Clinical Decision Support Coalition

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VIA EMAIL AND DOCKET SUBMISSION

September 5, 2017

Bakul Patel
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, Rm. 5458,
Silver Spring, MD 20993

Re: Docket No. FDA-2017-N-4301, Fostering Medical Innovation:
A Plan for Digital Health Devices; Software Precertification Pilot Program

Dear Mr. Patel,

The U.S. Food and Drug Administration ("FDA") has announced plans to evaluate a new approach toward software products, including a precertification program for the assessment of companies that perform high-quality software design and testing. This program is very important because FDA intends ultimately to replace the need for a premarket submission in some cases and allow for decreased submission content and/or faster review of marketing applications for software products in other cases.

The Federal Register notice announcing this program explains that "During the pilot program, FDA customers, including pilot participants, will have the opportunity to provide input on the development of the precertification program." In other materials, FDA explains that it will be working closely with the 3-9 pilot program participants to solicit ideas for program design, as well as hold a public meeting early next year to get broader input from other FDA stakeholders.

The CDS Coalition would like to offer some additional suggestions for how FDA can provide its stakeholders with "the opportunity to provide input on the development of the precertification program." By way of background, the CDS Coalition is a diverse group of stakeholders consisting of software providers, IT infrastructure manufacturers, healthcare providers, medical device and pharmaceutical manufacturers, trade groups and members of the clinical community. Focused on clinical decision support software, the Coalition's goal is to ensure a risk-based and clearly defined regulatory system for such software that appropriately balances the need for regulatory oversight with the need for innovation and access to new technology.

We are sure that FDA would agree that the initially 3, and then up to 9, members of the pilot program will be too small of a group to fully reflect the views and knowledge of the stakeholder community. Among other things, presumably they will only be developers of class II, FDA-regulated software, and

therefore will not include patients and healthcare professionals, or the provider community more generally. While the public meeting after the first of the year will be extremely helpful, we also anticipate that much of the work in thinking through the design of the precertification program will take place during the fall, as well as after the public meeting.

Therefore we recommend that FDA consider additional avenues for public involvement-- avenues that are designed for more ongoing and real time exchange with the public at large. We think this could be quite helpful to FDA as it sorts through issues like which key performance indicators are most useful, and which are already in common use.

Our suggestion is that FDA consider perhaps weekly blogging, with those blog posts distributed through social media such as LinkedIn and Twitter. The key, in our view, is that the mechanism FDA chooses for this larger public conversation is:

- Public, with few obstacles to public participation
- Ongoing, so that you can have more input along the way as you think through the myriad of choices you will be facing
- Interactive, giving the public an opportunity to brainstorm with you

Blogging supported by social media would seem to fit the bill.

In terms of content, while it could vary from week to week, there are three broad areas where we think dialogue would be particularly useful:

1. Ideas FDA is considering for structural elements of the precertification program;
2. Challenges FDA is finding as it works to develop this program, in particular where FDA doesn't yet have an identified solution; and
3. Areas where FDA would like to better understand the environment in which software is developed and the potential impact of its program, perhaps collected through the vehicle of a poll. Purely as an example, FDA could ask how many in the health information technology industry use a particular KPI.

We would recommend that this not be particularly formal. This is innovation and brainstorming in public policy. There is simply no reason for FDA to wait until it thinks it has all the answers to begin a dialogue with its stakeholders. This is an area where we can surely do the work better together than anyone of us could do it individually. And by doing it in such a public way, all stakeholders will have an equal opportunity to participate.

If you'd like to discuss this idea, we certainly would be glad to brainstorm with you on the mechanics of this process. Please just let us know how we can support the important work you are doing.

Very truly yours,

Bradley Merrill Thompson
General Counsel, CDS Coalition