

December 26, 2019

Stephen M. Hahn, MD
Commissioner
Food and Drug Administration
Department of Health and Human Services
Silver Spring, MD 20993

Dear Commissioner Hahn:

On behalf of the Healthcare Information and Management Systems Society ([HIMSS](#)) and the Personal Connected Health Alliance ([PCHAlliance](#)), we are pleased to provide written comments to the Food and Drug Administration's (FDA's) [Clinical Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff](#) (Docket Number: FDA-2017-D-6569) which was issued September 27, 2019. HIMSS and PCHAlliance appreciate the opportunity to leverage our members' expertise in offering feedback on the scope of FDA's oversight of manufacturers of clinical decision support (CDS) software intended for health care professionals, patients, or caregivers, as well as FDA's regulatory approach to CDS software functions.

HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments and market suppliers, ensuring they have the right information at the point of decision. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include nearly 80,000 individuals, 475 provider organizations and 650 health services organizations.

PCHAlliance, a membership-based HIMSS Innovation Company, accelerates technical, business and social strategies necessary to advance personal connected health and is committed to improving health behaviors and chronic disease management via connected health technologies. PCHAlliance is working to advance patient/consumer-centered health, wellness and disease prevention. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world.

HIMSS and PCHAlliance want a CDS software regulatory framework that sustains rather than stifles innovation to drive healthcare transformation, and ensures that there is an acceptable level of clarity and predictability in terms of regulation and/or oversight

while continuing to support reasonably safe and effective medical devices. The nature of health IT and its role in health care delivery decisions continues to evolve, and we recommend that any new policy offers predictable processes for health IT products.

We also believe the Draft Guidance is an opportunity for FDA to help minimize clinician burden. Such a focus by FDA would be in alignment with the entire Department of Health and Human Services (HHS) desire to mitigate clinician burden issues and ensure that new policies do not add to providers' busy workloads through the [Patients Over Paperwork Initiative](#).

Moreover, there continues to be pressure placed on our provider community to do more with less, including treating more patients as the [Silver Tsunami](#) results in more patients aging and seeking higher levels of healthcare services. Within the next few years, our provider community will need more digital health tools from manufacturers—such as innovations in remote monitoring, telehealth, and mobile health—that will play an even more vital role in making sure providers can navigate these changing dynamics. As a result, we are at a crucial time for the industry to decide where to invest and how to effectively implement those technologies, which includes CDS software.

As this Draft Guidance is FDA's second iteration on this topic, our comments build on our previous [letter](#) from February 6, 2018.

Overall, we support the intent of the Draft Guidance as well as the push towards a risk-based framework, but our community needs more clarity and streamlined guidance in order to implement the oversight of CDS software functions appropriately. We also encourage FDA to include additional examples in the Draft Guidance to ensure that the entire community is clear on expectations. FDA could also implement a CDS software section within the FDA.gov website, similar to the [Device Software Functions Including Mobile Medical Applications](#) page, thus allowing FDA to periodically add new de-identified examples of both Device and Non-Device CDS software.

With these factors in mind, HIMSS and PCHAlliance offer the following thoughts on the information included in the Draft Guidance:

Support for FDA's Efforts to Develop a Risk-Based Oversight Framework for CDS Software Functions

Based on the provisions of the [21st Century Cures Act](#), HIMSS and PCHAlliance support FDA's move toward implementing risk-based regulatory policies for CDS software functionality. The agency describes how the risk of a Device CDS software function is based, in part, on the state of the health care situation or condition for which it is intended. The Draft Guidance also signals how FDA intends to focus its regulatory oversight on higher risk Device CDS software functions. Moreover, for two types of low risk Device CDS software, FDA does not currently intend to enforce applicable medical device requirements. The agency's actions are informed by its current understanding of the risks of these devices.

Overall, the framework that FDA created is directionally-appropriate. However, HIMSS and PCHAlliance do have several ideas on how to strengthen and streamline the broad framework to provide greater clarity to the community around FDA CDS software oversight.

Streamline and Simplify the Concepts Underlying the International Medical Device Regulators Forum (IMDRF) Framework in Guidance Document

HIMSS and PCHAlliance question the direct inclusion of the IMDRF risk framework in the Draft Guidance as it leads to complexities around what is included under FDA regulation, as either an oversight focus or part of enforcement discretion.

We fully support the fundamental concept of risk-based policy for CDS software functions in the IMDRF Framework and believe that it is consistent with FDA's commitment to implement IMDRF documents as well as advance global medical device regulatory harmonization and convergence generally. IMDRF also calls for close collaboration between regulators, stakeholders, and regulated industry

However, we advocate for IMDRF documents to serve as broad directional guidelines and be used to establish guardrails to advise the regulatory community on CDS software oversight, but ask FDA to simplify the Draft Guidance without relying so absolutely on the IMDRF risk framework. As noted on the [IMDRF website](#),

If [IMDRF] is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.

