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Clinical Decision Support Software

Draft Guidance for Industry and Food and Drug Administration Staff

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Food and Drug Administration
Center for Devices and Radiological Health
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Preface

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Contains Nonbinding Recommendations

Draft – Not for Implementation

Table of Contents

I. Introduction 5

II. Background..... 6

 A. 21st Century Cures Act 6

 B. International Medical Device Regulators Forum Framework..... 7

III. Definitions 8

IV. Scope 9

V. Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act 9

 (1) Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system 10

 (2) Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information 11

 (3) Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition 11

 (4) Intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient 12

VI. Application of IMDRF Risk Categorization 13

 A. Significance of Information Provided by a SaMD to the Health Care Decision..... 13

 (1) Inform Clinical Management 13

 (2) Drive Clinical Management 14

 (3) Treat or Diagnose 14

 B. State of the Health Care Situation or Condition 14

 (1) Non-Serious Situations or Conditions..... 15

 (2) Serious Situations or Conditions 15

 (3) Critical Situations or Conditions 15

 C. Policy for Device CDS Functions 16

VII. Examples 18

 A. Examples of Non-Device CDS Functions 18

 B. Examples of Device CDS for which, based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable device requirements..... 20

 (1) Device CDS intended for HCPs 20

Contains Nonbinding Recommendations

Draft – Not for Implementation

(2) Device CDS intended for patients..... 21

C. Device CDS on which FDA intends to focus its regulatory oversight..... 23

(1) Device CDS intended for HCPs..... 23

(2) Device CDS intended for patients..... 23

D. Examples of device software functions that are not CDS on which FDA intends to focus its regulatory oversight 24

VIII. Conforming Changes to Existing Guidance 27

DRAFT

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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

The Food and Drug Administration (FDA) has long regulated software that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including software that is intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions (often referred to as clinical decision support software). This guidance provides clarity on the scope of FDA’s oversight of clinical decision support software intended for health care professionals, patients, or caregivers.

FDA recognizes that the term “clinical decision support” or “CDS” is used broadly and in different ways, depending on the context. CDS provides health care professionals (HCPs) and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.¹ In the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report of 2014, CDS is described as a variety of tools including, but not limited to: computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information.² For the purposes of this guidance, the term “CDS” is used to refer to functions that are either Device CDS or Non-Device CDS. FDA uses criteria from the 21st Century Cures Act (Cures Act) to determine if a software function is Device CDS or Non-Device CDS (see Section III).

The purpose of this guidance is to describe FDA’s regulatory approach to CDS software functions. The agency’s approach includes recent changes to the FD&C Act made by the Cures Act, which amended section 520 and excludes certain software functions from the device definition. This guidance clarifies the types of CDS software functions that: (1) do not meet the

¹ See Office of the National Coordinator for Health Information Technology, “What is Clinical Decision Support (CDS)?” at <https://www.healthit.gov/topic/safety/clinical-decision-support>.

² FDASIA Health IT Report, April 2014, available at <https://www.fda.gov/about-fda/cdrh-reports/fdasia-health-it-report>.

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Draft – Not for Implementation

34 definition of a device as amended by the Cures Act; (2) may meet the definition of a device but
35 for which, based on our current understanding of the risks of these devices, FDA does not intend
36 at this time to enforce compliance with applicable device requirements of the FD&C Act,
37 including, but not limited to, premarket clearance and premarket approval requirements; and (3)
38 meet the definition of a device and on which FDA intends to focus its regulatory oversight. In its
39 risk based approach to CDS regulation, FDA also intends to leverage the [Software as a Medical](#)
40 [Device: Possible Framework for Risk Categorization and Corresponding Considerations](#)
41 (IMDRF Framework).³

42 This guidance provides many examples of how FDA intends to regulate different kinds of
43 software functions, including:

- 44 • Non-Device CDS functions;
- 45 • Device CDS functions for which, based on our current understanding of the risks of these
46 devices, FDA intends at this time not to enforce compliance with applicable
47 requirements;
- 48 • Device CDS functions on which FDA intends to focus its regulatory oversight; and
- 49 • Non-CDS device functions on which FDA intends to focus its regulatory oversight.

50 FDA's guidance documents, including this draft guidance, do not establish legally enforceable
51 responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic
52 and should be viewed only as recommendations, unless specific regulatory or statutory
53 requirements are cited. The use of the word *should* in Agency guidance documents means that
54 something is suggested or recommended, but not required.

55 **II. Background**

56 **A. 21st Century Cures Act**

57 Section 3060(a) of the Cures Act amended the FD&C Act to add section 520(o) of the FD&C
58 Act, which excludes certain software functions from the definition of device in section 201(h)
59 of the FD&C Act. Certain CDS software functions are excluded from the definition of device by
60 section 520(o)(1)(E) of the FD&C Act. Specifically, this section excludes, from the definition of
61 device, software functions that meet all of the following four criteria:

62 (1) not intended to acquire, process, or analyze a medical image or a signal from an in
63 vitro diagnostic device or a pattern or signal from a signal acquisition system (section
64 520(o)(1)(E) of the FD&C Act);

65 (2) intended for the purpose of displaying, analyzing, or printing medical information
66 about a patient or other medical information (such as peer-reviewed clinical studies and
67 clinical practice guidelines) (section 520(o)(1)(E)(i) of the FD&C Act);

³ Available at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>.

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Draft – Not for Implementation

68 (3) intended for the purpose of supporting or providing recommendations to a health care
69 professional about prevention, diagnosis, or treatment of a disease or condition (section
70 520(o)(1)(E)(ii) of the FD&C Act); and

71 (4) intended for the purpose of enabling such health care professional to independently
72 review the basis for such recommendations that such software presents so that it is not the
73 intent that such health care professional rely primarily on any of such recommendations
74 to make a clinical diagnosis or treatment decision regarding an individual patient (section
75 520(o)(1)(E)(iii) of the FD&C Act).⁴

76 To explain FDA's interpretation of section 520(o)(1)(E), this guidance discusses each element of
77 section 520(o)(1)(E) of the FD&C Act in Section V of this guidance.

78 **B. International Medical Device Regulators Forum** 79 **Framework**

80 This guidance uses factors from the International Medical Device Regulators Forum (IMDRF)
81 Framework to apply a risk-based policy for CDS software functions. This approach is consistent
82 with FDA's commitment to implement IMDRF documents specifically and advance global
83 medical device regulatory harmonization generally.

84 In September 2014, the IMDRF, of which FDA is a member, issued a final document entitled
85 [Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding](#)
86 [Considerations](#) (IMDRF Framework) based on international public comment on a proposed
87 document.⁵ The objective of the IMDRF Framework is to introduce a foundational approach,
88 harmonized vocabulary, and general and specific considerations for manufacturers, regulators,
89 and users to address the unique challenges associated with the use of software as a medical
90 device (SaMD). The IMDRF Framework includes two factors important for SaMD
91 characterization:

92 (A) the significance of the information provided by a SaMD to a health care decision: to
93 treat or diagnose, to drive clinical management, or to inform clinical management; and

94 (B) the state of the patient's health care situation or condition: critical, serious, or non-
95 serious.

