Contains Nonbinding Recommendations

The 21st Century Cures Act (Cures Act), enacted on December 13, 2016, amended the definition of "device" in the Federal Food, Drug, and Cosmetic Act (FD&C Act) to exclude certain software functions. On September 27, 2019, FDA issued this guidance, "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act," to provide our current thinking regarding the amended device definition and the interpretation of section 3060(a) of the Cures Act, including sections 520(o)(1)(A)-(D) of the FD&C Act. This guidance also detailed changes the amended device definition had on FDA's guidances that existed at that time related to medical device software, including:

- General Wellness: Policy for Low Risk Devices
- Policy for Device Software Functions and Mobile Medical Applications
- Off-The-Shelf Software Use in Medical Devices
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

This guidance, "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act," remains FDA's policy and interpretation of section 3060(a) of the Cures Act, including sections 520(o)(1)(A)-(D) of the FD&C Act, and will continue to serve as reference for this topic. As of September 27, 2022, FDA does not intend to continue to update this guidance. Rather, as FDA receives comments from the public and FDA's thinking related to medical device software evolves, FDA's other guidances related to medical device software, including those referenced on this page, may be updated, if appropriate, in accordance with 21 CFR 10.115.

We also note that FDA has issued two other guidance documents related to FDA's interpretation of section 520(o) of the FD&C Act:

- Clinical Decision Support Software, which interprets and explains the changes in section 520(o)(1)(E) of the FD&C Act, and
- Multiple Function Device Products: Policy and Considerations, which interprets and presents FDA's approach to section 520(o)(2) of the FD&C Act.

FDA's guidances related to medical device software, including those listed above, will continue to be updated as FDA's thinking evolves, and should be consulted for FDA's current thinking on these topics.

Contains Nonbinding Recommendations

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

---

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.

The draft of this document was issued on December 8, 2017.

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health 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.



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

GRZAN

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-2017-D-6294. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 17030 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

GRZAN

Table of Contents

I. Introduction....1
II. Background....2
III. Scope....3
IV. Interpretation of the Cures Act and Modifications to Existing Guidance Documents....3
A. Software Function Intended for Administrative Support of a Health Care Facility....4
B. Software Function Intended for Maintaining or Encouraging a Healthy Lifestyle....4
C. Software Function Intended to Serve as Electronic Patient Records....7
D. Software Function Intended for Transferring, Storing, Converting Formats, Displaying Data and Results....11

GRZAN

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

Guidance for Industry and Food and Drug Administration Staff

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

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 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. The concepts detailed in this guidance are also reflected in the following guidance documents through Level 2 updates:[1]

- General Wellness: Policy for Low Risk Devices[2]
- Mobile Medical Applications[3]
- Off-The-Shelf Software Use in Medical Devices[4]

[1] A Level 2 guidance document sets forth "existing practices or minor changes in interpretation or policy. Level 2 guidance documents include all guidance documents that are not classified as Level 1" (21 CFR 10.115(c)(2)). Because this final guidance sets forth the initial interpretations of FDA's statutory and regulatory requirements relating to software functions, it is a Level 1 guidance (21 CFR 10.115(c)(1)). FDA is making Level 2 updates to the listed guidance documents to make them consistent with existing practices as expressed in this final guidance.

[2] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices.

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

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices.

- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices[5]

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

- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices

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

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 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

[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices.

> (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 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.[6, 7]

FDA provides clarification of its proposed 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 provides its proposed 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, described in Sections A – D below has been added to the Background sections of the indicated guidances that have been revised, after consideration of timely filed comments, through Level 2 updates to incorporate the changes detailed in this guidance. Similarly, FDA has made changes to the examples in the guidances, after consideration of comments, through Level 2 updates, as described below.

---

[6] 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).

[7] 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).

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, we have made changes to the relevant guidances, through Level 2 updates. Additionally, where appropriate, we are clarifying 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 has been changed to "software function," and the title of the guidance has been revised to "Policy for Device Software Functions and Mobile Medical Applications."

