new provision of the FD&C Act. This second category of general wellness intended uses relates to sustaining or offering general improvement to functions associated with a general state of health while making reference to help reduce the risk of or help living well with certain chronic diseases or conditions. Although this type of general wellness product is not excluded from the definition of device, we intend to continue to not enforce the applicable requirements for this type of general wellness software function where it presents a low risk to the safety of users and other persons. As described in the General Wellness Guidance, FDA does not intend to examine whether low risk general wellness products in the second category are devices within the meaning of the FD&C Act, or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations, including, but not limited to: registration and listing and premarket notification requirements (21 CFR Part 807); labeling requirements (21 CFR Part 801 and 21 CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21 CFR Part 820); and Medical Device Reporting (MDR) requirements (21 CFR Part 803).

According to section 520(o)(1)(B) of the FD&C Act, a software function with a healthy lifestyle claim (e.g., products that fall within the first category of general wellness intended uses as defined by the General Wellness Guidance) is not a device as long as its claims are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. For example, software with healthy lifestyle claims, such as weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function, are not devices when not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. Therefore, the following examples in Section V. of the General Wellness Guidance are not devices:

[3] Available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm429674.pdf .

- A mobile application that plays music to "soothe and relax" an individual and to "manage stress" (Illustrative Example 1)
- A mobile application that solely monitors and records daily energy expenditure and cardiovascular workout activities to "allow awareness of one's exercise activities to improve or maintain good cardiovascular health" (Illustrative Example 2)
- A mobile application that monitors and records food consumption to "manage dietary activity for weight management and alert the user, healthcare provider, or family member of unhealthy dietary activity" (Illustrative Example 3)

These examples will remain in the General Wellness Guidance, because they continue to meet the definition of general wellness products; however, the title of Section V. will be changed to "Examples of General Wellness Products that Are Not Medical Devices and Examples of General Wellness Products that Are Medical Devices for which FDA Does Not Intend to Enforce Requirements" to reflect that some of these examples are not medical devices under 201(h) of the FD&C Act.

For the MMA guidance, the following examples in Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) will be moved to Appendix A (Examples of mobile apps that are NOT medical devices) of the MMA Guidance, because they no longer meet the definition of the term "device" pursuant to section 520(o)(1)(B) of the FD&C Act:

- Mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness, such as those that:
  - Provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;
  - Provide dietary logs, calorie counters or make dietary suggestions;
  - Provide meal planners and recipes;
  - Track general daily activities or make exercise or posture suggestions;
  - Track a normal baby's sleeping and feeding habits;
  - Actively monitor and trend exercise activity;
  - Help healthy people track the quantity or quality of their normal sleep patterns;
  - Provide and track scores from mind-challenging games or generic "brain age" tests;
  - Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
  - Use social gaming to encourage healthy lifestyle habits;
  - Calculate calories burned in a workout.

C. Software Function Intended to Serve as Electronic Patient Records

Under section 520(o)(1)(C) of the FD&C Act, the term device does not include certain software functions that are intended to serve as electronic patient records. Specifically, software functions that are intended to transfer, store, convert formats, or display electronic patient records that are

the equivalent of a paper medical chart are not devices, if the following three criteria outlined in 520(o)(1)(C)(i) – (iii) are met:

1. Such records were created, stored, transferred, or reviewed by health care professionals (HCPs), or by individuals working under supervision of such professionals, (Section 520(o)(1)(C)(i) of the FD&C Act);

2. Such records are part of information technology certified by the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program[4] (Section 520(o)(1)(C)(ii) of the FD&C Act); and

3. Such software functions are not intended for interpretation or analysis of patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition (Section 520(o)(1)(C)(iii) of the FD&C Act).

FDA does not intend to enforce the FDA requirements for software functions that are not certified by ONC, if they meet the other criteria in section 520(o)(1)(C)(i) and (iii) of the FD&C Act.

Software functions that enable patients or non-HCPs to create, store, or transfer health records for their own record-keeping purposes that are not intended to be created, stored, transferred or reviewed by a HCP are considered personal health records (PHRs). These software functions in PHR systems that are not intended for use in the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition are not devices under section 201(h) of the FD&C Act.

