COLLEGE of AMERICAN PATHOLOGISTS

December 26, 2019

Stephan Hahn, M.D
Commissioner
US Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Clinical Decision Support Software Draft Guidance for Industry and Food and Drug Administration Staff DRAFT GUIDANCE [Docket No. FDA-2017-D-6569]

Submitted via Electronic Submission to www.regulations.gov

Dear Dr. Hahn:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Food and Drug Administration draft guidance entitled, *Clinical Decision Support Software Draft Guidance for Industry and Food and Drug Administration Staff*. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists have a long track record of delivering high quality diagnostic services to patients and other physicians.

Pathology was one of the earliest specialties to embrace health information technology (HIT). Pathologists and their laboratories have long relied on sophisticated computerized laboratory information systems (LISs) in order to support the work of analyzing patient specimens and generating test results, and it is with these LISs that EHRs or enterprise-wide clinical information systems exchange laboratory and pathology data. Advances in histopathological analysis, EHR documentation, and cellular biology techniques have allowed for acquisition of large amounts of digitized patient data and, subsequently, new workflows in the digital pathology laboratory. Therefore, clinical decision support software (CDS) has been adopted for a wide variety of uses including general alerts, reminders, summary dashboards, and automated information retrieval systems. Thus, a risk-based approach to oversight of CDS is appropriate; however, we seek clarity on the criteria used to determine the applicability of regulatory requirements given the implications on LISs. **Specifically, we seek clarity on 1) the conflicting uses of "analyze" to describe conditions for the device definition; 2) the use of bioinformatics software products being classed as devices; and 3) the definition of a health care professional (HCP) for the purposes of this document.**

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SPECIFIC COMMENTS

1. Page 6, lines 62-67: Conflicting Uses of "Analyze" to describe conditions for device definition.

The guidance document excludes, from the definition of device by section 520(o)(1)(E) of the FD&C Act, software functions that meet four criteria, of which two should be clarified: (1) if it is "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", and (2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines). CDS systems within EHRs and LISs use information (e.g. test results) reported elsewhere in the patient's chart to make clinical recommendations. Given the functionality of the LIS and EHR systems, we are concerned these systems would meet the definition of a medical device and thus be subjected to regulatory requirements despite providers' ability to independently review the basis of the CDS recommendations. It is appropriate to regulate information derived from a medical sensor rather than CDS software within the medical record; but the current language as drafted is confusing. **Therefore, the FDA should clarify that CDS is not a device if it uses data otherwise accessible to the provider and allows the provider to independently review the basis of the recommendation.**

2. Page 27, lines 788-803: Use of bioinformatics software products being classed as devices.

The guidance states that software products that provide patient specific information based on "omics" data often drive diagnostic and treatment decisions. These software products are device functions, because they are intended to aid in treatment of a disease or condition and because they process a signal from an IVD." In the next example, "Bioinformatics software products that query multiple genetic variants against reference databases or other information sources to make patient-specific recommendations about the significance of a patient's variants are devices, because the HCP is not expected to be able to independently evaluate the basis for the software's recommendations." As currently written, the guidance may improperly class as devices routine bioinformatics tools that molecular pathologists use to assist in the interpretation of variants. The recommendations of these tools are independently evaluated by pathologists, who would otherwise do the same work manually, and therefore would fulfill the requirements of a non-device CDS or a laboratory workflow software function, which is excluded from software device functions under Section 520(o)(1)(A) of the FD&C Act.

3. Page 7, line 71: Definition of a HCP for the purposes of this document

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The guidance frames the split of all CDS into "device" and "non-device" CDS partly based on whether the intended user is an HCP. However, no definition or reference to a previously made definition for HCP is provided. As currently written, the guidance lacks clarity for if it would apply to health care workers who do not directly treat patients but still access the medical record and therefore are a potential audience for CDS tools. For example, hypothetically: a hospital designs an automated rule in the electronic medical record that notifies laboratory staff whenever they receive a sample from patients taking daratumumab (a medication known to interfere with blood bank laboratory testing), or patients having high-dose biotin-containing supplements on their medication list (biotin being known to interfere with some laboratory tests). The laboratory technician can independently review the basis of the warning flag.

Depending on the definition of laboratory staff as HCP, or not, this medication rule could either be classed as "non-device CDS" if they are HCP, "device CDS" if they are non-HCP (since no other category for audience exists except for patients and caregivers), or not CDS at all, if this is a deemed to be a software function for "laboratory workflow", which is excluded from software device functions according to Section 520(o)(1)(A) of the FD&C Act. **Therefore, the FDA should use the definition of HCP as a physician (as defined in section 1861(r) of the Social Security Act) or a practitioner (as described in section 1842(b)(18)(C) of the Social Security Act), with the example above being treated as a laboratory workflow software function not in scope for this guidance.**

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with the FDA. Please direct questions on these comments to Helena Duncan at (202) 354-7131 or hduncan@cap.org.

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