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

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document regarding CDRH-regulated devices, contact the Office of the Center Director at 301-796-5900 or the Digital Health Program 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.

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

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

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Preface

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Draft Guidance for Industry and Food and Drug Administration Staff

> *This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 This draft guidance provides FDA's current thinking regarding the amended device definition and the resulting effect the amended definition has on FDA's guidances related to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 Upon finalization, the concepts detailed in this draft guidance will also be made through Level 2 updates to the following guidance documents: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

104   https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidan
105   ceDocuments/ucm401996.pdf
106
107
108 The following guidance document will be withdrawn, for the reasons described in Section IV.D:
109   •   Guidance for the Submission of Premarket Notifications for Medical Image Management
110   Devices, available at
111   https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocumen
112   ts/ucm073720.htm
113
114 FDA's guidance documents, including this draft guidance, do not establish legally enforceable
115 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should
116 be viewed only as recommendations, unless specific regulatory or statutory requirements are
117 cited. The use of the word *should* in Agency guidance means that something is suggested or
118 recommended, but not required.
119

II.   Background

120

121
122 On December 13, 2016, the Cures Act was enacted. Section 3060(a) of this legislation, titled
123 "Clarifying Medical Software Regulation," amended the FD&C Act to add section 520(o), which
124 describes software functions that are excluded from the definition of device in 201(h) of the
125 FD&C Act. Section 3060(d) of the Cures Act amended section 201(h) of the FD&C Act to state
126 that the term device does not include the software functions excluded pursuant to section 520(o).
127 This draft guidance focuses on section 520(o)(1)(A)-(D) of the FD&C Act, reproduced below.
128
129   Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j)
130   (o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—
131   (1) The term device, as defined in section 201(h), shall not include a software
132   function that is intended—
133   (A) for administrative support of a health care facility, including the
134   processing and maintenance of financial records, claims or billing information,
135   appointment schedules, business analytics, information about patient
136   populations, admissions, practice and inventory management, analysis of
137   historical claims data to predict future utilization or cost-effectiveness,
138   determination of health benefit eligibility, population health management, and
139   laboratory workflow;
140   (B) for maintaining or encouraging a healthy lifestyle and is unrelated
141   to the diagnosis, cure, mitigation, prevention, or treatment of a disease or
142   condition;
143   (C) to serve as electronic patient records, including patient-provided
144   information, to the extent that such records are intended to transfer, store,
145   convert formats, or display the equivalent of a paper medical chart, so long as—
146   (i) such records were created, stored, transferred, or reviewed
147   by health care professionals, or by individuals working under
148   supervision of such professionals;
149   (ii) such records are part of health information technology that
150   is certified under section 3001(c)(5) of the Public Health Service Act;
151   and

152   (iii) such function is not intended to interpret or analyze
153   patient records, including medical image data, for the purpose of the
154   diagnosis, cure, mitigation, prevention, or treatment of a disease or
155   condition;
156   (D) for transferring, storing, converting formats, or displaying clinical
157   laboratory test or other device data and results, findings by a health care
158   professional with respect to such data and results, general information about
159   such findings, and general background information about such laboratory test or
160   other device, unless such function is intended to interpret or analyze clinical
161   laboratory test or other device data, results, and findings…
162

III.   Scope

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

171 FDA intends to provide clarification of its interpretation of section 520(o)(1)(E) of the FD&C
172 Act, which is for software functions intended to provide decision support for the diagnosis,
173 treatment, prevention, cure, or mitigation of disease or other conditions (often referred to as
174 clinical decision support software), in a separate guidance document. Section 520(o)(2) of the
175 FD&C Act describes the regulation of a product with multiple functions, including at least one
176 device function and at least one software function that is not a device. FDA also intends to
177 provide recommendations on the regulation of such products with multifunctionality in a
178 separate guidance document.

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

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

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[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).

185 Background sections of the indicated guidances that will be revised, after consideration of timely
186 filed comments, through Level 2 updates to incorporate the changes detailed in this guidance.
187 Similarly, FDA will make changes to the examples in the guidances, after consideration of
188 comments, through level 2 updates, as described below.
189
190 Section 3060 of the Cures Act created a function-specific definition, and as such, the functions
191 excluded from the device definition under section 520(o) of the FD&C Act are independent of
192 the platform on which they might run. In order to clarify this, once this guidance is finalized, we
193 will make changes to the relevant guidances, through Level 2 updates, to clarify, where
194 appropriate, that the policies in the guidance documents are function-specific and apply across
195 platforms. For example, as appropriate, instances of "mobile application" in the Mobile Medical
196 Applications (MMA) guidance will be changed to "software function," and the title of the
197 guidance will likely be revised to "Mobile Medical Applications and Software Functions."

