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ADMINISTRATION

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# REPORT ON NON-DEVICE SOFTWARE FUNCTIONS: IMPACT TO HEALTH AND BEST PRACTICES – DECEMBER 2018

Submitted Pursuant to

Section 3060(b) of the 21st Century Cures Act

## Executive Summary

Section 3060(a) of the 21st Century Cures Act (herein referred to as the Cures Act), enacted on December 13, 2016 (Pub. L. 114-255), amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to exclude certain software functions from the definition of device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)). These software functions are specified in section 520(o)(1) of the FD&C Act and the intended uses of such software functions can be summarized as follows: (1) administrative support of a health care facility; (2) maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; (3) serving as electronic patient records when not intended to interpret or analyze patient records; (4) transferring, storing, converting formats, or displaying data; or (5) providing certain types of clinical decision support to a health care provider unless interpreting or analyzing a clinical test or other device data. Section 3060(b) of the Cures Act (herein referred to as section 3060(b)) requires that the Secretary of Health and Human Services (HHS) publish a report every two years that examines information available to the Secretary on any risks and benefits to health associated with the software functions described in section 520(o)(1) of the FD&C Act, and provides summary findings regarding the impact of these non-device software functions on patient safety, including best practices to promote safety, education, and competency. This document is the first report pursuant to section 3060(b) since the enactment of the Cures Act.

To identify relevant evidence and information published since the enactment of the Cures Act, the Food and Drug Administration (FDA) collected information from a variety of sources as defined in section 3060(b). This section 3060(b) report includes information reported on or pertaining to United States (U.S.) populations from December 13, 2016, to July 31, 2018 (for all sources).

The data and information from these sources were analyzed for evidence, published after the enactment of the Cures Act, regarding impact to patient safety, benefits and risks to health, and best practices to promote safety, education, and competency associated with the software functions described in section 520(o)(1) of the FD&C Act.

Using the outlined scope and methodology, this report summarizes the findings from this analysis. In general, the analysis found more benefits than risks to patient safety and health related to these software functions. In addition, this report details best practices related to implementation, training techniques, and use, which could promote safety, education, and competency related to these software functions.

As this report is required to be published every two years, future versions will capture findings and evidence published after July 31, 2018.

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## I. Introduction

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Section 3060(a) of the 21st Century Cures Act (herein referred to as the Cures Act), enacted on December 13, 2016 (Pub. L. 114-255), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to exclude certain software functions from the definition of device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)). These functions are described in section 520(o)(1) of the FD&C Act (21 U.S.C. 360j(o)(1)) and are the focus of this report.

Section 3060(b) of the Cures Act (herein referred to as section 3060(b)) requires a report to be published every two years that examines information available to the Secretary on any risks and benefits to health associated with the software functions described in section 520(o)(1) of the FD&C Act, and provides summary findings on the impact of non-device software functions on patient safety, including best practices. Specifically, section 3060(b) states:

*The Secretary of Health and Human Services (referred to in this subsection as the “Secretary”), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than 2 years after the date of enactment of this Act and every 2 years thereafter, that—*

- (1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary;*
- (2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 520(o)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as amended by subsection (a)); and*
- (3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.*

This document is the first report pursuant to section 3060(b), and includes findings related to information published from enactment of the Cures Act up until July 31, 2018.

## II. Background

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The description of non-device software functions in section 520(o)(1) of the FD&C Act (21 U.S.C. 360j(o)(1)(A)-(E)), as amended by the Cures Act, are the subject of this report. Specifically, section 520(o)(1) of the FD&C Act states:

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

- (A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict*

- future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;*
- (B) *for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;*
- (C) *to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—*
- (i) *such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;*
  - (ii) *such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and*
  - (iii) *such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;*
- (D) *for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or*
- (E) *unless the function is 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, for the purpose of—*
- (i) *displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);*
  - (ii) *supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and*
  - (iii) *enabling such health care professional 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.*

On December 8, 2017, the Food and Drug Administration (FDA) issued two draft guidance documents to provide FDA’s proposed interpretation of section 3060(a) and the types of software for which medical device regulation does and does not apply. The draft guidance documents are referenced below. The thinking reflected in these guidances about FDA’s proposed jurisdiction over software functions influenced the scope of this report:

**1. Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act<sup>1</sup>:** This draft guidance explains the proposed effect of section 3060 of the Cures Act on FDA’s regulation of software. This includes proposing a

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<sup>1</sup> Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act Guidance:  
<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf>.

description of how the change in device definition in section 201(h) of the FD&C Act affected preexisting FDA policy, including policy on mobile medical applications; medical device data systems used for the electronic transfer, storage, display, or conversion of medical device data; medical image storage devices used to store or retrieve medical images electronically; medical image communications devices used to transfer medical image data electronically between medical devices; software that automates laboratory workflow; and low-risk general wellness products.

