PHILIPS

February 23, 2016

The Honorable
Karen B. DeSalvo
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services
Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Madam Secretary:

We at Royal Philips share the principle that to achieve an open, connected care for our communities, we all have the responsibility to take action. To further these goals, we commit to the following principles to advance interoperability among health information systems enabling free movement of data, which are foundational to the success of delivery system reform.

1. **Consumer access:** To help consumers easily and securely access their electronic health information, direct it to any desired location, learn how their information can be shared and used, and be assured that this information will be effectively and safely used to benefit their health and that of their community.

2. **No Blocking/Transparency**: To help providers share individuals' health information for care with other providers and their patients whenever permitted by law, and not block electronic health information (defined as knowingly and unreasonably interfering with information sharing).

3. **Standards**: Implement federally recognized, national interoperability standards, policies, guidance, and practices for electronic health information, and adopt best practices including those related to privacy and security.

Philips has long history of pushing for the creation of standards that support the vision laid out in the ONC's Interoperability Roadmap to enable a "learning health system" in which health information flows seamlessly and is available to the right people, at the right place, at the right time. For the past 20 years Philips has worked to develop these standards to create an environment where we can seamlessly and securely access and use health information from different sources, not just what has been filed away in the electronic health record, where we can rapidly gain clinical insights and deliver meaningful actionable clinical decision support. From our devices to our Informatics solutions to our HealthSuite Digital Platform everything we build is meant to interoperate within the health system. Our entire portfolio depends on the free flow of an individual's health information from all of the other vendors' information systems. While we have seen much success in the creation and refinement of interoperability standards it has become clear that the adoption and enforcement of these standards will only come through a consolidated industry and government push.

Our track record is clear that Philips has supported through the entire continuum of interoperability standards development, implementation, and best practice adoption a high level of participation and leadership in order to achieve the goals of a "learning health system". I would like to offer a number of activities and engagements by Philips that attest to this commitment.

As far back as 1996, a future major Philips acquisition, the Hewlett-Packard (HP) Medical Products Group, formed and led the "Andover Working Group" as an industry consortium of vendors and providers to focus on healthcare interoperability towards the goal of Plug-and Play interoperability. With over 30 vendors and providers, this was the first industry effort to profile the existing HL7 v2.x messaging standard for specific clinical use cases. The results of this effort included the formation of the HL7 Conformance Work Group and the definition of message profiles for HL7 v2.x standards, as well as the formation of the Integrating the Healthcare Enterprise (IHE) consortium to focus specifically on profiling existing healthcare interoperability standards including HL7 and DICOM for important clinical scenarios. HP and subsequently Philips have long since been active members of IHE HL7 and DICOM.

The HP Medical Products Group also formed and led the Clinical Context Object Workgroup (CCOW) designed to enable disparate applications to synchronize in real time, and at the user-interface level. This effort became the HL7 CCOW Work Group and the specifications became the HL7 CCOW standards. These specifications were later referenced in IHE profiles – for both patient synchronized applications and single sign-on capabilities.

In addition, Philips has a record of participation in and is currently acting as co-chair of the IEEE 11073 Health Informatics standards committee. The ISO/IEEE 11073-10101 Nomenclature standard is used by IHE PCD to identify device data, and the 11073-10201 Domain Information Model is influential in IHE and HL7 device data representation.

Furthermore, Philips has a long history of supporting and chairing the HL7 Health Care Devices (HCD) Working Group (WG). The H7 Health Care Devices Work Group continues to collaborate with the various FHIR development entities in HL7 to refine device-related FHIR resources and align them with IEEE Medical Device Communications Domain Information Model and Nomenclature as FHIR develops its next Draft Standard, working to ensure there is a clear model to express medical device semantics in FHIR. In addition we have representatives on the HL7 Structured Documents WG, the Clinical Decision Support WG, the Imaging Integration WG, and recently the Clinical Quality Information WG. We also co-chair the Clinical Genomics Work Group. Philips has specifically been involved in the development of the Consolidated CDA Implementation Guides as well as the HL7 Context Aware Knowledge Retrieval (Infobutton) specifications.