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

200
201 Section 520(o)(1)(A) of the FD&C Act states that the term "device" does not include a software
202 function that is intended "for administrative support of a health care facility, including the
203 processing and maintenance of financial records, claims or billing information, appointment
204 schedules, business analytics, information about patient populations, admissions, practice and
205 inventory management, analysis of historical claims data to predict future utilization or cost-
206 effectiveness, determination of health benefit eligibility, population health management, and
207 laboratory workflow." FDA has not historically considered most of these software functions to
208 be devices; however, we propose the following modification in order to provide additional
209 clarity.
210
211 Section 3.2.2 of the Guidance for Off-the-Shelf Software Use in Medical Devices, titled
212 "Exemption of Laboratory Information Management Systems," will be removed from the
213 guidance. As software with functions intended for administrative support of laboratories and/or
214 for transferring, storing, converting formats, or displaying clinical laboratory test data and
215 results, Laboratory Information Management Systems (LIMS) are not within the definition of the
216 term device, according to 201(h) of the FD&C Act, as amended by the Cures Act (*see* section
217 520(o)(1)(A) and (D) of the FD&C Act). Therefore, these products are not subject to
218 requirements under the FD&C Act.
219

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

222
223 Section 520(o)(1)(B) of the FD&C Act states that the term device does not include a software
224 function that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to
225 the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." FDA
226 considers a product with an intended use for maintaining or encouraging a "healthy lifestyle" to

227 mean a product with an intended use that encourages or maintains a "general state of health or
228 healthy activity," as defined in the FDA guidance General Wellness: Policy for Low Risk
229 Devices ("General Wellness Guidance").[3] In that guidance CDRH defines a general wellness
230 product as products that (1) are intended for only general wellness use, as defined in that
231 guidance, and (2) present a low risk to the safety of users and other persons. That guidance
232 defines two categories of general wellness intended uses: (1) an intended use that relates to
233 maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use
234 that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain
235 chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle
236 choices may play an important role in health outcomes for the disease or condition.
237
238 If the intended use of the software function is related to the diagnosis, cure, mitigation,
239 prevention, or treatment of a disease or condition, then the product is not excluded from the
240 definition of the term "device" under section 520(o)(1)(B) of the FD&C Act. Since the second
241 category of a general wellness intended uses, as defined in the General Wellness Guidance,
242 relates to the mitigation or prevention of a disease or condition, these products are not excluded
243 from the definition of device as modified by this new provision of the FD&C Act. This second
244 category of general wellness intended uses relates to sustaining or offering general improvement
245 to functions associated with a general state of health while making reference to help reduce the
246 risk of or help living well with certain chronic diseases or conditions. Although this type of
247 general wellness product is not excluded from the definition of device, we intend to continue to
248 not enforce the applicable requirements for this type of general wellness software function where
249 it presents a low risk to the safety of users and other persons. As described in the General
250 Wellness Guidance, FDA does not intend to examine whether low risk general wellness products
251 in the second category are devices within the meaning of the FD&C Act, or, if they are devices,
252 whether they comply with the premarket review and post-market regulatory requirements for
253 devices under the FD&C Act and implementing regulations, including, but not limited to:
254 registration and listing and premarket notification requirements (21 CFR Part 807); labeling
255 requirements (21 CFR Part 801 and 21 CFR 809.10); good manufacturing practice requirements
256 as set forth in the Quality System regulation (21 CFR Part 820); and Medical Device Reporting
257 (MDR) requirements (21 CFR Part 803).
258
259 According to section 520(o)(1)(B) of the FD&C Act, a software function with a healthy lifestyle
260 claim (e.g., products that fall within the first category of general wellness intended uses as
261 defined by the General Wellness Guidance) is not a device as long as its claims are unrelated to
262 the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. For example,
263 software with healthy lifestyle claims, such as weight management, physical fitness, relaxation
264 or stress management, mental acuity, self-esteem, sleep management, or sexual function, are not
265 devices when not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease
266 or condition. Therefore, the following examples in Section V. of the General Wellness Guidance
267 are not devices:

