Dear Dr. DeSalvo:

HL7 appreciates the opportunity to provide feedback on the ONC’s Draft 2016 Interoperability Standards Advisory (Advisory). As the global authority on interoperability in healthcare, HL7 is a critical leader and driver in the standards arena. The products of our organization provide the underpinnings for connected, well functioning and learning health care. And the people of HL7, our members, represent an extremely diverse ecosystem of stakeholders who together provide a very comprehensive and actionable picture of how a standards-based health care system can and should work, as well as realistic, expert views about where standards maturity is today and the path to progress for tomorrow. Our comments on the Advisory reflect these points.

HL7 has a very productive and on-going dialogue with ONC and in our comments we propose ways to enhance this discussion for the good of the nation. Overall, HL7 believes that the Advisory is a good, progressive step forward, although some areas still need notable attention and work. Its restructuring allows for a better sense of the current state of adoption. The introduction of the six characteristics (Standards Process Maturity, Implementation Maturity, Adoption Level, Regulated, Cost, and Test Tool Availability) is helpful in understanding whether a standard is fit for regulatory endorsement, i.e., wide industry adoption.

HL7 emphasizes in its comments the importance of clarifying “the best standard for what”. While the Advisory’s new organization and section titles are a step in the right direction, it is still harder to understand specific uses. HL7 highlights that without such perspective, valuation of the Advisory remains elusive. Endorsing standards without such an understanding, results in the unintended consequence of investing in the wrong solutions and even hampering innovation. Also on this topic, we call for clarification on how use cases are being established that are in need of standards. The 2016 Advisory and its approach seem to be built around known standards rather than from critical use cases, gaps and input on user needs.
Some other key, high-level areas highlighted in our comments include the need for:

- **Testing** - Sufficient testing of proposed standards prior to inclusion in rule-making;
- **Functionality** - Creating a new category in the 2016 Standards Advisory focused on system/software functionality;
- **Privacy, Security and Data Provenance** - Key recommendations and needed changes/inclusions to ensure optimal protections and data transfer in this area are outlined.
- **Downstream Use** - Encouraging ONC to work with industry to make appropriate, e.g., LOINC, UCUM, and UDI codes available further upstream from originating devices for downstream use.

Our in-depth comments are embedded in the draft Advisory text in the attached file. HL7’s leadership, Policy Advisory Committee and Work Groups contributed notable time and effort to these comments. We would be happy to answer questions or provide further information to you.

Sincerely,

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

Stanley M. Huff, MD  
Board of Directors, Chair  
Health Level Seven International