As a voluntary group, IMDRF is not itself a regulatory body nor does it draft or approve laws or regulation. The documents generated by the various IMDRF working groups is meant to serve as foundational references and not necessarily be included verbatim in member country regulations.

To apply the intent of the IMDRF risk framework, we considered the salient questions posed in the Draft Guidance. For HIMSS and PCHAlliance, the Draft Guidance really amounts to determinations on two questions: (1) is the intended user a healthcare professional; and, (2) can the user independently review the basis for the determination without relying primarily upon the recommendation.

If each question is answered affirmatively, then we are discussing Non-Device CDS software; if the user cannot independently review the basis for the determination, then it is Device CDS software and should be considered a medical device. The level of regulatory oversight imposed by FDA, including enforcement discretion, then becomes a question of Critical, Serious or Non-Serious risk¹. Use of the IMDRF risk framework concepts to these two questions are answered in Table 3 of the Draft Guidance.

¹ As defined in ISO 14971

Inclusion of definitions for the IMDRF risk categorization would be the only additional information necessary to understand the information in Table 3.

We want to ensure that the Draft Guidance is as streamlined and straightforward as possible, does not complicate oversight determination for the community, and encourages new market entrants to want to innovate in the CDS software space. From our perspective, using the IMDRF Framework verbatim only incorporates an additional layer of complexity to the oversight mechanisms without adding value for the community. We believe that through inclusion of Table 3 with appropriate definitions and explanation of the table reduces complication without losing the intent from FDA.

More Definitional Clarity is Needed around Several Terms in the Draft Guidance

Simply stated, definitions matter, and based on this document, HIMSS and PCHAlliance ask FDA for more precision around several definitions to reduce ambiguity and appropriately advise the community on implementation questions. These areas include:

- “Independently Review” and “Rely Primarily”

21st Century Cures (§ 3060) excludes certain CDS software functions from the CDS device definition if certain criteria are met. The specific language of interest within the criteria, now within the Food, Drug and Cosmetic Act, Section 520(o)(1)(E)(iii), is as follows (emphasis added):

“intended for the purpose of enabling a 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.”

We emphasize “intended for²” to highlight that the audience for the Draft Guidance is Industry and FDA, not the healthcare provider or clinician. The definitions for “independently review” and “rely primarily on” must be within the context of what the persons legally responsible for the labeling of devices objectively intend for the CDS software to be used for. The persons legally responsible for the labeling of devices is principally the manufacturer³. FDA needs to provide clarity around how it plans to look at the questions of intent for the manufacturer from the “independently review” and “rely primarily” discussion.

In some instances, the Draft Guidance appears to be considering intent from the clinician perspective, stating that the healthcare professional “does not rely” on CDS software recommendation (practice of medicine); in other examples, FDA appears to be operating from the manufacturer’s viewpoint, and discusses intent by stating that the healthcare professional “is not intended to” be able to independently evaluate the

² Refer to <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.4>

³ Refer to <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.3>

basis for the recommendation. FDA should avoid language that appears to regulate the practice of medicine.

HIMSS and PCHAlliance request FDA to provide clarity around the phrases “independently review” and “rely primarily”, as well as examples on how a manufacturer could meet these requirements.

For “independently review”, FDA should describe what information a manufacturer needs to provide to ensure a clinician would need to possess to independently review the CDS software recommendations. Several related questions arise, including:

- Does “independently review” mean that a clinician, on their own and without other consult, be able to review the recommendation provided by the CDS software? In other words, can FDA clearly define what “independently review” is, as well as what it is not?
- Does “review” mean the clinician needs to be able to reach the identical recommendation provided by the CDS software or is a clinically viable analog with similar risks sufficient?
- From FDA’s perspective, what level of detail would a clinician need from the manufacturer to independently review a CDS software recommendation?
- What level of evidence do developers need to have available in their design records to prove that a clinician is capable of independently reviewing the CDS recommendation?
- What salient information should developers utilize to differentiate between software functionality that “informs clinical management” and functionality intended to “drive clinical management”?

The other part of the criteria indicates that the manufacturer cannot intend for the clinician to “rely primarily” on the CDS recommendations. Beyond a statement in the product labeling, FDA should explain what information a manufacturer needs to obtain to satisfy FDA’s expectation of a clinician not relying primarily upon the CDS software recommendation. Moreover, how should manufacturers view the term “primarily”; does over a 50 percent reliance on a recommendation constitute a primary dependence? What types of information would FDA expect as a measure of reliance? Could the information be a post-market and based upon real-world evidence?