Software functions excluded from the device definition by section 520(o)(1)(C) of the FD&C Act may be contained in electronic health record (EHR) systems, PHR systems, and other health information technology. Such systems may also contain other software functions that could meet the definition of a device. FDA's approach to oversight of software functions that meet the definition of a device in a system with software functions that do not meet the definition of device (products with multiple functions) will be addressed in a separate guidance document.

Therefore, in the MMA Guidance, the following examples in Section V.B. (Mobile Apps for which FDA intends to exercise enforcement discretion) are not devices (pursuant to section 520(o)(1)(C) of the FD&C Act), and will be moved to Appendix A (Examples of mobile apps that are NOT medical devices) of that guidance:

- **Mobile apps that enable individuals to interact with ONC-certified EHR systems** -- These are apps that provide individuals with mobile access to health record systems or enable them to gain electronic access to health information stored within an EHR system. Applications that only allow individuals to view or download EHR data are also included

[4] "About the ONC Health IT Certification Program," available at https://www.healthit.gov/policy-researchers-implementers/about-onc-health-it-certification-program.

in this category. These mobile apps are generally meant to facilitate general patient health information management and health record-keeping activities.
    - Note: This example has been changed to clarify that only ONC-certified EHR functions are not devices according to the FD&C Act, as amended by 21st Century Cures.
    - For clarity, this example and other types of electronic patient record functions must meet the full description of section 520(o)(1)(C) in the FD&C Act, in that they are not devices only if they are reviewed by HCPs, certified by ONC, and are not intended for interpretation or analysis for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. However, FDA does not intend to enforce compliance with requirements that apply to these software functions if they are not certified by ONC.
- Provide patients with simple tools to organize and track their health information;
- Provide easy access to information related to patients' health conditions or treatments;
- Help patients document, show, or communicate potential medical conditions to health care providers

And in the MMA Guidance, the following examples will be moved from Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) to Appendix A (Examples of Mobile Apps that are Not Medical Devices) as long as the products are ONC-certified:

- Mobile apps that enable, during an encounter, a health care provider to access their patient's personal health record (health information) that is hosted on a web-based or other platform
- Mobile apps for HCPs that help track or manage patient immunizations by documenting the need for immunization, consent form, and immunization lot number.
    - This example has been changed from "assessing the need for immunization" to "documenting the need…" because the example is intended to serve as an example of an electronic patient record, and not clinical decision support software. FDA intends to provide clarification of section 520(o)(1)(E) of the FD&C Act and clinical decision support software in a separate guidance document.

D. Software Function Intended for Transferring, Storing, Converting Formats, Displaying Data and Results

Under section 520(o)(1)(D) of the FD&C Act, the term "device" does not include a software function that is intended "for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings" (section 520(o)(1)(D) of the FD&C Act).

The software functions that meet the definitions of Medical Device Data Systems (MDDS), medical image storage devices, or medical image communications devices provided in the Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices Guidance (or MDDS Guidance), and the Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, are, thus, now not devices under section 201(h) of the FD&C Act, pursuant to section 520(o)(1)(D) of the FD&C Act. As such, products 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. 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.

FDA does not consider the following functions to meet the definition of device under section 201(h) of the FD&C Act, as amended by the Cures Act:

1. Medical Device Data System (MDDS), defined as a software, electronic, or electrical hardware that is intended to provide one or more of the following uses, whether or not the use is for immediate clinical action, without controlling or altering the functions or parameters of any connected medical devices:
    a. The electronic transfer of medical device data;
    b. The electronic storage of medical device data;
    c. The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
    d. The electronic display of medical device data.