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

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

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

282

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

287   •   Mobile apps that are intended for individuals to log, record, track, evaluate, or make
288   decisions or behavioral suggestions related to developing or maintaining general fitness,
289   health or wellness, such as those that:
290   ○   Provide tools to promote or encourage healthy eating, exercise, weight loss or
291   other activities generally related to a healthy lifestyle or wellness;
292   ○   Provide dietary logs, calorie counters or make dietary suggestions;
293   ○   Provide meal planners and recipes;
294   ○   Track general daily activities or make exercise or posture suggestions;
295   ○   Track a normal baby's sleeping and feeding habits;
296   ○   Actively monitor and trend exercise activity;
297   ○   Help healthy people track the quantity or quality of their normal sleep patterns;
298   ○   Provide and track scores from mind-challenging games or generic "brain age"
299   tests;
300   ○   Provide daily motivational tips (e.g., via text or other types of messaging) to
301   reduce stress and promote a positive mental outlook;
302   ○   Use social gaming to encourage healthy lifestyle habits;
303   ○   Calculate calories burned in a workout.
304

C.   Software Function Intended to Serve as Electronic Patient Records

305
306
307
308 Under section 520(o)(1)(C) of the FD&C Act, the term device does not include certain software
309 functions that are intended to serve as electronic patient records. Specifically, software functions
310 that are intended to transfer, store, convert formats, or display electronic patient records that are

311 the equivalent of a paper medical chart are not devices, if the following three criteria outlined in
312 520(o)(1)(C)(i) – (iii) are met:
313
314   1. Such records were created, stored, transferred, or reviewed by health care
315   professionals (HCPs), or by individuals working under supervision of such professionals,
316   (Section 520(o)(1)(C)(i) of the FD&C Act);
317
318   2. Such records are part of information technology certified by the Office of the
319   National Coordinator for Health Information Technology (ONC) Health IT Certification
320   Program[4] (Section 520(o)(1)(C)(ii) of the FD&C Act); and
321
322   3. Such software functions are not intended for interpretation or analysis of patient
323   records, including medical image data, for the purpose of the diagnosis, cure, mitigation,
324   prevention, or treatment of a disease or condition (Section 520(o)(1)(C)(iii) of the FD&C
325   Act).
326
327 FDA does not intend to enforce the FDA requirements for software functions that are not
328 certified by ONC, if they meet the other criteria in section 520(o)(1)(C)(i) and (iii) of the FD&C
329 Act.
330
331 Software functions that enable patients or non-HCPs to create, store, or transfer health records
332 for their own record-keeping purposes that are not intended to be created, stored, transferred or
333 reviewed by a HCP are considered personal health records (PHRs). These software functions in
334 PHR systems that are not intended for use in the diagnosis, cure, mitigation, prevention, or
335 treatment of a disease or condition are not devices under section 201(h) of the FD&C Act.
336
337 Software functions excluded from the device definition by section 520(o)(1)(C) of the FD&C
338 Act may be contained in electronic health record (EHR) systems, PHR systems, and other health
339 information technology. Such systems may also contain other software functions that could meet
340 the definition of a device. FDA's approach to oversight of software functions that meet the
341 definition of a device in a system with software functions that do not meet the definition of
342 device (products with multiple functions) will be addressed in a separate guidance document.
343
344 Therefore, in the MMA Guidance, the following examples in Section V.B. (Mobile Apps for
345 which FDA intends to exercise enforcement discretion) are not devices (pursuant to section
346 520(o)(1)(C) of the FD&C Act), and will be moved to Appendix A (Examples of mobile apps
347 that are NOT medical devices) of that guidance:
348 •   **Mobile apps that enable individuals to interact with ONC-certified EHR systems** --
349   These are apps that provide individuals with mobile access to health record systems or
350   enable them to gain electronic access to health information stored within an EHR system.
351   Applications that only allow individuals to view or download EHR data are also included

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

352 in this category. These mobile apps are generally meant to facilitate general patient health
353 information management and health record-keeping activities.

354   o Note: This example has been changed to clarify that only ONC-certified EHR
355   functions are not devices according to the FD&C Act, as amended by 21st
356   Century Cures.
357   o For clarity, this example and other types of electronic patient record functions
358   must meet the full description of section 520(o)(1)(C) in the FD&C Act, in that
359   they are not devices only if they are reviewed by HCPs, certified by ONC, and are
360   not intended for interpretation or analysis for the purpose of the diagnosis, cure,
361   mitigation, prevention, or treatment of a disease or condition. However, FDA
362   does not intend to enforce compliance with requirements that apply to these
363   software functions if they are not certified by ONC.