⁴ The Cures Act provides that a software function described in section 520(o)(1)(E) of the FD&C Act will not be excluded from the device definition under section 201(h) if the software meets the criteria under section 513(a)(1)(C) of the FD&C Act or if the software is 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) and (C) of the FD&C Act. In addition, the Cures Act provides that software will not be excluded if the Secretary of Health and Human Services issues a final order, after notification and a period for comment, that the software function would be reasonably likely to have serious adverse health consequences; section 520(o)(3) of the FD&C Act.

⁵ Available at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>.

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96 See Section VI of this guidance for additional information on the IMDRF Framework and how
97 FDA applies the Framework to its risk-based policy for CDS software functions.

98 III. Definitions

99 As noted in the Introduction, the term CDS can be used more broadly to mean technology that
100 provides HCPs and patients with knowledge and person-specific information, intelligently
101 filtered or presented at appropriate times, to enhance health and health care. For the purposes of
102 this guidance, FDA uses section 520(o)(1)(E) criteria to determine if a software function is
103 Device CDS or Non-Device CDS. The term “CDS” is used to refer to functions that are either
104 Device CDS or Non-Device CDS.

105
106 A software function is considered CDS, for the purposes of this guidance, if it meets the
107 following:

- 108 • Not intended to acquire, process, or analyze [criterion (1)];
- 109 • Intended for the purpose of displaying, analyzing, or printing medical information
110 [criterion (2)]; and
- 111 • Intended for the purpose of supporting or providing recommendations [part of criterion
112 (3)].

113
114
115 CDS (as defined above) is not a device when the HCP can independently review the basis for the
116 recommendation.⁶ Thus, for the purposes of this guidance, CDS that meets all parts of the four
117 section 520(o)(1)(E) criteria is Non-Device CDS. If CDS (as defined above) fails to meet part of
118 criterion (3) and/or part or all of criterion (4), then it is Device CDS. This is illustrated in the
119 following table.

120 **Table 1. Is a CDS Software Function Device or Non-Device?**

121

Is the Intended User an HCP? [part of criteria (3) and (4)]	Can the User Independently Review the Basis?*	Is it Device CDS?
Yes	Yes	No, it is Non-Device CDS because it meets all of section 520(o)(1)(E) criteria
	No	Yes, it is Device CDS
No, it is a patient or caregiver	Yes	Yes, it is Device CDS
	No	Yes, it is Device CDS

122 * “Can the user independently review the basis?” asks whether the function is intended for the purpose of enabling
123 the user to independently review the basis for the recommendations so that it is not the intent that user rely primarily
124 on any such recommendation (part of criterion (4)).

⁶ That is, the CDS is intended for the purpose of enabling an HCP to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient [criterion (4)].

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125 **Non-Device CDS:** Consistent with the Cures Act, for the purposes of this guidance, Non-Device
126 CDS includes software functions that meet all four criteria of section 520(o)(1)(E) as listed in
127 Section II.A above.⁷ Non-Device CDS is intended for HCPs only, as required by criterion (3).
128 Section V provides an explanation for each of the four criteria.

129 **Device CDS:** For the purposes of this guidance, Device CDS includes software functions that
130 meet criteria (1) and (2) of section 520(o)(1)(E) as listed in Section II.A and are intended for the
131 purpose of supporting or providing recommendations to an HCP, patient, or caregiver about
132 prevention, diagnosis, or treatment of a disease or condition. These software functions may not
133 meet parts of either criterion (3) or (4) (see Table 1 above).

134 **IV. Scope**

135 This guidance describes CDS that does not meet the definition of a device (Non-Device CDS) in
136 the context of and using language from section 520(o) of the FD&C Act, which excludes certain
137 software functions from the device definition, including certain CDS software functions intended
138 for HCPs. This guidance also describes FDA’s risk-based enforcement discretion policy for
139 software functions that are intended for HCPs, patients, or caregivers and may meet the
140 definition of a device but for which, based on our current understanding of the risks of these
141 devices, FDA does not intend at this time to enforce compliance with applicable device
142 requirements of the FD&C Act, including, but not limited to, premarket clearance and premarket
143 approval requirements.

144 This guidance presents the agency’s current thinking on which CDS are and are not devices. The
145 guidance does not address which FDA statutory or regulatory requirements apply to Device
146 CDS, including which regulatory requirements may apply to a Device CDS that is part of a
147 combination product, nor does it address labeling requirements for CDS disseminated by or on
148 behalf of a drug or biological product sponsor.

149 **V. Interpretation of Criteria in Section 520(o)(1)(E) of the** 150 **FD&C Act**

151 For a software function to be Non-Device CDS, it must meet all of the following four criteria to
152 be excluded from the device definition under section 520(o) of the FD&C Act. The functions
153 excluded from the device definition are independent of the platform on which they might run.⁸
154 The first criterion describes what CDS software functions must *not* be intended to do if they are
155 to be excluded from the device definition under section 520(o) of the FD&C Act. The remaining

⁷ Some software functions that have traditionally been considered CDS software functions never were considered device functions, because they are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease (section 201(h) of the FD&C Act). These CDS functions, such as software that presents best practices in an institution or facilitation of access to treatment guidelines, continue to not be device functions and are outside the scope of this draft guidance.

⁸ The exclusions are subject to the limitations described in footnote 4.

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156 three criteria describe purposes for which software functions must be intended in order to be
157 excluded from the device definition under section 520(o) of the FD&C Act.

158 **(1) Not intended to acquire, process, or analyze a medical**
159 **image or a signal from an in vitro diagnostic device or a**
160 **pattern or signal from a signal acquisition system**

161 Under section 520(o)(1)(E), software functions that are intended to acquire, process, or analyze a
162 medical image, a signal from an in vitro diagnostic device, or a pattern or signal from a signal
163 acquisition system and are intended for a purpose identified in section 201(h) of the FD&C Act
164 remain devices and therefore continue to be subject to FDA oversight. Products that acquire an
165 image or physiological signal from the body, or from a sample from the body, or that process or
166 analyze such information, or both, have been regulated for many years as devices when such
167 acquisition, processing, or analyzing is intended for a purpose identified in the statutory device
168 definition.

169 We generally consider the term *physiological signals* to include those signals that require use of
170 either:

- 171 • An in vitro diagnostic device, which typically includes an electrochemical or photometric
172 response generated by an assay and instrument that may be further processed by software to
173 generate a clinical test result, or
- 174 • A signal acquisition system that measures a parameter from within, attached to, or external to
175 the body for a medical purpose and often includes:
 - 176 ○ use of sensors (e.g., electrocardiogram (ECG) leads) along with electronics and
177 software function that is used for signal generation (e.g., ECG);
 - 178 ○ collections of samples or specimens such as tissue, blood, or other fluids, (e.g.,
179 conducting a pathological study using software such as digital pathology); or
 - 180 ○ use of radiological imaging systems (e.g., computed tomography (CT)) and a
181 software function for image generation.

182 Examples of this type of software function that are medical devices include software that process
183 physiologic data to generate new data points (such as ST-segment measurements from ECG
184 signals), analyze information within the original data (such as feature identification in image
185 analysis), or analyze and interpret genomic data, such as identifying a patient's genetic variations
186 for the purpose of determining a patient's risk for a particular disease. Other examples of device
187 functions include use of an accelerometer for measuring tremors for early detection of
188 Parkinson's disease or for measuring progression of other neurological disorders.