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,[8] titled "Exemption of Laboratory Information Management Systems," has been removed from the guidance. Laboratory Information Systems (LIS) and Laboratory Information Management Systems (LIMS) functions intended for administrative support of laboratories and/or for transferring, storing, converting formats, or displaying clinical laboratory test data and results are not considered to be within the definition of the term device, according to section 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 software functions are not subject to requirements under the FD&C Act. However, some LIS and LIMS include software functions that remain device functions, including software functions that analyze medical device data in order to provide a notification or flag (e.g., that a parameter is out of range) and such functions will continue to be regulated as devices as specified in Section IV.D.

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

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

[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices.

Risk Devices ("General Wellness Guidance").[9] 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.

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." This provision affects the two categories of general wellness intended uses differently, as described below:

1. General Wellness Intended Use That Relates to Maintaining or Encouraging a General State of Health or a Healthy Activity

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.

Section 520(o)(1) of the FD&C Act describes software functions, not hardware products, that do not meet the definition of a device under section 201(h) of the FD&C Act as amended. Therefore, hardware with general wellness intended uses that relate to maintaining or encouraging a general state of health or healthy activity that otherwise meet the definition of device in section 201(h) will continue to be regulated as devices. FDA notes that many such functions do not otherwise meet the definition of a device under section 201(h) of the FD&C Act; however, for those hardware products that do otherwise meet the definition of device, FDA intends to apply the considerations in the General Wellness Guidance.

2. General Wellness Product 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

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices.

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. FDA's policy for general wellness products in the second category can be found in the General Wellness Guidance.[10]

The following examples in Section V of the General Wellness Guidance are not devices:

- A mobile application that plays music to "soothe and relax" an individual and to "manage stress." Such a software function is not a device function (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." Such a software function is not a device function (Illustrative Example 2).
- A mobile application that monitors and records food consumption to "manage dietary activity for weight management and alert the user, health care provider, or family member of unhealthy dietary activity." Such a software function is not a device function (Illustrative Example 3).

These examples remain in the General Wellness Guidance, because they continue to meet the definition of general wellness products; however, the title of Section V has been 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 the bullets above that indicate that some of these examples are not medical devices under section 201(h) of the FD&C Act.

For the MMA guidance,[11] the following examples in Appendix B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) have been 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;

[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices.
[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.

- 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 all the following three criteria outlined in section 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 under a program of voluntary certification kept or recognized by the Office of the National Coordinator for Health Information Technology (ONC) under section 3001(c)(5) of the Public Health Service Act ("ONC Health IT Certification Program")[12] (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).

1. Records created, stored, transferred, or reviewed by HCPs, patients, or other individuals

Section 520(o)(1)(C)(i) of the FD&C Act describes software functions that are intended to transfer, store, convert formats, or display electronic patient records that are not devices, if those functions are performed by HCPs or individuals working under HCP supervision.

[12] "About the ONC Health IT Certification Program," available at https://www.healthit.gov/policy-researchers-implementers/about-onc-health-it-certification-program. A comprehensive listing of all health information technology, which has been certified under the ONC Health IT Certification program, is available at the Certified Health IT Product List at https://chpl.healthit.gov/#/resources/overview.

Software functions that enable patients, individuals, or non-HCPs to create, store, or transfer health records 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.

2. Certified under ONC Health IT Certification Program

Under section 520(o)(1)(C) of the FD&C Act, the term device does not include software functions that meet the other criteria in section 520(o)(1)(C)(i) and (iii) of the FD&C Act and that are certified under the ONC Health IT Certification Program.

Based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance to the requirements of the FD&C Act for software functions that are not certified under the ONC Health IT Certification Program if they meet the other criteria in section 520(o)(1)(C)(i) and (iii) of the FD&C Act.[13]

As described above, software functions in PHR systems that are intended for use by patients, individuals, or non-HCPs are not devices under section 201(h) of the FD&C Act (not by operation of section 520(o) of the FD&C Act). As such, there is no requirement for ONC certification of these PHR software functions.