2. **Clinical and Patient Decision Support Software<sup>2</sup>:** This draft guidance proposed an interpretation of the definition for clinical decision support in section 3060(a)(1)(E) of Cures Act, which amended section 520 of the FD&C Act (21 U.S.C. 360j) and excludes certain software functions from the device definition. This draft guidance also proposed the types of decision support software functionalities that: (1) do not meet the definition of a device, in light of the Cures Act; (2) may meet the definition of a device but for which FDA does not intend to enforce compliance with applicable requirements of the FD&C Act, including, but not limited to, premarket clearance and premarket approval requirements; and (3) meet the definition of device and for which FDA intends to focus its regulatory oversight on.

These draft guidance documents, when finalized, will represent the agency's current thinking on these topics and should not be considered final approaches to or determinations on software as it relates to the Cures Act. Nonetheless, this report examined the relevant software functions consistent with the thinking in the draft guidances. Future reports required by section 3060(b) will be based on the most recent FDA guidance, and, therefore, may have different interpretations of software that falls under section 3060(a).

In addition to FDA guidance documents, the Agency for Healthcare Research and Quality (AHRQ) and the Office of the National Coordinator for Health Information Technology (ONC) routinely publish reports related to health information technology.<sup>3,4</sup> Reports that were published prior to the enactment of the Cures Act or were otherwise found to be out of scope of this report are not included in this report's analysis.

### III. Methodology

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**Sources.** Information used to generate this report came from a variety of sources as defined in section 3060(b). This includes: consultation with agencies and offices of the Department of Health and Human Services involved in health information technology; input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology

<sup>2</sup> Clinical and Patient Decision Support Software Guidance: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819.pdf>.

<sup>3</sup> Agency for Healthcare Research and Quality. Evidence-Based Reports; [https://www.ahrq.gov/research/findings/evidence-based-reports/search.html?f%5B0%5D=field\\_evidence\\_based\\_reports%3A14024](https://www.ahrq.gov/research/findings/evidence-based-reports/search.html?f%5B0%5D=field_evidence_based_reports%3A14024). Accessed August 30, 2018.

<sup>4</sup> Office of the National Coordinator for Health Information Technology. Health IT Dashboard. 2018; <https://dashboard.healthit.gov/evaluations/library.php>. Accessed August 30, 2018.

vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise; and [other] information available to the [HHS] Secretary on any risks and benefits to health associated with software functions described in section 520(o)(1) [of the FD&C Act]. A list of sources can be found in Appendix A.

**Inclusion/Exclusion Criteria.** Parameters for all sources included information reported on or pertaining to United States (U.S.) populations from December 13, 2016, to July 31, 2018. This date range was selected to capture evidence published since the enactment of the Cures Act. The rationale for this is that evidence published prior to the Cures Act was used to inform section 3060 of the Cures Act, and the purpose of this report is to capture new information.

**Definitions.** The Cures Act requires information to be reported about the “impacts to patient safety” and “benefits and risks to health.” This report uses the following existing FDA and World Health Organization (WHO) definitions regarding patient safety and health:

- **Impacts to Patient Safety:** A *negative impact* to patient safety is defined as a risk that leads to a serious adverse event<sup>5</sup> (i.e., death, life-threatening, hospitalization, disability or permanent damage, congenital abnormality/birth defect, required intervention to prevent permanent impairment or damage, other serious [important medical events]). Whereas a *positive impact* to patient safety is defined as reducing the rate of a serious adverse event.
- **Benefits and Risks to Health:** Health is defined as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.<sup>6</sup>

**Analysis Approach.** The Cures Act requires a report summarizing findings corresponding to safety, risks and benefits, and best practices categories. Thus, this analysis includes reviews of all sources identified in the methods section above to generate the summarized findings of the report. The summaries include information and evidence regardless of the rigor of the design, the grade of study quality, and strength of evidence, in an effort to provide comprehensive findings. Due to the short time beyond enactment, summary findings of the impact of non-device software functions on patient safety, the risks and benefits to health associated with the software functions, and best practices may not be clear. Given that all software products that could fall under section 3060(a) is both unknown and extensive, analysis was limited to findings related to specific software identified during the research phase of report development.