189 Although most physiological signal acquisition systems are intended to monitor physiological
190 signals for medical purposes and, therefore, are considered medical devices, some are not. For
191 example, activity monitors or other signal acquisition systems that measure physiological
192 parameters that are not specifically intended or marketed for a purpose identified in the device
193 definition are not medical devices. We encourage manufacturers to engage with FDA if a
194 physiological signal acquisition system previously only considered for a medical purpose is

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195 intended to be used for a non-medical purpose. For example, software functions that use input
196 from sensors and a signal acquisition system to measure physiological parameters for purposes
197 of biometrics identification, such as retinal image analysis for secure access to a facility, are not
198 devices.

199 **(2) Intended for the purpose of displaying, analyzing, or**
200 **printing medical information about a patient or other**
201 **medical information**

202 Section 520(o)(1)(E)(i) of the FD&C Act describes software functions that are intended to
203 display, analyze, or print medical information about a patient or other medical information (such
204 as peer-reviewed clinical studies and clinical practice guidelines). FDA interprets this to include
205 software functions that display, analyze, or print patient-specific information, such as
206 demographic information, symptoms, test results, medical device outputs (such as heart rate or
207 blood pressure), patient discharge summaries, and/or medical information (such as clinical
208 practice guidelines, peer-reviewed clinical studies, textbooks, approved drug or medical device
209 labeling, and government agency recommendations). In general, this is the kind of information
210 used by the intended user to make decisions about prevention, diagnosis, or treatment of a
211 disease or condition for an individual patient. These software functions are not devices only if
212 they also meet the other three criteria of section 520(o)(1)(E) of the FD&C Act.

213 **(3) Intended for the purpose of supporting or providing**
214 **recommendations to an HCP about prevention, diagnosis,**
215 **or treatment of a disease or condition**

216 Section 520(o)(1)(E)(ii) describes software functions that are intended to support or provide
217 recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition.
218 (Software functions that support or provide such recommendations to patients or caregivers – not
219 HCPs – therefore remain in the definition of device.) Such functions are intended to assist HCPs
220 in making patient-specific care decisions. These functions are evidence-based tools that support
221 HCP decision-making when considering treatment options or diagnostic tests for a patient. They
222 do not treat a patient, determine a patient’s treatment, or provide a definitive diagnosis of a
223 patient’s disease or condition. Instead, these functions collate or develop recommendations based
224 on an analysis of patient-specific information to an HCP, who may then use this information to
225 make a decision about the care of a patient (e.g., treatment), along with other information and
226 factors of which the HCP is aware. Examples of such recommendations include software that
227 suggests possible diagnoses and recommends treatment plans or diagnostic tests based on
228 patient-specific information that when combined with other information the intended HCP would
229 generally use, would inform the HCP’s decision regarding the prevention, diagnosis, or treatment
230 of a patient’s disease or condition.

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232 Software functions intended to support or provide recommendations align with the IMDRF
233 Framework category of SaMD functions that inform clinical management. (See Section VI for
234 discussion of the IMDRF Framework.)

235 These software functions are not devices only if they also meet the other three criteria of section
236 520(o)(1)(E) of the FD&C Act. (See Section VII.A for additional examples.)

237 **(4) Intended for the purpose of enabling an HCP to**
238 **independently review the basis for the recommendations**
239 **that such software presents so that it is not the intent that**
240 **the HCP rely primarily on any of such recommendations to**
241 **make a clinical diagnosis or treatment decision regarding**
242 **an individual patient**

243 Section 520(o)(1)(E)(iii) states that, in order to be excluded from the definition of a device by
244 operation of section 520(o)(1)(E) of the FD&C Act, the CDS function must be intended to enable
245 HCPs to independently review the basis for the recommendations presented by the software so
246 that they do not rely primarily on such recommendations, but rather on their own judgment, to
247 make clinical decisions for individual patients.

248 FDA interprets section 520(o)(1)(E)(iii) to mean that manufacturers of Non-Device CDS should
249 describe their software functions in plain language, including:

- 250 1) The purpose or intended use of the software function;
- 251 2) The intended user (e.g., ultrasound technicians, vascular surgeons);
- 252 3) The inputs used to generate the recommendation (e.g., patient age and sex); and
- 253 4) The basis for rendering a recommendation.

254 In order to describe the basis for a recommendation, regardless of the complexity of the software
255 and whether or not it is proprietary, the software developer should describe the underlying data
256 used to develop the algorithm and should include plain language descriptions of the logic or
257 rationale used by an algorithm to render a recommendation. The sources supporting the
258 recommendation or the sources underlying the basis for the recommendation should be identified
259 and available to the intended user (e.g., clinical practice guidelines with the date or version,
260 published literature, or information that has been communicated by the CDS developer to the
261 intended user) and understandable by the intended user (e.g., data points whose meaning is well
262 understood by the intended user). A practitioner would be unable to independently evaluate the
263 basis of a recommendation, and therefore would be primarily relying upon it, if the
264 recommendation were based on information whose meaning could not be expected to be
265 independently understood by the intended HCP user (e.g., the inputs used to generate the
266 recommendation are not identified).

267 **VI. Application of IMDRF Risk Categorization**

268 FDA intends to apply a risk-based policy to its regulation of Device CDS functions by
269 leveraging the IMDRF Framework.⁹ The IMDRF Framework describes two major factors for the
270 risk categorization of a SaMD (Table 2): (A) the significance of information provided by a
271 SaMD to the health care decision, and (B) the state of the health care situation or condition. The
272 IMDRF Framework applies to many more software functions than Device CDS and Non-Device
273 CDS functions, as those terms are used in this guidance. The Framework is explained here,
274 because FDA is using parts of the Framework in its CDS policy.

275
276 **Table 2. SaMD Categories established in IMDRF Framework**
277

State of health care situation or condition	Significance of information provided by SaMD to health care decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

278

279 **A. Significance of Information Provided by a SaMD to the**
280 **Health Care Decision**

281 The risk of a Device CDS function is based, in part, on significance of information provided by
282 that software function. The IMDRF Framework defines three categories of significance of
283 information for a SaMD function: (1) to inform clinical management, (2) to drive clinical
284 management, or (3) to treat or diagnose.

285 **(1) Inform Clinical Management**

286 IMDRF describes the SaMD function to inform clinical management (IMDRF Framework
287 Section 5.1.3) as “the information provided by the SaMD will not trigger an immediate or near-
288 term action:

- 289 • To inform of options for treating, diagnosing, preventing, or mitigating a disease or
290 condition.
- 291 • To provide clinical information by aggregating relevant information (e.g., disease,
292 condition, drugs, medical devices, population, etc.).”

293 CDS functions, as defined in this guidance, inform clinical management, because the software
294 functions intended to provide information, such as treatment or diagnostic options or aggregating

⁹ The IMDRF framework is available at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>. This guidance summarizes the IMDRF Framework and explains how it is applied for Device CDS. As explained later, the spectrum of software functions in the IMDRF Framework extends beyond Device CDS. FDA’s interpretation of the IMDRF framework and its application to other software functions is outside the scope of this guidance.

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295 clinical information, may support a recommendation to an HCP, patient, or caregiver. Such
296 functions provide information that is not necessary to decision-making for a patient’s care.

