



February 6, 2015

**RE: Comments from UL in Response to Office of the National Coordinator
regarding *Federal Health IT Strategic Plan 2015-2020***

Dear Dr. DeSalvo:

Underwriters Laboratories (UL) appreciates the opportunity to comment on the Office of the National Coordinator (ONC)'s *Federal Health IT Strategic Plan 2015-2020*. UL has been involved in the interoperability of electrical distribution systems and from our founding. Just as appliances can safely be plugged in to outlets without having to think about safety implications, UL would like to see that same level of confidence in safety brought to digital health.

As health care delivery is becoming increasingly digital, health care providers and health care systems are facing new and emerging challenges, resulting in potentially a negative impact to patient safety. It is critical that patients receive innovative products in a timely manner that are also safe, effective and interoperable. UL believes that the best way to protect patient safety with new technology is to make sure that all aspects of telehealth are structured and monitored, even if the individual impact of one part of the technology seems to be of low risk. Once all parts of a Health IT (HIT) system are integrated, there are new challenges that can arise from connectivity or interoperability that can endanger patients. UL believes that ONC should continue to monitor these technologies through post market surveillance, adverse event reporting, and by looking at monitoring full health care systems.

Introduction

UL is a premier global independent safety science company that has championed progress and safety for 120 years. UL's more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people. UL uses research, standards, and conformity assessment to continually advance and meet ever-evolving safety needs. We partner with businesses, manufacturers, trade associations, and international regulatory authorities to bring solutions to increasingly complex global supply chains.

UL Life & Health Sciences (LHS) is focused on the healthcare sector, working on the safety of medical devices, software and the larger health environment. UL LHS is an internationally accredited and recognized third party authorized body (e.g.: PAL, Japan, CMDCAS, Canada) and Notified Body in Europe for CE marking certification. Leading global medical device manufacturers use UL to test and certify their products. As this division has evolved, UL LHS has recognized the increasingly integrated and digitized healthcare sector has new needs for standards and safety.

Additionally, UL is a Standard Development Organization (SDO) accredited by ANSI (American National Standards Institute) with a long history in standards development. As such, UL works to contribute to telehealth developments through the creation of standards focused on the safety aspects of medical devices interoperability. UL has partnered with the Association for the Advancement of Medical Instrumentation (AAMI) to develop standards in the area that are focused at achieving the goal of safety in the telehealth space.

Overview

While much has been accomplished to initiate interoperability and safety in healthcare, the infrastructure is in its infancy of deployment and still has to mature to achieve the same level of confidence in safety that is enjoyed with established technologies such as electricity, transportation, and telecommunications. UL believes that as conversations progress around telehealth and digital medicine, it is important to keep patient safety a paramount priority through the certification of systems and components within HIT. UL also feels that it is important to consider the timelines



proposed in this plan to ensure they are quick enough to encourage innovation and usage of health IT.

HIT Safety Should Be Focused on Full Healthcare Ecosystems

Throughout the Strategic Plan, it is UL's interpretation that ONC is focused on individual digital health care products, such as Electronic Health Records (EHR) systems. UL recommends that ONC look to focus on the full healthcare ecosystem: medical devices, infrastructure (e.g. medical device data systems), and EHRs as well as their connections, as opposed to focusing on singular digital health care products. This approach will help ensure that the unregulated domains of the ecosystem cannot compromise the safety of the regulated domains with which they are interconnected. Additionally, UL is supportive of Objective 1B and is pleased to see the focus on safety and increasing this within the HIT space.

When looking at how technology is introduced into the HIT environment, particularly in situations where there are integrated devices from multiple vendors, the intended use for an individual device is often not as relevant for risk as the system integration and purpose (i.e. intended use) of the larger interoperable system. For example, consider a situation where there are two individual standalone devices from separate manufacturers "A" and "B" that include indications for use in an integrated system. The ultimate clinical benefit of combining those two devices would be under the design of the system integrator. In this situation, the system integrator would determine the intended use and constraints associated with the emergent system that is neither a direct function of "A" nor "B." The intended use of a medical device, when planned for use in a broader, connected environment such as a HIT system, has to take into account certain connectivity and functionality. UL believes that risk needs to be assessed not only based on intended use, but also on the impact a device or system can have to patient safety in the context of the entire HIT ecosystem in which it is connected.