3. Not intended for interpretation or analysis of patient records

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 (IT). Such EHR or PHR 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. Similarly, FDA's approach to oversight of software functions that provide interpretation or analysis of records will be addressed in a separate guidance document on section 520(o)(1)(E) of the FD&C Act.

Therefore, in the MMA Guidance,[14] the following examples in Section V.B (Examples of 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 have been moved to Appendix A (Examples of mobile apps that are NOT medical devices) of that guidance:

- **Software functions that enable individuals to interact with EHR software certified under the ONC Health IT Certification Program** – These are software functions that provide individuals with access to health record systems or enable them to gain electronic

[13] "Nothing in this subsection shall be construed as limiting the authority of the [FDA] to— (A) exercise enforcement discretion as to any device subject to regulation under this Act . . ." (section 520(o)(4) of the FD&C Act).

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

access to health information stored within an EHR system. Software functions that only allow individuals to view, transfer, or download EHR data are also included in this category. These software functions 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 EHR software functions certified under the ONC Health IT Certification Program are not devices according to the FD&C Act, as amended by the Cures Act. This example has also been changed where it previously described "mobile apps" to the term "software function." As described above, similar changes are made throughout the MMA guidance, but not detailed in this guidance.
  - 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 under the ONC Health IT Certification Program, 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, at this time and based on our current understanding of the risks of these devices, to enforce compliance with requirements of the FD&C Act that apply to these software functions if the only requirement of 520(o)(1)(C) that they fail to meet is certification under the ONC Health IT Certification Program.

- 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;
- **Mobile apps that provide patients with simple tools to organize and track their health information** – These are apps that provide patients with tools to organize and track health information without providing recommendations to alter or change a previously prescribed treatment or therapy. Examples include:
  - Apps that provide simple tools for patients with specific conditions or chronic disease (e.g., obesity, anorexia, arthritis, diabetes, heart disease) to record their events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their health care provider as part of a disease-management plan.
    - Note this example has been modified to replace "log, track, or trend" with "record" to align with the language in the Cures Act.
- **Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions** – These products either pose little or no risk, or are the sole responsibility of the health care providers who have used them in medical applications. Examples include:
  - Apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications between patients, health care providers, and caregivers;
  - Note this example has been modified to remove the sentence: These are apps that in their labeling or promotional materials are not promoted for medical uses but which, by virtue of other circumstances surrounding their distribution, may meet the definition of a medical device.

  - The second example included as a sub-bullet remains a device function under enforcement discretion, because its functions extend beyond functions intended to transfer, store, convert formats, or display the equivalent of a paper medical chart. This example remains in Section V.B (Examples of mobile apps for which FDA intends to exercise enforcement discretion) of the MMA guidance: Apps specifically intended for medical uses that utilize the mobile device's built-in camera or a connected camera for purposes of documenting or transmitting pictures (e.g., photos of a patient's skin lesions or wounds) to supplement or augment what would otherwise be a verbal description in a consultation between health care providers or between health care providers and patients/caregivers.

And in the MMA Guidance,[15] the following examples have been 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). The phrase "that is [or are] certified under the ONC Health IT Certification Program" was added to these examples, as appropriate, to clarify that EHR software functions are not devices only if they are certified under the ONC Health IT Certification Program.

- 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;
- Software functions for HCPs certified under the ONC Health IT Certification Program, such as those 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.
- Mobile apps that help asthmatics record (i.e., collect and log) inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks.
  - Note this example has been changed to replace the word "track" with "record (i.e., collect and log)".
- Software functions certified under the ONC Health IT Certification Program that prompt the HCP to manually enter symptomatic, behavioral or environmental information, the specifics of which are pre-defined by a HCP, and store the information for later review;
- Mobile apps that record the clinical conversation a clinician has with a patient and sends it (or a link) to the patient to access after the visit;
- Mobile apps that allow a user to record (i.e., collect and log) data, such as blood glucose, blood pressure, heart rate, weight, or other data from a device to eventually share with a