297 **(2) Drive Clinical Management**

298 IMDRF describes the SaMD function to drive clinical management (IMDRF Framework Section
299 5.1.2) as follows: “driving clinical management infers that the information provided by the
300 SaMD will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a
301 disease or condition will be used to guide next diagnostics or next treatment interventions:

- 302 • To aid in treatment by providing enhanced support to safe and effective use of medicinal
303 products or a medical device.
- 304 • To aid in diagnosis by analyzing relevant information to help predict risk of a disease or
305 condition or as an aid to making a definitive diagnosis.
- 306 • To triage or identify early signs of a disease or condition.”

307 SaMD functions that drive clinical management are not CDS, as defined in the Cures Act and
308 used in this guidance, because they go beyond supporting or providing recommendations to an
309 HCP, patient, or caregiver (i.e., they do not meet criterion (3)). Drive functions provide enhanced
310 support beyond simply supporting or providing a recommendation about prevention, diagnosis,
311 or treatment of a disease or condition. Drive functions are relied on to guide next diagnostics or
312 treatment interventions, and therefore are not CDS.

313 **(3) Treat or Diagnose**

314 IMDRF describes the SaMD function to treat or to diagnose (IMDRF Framework Section 5.1.1)
315 as follows: “treating and diagnosing infers that the information provided by the SaMD will be
316 used to take an immediate or near-term action:

- 317 • To treat/prevent or mitigate by connecting to other medical devices, medicinal products,
318 general purpose actuators or other means of providing therapy to a human body.
- 319 • To diagnose/screen/detect a disease or condition (i.e., using sensors, data, or other
320 information from other hardware or software devices, pertaining to a disease or
321 condition).”

322 SaMD functions that treat or diagnose are not CDS, as defined in the Cures Act and used in this
323 guidance, because they also go beyond supporting or providing recommendations to an HCP,
324 patient, or caregiver (i.e., they do not meet criterion (3)). Rather, treatment or diagnosis functions
325 provide the actual diagnosis or prompt an immediate or near-term action – functions that are well
326 beyond the scope of supporting or providing recommendations.

327 **B. State of the Health Care Situation or Condition**

328 The risk of a Device CDS function also is based, in part, on the state of the health care situation
329 or condition for which it is intended. The IMDRF Framework defines three categories for the
330 state of the health care situation or condition: (1) non-serious, (2) serious, or (3) critical.

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331 **(1) Non-Serious Situations or Conditions**

332 IMDRF defines non-serious situations or conditions (IMDRF Framework Section 5.2.3) as
333 “situations or conditions where an accurate diagnosis and treatment is important but not critical
334 for interventions to mitigate long term irreversible consequences on an individual patient's health
335 condition or public health.” Non-serious situations or conditions may also include situations or
336 conditions where:

- 337 • An accurate and timely diagnosis, or timely treatment action or intervention is important,
338 but not critical to prevent or mitigate long-term irreversible consequences on an
339 individual patient's health condition, which may include short-lived or self-limiting
340 disease processes, or temporary injury or impairment not requiring professional medical
341 intervention (e.g., mild to moderate seasonal allergy symptoms); or
- 342 • An accurate and timely diagnosis, or timely treatment action or intervention is important,
343 but not critical to mitigate long-term irreversible public health consequences.

344 **(2) Serious Situations or Conditions**

345 IMDRF defines serious situations or conditions (IMDRF Framework Section 5.2.2) as
346 “situations or conditions where accurate diagnosis or treatment is of vital importance to avoid
347 unnecessary interventions (e.g., biopsy) or timely interventions are important to mitigate long
348 term irreversible consequences on an individual patient’s health condition or public health.”

349 Serious situations or conditions may include situations or conditions where:

- 350 • Accurate and timely diagnosis, or timely treatment action or intervention is of importance
351 to avoid unnecessary major interventions (e.g., biopsy, surgery); or
- 352 • Accurate and timely diagnosis, or timely treatment action or intervention is of importance
353 to prevent or mitigate persistent or recurrent disease processes that have a substantial
354 impact on day-to-day functioning; or
- 355 • Accurate and timely diagnosis, or timely treatment action or intervention is of importance
356 to prevent progression of disease processes that have the potential to be substantially
357 disabling or may result in injury or impairment requiring professional medical
358 intervention to mitigate long-term irreversible consequences on an individual patient’s
359 health condition; or
- 360 • Accurate and timely diagnosis, or timely treatment action or intervention is of importance
361 to mitigate long-term irreversible public health consequences.

362 **(3) Critical Situations or Conditions**

363 IMDRF defines critical situations or conditions (IMDRF Framework Section 5.2.1) as “situations
364 or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death,
365 long-term disability or other serious deterioration of health of an individual patient or to
366 mitigating impact to public health.” Critical situations or conditions may include situations or
367 conditions where:

- 368 • Accurate and timely diagnosis, or timely treatment action or intervention is vital to avoid
369 death, permanent impairment, life-threatening injury, or other serious deterioration of
370 health (e.g., paralysis) for an individual patient;

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371 • Accurate and timely diagnosis, or timely treatment action or intervention is vital to
372 mitigate a serious impact to public health (e.g., Ebola); or

373 • The intended target population is fragile with respect to the disease or condition (e.g.,
374 pediatrics, high risk populations, etc.).

375 Also included are situations or conditions in which inaccurate or misinterpreted diagnoses or
376 treatment recommendations are likely to:

377 • Result in death, permanent impairment, life-threatening injury, or other serious
378 deterioration of health for an individual patient (e.g., misdiagnosis of stroke); or

379 • Seriously or negatively impact public health for a pandemic or epidemiology situation
380 (e.g., failure to recognize/diagnose Ebola).

381 **C. Policy for Device CDS Functions**

382 Using the IMDRF risk categorizations described above, FDA intends to apply a risk-based policy
383 to its regulation of Device CDS functions. For two types of low risk Device CDS, informed by
384 our current understanding of the risks of these devices, FDA does not intend at this time to
385 enforce applicable device requirements.

386
387 As described in Section V.3 above, CDS software functions intended for the purpose of
388 supporting or providing recommendations to patients or caregivers – not HCPs – to prevent,
389 diagnose, or treat a disease or condition are still devices, because the Cures Act excludes only
390 certain CDS functions intended for HCPs from the device definition. FDA considers such Device
391 CDS functions, which are intended for patients or caregivers to inform clinical management for
392 non-serious health care situations or conditions (i.e., inform x non-serious), to be low risk when
393 the CDS function is intended for a patient or caregiver using the device to be able to
394 independently review the basis for its recommendations. The software manufacturer should
395 provide information to the patient about the inputs and basis of the recommendations made by
396 the software, as described in Section V.4. Because these Device CDS functions are low risk,
397 based on our current understanding of these devices, FDA does not intend at this time to enforce
398 compliance with applicable device requirements of the FD&C Act for them. The
399 recommendation for the type of decision to prevent, diagnose, or treat should be the type of
400 decision a patient or caregiver would routinely make without the input of a health care
401 professional, and the data used by the CDS function and the basis for its recommendations would
402 be of a kind that patients or caregivers understand.