For each of the five software functions, findings were analyzed in three categories, which align to the requirements of the Cures Act:

1. Impact to patient safety
2. Benefits and risks to health
3. Best practices to promote safety, education, and competency

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<sup>5</sup> FDA. What is a Serious Adverse Event? <https://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm>. Accessed August 23, 2018.

<sup>6</sup> World Health Organization. Constitution of WHO: principles. <http://www.who.int/about/mission/en/>. Accessed August 23, 2018.

## IV. Summary Findings as Required by Section 3060(b) of the 21st Century Cures Act

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The majority of findings detailed in this report correspond to positive impacts on patient safety and health benefits related to use of the five software functions. This report identifies only a few reported negative impacts on patient safety and health.

The sections below provide an overview of the findings for each of the five software functions. They are organized into the following three categories to reflect the stated focus of sections 3060(b)(2) and (3): impact on patient safety, benefits and risks to health, and best practices to promote safety, education, and competency. Appendix A provides details on all sources that contributed to the report and are cited in the sections below.

### A. Administrative Support of a Health Care Facility

Software functions included in this category are defined in section 3060(a) as intended:

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

#### **Impact to Patient Safety**

FDA received three adverse events<sup>7</sup> related to this software function. Two of these events were reported to be related to the malfunction of e-prescribing software, software that sends a prescription directly from the point-of-care to a pharmacy,<sup>8</sup> which may have led to a missed dose of medication, or medication being given to the wrong patient. In these cases, the e-prescribing software (1) failed to send prescriptions to the pharmacy, or (2) ordered prescriptions to the wrong patient chart, respectively. One death was reported with these events; however, a clear causal relationship between the reported death and the software function has not been established. While this e-prescribing software issue may have contributed to a clinician giving medication to the wrong patient, it has not been determined to be the cause of death. The third event was reported to be related to the malfunction of transfer care order software (e.g., tests and treatments). This event led to an undefined amount of orders not being received by the intended recipient or ancillary service resulting in incomplete tests and treatments causing delayed care. Users (e.g., providers) were not notified when ordered tests were not completed. No direct patient problems were reported along with this event.

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<sup>7</sup> FDA does not substantiate the adverse event reports it receives. Submission of an adverse event report does not constitute an admission that a product, user facility, importer, distributor, manufacturer, or medical personnel caused or contributed to the event.

<sup>8</sup> Centers for Medicare and Medicaid Services. E-Prescribing. <https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html>. Accessed December 3, 2018.



## **Benefits and Risks to Health**

One retrospective cohort analysis reviewed how electronic prescription refills, using personal health records or ‘patient portals’ to request prescription refills through electronic messaging, could support patient self-management of chronic conditions. This study found a statistically significant positive association between the use of electronic prescription refills and a change in HIV viral load status.<sup>9</sup>

Another study described the implementation of a store and forward (SAF) teledermatology system within an existing electronic health record (EHR) system. These SAF systems ‘store’ an image or data that is then ‘forwarded’ via telecommunication to another site for consultation.<sup>10</sup> This pilot study found that the SAF system, “improved access to care by decreasing wait time to evaluation, decreased treatment time for skin diseases, and increased the percentage of patients referred to a dermatologist”.<sup>11</sup>

## **Best Practices to Promote Safety, Education, and Competency**

A mixed-method, pilot comparative study evaluated the acceptability and feasibility of electronic screening forms versus paper screening forms. It was suggested that software tools, such as electronic screening forms, were "acceptable and feasible" when “contextual factors, such as technology capabilities, available software, and day-to-day practice functioning” were considered.<sup>12</sup> In a series of interviews with outside experts, it was suggested that patient safety issues may arise if information is not complete and accurate. For instance, patient name fields have been historically limited to 20 characters. If a patient has a longer name, there may be downstream misidentification since their full name is not displayed. It was recommended that in order to prevent these errors, character fields should be longer (e.g., 50 characters).

