Development of 21st Century Cures Act Section 3060 Required Report: Request for Input

Background

FDA has long regulated software that meets the definition of a device. Section 3060(a) of the 21st Century Cures Act (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 medical software functions from the definition of device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)). The Cures Act reflected, and in some cases expanded, policies FDA had already begun to implement. Under sections 520(o)(1) of the FD&C Act (21 U.S.C. 360j(o)(1)(A)-(E)), as added by the Cures Act, certain medical software functions are not medical devices, including software functions that are intended (1) for administrative support of a health care facility, (2) for maintaining or encouraging a healthy lifestyle, (3) to serve as electronic patient records, (4) for transferring, storing, converting formats, or displaying data, or (5) to provide limited clinical decision support.

On September 27, 2019, FDA issued a guidance document – Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act – and a draft guidance document – Clinical and Patient Decision Support Software – with the most current interpretations, and draft interpretations, respectively, of the medical software provisions in the Cures Act.

In accordance with section 3060(b) of the Cures Act, FDA, in consultation with agencies and offices of the Department of Health and Human Services (HHS) involved in health information technology, is examining information on any risks and benefits to health associated with these non-device software functions. FDA is developing a report to summarize the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions. This report shall update the findings of – REPORT ON NON-DEVICE SOFTWARE FUNCTIONS: IMPACT TO HEALTH AND BEST PRACTICES – DECEMBER 2018. FDA intends to work with agencies in HHS, such as the Office of the National Coordinator for Health Information Technology, to gather and summarize information related to risks and benefits for non-device software functions.

Request for Input

FDA requests input on patient safety, including best practices to promote patient safety, education, and competency, associated with the software functions excluded from the device definition by the Cures Act. FDA seeks input from all interested parties, including patients, consumers, healthcare providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small business purchasers, employers, and other stakeholders. You may submit comments to the public docket at www.regulations.gov using docket number FDA-2018-N-1910. Please submit comments for consideration in the development of the report by July 13, 2020. FDA will incorporate this input as we develop the report on the risks and benefits to health of these software functions.

Details of Non-Device Software Functions

FDA welcomes input regarding the impact of non-device software functions on patient safety. In particular, FDA seeks input on impacts to (1) patient safety, (2) benefits and risks to health, and (3) best

practices to promote safety, education, and competency associated with these non-device software functions.

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.