364 • Provide patients with simple tools to organize and track their health information;
365 • Provide easy access to information related to patients' health conditions or treatments;
366 • Help patients document, show, or communicate potential medical conditions to health
367   care providers
368

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

373 • Mobile apps that enable, during an encounter, a health care provider to access their
374   patient's personal health record (health information) that is hosted on a web-based or
375   other platform
376 • Mobile apps for HCPs that help track or manage patient immunizations by documenting
377   the need for immunization, consent form, and immunization lot number.

378   o This example has been changed from "assessing the need for immunization" to
379   "documenting the need…" because the example is intended to serve as an
380   example of an electronic patient record, and not clinical decision support
381   software. FDA intends to provide clarification of section 520(o)(1)(E) of the
382   FD&C Act and clinical decision support software in a separate guidance
383   document.
384
385

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

388
389 Under section 520(o)(1)(D) of the FD&C Act, the term "device" does not include a software
390 function that is intended "for transferring, storing, converting formats, or displaying clinical
391 laboratory test or other device data and results unless such function is intended to interpret or
392 analyze clinical laboratory test or other device data, results, and findings" (section 520(o)(1)(D)
393 of the FD&C Act).
394

395 The software functions that meet the definitions of Medical Device Data Systems (MDDS),
396 medical image storage devices, or medical image communications devices provided in the
397 Medical Device Data Systems, Medical Image Storage Devices, and Medical Image
398 Communications Devices Guidance (or MDDS Guidance), and the Guidance for the Submission
399 of Premarket Notifications for Medical Image Management Devices, are, thus, now not devices
400 under section 201(h) of the FD&C Act, pursuant to section 520(o)(1)(D) of the FD&C Act. As
401 such, products that are solely intended to transfer, store, convert formats, and display medical
402 device data and results, including medical images, waveforms, signals, or other clinical
403 information are not devices and thus are not subject to FDA regulatory requirements. However,
404 software functions that analyze or interpret medical device data in addition to transferring,
405 storing, converting formats, or displaying clinical laboratory test or other device data and results
406 remain subject to FDA's regulatory oversight.
407
408 FDA does not consider the following functions to meet the definition of device under section
409 201(h) of the FD&C Act, as amended by the Cures Act:
410   1. Medical Device Data System (MDDS), defined as a software, electronic, or electrical
411   hardware that is intended to provide one or more of the following uses, whether or not the
412   use is for immediate clinical action, without controlling or altering the functions or
413   parameters of any connected medical devices:
414   a. The electronic transfer of medical device data;
415   b. The electronic storage of medical device data;
416   c. The electronic conversion of medical device data from one format to another
417   format in accordance with a preset specification; or
418   d. The electronic display of medical device data.
419   Examples of MDDS include physical communications medium (including
420   wireless hardware), modems, interfaces, and a communications protocol.
421   2. Medical image storage device, defined as a device that provides electronic storage and
422   retrieval functions for medical images. Examples include devices employing magnetic
423   and optical discs, magnetic tape, and digital memory.
424   3. Medical image communications device, defined as a device that provides electronic
425   transfer of medical image data between medical devices. It may include a physical
426   communications medium, modems, interfaces, and a communications protocol. [5]
427
428 Section 520(o)(1)(D) of the FD&C Act does not capture software functions intended to generate
429 alarms or alerts or prioritize multi-patient displays, because these functions involve analysis or
430 interpretation of laboratory test or other device data and results. For example, if a software
431 function is intended to prioritize patients in an Intensive Care Unit based on their clinical status,
432 then this function is intended to interpret or analyze device data, results, and findings and is,
433 therefore, not excluded from the definition of device under section 520(o)(1)(D) of the FD&C
434 Act. Similarly, software functions that analyze medical device data in order to provide a

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[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.