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

health care provider, or upload it to an online (cloud) database, personal health record, or electronic health record that is certified under the ONC Health IT Certification Program.
    - Note this example has been modified to replace "collect, log, track and trend" with "record (i.e., collect and log)".
- Enable patients or providers to interact with PHR systems or EHR systems that are certified under the ONC Health IT Certification Program.
    - Note, this example is considered not a medical device because interacting with PHR or EHR systems is an example of transferring, storing, converting formats, or displaying EHR or PHR data.

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).

Medical Device Data Systems, medical image storage devices, and medical image communications devices are defined as:

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 it is intended for immediate clinical action (i.e., active patient monitoring), 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.

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),[16] and the Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, are 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, 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. 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.

Section 520(o)(1) of the FD&C Act describes software functions, not hardware products, that do not meet the definition of a device under section 201(h) of the FD&C Act. Therefore, the hardware included in the identification above (such as electrical hardware, magnetic and optical discs, physical communications medium, etc.) that are intended to transfer, store, convert formats, and display medical device data and results remain devices. FDA's existing policy, described in the MDDS Guidance,[17] applies to 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. 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.

There may be MDDS products that are considered multiple function products in that they may have a software function that is not a device and another function that is a device. Consistent with section 520(o)(2) of the FD&C Act, FDA does not regulate the MDDS software functions that meet the definition of 520(o)(1)(D) of the FD&C Act in a MDDS multiple function product. If a multiple function product contains MDDS hardware functions, FDA does not, at this time and based on 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 software and hardware MDDS functions have on the safety and effectiveness of the device function(s) in a multiple function device product. As noted above, FDA intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.

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

[16] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices.
[17] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices.

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.

Section 520(o)(1)(D) of the FD&C Act does not capture software functions intended to generate alarms or alerts or prioritize patient-related information on 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 notification or flag (e.g., that a parameter is out of range) are not excluded from the definition of device under subsection (D)). The examples included in the draft of this guidance that described alarms, alerts, or flags have been removed from this guidance, because they are not excluded from the definition of device under subsection (D). These functions are addressed in section 520(o)(1)(E) of the FD&C Act, the regulation of which will be described in a separate guidance document.

The MDDS Guidance[18] has been revised to clarify that 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, whether or not the use is for immediate clinical action. Accordingly, the definition of MDDS has been revised in that guidance to describe hardware that transfers, stores, converts formats, and displays medical device data as "Device-MDDS" whereas the software functions that transfer, store, convert formats, and display data have been defined as "Non-Device-MDDS." Additional updates to the MDDS guidance include:

- In the Background section, the following list of examples has been labeled as Non-Device-MDDS, because they are examples of MDDS software functions:
    - 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.

[18] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices.

- In the Background section, the following examples of MDDS have been revised to clarify that only the software functions are Non-Device-MDDS:
    - Any assemblage or arrangement of network components that includes specialized software expressly created for a purpose consistent with the intended for use in the MDDS regulation.
        - Note "or hardware" has been removed from this example.
    - Software functions specifically labeled (per 21 CFR Part 801) by the manufacturer as a MDDS, provided such software functions do not provide additional functionality.
        - Note "products" has been replaced with "software functions."
    - 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 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.
        - Note "or hardware" has been removed from this example.
- In the Background section, the section title "Examples of devices that perform monitoring but are not considered to perform 'active patient monitoring'" has been revised to "Examples of products that transfer, store, convert formats, or display medical device data and are Non-Device-MDDS."
- In the Policy section of the MDDS guidance, FDA describes its compliance policy with respect to the following devices:
    - MDDS subject to 21 CFR 880.6310,
    - Medical image storage devices subject to 21 CFR 892.2010, and
    - Medical image communications devices subject to 21 CFR 892.2020.

