Pharmacy Health Information Technology Collaborative

Via Electronic Submission to: www.regulations.gov

December 26, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
Attention: FDA-2017-D-6569
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA-2017-D-6569; Guidance Document: Clinical Decision Support Software, Guidance for Industry and Food and Drug Administration Staff

Dear Commissioner Sharpless:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments regarding the *Guidance Document: Clinical Decision Support Software, Guidance for Industry and Food and Drug Administration Staff.*

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC), developing the national health information technology (HIT) framework since 2010.

Pharmacists provide essential patient-centered care and services and are users of health IT, particularly those used for clinical decision support (CDS). The Collaborative supports the use of these systems, which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing.

The following are our comments regarding the *Guidance Document: Clinical Decision Support Software, Guidance for Industry and Food and Drug Administration Staff.*

V. (4) Intended for the purpose of enabling an HCP to independently review the basis for recommendations that such software presents, etc.

Based on FDA's interpretation of 520(o)(1)(E)(iii), the Collaborative agrees that manufacturers of non-device CDS should describe their software functions in plain language, including the purpose of the intended use of the software function; the intended user; the inputs used to generate the recommendation; and the basis for rendering a recommendation.

VI. C. Policy for Device CDS Functions

The Collaborative supports FDA's approach that developers of CDS software functions that are not medical devices and those functions that are medical devices should be vigilant that their software and cyber design are consistent with applicable FDA guidance. Additionally, the Collaborative would encourage FDA to ensure that such software that are not medical devices and those that are medical devices be certified. We understand, however, that FDA does not intend to enforce the Food Drug and Cosmetic (FD&C) Act requirements to implement a quality system consistent with the International Medical Device Regulators Forum (IMDRF) Software as a Medical Device (SaMD) framework at this time, which makes certification of these products even more crucial.

CDS tools used by pharmacists, physicians, and other health care practitioners can provide significant time and cost savings that ultimately would aid in producing effective outcomes for patients and reduce health care providers' (HCPs) administrative burdens.

VII. A. Examples of Non-Device CDS Functions

The Collaborative appreciates FDA citing as examples of non-device CDS functions that pertain to pharmacists and are applicable to the practice of pharmacy and supports the following as non-device CDS:

- Software that provides recommendations to HCPs by matching patient-information (e.g., diagnosis, treatments, allergies, signs of symptoms) to reference information the medical community routinely uses in clinical practice;
- Software that helps identify drug-drug interactions and drug-allergy contraindications, based on the current version of FDA-approve drug or medical device labeling or other up-to-date reliable sources, to attempt to prevent adverse drug events;
- Software that provides and describes recommendations on the use of a prescription drug that are consistent with FDA-required labeling so that the HCP does not rely primarily on the software's recommendation;
- Software that suggests an intervention or test, consistent with clinical guidelines and drug labeling, based on or in response to a physician's order;

- Software that compares patient signs, symptoms, or results with available practice guidelines; and
- Software that presents and prioritizes alternatives to the HCP's orders, drugs, or therapies using practice guidelines and other generally accepted practices.

As noted previously, CDS tools used by pharmacists, physicians, and other health care practitioners can provide significant time and cost savings that ultimately would aid in producing effective outcomes for patients and reduce HCPs administrative burdens.

VII. 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

(1) Device CDS intended for HCPs

- Machine-learning algorithm, for which the logic and inputs are not explained, that trends and classifies patient-specific data (e.g., blood test results, weight) to alert HCPs to potential triggers that may be indicative of cholesterol management issues.

Although the Collaborative generally supports the use of artificial intelligence (AI) in CDS, it is important that the AI is designed using United States authoritative evidence-based clinical research and data and that the algorithm used should be U.S. certified. Provider and patient education regarding CDS, including CDS use limitations, may also be warranted. Patient safety should be among the top factors related to AI tools that should be considered.

(2) Device CDS intended for patients

Based on FDA's analysis of low risk and explanation for not intending to enforce compliance with applicable requirements of the FD&C Act for Device CDS software functions intended for non-serious situations or conditions and that the patient would be able to independently evaluate the basis for the software's recommendations, the Collaborative is supportive of the following being included in this category:

- Software that provides information to a patient about the use of a prescription drug that is consistent with the FDA-required labeling and the patient's prescription, such as reminding the patient how or when to take a prescribed drug (software does not recommend changes in dose or drug discontinuation that HCPs do not oversee).
- Software that assists a patient identifying OTC cold or allergy medication to consider purchasing based on symptoms.

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

(1) Device CDS intended for HCPs
(2) Device CDS intended for Patients

The draft guidance states that FDA intends to conduct regulatory oversight in these two categories for device functions that use machine-learning algorithms, also known as artificial intelligence (AI), to inform clinical management for serious or critical situations or conditions for seasonal influenza, signs of opioid addiction, and hospitalized, type 1 diabetic patients at increased risk of post-operative cardiovascular events, as well as for a non-serious situations or conditions for glucose monitoring, activity trackers, and food logs to help-insulin dependent type 2 diabetic patients identify potential lifestyle triggers for hypoglycemic events and recommend corrective treatment measures.

As stated previously, although the Collaborative generally supports the use of AI in CDS, it is important that the AI (machine-learning algorithm) is designed using United States authoritative evidence-based clinical research and data and that the algorithm used should be U.S. certified. Provider and patient education regarding CDS, including CDS use limitations, may also be warranted. Patient safety should be among the top factors related to AI tools that should be considered.

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative's membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and 17 associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-center care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists' use of health IT; provides resources, guidance, and support for the adoption and implementation of standards driven health IT; and guides health IT standards development to address pharmacists' needs. For additional information, visit www.pharmacyhit.org.

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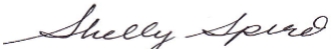
On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *Guidance Document: Clinical Decision Support Software, Guidance for Industry and Food and Drug Administration Staff*.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,



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