435 notification or flag (e.g., that a parameter is out of range) are not excluded from the definition of
436 device under subsection (D). However, FDA does not intend to enforce requirements under the
437 FD&C Act and implementing regulations for these low risk software functions, such as the
438 analysis of data to provide a notification, for which immediate clinical action is not needed.
439 FDA intends to focus its regulatory oversight on software functions intended to generate alarms
440 or alerts or prioritize multi-patient displays if they are intended to alert a caregiver to take an
441 immediate clinical action.
442
443 The MDDS Guidance will be revised to clarify that products that are solely intended to transfer,
444 store, convert formats, and display medical device data and results, including medical images,
445 waveforms, signals, or other clinical information are not devices and thus are not subject to FDA
446 regulatory requirements, whether or not the use is for immediate clinical action. Accordingly,
447 the definition of MDDS will be revised in that guidance to the definition in item 1 above. The
448 discussion and examples of devices that are used for immediate clinical action (active patient
449 monitoring) will be revised:
450 - *Examples of devices that provide active patient monitoring* will be revised to *Examples of*
451 *devices that analyze or interpret laboratory test or other device data that are the focus of*
452 *FDA's regulatory oversight*
453 - A nurse telemetry station that analyzes or interprets information from a bedside
454 hospital monitor in an ICU in order to produce alarms or notifications.
455 - A device that generates alarms or alerts from a monitoring device in a home setting
456 and is intended to alert a caregiver to take an immediate clinical action.
457 - *Examples of devices that perform monitoring but are not considered to perform "active*
458 *patient monitoring"* will be revised to *Examples of products that transfer, store, convert*
459 *formats, or display medical device data and are not devices*
460
461 In the MMA Guidance, the following example will be revised and moved from Section V.A.
462 (Subset of mobile apps that are the focus of FDA's regulatory oversight) to Appendix B
463 (Examples of mobile apps for which FDA intends to exercise enforcement discretion):
464 - *Examples of displays of patient-specific medical device data include:* display of medical
465 images directly from a Picture Archiving and Communication System (PACS) server and
466 remote display of data from bedside monitors (note that software functions that analyze or
467 interpret medical device data to generate alarms or alerts that are intended to be relied
468 upon in deciding to take immediate clinical action, are subject to regulations associated
469 with such devices)
470 - The parenthetical note in this example has been changed from "note that mobile
471 medical apps that display medical device data to generate alarms or alerts that are
472 intended to be relied upon in deciding to take immediate clinical action, are subject
473 to regulations associated with such devices" to the text above, because software
474 functions that merely display medical device data are not medical devices.
475 Software functions that analyze or interpret medical device data are medical
476 devices and subject to FDA's regulatory oversight.
477
478 And the following example will be added to Appendix B (Examples of mobile apps for which
479 FDA intends to exercise enforcement discretion) of the MMA Guidance:

480   •   Software tools that analyze stored clinical information to flag patient results based on
481   specific clinical parameters (e.g., out of range results, potential drug interactions,
482   opportunities for complementary tests, create disease registries, summarize patient-
483   specific information in an integrated report, and/or track a patient's treatment or disease
484   outcome) provided that the analysis performed by these software is not intended for
485   immediate clinical action and does not represent a unique interpretation function but
486   rather summarizes standard interpretation of individual variables that healthcare
487   practitioners could do themselves.
488
489 In the MMA Guidance, the following examples will be moved from Appendix B (Examples of
490 mobile apps for which FDA intends to exercise enforcement discretion) to Appendix A
491 (Examples of Mobile Apps that are Not Medical Devices):
492   •   Mobile apps or software functions that are intended for transferring, storing, converting
493   formats or displaying clinical laboratory test or other device data and results, findings by
494   a health care professional with respect to such data and results, general information about
495   such findings and general background information about such laboratory test or other
496   device, unless such function is intended to interpret or analyze clinical laboratory test or
497   other device data, results and findings.
498   o   Mobile apps that transfer, store, convert formats, and display medical device data
499   without modifying the data and do not control or alter the functions or parameters of
500   any connected medical device (i.e., mobile apps that meet the definition of MDDS).
501   o   Mobile apps that meet the definition of MDDS and connect to a nursing central
502   station and display medical device data to a physician's mobile platform for
503   review.
504   o   Mobile apps that are not intended for diagnostic image review such as image display
505   for multidisciplinary patient management meetings (e.g., rounds) or patient
506   consultation (and include a persistent on-screen notice, such as "for informational
507   purposes only and not intended for diagnostic use").
508
509 And the following example of a software function and its associated text in Section V.B. of the
510 MMA Guidance is no a longer device pursuant to section 520(o)(1)(D) of the FD&C Act and
511 will be moved to Appendix A (Examples of Mobile Apps that are Not Medical Devices) of that
512 guidance:
513   •   Mobile apps that meet the definition of Medical Device Data Systems
514
515 The Guidance for the Submission of Premarket Notifications for Medical Image Management
516 Devices will be withdrawn, because some software functions described in that guidance no
517 longer meet the definition of a device, as amended. For the limited subset of Medical Image
518 Management Devices that continue to meet the definition of a device and continue to require a
519 510(k) submission, the information provided in that document, which was written in 2000, is out
520 of date. CDRH encourages manufacturers to reference the most recent FDA-recognized versions
521 of relevant voluntary consensus standards instead.
522
523