In addition, outside experts stated that the level of confidence with the information in the system should be assessed. They explained that this is important with population health management software. Further, they stated that if the information contained in the software is being analyzed and the resulting analysis will have impact on patient care, any decision related to that analysis should be tempered against the quality of the information.<sup>13</sup>

## **B. Maintaining or Encouraging a Healthy Lifestyle**

Software functions included in this category are defined in section 3060(a) as intended:

<sup>9</sup> McInnes DK, Shimada SL, Midboe AM, et al. Patient use of electronic prescription refill and secure messaging and its association with undetectable HIV viral load: a retrospective cohort study. *J Med Internet Res.* 2017;19(2):e34.

<sup>10</sup> Medicaid. Telemedicine. <https://www.medicaid.gov/medicaid/benefits/teledmed/index.html>. Accessed December 6, 2018.

<sup>11</sup> Carter ZA, Goldman S, Anderson K, Li X, Hynan LS, Chong BF, Dominguez AR. Creation of an internal teledermatology store-and-forward system in an existing electronic health record: a pilot study in a safety-net public health and hospital system. *JAMA Dermatol.* 2017;153(7):644-650.

<sup>12</sup> O'Brien MA, Sullivan F, Carson A, Siddiqui R, Syed S, Paszat L. Piloting electronic screening forms in primary care: findings from a mixed methods study to identify patients eligible for low dose CT lung cancer screening. *BMC Fam Pract.* 2017;18(1):95.

<sup>13</sup> Interview for the Fulfillment of 21st Century Cures Act Section 3060 Required Report. September 2018.

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

### **Impact to Patient Safety**

The analysis of all sources identified no direct impacts to patient safety. However, it should be noted that evidence regarding this topic could have been published prior to the Cures Act and, therefore, is outside the scope of this report.

### **Benefits and Risks to Health**

A single-arm, survey-based study found that the use of mindfulness smartphone applications was associated with an increase in self-reported mindfulness and an upward trend in positive affect.<sup>14</sup> Similarly, another experimental design study found a significantly greater association between the smartphone-delivered mindfulness intervention and users' self-reported ability to "[act] with awareness" than with a traditionally delivered mindfulness intervention (i.e., an in-person intervention). The study also found a positive association, albeit less significant, between smartphone-delivered mindfulness intervention use and increased compassion satisfaction, and decreased burnout.<sup>15</sup>

Evidence from an intervention study showed a significant increase in activity when a daily activity tracker was used to monitor physical activity. The authors reported that "estimated increases in step counts from baseline to the end of the intervention reflect a 73% increase in steps/day".<sup>16</sup> A systematic review analyzed the current evidence of wearable activity devices when used to aid in weight loss and found that using an activity tracker as part of a weight loss program provided "superior short term results than a standard weight loss program in middle age or older adults".<sup>17</sup> A randomized, controlled study found that individuals using a smartphone application for weight loss lost "significantly more weight, had a decrease in body mass index, and significantly decreased their waist circumference compared to the control group".<sup>18</sup> Another randomized, controlled study showed a smartphone-based smoking cessation application was rated by users as being "most effective" at helping to quit smoking, helping to remain quit, and providing resources for support and information about smoking cessation.<sup>19</sup> Another set of

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<sup>14</sup> Wen L, Sweeney TE, Welton L, Trockel M, Katznelson L. Encouraging mindfulness in medical house staff via smartphone app: a pilot study. *Acad Psychiatry*. 2017;41(5):646-650.

<sup>15</sup> Morrison Wylde C, Mahrer NE, Meyer RML, Gold JI. Mindfulness for novice pediatric nurses: smartphone application versus traditional intervention. *J Pediatr Nurs*. 2017;36:205-212.

<sup>16</sup> Abrantes AM, Blevins CE, Battle CL, Read JP, Gordon AL, Stein MD. Developing a Fitbit-supported lifestyle physical activity intervention for depressed alcohol dependent women. *J Subst Abuse Treat*. 2017;80:88-97.

<sup>17</sup> Cheatham SW, Stull KR, Fantigrassi M, Motel I. The efficacy of wearable activity tracking technology as part of a weight loss program: a systematic review. *J Sports Med Phys Fitness*. 2018;58(4):534-548.