Philips has taken an extremely active role in Integrating the Healthcare Enterprise (IHE) as we recognize the need to go beyond standards that are so permissively defined that any two valid implementations are not typically interoperable. We have been active in numerous IHE International domains including Patient Care Devices (technical committee co-chair), Cardiology (former co-chair), Radiology (former co-chair), Radiation Oncology, IT Infrastructure (former co-chair), and Patient Care Coordination. Philips' leadership on IHE is not limited to the United States. Philips is also the current president of the IHE Brazil national deployment organization, and is actively engaged in IHE Europe and IHE China activities.

From a medical specialty perspective, Philips has played an active role in the IHE Cardiology domain, including past chair of the technical committee. A specific focus for us has been to ensure the application of the already existing HL7 CDA standard as part of authoring the first IHE profile based on the HL7 Consolidated CDA Implementation Guide. Subsequently Philips become the lead author responsible for the Cath Report Content profile and drove this standards development activity through to completion and was available for testing at the 2013 NA Connectathon. In another activity, Philips co-authored the EP Report Content profile and continues to work on developing the Cath Report Content profile to support new types of cardiac procedures – including TAVR and EP ablation. Moreover, Philips has participated as members of the Patient Care Coordination (PCC) technical and planning committees and pushed for focus on PCC to align the current CDA content modules with HL7 consolidated CDA. Also of note Philips has been a strong advocate and participant in the IHE Connectathons – both in the US and in Europe as venues for ensuring that these profiles truly interoperate, and will deliver as promised into a learning health system vision. Philips has been participating every year in the annual IHE Connectathons in the US and also have participated in the IHE European Connectathons. Philips recently successfully tested 7 solutions at the 2016 IHE North American Connectathon and had registered 4 additional solutions which were dropped due to a lack of partners to test with. As well, Philips has frequently been an early adopter of IHE profiles – and has been the first tester of several profiles including the Cardiac Imaging Report Content and Resting ECG Workflow profiles (cardiology), as well as the Device Enterprise Communication, Infusion Pump Event Communication, and Alert Communication Management profiles (patient care devices). Philips has also been a leader in participation at the HIMSS Interoperability Showcases – featuring solutions focused on medical devices, departmental systems, and integration across the healthcare enterprise.

For imaging related interoperability, Philips has been a long time leader in the DICOM standardization efforts, including chair of the DICOM standards committee and base standard. Currently Philips chairs several of the Work Groups, including ultrasound, nuclear medicine, and display standards. Philips has also been active in the development of the integration of the imaging domain with HIT, including specifically the mapping of DICOM SR to HL7 CDA for reporting as well as for the mapping from the DICOM object model to the HL7 FHIR resources. Philips was also participating in the development of DICOMweb for access to DICOM objects through web services and RESTful interfaces.

Philips has demonstrated its commitment to these interoperability standards by adopting many of these healthcare interoperability standards. The Philips solutions portfolio includes support for the IHE XDS infrastructure profiles, the departmental workflow profiles, and for making the clinical information generated from the Philips devices and solutions available to the healthcare providers using both messaging and document formats. Philips currently has 125 IHE Integration Statements published (http://product-registry.ihe.net/PR/pr/search.seam?date=ANY|1455447604798|1455447604798&institution=40).

A number of our informatics product lines make use of Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) from the International Health Terminology Standards Organization. It is through the use of common nomenclature systems that we allow for the sematic exchange of data. In addition there is Logical Observation Identifiers and Codes (LOINC) originally produced by Regenstreif Institute as a set of identifiers for medical laboratory results, but has been expanded into other domains. Philips has supported efforts to cross-map SNOMED, LOINC, and IEEE 11073 to address some gaps in the device observation nomenclature.

Philips also has representation on the International Standards Organization (ISO) Technical Committee 215 Health Informatics which is the locus for work in interoperability standards for international adoption as well standards development and editing.

Philips is pleased and proud to be and to have been a long-time, active participant and a leader in numerous efforts to promote standards and interoperability to help deliver on the promise of data available to patients and providers with the goal of lower costs and improving the quality of care in the United States.

Sincerely,

[signed]

Brent Shafer
Chief Executive Officer
Royal Philips North America