403
404 Device CDS functions also include functions intended for HCPs that do not meet criterion (4) of
405 section 520(o)(1)(E) of the FD&C Act because they are not intended for the HCP to be able to
406 independently review the basis for its recommendation, and therefore an HCP would primarily
407 rely upon it. FDA also considers this category of Device CDS functions (i.e., inform x non-
408 serious) to be low risk. Therefore, if an “inform x non-serious” CDS function that is intended for
409 HCPs is not intended for the HCP to be able to independently review the basis for its
410 recommendations, then based on our current understanding of these devices, FDA does not
411 intend at this time to enforce compliance with the applicable device requirements of the FD&C
412 Act.

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414 FDA intends to focus its regulatory oversight on higher risk Device CDS software functions:
415 Device CDS functions intended for patients, caregivers, or HCPs that inform clinical
416 management for serious and critical health care situations or conditions. In Section VII.D, FDA
417 also describes device software functions that are not CDS and on which FDA also intends to
418 focus its regulatory oversight.

419
420 FDA encourages developers of CDS software functions that are not medical devices or are
421 medical devices for which at this time FDA does not intend to enforce compliance with FD&C
422 Act requirements to implement a quality system consistent with IMDRF’s [Software as a Medical
423 Device \(SaMD\): Application of Quality Management System](#)¹⁰ and to apply good cyber hygiene,
424 such as through software design and cyber vigilance, consistent with applicable FDA guidance.¹¹
425

426 Table 3 summarizes FDA’s approach to its regulation of CDS software functions. Those
427 functions that are the focus of FDA’s oversight are marked as “Oversight Focus,” while those for
428 which at this time FDA does not intend to enforce compliance with applicable device
429 requirements based on our current understanding of the risks of these devices are marked as
430 “Enforcement Discretion.” Non-Device CDS functions are marked as “Not a Device.”

Table 3. Summary of Regulatory Policy for CDS Software Functions

IMDRF Risk Categorization	Can the User Independently Review the Basis?*	Intended User is HCP	Intended User is Patient or Caregiver
		FDA Regulation	FDA Regulation
Inform x Critical	Yes	Not a Device	Oversight Focus
	No	Oversight Focus	Oversight Focus
Inform x Serious	Yes	Not a Device	Oversight Focus
	No	Oversight Focus	Oversight Focus
Inform x Non-Serious	Yes	Not a Device	Enforcement Discretion**
	No	Enforcement Discretion**	Oversight Focus

¹⁰ Available at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf>.

¹¹ Applicable guidance documents may include: General Principles of Software Validation (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation>); Cybersecurity for Networked Medical Devices Containing Off-the-Shelf Software (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-networked-medical-devices-containing-shelf-ots-software>); Postmarket Management of Cybersecurity in Medical Devices (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices>); or Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices>).

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434 * “Can the User Independently Review the Basis?” asks whether the function is intended for the purpose of enabling
435 the user to independently review the basis for the recommendations so that it is not the intent that user relies
436 primarily on any such recommendation (part of criterion (4)).

437 ** “Enforcement Discretion” indicates that, based on our current understanding of the risks of these devices, FDA
438 does not intend at this time to enforce compliance with applicable device requirements.

439 **VII. Examples**

440 The following sections describe examples of CDS software functions that are not devices
441 (VII.A), Device CDS functions that remain devices for which, based on our current
442 understanding of the risks of these devices, FDA does not intend at this time to enforce
443 compliance with applicable device requirements of the FD&C Act, including, but not limited to,
444 premarket clearance and premarket approval requirements (VII.B), and Device CDS functions
445 that remain devices and on which FDA intends to focus its regulatory oversight (VII.C). These
446 examples apply section 520(o)(1)(E) criteria and the IMDRF risk categorization to evaluate
447 whether the software function is not a device, is a function for which FDA does not intend to
448 enforce compliance with applicable requirements at this time, or is a function on which FDA
449 intends to focus its regulatory oversight. Note that while a particular health care situation or
450 condition may be described as “critical,” “serious,” or “non-serious” for a particular example of a
451 software function, it may be considered differently for another software function given the
452 context of use. Section VII.D provides examples of device software functions that are not CDS
453 and on which FDA intends to focus its regulatory oversight.

454 **A. Examples of Non-Device CDS Functions**

455 Below are examples of CDS functions that do not meet the definition of device in section 201(h),
456 as amended by the Cures Act, because they meet all four criteria described in section
457 520(o)(1)(E). Provided that the CDS function meets the criteria described in section 520(o)(1)(E)
458 of the FD&C Act, as described in Section V of this guidance, the function is Non-Device CDS
459 regardless of the healthcare situation or condition (i.e., “critical,” “serious,” or “non-serious”).

- 460 • Software that provides recommendations to HCPs by matching patient-specific
461 information (e.g., diagnosis, treatments, allergies, signs or symptoms) to reference
462 information the medical community routinely uses in clinical practice (e.g., practice
463 guidelines) to facilitate assessments of specific patients. The software explains that the
464 basis of the recommendation is developed from authoritative medical sources, as
465 recognized by the field or discipline that is the subject of the software and provides or
466 cites those materials. Examples include:
 - 467 ○ Software that uses a patient’s diagnosis to provide an HCP with current practice
468 treatment guidelines for common illnesses or conditions such as influenza, and
469 provides the source of the guidelines; and
 - 470 ○ Software that helps to identify drug-drug interaction and drug-allergy
471 contraindications, based on the current version of FDA-approved drug or medical
472 device labeling or other up-to-date and reliable sources and patient-specific
473 information, to attempt to prevent adverse drug events.

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- 474 • Software that provides HCPs with recommendations on the use of a prescription drug¹²
475 that are consistent with the FDA-required labeling.^{13,14} The software describes that the
476 recommendations are based on FDA-required labeling, such that the HCP does not rely
477 primarily on the software’s recommendation.
- 478 • Software that provides HCPs with recommendations on the use of a medical device that
479 are consistent with the FDA-required labeling or that are described in other sources, such
480 as those identified in the definition of CDS, such that the HCP does not rely primarily on
481 the software’s recommendation.
- 482 • Software that suggests an intervention or test, consistent with clinical guidelines and/or
483 drug labeling, based on or in response to a physician’s order, such as, for example,
484 software suggesting that an HCP order G6PD deficiency tests before starting an
485 antimalarial. The software describes the inputs and basis for the recommendations – i.e.,
486 the physician’s order for medication, drug labeling, and clinical guidelines – that are
487 made available to the HCP or cited by the software, such that the HCP does not rely
488 primarily on the software’s recommendation.
- 489 • Software that makes chemotherapeutic suggestions to an HCP based on patient history,
490 test results, and patient characteristics, including, for example, software suggesting a
491 FDA-approved chemotherapy for BRCA-positive individuals, that is consistent with
492 clinical guidelines and/or the drug labeling, which are described as the basis for the
493 recommendation and provided for the HCP to review, based on available information in
494 the patient’s electronic health record, such that the HCP does not rely primarily on the
495 software’s recommendation.
- 496 • Software that compares patient signs, symptoms, or results with available practice
497 guidelines (institutions-based or academic/clinical society-based) to recommend
498 condition-specific diagnostic tests, investigations, or therapy. The practice guidelines are
499 described as the basis for the recommendation and provided for the HCP to review, such
500 that the HCP does not rely primarily on the software’s recommendation.
- 501 • Software that contains tools, calculators, guidelines, and protocols for ordering total
502 parenteral nutrition (TPN), enteral nutrition, or other alimentation procedures. This would
503 include, for example, software recommending increased protein in TPN for patients with
504 active infection, consistent with generally accepted clinical practice, which is described

¹² Information relied upon by the software should be kept up-to-date while prominently displaying the source of the information (e.g., FDA approved labeling), and provide options to users to obtain up-to-date information. (For example, software that provides alerts for potential drug-drug interactions should provide a link directly to a trusted and up-to-date source for that information (e.g., DailyMed for drug labeling)).