<sup>18</sup> Stephens JD, Yager AM, Allen J. Smartphone technology and text messaging for weight loss in young adults: a randomized controlled trial. *J Cardiovasc Nurs*. 2017;32(1):39-46.

<sup>19</sup> Hicks TAB, Thomas SP, Wilson SM, Calhoun PS, Kuhn ER, Beckham JC. A preliminary investigation of a relapse prevention mobile application to maintain smoking abstinence among individuals with posttraumatic stress disorder. *J Dual Diagn*. 2017;13(1):15-20.

researchers used a prospective intervention and found that wearable device reminders were effective in changing student behavior, but changes to health were inconclusive.<sup>20</sup>

### **Best Practices to Promote Safety, Education, and Competency**

When outside experts were interviewed they recommended that users should be educated on the difference between a health product (e.g., software relating to maintaining or encouraging a healthy lifestyle) and a medical device. In addition, they felt that there should be consistency in how these are defined, and how the patient/consumer is educated regarding the credence of information being produced from health products.<sup>13</sup>

### **C. Electronic Patient Records**

Software functions included in this category are defined in section 3060(a) as intended:

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

- “(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;*
- “(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and*
- “(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.*

### **Impact to Patient Safety**

A retrospective study observed an overall decline of 27% in reported patient safety events associated with the use of electronic medical records. In particular, the study stated that there was a 30% decrease in reported events related to medication errors and a 25% decrease in reported events related to complications.<sup>21</sup>

Another retrospective study analyzed patient safety reports for potential risks associated with EHRs in the Pennsylvania Patient Safety Authority database. In the 1.735 million reported events evaluated, 0.03% stated that EHR usability issues contributed to patient harm, however, the authors noted that a causal effect could not be identified due to limited information in the patient safety reports.<sup>22</sup>

<sup>20</sup> Frank HA, Jacobs K, McLoone H. The effect of a wearable device prompting high school students aged 17-18 years to break up periods of prolonged sitting in class. *Work* (Reading, Mass). 2017;56(3):475-482.

<sup>21</sup> Hydari MZ, Telang R, Marella WM. Saving patient ryan—can advanced electronic medical records make patient care safer? *Mgmt Sci*. 2018.

<sup>22</sup> Howe JL, Adams KT, Hettinger AZ, Ratwani RM. Electronic health record usability issues and potential contribution to patient harm. *JAMA*. 2018;319(12):1276-1278.

One adverse event<sup>23</sup> related to EHRs was reported to FDA. The report stated that the EHR included erroneous information, which led to incorrect care and resulted in the patient's death. As with the retrospective study, a causal relationship between the EHR issue and the limited information provided in the adverse event report could not be determined.

### **Benefits and Risks to Health**

A prospective, intervention study evaluated patients' electronic sharing of personal health records with their providers. Results indicated that providers reported confidence in the accuracy of the information as well as improving their ability to have an accurate medication list and helped them make medication treatment decisions.<sup>24</sup> Similarly, a 6-month, pre-post design study found that integrating patient generated data and EHRs was associated with improved clinical outcomes (i.e., reduction in blood pressure, body mass index, and body weight) related to blood pressure treatment.<sup>25</sup>

### **Best Practices to Promote Safety, Education, and Competency**

Outside experts stated that patient education information and care plan details should be included in the patient's EHR portal. The experts suggested that this gives the patient the opportunity to be more engaged and informed about their treatment.<sup>13</sup> A peer-reviewed article discussed that medical terminology is not easily understandable to laypeople. It was also suggested that in order to mitigate issues with terminology, targeted education could be used to improve patient comprehension of EHR notes. In addition, it was noted that educating patients on the medical terms that are most meaningful to them may help patients to focus when reviewing their records.<sup>26</sup>

In terms of health care staff education, outside experts suggested that in order for staff to fully understand the implications of their actions, they should be trained on all processes that impact patient care and why the process is important, even if they are not involved with that particular process.<sup>13</sup>

Regarding software design, outside experts mentioned that, when developing this type of software, developers may not have the clinical understanding to address all safety elements of the software design, as well as any changes to the design. To mitigate this, outside experts suggested that all the stakeholders that touch EHRs be engaged in development, verification, and validation activities.<sup>13</sup> Authors of the aforementioned study also emphasized that the design of the user interface should account for differing skill levels among users to allow for meaningful use.<sup>24</sup> In order to maximize a patient's understanding of his/her health data, recommendations

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<sup>23</sup> FDA does not substantiate the adverse event reports it receives. Submission of an adverse event report does not constitute an admission that a product, user facility, importer, distributor, manufacturer, or medical personnel caused or contributed to the event.