The concept of “rely primarily” without additional context also creates opportunity for subjectivity when considering the breadth of potential experience and training intended users have. For example, what information would FDA expect from manufacturers related to the experience of intended clinicians or patients? Should a manufacturer expect that a more seasoned practitioner have less reliance on the CDS software recommendation than a physician right out of medical school? Would a patient or caregiver that has managed a chronic disease for multiple years have less reliance on the CDS software than a recently diagnosed individual? These are the kinds of questions that FDA needs to clarify in a final guidance document to appropriately advise the community.

Ensure that the CDS Guidance Empowers Patients and Caregivers

The Draft Guidance appears to discount the potential contribution of patients to their care treatment plans by applying oversight focus for basically all the risk categories related to CDS software where the intended user is a patient or caregiver. HIMSS and PCHAlliance want to emphasize that patients are often very experienced in treating their own conditions and diseases, and therefore should have a role in any care processes that directly impacts them. We view this as a responsibility for shared decision-making between a health care professional and their patient, and this Draft Guidance should seek to empower rather than overlook the vital role of the patient in our deliberations.

In some cases, patients are more likely equipped than a provider to assess the suitability of a particular CDS software for their specific use in their specific disease. For example, an endocrinologist that is treating a 30-year old patient who has been a Type 1 Diabetic since they were a juvenile. The patient knows a great deal about their condition and their specific circumstances. They likely know far more than a provider would about their particular unique circumstances, as they have lived with that disease their entire life. In this case, the patient is the expert in their own diabetes, and more than qualified to work with their clinician and the CDS software functionality to contribute meaningfully to their treatment plan.

We do not want to see creation through guidance of a completely different set of knowledge and person-specific informational tools for patients and health care professionals. We are concerned that the application of oversight focus included in the Draft Guidance will cause some manufacturers to avoid certain user populations simply because of the regulatory oversight focus. HIMSS and PCHA encourage FDA to convene disease-specific patient advocacy groups from across the care spectrum to discuss the best way to proceed with this Draft Guidance and ensure that the role of the patient is maximized in any of these processes. The advocacy groups should include voices of patients, caregivers, clinicians, manufacturers, and FDA at the table.

The Interface of Artificial Intelligence / Machine Learning (AI/ML) and CDS software

With all the new burdens facing clinicians, their ability to effectively manage an influx of more robust data streams and information will present its own set of challenges. HIMSS and PCHAlliance want the Draft Guidance to strike a balance and ensure that our regulatory infrastructure is appropriately supportive of more development and innovation in the AI/ML space, leading to even better and faster processes that help practitioners analyze more data while also delivering better outcomes for their patients.

For artificial intelligence (AI) and machine learning (ML) technology developers, the CDS software requirements in the Draft Guidance related to independent review and user reliance can be challenging to meet, depending upon the complexity and application of AI/ML in the CDS software. Related to “independently review”, FDA is asking that CDS software manufacturers describe the underlying data used to develop the algorithm(s) and include plain language descriptions of the logic or rationale used by an algorithm to render a recommendation. Sources supporting the recommendation should be identified and available to (e.g., within public domain), as

well as understandable by, the intended user. Because of these transparency questions, it will be taxing for some AI/ML-based CDS software to fall outside of the medical device definition or outside of enforcement discretion, regardless of the overall risk the CDS software may pose.

HIMSS and PCHAlliance want to ensure that developers are encouraged to continue to innovate in the AI/ML space and advance the field in support of CDS software. There could be reluctance from some developers to participate in further healthcare efforts if they are required to share information on their proprietary algorithms. We want to work with FDA and the stakeholder community to find a solution that allows healthcare professionals to meet the "independently review" and user reliance requirements and promotes more innovation and investment in the AI/ML healthcare space. We ask that FDA consider hosting a public forum to discuss the challenges inherent in some AI/ML CDS software relative to these requirements.

Overall, HIMSS and PCHAlliance are eager to work with FDA to foster a culture where health information and technology are optimally harnessed to transform health and healthcare by improving quality of care and patient safety.

We look forward to the opportunity to discuss these issues in more depth. Please feel free to contact Jeff Coughlin, HIMSS Senior Director of Federal & State Affairs at jcoughlin@himss.org; Eli Fleet, HIMSS Director of Federal Affairs at efleet@himss.org; or, Robert Havasy, Managing Director of PCHAlliance at ravasy@pchalliance.org, with questions or for more information.

Thank you for your consideration.

Sincerely,



Harold F. Wolf III, FHIMSS
President & CEO
HIMSS and PCHAlliance