¹³ Drug labeling includes prescribing information (also referred to as package insert or physician labeling); patient labeling, including patient package inserts and Medication Guides; the Drug Facts Label; the product’s immediate container label; outer container; the outside package; and other written, printed, or graphic information that accompanies the product. For more information, see the notice issued by FDA in the Federal Register regarding Prescription Drug-Use-Related Software (83 FR 58574).

¹⁴ See FDA guidance entitled “Medical Product Communications that are Consistent with FDA-Required Labeling,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-product-communications-are-consistent-fda-required-labeling-questions-and-answers>.

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- 505 as the basis for the recommendation and provided for the HCP to review, such that the
506 HCP does not rely primarily on the software’s recommendation.
- 507 • Software that provides HCPs with a report based on arterial blood gas results that
508 includes a calculated anion gap and recommends whether the patient has high anion gap
509 metabolic acidosis and possible next steps, based on practice guidelines, which are
510 described as the basis for the recommendation and provided for the HCP to review, such
511 that the HCP does not rely primarily on the software’s recommendation.
 - 512 • Software that presents and prioritizes alternatives to the HCP’s orders, drugs, or therapies
513 using practice guidelines and other generally accepted practices, such as rule-based tools
514 allowing HCPs to efficiently select diagnostic tests, drugs, devices, or therapies in
515 accordance with clinical practice guidelines, peer-reviewed clinical studies, textbooks, or
516 other appropriate sources, and their approved or cleared labeling. The software describes
517 the logic for the rule-based tools and provides or cites the sources, such that the HCP
518 does not rely primarily on the software’s recommendation.
 - 519 ○ A specific example is software that uses data from a ventilator to facilitate patient
520 status assessments by the clinician based on hospital practice guidelines or
521 clinical literature.
 - 522 • Software intended for use by HCPs to provide options for diagnosing patients suspected
523 to have diabetes mellitus. The HCP enters patient parameters and laboratory test results
524 (e.g., fasting plasma glucose, oral glucose tolerance test results, and/or hemoglobin A1c
525 test results), and the device suggests whether the patient’s condition meets the definition
526 of diabetes based on established guidelines, which are described as the basis for the
527 recommendation and provided for the HCP to review, such that the HCP does not rely
528 primarily on the software’s recommendation.
 - 529 • Software tools that analyze a patient’s stored clinical information based on specific
530 clinical parameters to make recommendations to an HCP for opportunities for
531 complementary tests, and the basis for the recommendation is provided so that the HCP
532 does not rely primarily on the recommendation.
 - 533 • Software that allows for simple and detailed calculation of the volume of intravenous
534 fluids estimated for the patient based on the total surface area of burns and the Parkland
535 formula, which is described as the basis for the recommendation, so that the HCP does
536 not rely primarily on the recommendation.

537 **B. Examples of Device CDS for which, based on our current** 538 **understanding of the risks of these devices, FDA does not** 539 **intend at this time to enforce compliance with applicable** 540 **device requirements**

541 **(1) Device CDS intended for HCPs**

542 Based on our current understanding of the risks of these devices, FDA does not intend at this
543 time to enforce compliance with applicable requirements of the FD&C Act for Device CDS

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544 software functions intended for HCPs that (using the IMDRF Framework) are intended to
545 “inform clinical management” for “non-serious situations or conditions.”

- 546 • Software that provides recommendations of potential allergens and common cold
547 symptoms based on location-specific electronic health records, environmental conditions,
548 and patient-reported outcomes to provide the HCP with options for different diagnoses
549 (e.g., seasonal allergic rhinitis vs. common cold). This software is a Device CDS
550 function, because the HCP is not intended to be able to independently evaluate the basis
551 for the software’s recommendations. At this time, FDA does not intend to enforce
552 compliance with applicable requirements of the FD&C Act for this Device CDS, because
553 it is an aggregation of data intended to provide clinical information for a non-serious
554 situation or condition (i.e., “inform x non-serious”).
- 555 • Machine-learning algorithm, for which the logic and inputs are not explained, that trends
556 and classifies patient-specific data (e.g., blood test results, weight) to alert HCPs to
557 potential triggers that may be indicative of cholesterol management issues. At this time,
558 FDA does not intend to enforce compliance with applicable requirements of the FD&C
559 Act for this Device CDS, because it is an aggregation of data intended to provide clinical
560 information for a non-serious situation or condition (i.e., “inform x non-serious”).
- 561 • Software intended for HCPs where the basis for the recommendation is not disclosed to
562 the user to analyze patient information to determine which over-the-counter (OTC)
563 allergy drug class is likely to be most effective in alleviating the patient’s seasonal
564 allergies. This software is a Device CDS function, because the HCP is not intended to be
565 able to independently evaluate the basis for the recommendation. At this time, FDA does
566 not intend to enforce compliance with applicable requirements of the FD&C Act for this
567 Device CDS, because it provides treatment options for a non-serious situation or
568 condition (i.e., “inform x non-serious”).

569 **(2) Device CDS intended for patients**

570 Based on our current understanding of the risks of these devices, FDA does not intend at this
571 time to enforce compliance with applicable requirements of the FD&C Act for Device CDS
572 software functions intended for patients that (using the IMDRF Framework) are intended to
573 “inform clinical management” for “non-serious situations or conditions” and that, in addition, are
574 intended for the patient to be able to independently evaluate the basis for the software’s
575 recommendations.

- 576 • Software that provides information to a patient about the use of a prescription drug that is
577 consistent with the FDA-required labeling¹⁵ and the patient’s prescription, such as
578 reminding the patient how or when to take a prescribed drug. Such software does not
579 recommend changes in dose or drug discontinuation that HCPs do not oversee (unless
580 drug labeling includes such recommendations). This software is Device CDS, because it
581 is intended for a patient. At this time, FDA does not intend to enforce compliance with

¹⁵ Information relied upon by the software should be kept up-to-date while prominently displaying the source of the information (e.g., FDA-approved labeling), and provide options to users to obtain up-to-date information. For example, software that provides alerts for potential drug-drug interactions should provide a link directly to a trusted and up-to-date source for that information (e.g., DailyMed for drug labeling).

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582 applicable requirements of the FD&C Act for this software function, because it is an
583 aggregation of data intended to provide clinical information for a non-serious situation or
584 condition (i.e., “inform x non-serious”) and because the basis for the recommendation
585 (FDA-required labeling) is described to the user, so that the software is intended for the
586 patient to be able to independently evaluate the basis for the software’s
587 recommendations.