<sup>24</sup> Klein DM, Pham K, Samy L, et al. The veteran-initiated electronic care coordination: a multisite initiative to promote and evaluate consumer-mediated health information exchange. *Telemed J E Health*. 2017;23(4):264-272.

<sup>25</sup> Lv N, Xiao L, Simmons ML, Rosas LG, Chan A, Entwistle M. Personalized hypertension management using patient-generated health data integrated with electronic health records (EMPOWER-H): six-month pre-post study. *J Med Internet Res*. 2017;19(9):e311.

<sup>26</sup> Chen J, Yu H. Unsupervised ensemble ranking of terms in electronic health record notes based on their importance to patients. *J Biomed Inform*. 2017;68:121-131.

included using pictures and graphs to explain data whenever possible, using lay terminology whenever possible, building targeted education into EHR notes, as well as using natural language processing models to modify information from provider notes to better fit the patient context.<sup>27</sup>

Outside experts suggested that a cohesive plan across and within departments should be implemented as breakdowns can occur when someone does not understand the flow of care and how it relates to administrative processes. The experts recognize that a variety of individuals and software systems interact with the EHR. They suggest that an EHR can be designed appropriately, but the impact of the individuals using the EHR and the other systems that interface with it need to be understood, as it can have downstream implications for patient care (e.g., quality data flowing into the system). They recommend that these interfaces should be monitored by an analytics program to identify breakdowns and potential issues.<sup>13</sup>

#### **D. Transferring, Storing, Converting Formats, or Displaying Clinical Laboratory Test or Other Device Data and Results**

Software functions included in this category are defined in section 3060(a) as intended:

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

#### **Impact on Patient Safety**

The analysis of all sources identified no direct impacts to patient safety. However, it should be noted that evidence regarding this topic could have been published prior to the Cures Act and, therefore, is outside the scope of this report.

#### **Benefits and Risks to Health**

The analysis of all sources identified no direct benefits or risks to health. However, it should be noted that evidence regarding this topic could have been published prior to the Cures Act and, therefore, is outside the scope of this report.

#### **Best Practices to Promote Safety, Education, and Competency**

Outside experts suggested that when transferring, storing, converting, or displaying data and information, an overlay can be used that will extract-transform-load (ETL) the information while keeping legacy data intact. In other words, a software overlay can be used to collect data from databases (extract), format the data and information in a uniform language (transform), and then transfer or insert the data and information into the targeted software (load). They explain that such functionality allows data that is collected, created, and/or contained by different software to be

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<sup>27</sup> Bouayad L, Ialynytchev A, Padmanabhan B. Patient health record systems scope and functionalities: literature review and future directions. *J Med Internet Res.* 2017;19(11):e388.

merged. In addition, they considered it important that these software functions implement and utilize industry consensus standards such as Digital Imaging and Communications in Medicine (DICOM) standards that are the international standards for transmitting, storing, retrieving, printing, processing and displaying medical information.<sup>13, 28</sup>

### **E. Certain Types of Clinical Decision Support**

Software functions included in this category are defined in section 3060(a) as intended:

*...unless the function is 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, for the purpose of—*

*“(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);*

*“(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and*

*“(iii) enabling such health care professional 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.*

### **Impact to Patient Safety**

Research identified an association between software types, such as those used to identify drug-drug interaction (DDI)-induced adverse drug reactions (ADRs) and multi-step biomedical informatics screening, and outcomes that could positively impact patient safety. The literature suggests that information populated from these software functions can be used to select drug combinations that avoid potential ADRs, suggest alternatives that minimize the number of DDI-induced ADRs, facilitate drug repurposing, and screen for drug combinations that either mitigate undesirable toxicity or synergize therapeutic effects.<sup>29, 30</sup> Implementation of other clinical decision support tools using a prospective pre- and post-intervention design showed a positive impact on standard of care guideline discussions during clinical care rounds.<sup>31</sup>

FDA received one adverse event<sup>32</sup> related to a clinical decision support software function. The particular software bug led to a dosage calculator using the incorrect date of birth to calculate

<sup>28</sup> Digital Imaging and Communications in Medicine. <https://www.dicomstandard.org/>. Access September 27, 2018.

