May 24, 2018

Gail M. Rodriguez, PhD
Senior Policy Advisor
Food and Drug Administration (FDA)
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Rodriguez:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on the consultation document released by the International Medical Device Regulators Forum (IMDRF) Standards Working Group entitled “Optimizing Standards for Regulatory Use.” Given the depth, breadth and anticipated impact of the “Optimizing Standards for Regulatory Use” document, HL7 wishes to emphasize its strong interest in actively participating in conversations with both FDA and IMDRF related to the use of standards in medical device regulation and contribute our extensive experience and best practices to help guide this important initiative toward an effective solution that advances the collective good.

The consultation document notes “standards offer a means to streamline and harmonize regulatory processes around the world.” We could not agree more. As the global authority on interoperability in healthcare, HL7 is a critical leader and driver in the healthcare standards arena, in the U.S. and internationally. The products of our organization – including the widely adopted and rapidly evolving FHIR® standards - provide the underpinnings for connected, patient-centered health care on a global scale and an information highway for improving patient safety, advancing research into improved treatments, and achieving ambitious visionary programs such as precision medicine. HL7 is comprised of members from over 50 countries and is integrally involved in global standards policy, regulation and harmonization as well as standards development.

We appreciate the collective effort to create a guide serving as an educational resource for regulators, standards developers, and other interested stakeholders to ensure that consensus standards are useful for the regulatory oversight of medical devices. We applaud the document’s emphasis on regulatory engagement with standards development processes and the recognition of the criticality of standards in achieving global interoperability.

We wish to highlight that HL7 possesses notable expertise and current work in this space, as an ANSI-accredited, consensus-based standards organization with active initiatives on health care devices and involvement from international regulators. As you know, ANSI is the sole U.S. representative to ISO, and as a lead member of ANSI in health informatics, HL7 has worked successfully to move many of our standards into the ISO standards process. For example, many ISO standards used by industry and regulators — like Individual Case Safety Report (ICSR) and Identification of Medicinal Products (IDMP) — originated with HL7.

HL7 has more than 50 active work groups. Those listed below are most relevant to the scope of the consultation document:

- Biomedical Research and Regulation
- Clinical Quality Information
- Conformance
- Health Care Devices
- Patient Care
- Pharmacy

Health Level Seven and HL7 are registered trademarks of Health Level Seven International. Registered in the U.S. Trademark Office.
In addition to cooperative and coordinated work efforts, HL7 also has important leadership links with ISO on these topics. HL7’s Health Care Devices Work Group Co-Chair, Todd Cooper, is also the ISO/TC 215 US TAG Chair. The National Cancer Institute’s Bron Kisler also actively participates in the HL7 Work Groups relating to: Biomedical Research and Regulation, Clinical Genomics and the Clinical Interoperability Council. As the ISO/TC 215 convener for the Systems and Device Interoperability work group, he also serves as an important link between the two organizations.

Attached we have provided specific comments in the provided review template. One particularly important point HL7 re-emphasizes here is that relevant national and international SDOs beyond ISO and IEC should be acknowledged specifically and referenced in the consultation document, especially those like HL7 that are accredited or otherwise affiliated by national standards bodies like ANSI that are ISO affiliates. We recognize that page 5 of the consultation document observes that, “while we refer specifically to ISO and IEC in this important document, most consensus-based SDOs follow similar procedures and rules.” We believe that that document should go beyond this process-focused point. The work of national and international SDOs like HL7 is not always tracked nor part of the formal ISO process without specific coordination efforts and it will be essential that national regulators understand and are able to act on this point. We suggest therefore that, when ISO and IEC are mentioned, such as in Section 7.1 on page 16 entitled “International, regional and national level participation: joining the conversation” the phrase and relevant SDOs, such as HL7 International should be added.

Please do not hesitate to contact us to discuss the consultation document and our suggestions in more detail. Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Calvin Beebe
Board of Directors, Chair
Health Level Seven Internati