- 588 • Software that assists a patient in identifying OTC cold or allergy medications to consider
589 purchasing based on symptoms. For example, once a patient or non-HCP caregiver inputs
590 the symptoms of the person needing a cold or allergy medication, the software provides a
591 prioritized list of OTC medications that match the person's symptoms. In this example,
592 inclusion of appropriate warnings about products with overlapping active ingredients
593 (e.g., multiple products containing acetaminophen) would be an important mechanism to
594 prevent risks to patients that might arise from using this software. This software is Device
595 CDS, because it is intended for a patient. At this time, FDA does not intend to enforce
596 compliance with applicable requirements of the FD&C Act for this software function,
597 because it is intended to provide options for the treatment of a non-serious situation or
598 condition (i.e., “inform x non-serious”) and because it is intended for the patient to be
599 able to independently evaluate the basis for the software’s recommendations.¹⁶
- 600 • Software that provides information or general instructions to patients or non-HCP
601 caregivers that are not specific to any drug, biological product, or medical device
602 labeling, such as general pre- and post-surgical care preparation and instructions. This
603 software is Device CDS, because it is intended for a patient. At this time, FDA does not
604 intend to enforce compliance with applicable requirements of the FD&C Act for this
605 software function because it is an aggregation of data intended to provide clinical
606 information for a non-serious situation (i.e., “inform x non-serious”) and because it is
607 intended for the patient to be able to independently evaluate the basis for the software’s
608 recommendations.¹⁷
- 609 • Software that assists patients with choosing OTC sunscreen (based on use, time,
610 ingredients, etc.), as well as best practices for selection and application to prevent
611 sunburn. This software is Device CDS, because it is intended for a patient. At this time,
612 FDA does not intend to enforce compliance with applicable requirements of the FD&C
613 Act for this software function, because it is an aggregation of data intended to provide
614 clinical information for a non-serious situation or condition (i.e., “inform x non-serious”)
615 and because it is intended for the patient to be able to independently evaluate the basis for
616 the software’s recommendations.¹⁸

¹⁶ Such information sources (identified by the software) may include FDA-approved labeling or DailyMed for drug labeling.

¹⁷ Such information sources (identified by the software) may aggregate general instructions and recommendations from the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), among others.

¹⁸ Sources (identified by the software) may include information from OTC sunscreen from multiple manufacturers and recommendations by clinical practice guidelines, for example.

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617 **C. Device CDS on which FDA intends to focus its regulatory**
618 **oversight**

619 **(1) Device CDS intended for HCPs**

620 FDA intends to focus its regulatory oversight on Device CDS functions intended for HCPs that
621 are intended (using the IMDRF Framework) to “inform clinical management” for “serious or
622 critical situations or conditions” and that, in addition, are not intended for the HCP to be able to
623 independently evaluate the basis for the software’s recommendations.

624 • Machine-learning algorithm, for which the logic and inputs are not explained, that
625 categorizes likely symptoms of seasonal influenza for each flu season based on location
626 and current electronic health records of patients diagnosed or suspected to have influenza
627 to assist HCPs in differentiating between common flu symptoms and other illnesses (e.g.,
628 common cold) in a particular season. This software is a Device CDS function, because
629 the HCP is not expected to be able to independently evaluate the basis for the software’s
630 recommendations. FDA intends to focus its regulatory oversight on this software,
631 because it is intended to inform clinical management for a serious situation or condition.

632 ○ Note: If the HCP could evaluate the basis for the software’s recommendations,
633 because the logic and inputs for the machine-learning algorithm and data inputs
634 used for the algorithm were explained and available to the HCP, then this
635 software would be considered Non-Device CDS (Section VII.A).

636 • Software, for which the inputs are not explained, that identifies patients who may exhibit
637 signs of opioid addiction based on patient-specific data, family history, electronic health
638 records data, prescription patterns, and geographical data. This software is a Device CDS
639 function, because the HCP is not expected to be able to independently evaluate the basis
640 for the software’s recommendations. FDA intends to focus its regulatory oversight on this
641 software, because it is intended to inform clinical management for a critical situation or
642 condition.

643 • Machine learning algorithm, for which the logic and inputs are not explained, that
644 identifies hospitalized, type 1 diabetic patients at increased risk of postoperative
645 cardiovascular events. This software is a Device CDS function, because the HCP is not
646 expected to be able to independently evaluate the basis for the software’s
647 recommendations. FDA intends to focus its regulatory oversight on this software,
648 because it is intended to inform clinical management for a critical situation or condition.

649 ○ Note: If the HCP could evaluate the basis for the software’s recommendations,
650 because the logic and data inputs for the machine learning algorithm and criteria
651 for risk of cardiovascular events were explained and available to the HCP, then
652 this software would be considered Non-Device CDS (Section VII.A).

653 **(2) Device CDS intended for patients**

654 FDA intends to focus its regulatory oversight on Device CDS functions intended for patients that
655 (using the IMDRF framework) are intended to “inform clinical management” for a “non-serious
656 situation or condition” and that, in addition, are not intended for the patient to be able to
657 independently evaluate the basis for the software’s recommendations. FDA also intends to focus

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658 its regulatory oversight on Device CDS functions intended for patients that are intended to
659 “inform clinical management” for “a serious or critical situation or condition,” whether or not the
660 software is intended for the patient to be able to independently evaluate the basis for the
661 software’s recommendations.

662 • Software that aggregates data from continuous glucose monitoring, activity trackers, and
663 food logs to help insulin-dependent type 2 diabetic patients identify potential lifestyle
664 triggers for hypoglycemic events and recommends corrective treatment options (e.g.,
665 timing of insulin dosing). This software is a Device CDS function, because it is intended
666 for patients and to inform clinical management. FDA intends to focus its regulatory
667 oversight on this software, because it is intended to inform clinical management for a
668 serious situation or condition.

669 • Software intended for patients that provides a questionnaire to assess a patient’s level of
670 stress and anxiety (prior to any diagnosis of general anxiety disorder) and recommends
671 treatment options based on the output of the assessment. This software is a Device CDS
672 function, because it is intended for patients and to inform clinical management. FDA
673 intends to focus its regulatory oversight on this software, because it is intended to inform
674 clinical management for a non-serious situation or condition, but the patient is not
675 expected to be able to independently evaluate the basis for the software’s
676 recommendations.

677 ○ Note: If the patient could understand the software’s recommendation, for
678 example, if the software provided the basis of the recommendation that is
679 understandable to the patient of how the questionnaire assesses stress and anxiety,
680 and how the recommendation is based on peer-reviewed publications and/or
681 clinical practice guidelines and the patient’s answers, then this software would be
682 considered Device CDS, but for which, based on our current understanding of the
683 risks of these devices, FDA does not intend at this time to enforce compliance
684 with applicable device requirements (Section VII.B.2).

685 • A software function that provides recommendations to caregivers of pediatric patients
686 with cystic fibrosis by aggregating information on when they should bring such children
687 to the emergency room, based on patient-specific symptoms and care guidelines. This
688 software is a Device CDS function, because it is intended for caregivers and to inform
689 clinical management. FDA intends to focus its regulatory oversight on this software,
690 because it is intended to inform clinical management for a critical situation or condition,
691 because the target population is fragile with respect to the disease or condition.

D. Examples of device software functions that are not CDS on which FDA intends to focus its regulatory oversight

694 FDA intends to focus its regulatory oversight on device functions that do not meet the definition
695 of Device CDS, as defined by the Cures Act and used in this guidance, but are devices.