    Examples of MDDS include physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol.
2. Medical image storage device, defined as a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.
3. Medical image communications device, defined as a device that provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, interfaces, and a communications protocol. [5]

Section 520(o)(1)(D) of the FD&C Act does not capture software functions intended to generate alarms or alerts or prioritize multi-patient displays, because these functions involve analysis or interpretation of laboratory test or other device data and results. For example, if a software function is intended to prioritize patients in an Intensive Care Unit based on their clinical status, then this function is intended to interpret or analyze device data, results, and findings and is, therefore, not excluded from the definition of device under section 520(o)(1)(D) of the FD&C Act. Similarly, software functions that analyze medical device data in order to provide a

[5] The identification statement of 21 CFR 892.2020 no longer meets the definition of a device as amended by the Cures Act. However, there are products regulated under § 892.2020 that continue to meet the definition of a device, according to the description in section 520(o)(1)(E) of the FD&C Act. FDA intends to issue separate guidance on section 520(o)(1)(E) of the FD&C Act.

notification or flag (e.g., that a parameter is out of range) are not excluded from the definition of device under subsection (D). However, FDA does not intend to enforce requirements under the FD&C Act and implementing regulations for these low risk software functions, such as the analysis of data to provide a notification, for which immediate clinical action is not needed. FDA intends to focus its regulatory oversight on software functions intended to generate alarms or alerts or prioritize multi-patient displays if they are intended to alert a caregiver to take an immediate clinical action.

The MDDS Guidance will be revised to clarify that products 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, whether or not the use is for immediate clinical action. Accordingly, the definition of MDDS will be revised in that guidance to the definition in item 1 above. The discussion and examples of devices that are used for immediate clinical action (active patient monitoring) will be revised:

- *Examples of devices that provide active patient monitoring* will be revised to *Examples of devices that analyze or interpret laboratory test or other device data that are the focus of FDA's regulatory oversight*
    - A nurse telemetry station that analyzes or interprets information from a bedside hospital monitor in an ICU in order to produce alarms or notifications.
    - A device that generates 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"* will be revised to *Examples of products that transfer, store, convert formats, or display medical device data and are not devices*

In the MMA Guidance, the following example will be revised and moved from Section V.A. (Subset of mobile apps that are the focus of FDA's regulatory oversight) to Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion):

- *Examples of displays of patient-specific medical device data include:* display of medical images directly from a Picture Archiving and Communication System (PACS) server and remote display of data from bedside monitors (note that software functions that analyze or interpret medical device data to generate alarms or alerts that are intended to be relied upon in deciding to take immediate clinical action, are subject to regulations associated with such devices)
    - The parenthetical note in this example has been changed from "note that mobile medical apps that display medical device data to generate alarms or alerts that are intended to be relied upon in deciding to take immediate clinical action, are subject to regulations associated with such devices" to the text above, because software functions that merely display medical device data are not medical devices. Software functions that analyze or interpret medical device data are medical devices and subject to FDA's regulatory oversight.

And the following example will be added to Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) of the MMA Guidance:

- Software tools that analyze stored clinical information to flag patient results based on specific clinical parameters (e.g., out of range results, potential drug interactions, opportunities for complementary tests, create disease registries, summarize patient-specific information in an integrated report, and/or track a patient's treatment or disease outcome) provided that the analysis performed by these software is not intended for immediate clinical action and does not represent a unique interpretation function but rather summarizes standard interpretation of individual variables that healthcare practitioners could do themselves.

In the MMA Guidance, the following examples will be moved from Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) to Appendix A (Examples of Mobile Apps that are Not Medical Devices):

- Mobile apps or software functions that are intended for transferring, storing, converting formats or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results and findings.
  - 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).
  - Mobile apps that meet the definition of MDDS and connect to a nursing central station and display medical device data to a physician's mobile platform for review.
  - Mobile apps that are not intended for diagnostic image review such as image display for multidisciplinary patient management meetings (e.g., rounds) or patient consultation (and include a persistent on-screen notice, such as "for informational purposes only and not intended for diagnostic use").

And the following example of a software function and its associated text in Section V.B. of the MMA Guidance is no a longer device pursuant to section 520(o)(1)(D) of the FD&C Act and will be moved to Appendix A (Examples of Mobile Apps that are Not Medical Devices) of that guidance:

- Mobile apps that meet the definition of Medical Device Data Systems

The Guidance for the Submission of Premarket Notifications for Medical Image Management Devices will be withdrawn, because some software functions described in that guidance no longer meet the definition of a device, as amended. For the limited subset of Medical Image Management Devices that continue to meet the definition of a device and continue to require a 510(k) submission, the information provided in that document, which was written in 2000, is out of date. CDRH encourages manufacturers to reference the most recent FDA-recognized versions of relevant voluntary consensus standards instead.