<sup>29</sup> Liu R, AbdulHameed MDM, Kumar K, Yu X, Wallqvist A, Reifman J. Data-driven prediction of adverse drug reactions induced by drug-drug interactions. *BMC Pharmacol Toxicol*. 2017;18(1):44.

<sup>30</sup> Xu D, Ham AG, Tivis RD, et al. MSBIS: A multi-step biomedical informatics screening approach for identifying medications that mitigate the risks of metoclopramide-induced tardive dyskinesia. *EBioMedicine*. 2017;26:132-137.

<sup>31</sup> Hulyalkar M, Gleich SJ, Kashyap R, et al. Design and alpha-testing of an electronic rounding tool (CERTAINp) to improve process of care in pediatric intensive care unit. *J Clin Monit Comput*. 2017;31(6):1313-1320.

<sup>32</sup> FDA does not substantiate the adverse event reports it receives. Submission of an adverse event report does not constitute an admission that a product, user facility, importer, distributor, manufacturer, or medical personnel caused or contributed to the event.

estimated values needed in a medication dosage computation, which could result in a patient receiving an incorrect dose.

### **Benefits and Risks to Health**

One retrospective study assessed the impact of a proprietary consultant pharmacist software (e.g., commercial software) on the completion of comprehensive medication reviews. The researchers found that using this proprietary software led to higher completion rates of the medication reviews as part of medication therapy management. Higher completion rates, the researchers noted, can “reduce the risk of adverse events and improve medication adherence”.<sup>33</sup>

### **Best Practices to Promote Safety, Education, and Competency**

Scholars have suggested that to assist in user competency, DDI or allergy alerts to physicians should be timed in a manner that allows for appropriate actions to be carried out and does not require medical staff to reassess or repeat thought processes.<sup>34</sup> Outside experts stated that to avoid negative outcomes as a result of poor human clinical documentation where the alert system is given bad information, the use of structured data fields can optimize the opportunity for the correct information to be entered into the system. They go on to suggest that the design of this software should make it possible for doctors to use clinical intuition as well and work around the alerts. They also recommend that if an alert is ignored, documentation as to the rationale should be required.<sup>13</sup>

Outside experts suggested that the user experience should take into consideration the timing of when the information is presented, so it is available before the provider makes decisions and takes into account the level of severity of information being presented. In addition, they note that the quality of documentation should be monitored, and poor information should be remedied. They believe that the thoughtfulness of the clinical decision support software design needs to reflect not only universal best practices, but the organizational culture it is operating within, to account for variations in processes (e.g., nurse receiving the alert versus physician).<sup>13</sup>

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<sup>33</sup> O'Shea TE, Zarowitz BJ, Erwin WG. Comprehensive medication reviews in long-term care facilities: history of process implementation and 2015 results. *J Manag Care Spec Pharm.* 2017;23(1):22-26.

<sup>34</sup> Wong A, Wright A, Seger DL, Amato MG, Fiskio JM, Bates D. Comparison of overridden medication-related clinical decision support in the intensive care unit between a commercial system and a legacy system. *Appl Clin Inform.* 2017;8(3):866-879.

## Appendices

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### A. List of Sources

The following list of sources was compiled by the information collection activities conducted to generate the findings summarized in this report.

#### Interviews

- Amida Technology Solutions – September 12, 2018
- Health Information and Management Systems Society (HIMSS) – September 18, 2018
- Cerner Corporation – September 11, 2018
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- Centers for Medicare and Medicaid Services (CMS), E-prescribing: <https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html>.
- Consumer Product Safety Commission (CPSC), National Electronic Injury Surveillance System (NEISS): <https://www.cpsc.gov/cgibin/NEISSQuery/home.aspx>.

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- Digital Imaging and Communications in Medicine (DICOM): <https://www.dicomstandard.org/>.
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- Pennsylvania Patient Safety Authority, Pennsylvania Patient Safety Reporting System: <http://patientsafety.pa.gov/PA-PSRS>.
- Total Product Lifecycle (TPLC) database: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>.
- World Health Organization: <https://www.who.int/about/mission/en/>.