696 • Software that uses a patient’s image sets (e.g., CT, magnetic resonance (MR)) to create
697 an individual treatment plan for review by an HCP for patients undergoing radiation
698 therapy treatment with external beam or brachytherapy. This software is a device

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- 699 function, because this software is intended to analyze a medical image and to generate the
700 treatment plan, which is intended to guide the next treatment intervention.
- 701 • Software that manipulates or analyzes images and other data obtained from a radiological
702 device (e.g., CT, bone density, and distance) to create 3D models of the region intended
703 to be used in planning orthopedic/dental surgical treatments with a device. This software
704 is a device function, because this software is intended to analyze a medical image and to
705 generate the models for planning treatment.
 - 706 • Software that manipulates or interpolates data from a patient’s CT scan, providing 3D
707 reconstruction for visualization of the interior of the bronchial tree to aid in the placement
708 of catheters in lung tissue; and placement of markers into soft lung tissue to guide
709 radiosurgery and thoracic surgery. This software is a device function, because it is
710 intended to analyze a medical image and to guide surgery.
 - 711 • Software that helps create custom implants and/or instrumentation based on analysis of
712 imaging and device characteristics for orthopedic or dental implant procedures. This
713 software is a device function, because it is intended to analyze a medical image and to
714 guide treatment through the design of custom implants.
 - 715 • Software that analyzes multiple physiological signals (e.g., sweat, heart rate, eye
716 movement, breathing – from FDA-regulated devices) to monitor whether a person is
717 having a heart attack or narcolepsy episode. The software is a device function, because it
718 is intended to analyze medical signals and to aid in diagnosis.
 - 719 • Software that analyzes near-infrared camera signals of a patient intended for use in
720 determining and/or diagnosing brain hematoma. The software is a device function,
721 because it is intended to analyze a medical signal and to aid in diagnosis.
 - 722 • Software that calculates the fractal dimension of a lesion and surrounding skin image and
723 builds a structural map to provide diagnosis or identify whether the lesion is malignant or
724 benign. This software is a device function, because it is intended to analyze a medical
725 image and to diagnose a disease or condition.
 - 726 • Software that analyzes CT images to compute and/or approximate fractional flow reserve.
727 In this case, the software performs and provides the HCP an image analysis that the HCP
728 could not independently derive. The intended use is to determine the likelihood that the
729 stenosis impedes oxygen delivery to the heart muscle (myocardial ischemia). This
730 software is a device function, because it is intended to analyze a medical image and to aid
731 in diagnosis of a disease or condition.
 - 732 • Software that is intended to perform image analysis for diagnostically differentiating
733 between ischemic and hemorrhagic stroke. In this case, the software performs and
734 provides the HCP an image analysis that the HCP could not independently derive. This
735 software is a device function, because it is intended to analyze a medical image and to aid
736 in diagnosis of a disease or condition.

Contains Nonbinding Recommendations

Draft – Not for Implementation

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- Software that analyzes signals from an FDA-cleared trans-abdominal electromyography device and an FDA-cleared fetal heart rate, intrauterine pressure catheter intended to determine a C-section intervention for an “at term” pregnant woman. This software is a device function, because it is intended to analyze a medical signal and to aid in treatment of a disease or condition.
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- Software that performs analysis of cerebrospinal fluid (CSF) spectroscopy data to diagnose tuberculosis meningitis or viral meningitis in children. This software is a device function, because it is intended to analyze a medical signal and to diagnose a disease or condition.
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- Software intended to generate an alarm or an alert to notify a caregiver of a life-threatening condition, such as stroke, and the caregiver relies primarily on this alarm or alert to make a treatment decision. This software is a device function, because it is intended to analyze a medical signal and to aid in treatment of a disease or condition.
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- Note the following low-risk example, which is also a device function but not Device CDS, and for which, based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with the applicable requirements of the FD&C Act: Software intended to analyze or interpret laboratory test or other device data and results to flag patient results based on specific clinical parameters (e.g., out of range test results where the reference ranges are predetermined by the lab) 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. This software is a device function, because it is intended to analyze a medical signal. However, in accordance with current practice, FDA does not intend to enforce compliance with the applicable device requirements of the FD&C Act for this flag/notification software function, because it is low risk. The example immediately above of an alarm or an alert that a caregiver relies on to make a treatment decision remains the focus of FDA’s regulatory oversight, because it is high risk.
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- Software function that provides a characterization of a patient’s abnormality based on its size, shape, appearance, or other functional aspects visible in the image. This software is a device function, because it is intended to analyze a medical image and to aid in diagnosis of a disease or condition.
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- Software that detects and highlights abnormalities (Computer-Assisted Detection, CAdE) and assesses associated disease severity (Computer-Assisted Diagnosis, CAdx). This software is a device function, because it is intended to analyze a medical image and to aid in diagnosis of a disease or condition.
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- Software that analyzes sound waves captured when users recite certain sentences to diagnose bronchitis or sinus infection. This software is a device function, because it is intended to analyze a medical signal and to diagnose a disease or condition.

Contains Nonbinding Recommendations

Draft – Not for Implementation

- 778 • Software that analyzes breathing patterns from a sleep apnea monitor to diagnose sleep
779 apnea or other conditions in patients. This software is a device function, because it is
780 intended to analyze a medical signal and to diagnose a disease or condition.
- 781 • Software that analyzes images of body fluid preparations or digital slides (digital
782 pathology) to perform cell counts and morphology reviews. This software is a device
783 function, because it is intended to analyze a medical image.
- 784 • Software that helps diabetic patients by calculating bolus insulin dose based on
785 carbohydrate intake, pre-meal blood glucose, and anticipated physical activity reported to
786 adjust carbohydrate ratio and basal insulin. This software is a device function, because it
787 is intended to aid in treatment of a disease or condition.
- 788 • Bioinformatics software products used to process high volume “omics” data (e.g.,
789 genomics, proteomics, metabolomics) process a signal from an in vitro diagnostic (IVD)
790 and are generally not considered to be CDS. Software products that provide patient-
791 specific information based on “omics” data often drive diagnostic and treatment
792 decisions. These software products are device functions, because they are intended to aid
793 in treatment of a disease or condition and because they process a signal from an IVD.
- 794 • Bioinformatics software products that query multiple genetic variants against reference
795 databases or other information sources to make patient-specific recommendations about
796 the significance of a patient’s variants are devices, because the HCP is not expected to be
797 able to independently evaluate the basis for the software’s recommendations. The
798 information excluded in the process of making an assertion about a genetic variant is not
799 provided to the user; therefore, the user cannot verify that the determination to exclude
800 such information was appropriate. These software products are device functions, because
801 they are intended to aid in treatment of a disease or condition and because the HCP is not
802 expected to be able to independently evaluate the basis for the software products’
803 recommendations.

804 **VIII. Conforming Changes to Existing Guidance**

805 Once this guidance is finalized, FDA intends to make conforming edits to the FDA Guidance
806 [Policy for Device Software Functions and Mobile Medical Applications](#)¹⁹ to make it consistent
807 with the interpretations and policies in this guidance. For example, software functions that use
808 patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific
809 screening, counseling, and preventative recommendations from well-known and established
810 authorities (listed in Appendix B of the guidance) are not devices.

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