  As described above, FDA intends to continue this policy for hardware products considered MDDS, medical image storage, or medical image communications devices, provided that the hardware function is limited to the excluded software functions of electronic transfer, storage, conversion of formats, or display of medical device data. FDA intends to amend the regulations so that they describe the hardware functions that remain device functions, and to remove reference to software functions that are not device functions pursuant to section 520(o)(1)(D) of the FD&C Act. Accordingly, the Policy section has been amended to include the following:
    - Software functions that meet the definitions of MDDS, medical image storage devices, or medical image communications devices are not devices under section 201(h) of the FD&C Act. Hardware that are intended to transfer, store, convert formats, and display medical device data and results remain devices. FDA does not intend to enforce the requirements under the FD&C Act for hardware products considered MDDS, medical image storage, or medical image communications devices.

In the MMA Guidance,[19] the following example has been revised and moved from Section V.A (Subset of mobile apps that are the focus of FDA's regulatory oversight) to Appendix A (Examples of mobile apps that are NOT medical devices):

- *Examples of displays of patient-specific medical device data include:* software function to display medical images directly from a Picture Archiving and Communication System (PACS) server.
    - Note: The remote display of data from bedside monitors has been removed from this example, because such non-device display functions are covered in other examples, while this example is not likely to be a real-world example of a product, since such product would likely include other software functions that analyze or interpret medical device data that may continue to be subject to FDA's regulatory oversight.

In the MMA Guidance, the following examples have been 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):

- 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.
    - Software functions 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).
    - Software functions that meet the definition of MDDS and connect to a nursing central station and display (but do not analyze or interpret) medical device data to a physician's mobile platform for review.
    - Software functions 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").
    - Note that in these examples, "mobile apps" has been replaced with "software functions" to clarify that the software functions are Non-Device-MDDS.

In the MMA Guidance, the following examples in Appendix C (Examples of mobile apps that are the focus of FDA's regulatory oversight) have been revised as described below:

- Mobile apps that are used in active patient monitoring or analyzing patient-specific medical device data and therefore are the focus of FDA's regulatory oversight:

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

  - Mobile apps that connect to bedside (or cardiac) monitors and transfer the data to a central viewing station for display and active patient monitoring. Possible product code(s): DSI, MHX, MLD (21 CFR 870.1025), DRT, MWI, MSX (21 CFR 870.2300).
    - This sub-bullet has been revised to say: Software functions that acquire or process physiological signals. Possible product code(s): DSI, MHX, MLD (21 CFR 870.1025), DRT, MWI, MSX (21 CFR 870.2300).
  - Mobile apps that connect to a perinatal monitoring system and transfer uterine contraction and fetal heart rate data to another display to allow for remote monitoring of labor progress. Possible product code(s): HGM (21 CFR 884.2740).
    - This sub-bullet has been revised to say: Software functions that process uterine contraction and fetal heart rate data for remote monitoring of labor progress. Possible product code(s): HGM (21 CFR 884.2740).
  - Mobile apps that are intended to display images for diagnostic review may be regulated as a picture archiving and communications system. Possible product code(s): LLZ (21 CFR 892.2050).
    - This sub-bullet has been revised to say: Software functions that are intended to process images for diagnostic review may be regulated as a picture archiving and communications system. Possible product code(s): LLZ (21 CFR 892.2050).

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 has been moved to Appendix A (Examples of mobile apps that are NOT medical devices) of that guidance:

- Software functions that meet the definition of Medical Device Data Systems – These are software functions that are intended to transfer, store, convert formats, and display medical device data, without controlling or altering the functions or parameters of any connected medical device. These include those software functions for a secondary display to a regulated medical device when these apps are not intended to provide primary diagnosis, to be used to make treatment decisions, or to be used in connection with active patient monitoring.
  - Note the text of this example has been modified to clarify that only the software functions intended to transfer, store, convert formats, and display medical device data are not medical devices (i.e., Non-Device-MDDS).

The Guidance for the Submission of Premarket Notifications for Medical Image Management Devices has been 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.