Additionally, there may also be risk from what certain regulators classify as "low risk systems" in terms of the movement of data. Data originating from one source, such as an HER, that would then enter another regulated device, like a medical device, could cause harm or damage to the second device if it was corrupted or malicious data. Such movement of malicious data can be part of a causal chain for harm to the patient. UL believes that all parts of this chain (including the nature of the movement of data) need to be considered when classifying risk.

One way to mitigate many of these challenges is through improving safety labeling requirements. The HIT industry can look to the factory automation industry for an example. In factories, there are safety systems that are put in place. These often involve things like punch presses and light curtains that shut down a machine if someone gets too close. The labeling on these two different products helps to capture key safety attributes and communicates those to the system integrator. This is very important for making sure the devices work together and keep the integrator informed. Applying this idea to the healthcare world, when there are products from disparate vendors and a separate systems integrator, having that minimum safety information available on labeling related to intended use and indications for use could be useful for safe systems integration.

Utilize Private Sector Standards Activities and Third Party Testing To Supplement Government Regulation in the Area of Software Certification

UL is constantly looking for ways to improve the regulatory environment for manufacturers, doctors, and patients. UL understands that there is currently a very intricate process of regulation around entering the market in many aspects of digital health, and feels that third party testing is a way to help support this type of testing. Currently, there are often long backlogs for drugs, medical devices, and systems to enter the health market due to the limited resources of the government. By using third party testing organizations, innovations can be tested to the same high standards, but enter the market more quickly by using testing organizations with a smaller backlog. This balance of high standards and regulation with testing organizations that have the capacity and capability to do the testing could help achieve the goals of quickly getting quality products in to the health care market.



UL believes that regulators should consider recommending the use of independent Third Party Certification via Nationally Recognized Testing Laboratories (NRTL) to enhance existing regulatory processes. Currently, regulators in the telehealth space are often overburdened with the scope of requirements placed on telehealth systems, and particularly EHR systems. UL believes that this burden can be eased and the process made more efficient through the use of Third Parties to complete verification and certification of telehealth products and systems. The Occupational Safety & Health Administration (OSHA) requires that specified equipment and materials (products) be tested and certified for safety by an OSHA-recognized organization, called a Nationally Recognized Testing Laboratory. OSHA's NRTL program fulfills this responsibility by recognizing the capabilities of private sector testing organizations to test and certify such products for manufacturers, according to a specifically pre-defined scope. The NRTL Program, in operation since 1988, is an effective public and private partnership. Rather than performing product testing and certification itself, OSHA relies on private sector organizations to do so. Using existing private sector systems to perform the work eliminates the need for creating and maintaining government facilities. Additionally, it drives down the costs for manufacturers as NRTLs compete for business. An organization must have the necessary capabilities both as a testing laboratory and as a product certification body, for the specific products covered within its scope of recognition, to be designated as a NRTL. UL believes this policy and precedent should be applied to HIT systems and products.

UL believes that given the diverse landscape of issues surrounding HIT and regulation that third party testing and industry driven consensus standards can help to provide guard rails to the industry in terms of safety. UL believes this type of testing can provide confidence in the quality of products entering the market and provide a level of credibility for patients and doctors to reference. At present, certain regulatory agencies rely on third party certification that's market driven to support the regulatory processes. We recommend that regulators consider introducing those processes into the current HIT regulatory environment.

An FDA-operated certification and accreditation process which enhances the accredited party inspection system will improve medical device oversight, provide FDA with needed flexibility to concentrate its resources on more critical tasks, and provide a reasonable assurance of safety and effectiveness of medical devices for patients. The use of accredited party organizations to conduct things like medical device facility inspections is a means of improving and helping to safeguard the public by preserving device safety and accelerating product time to market so that patients can have access to the medical devices they require without sacrificing safety or quality. FDA can leverage trusted and certified accredited party resources to enhance medical device safety, advance innovation, and improve manufacturing quality by providing support and additional resources to FDA. This will allow FDA to focus on and administer the more challenging elements of its regulatory responsibilities while creating a true public-private partnership. This cooperative arrangement with qualified accredited parties is in widespread use in many regulatory agencies outside the U.S. and allows them effectively and efficiently to fulfill their obligations for the protection of health, safety and the environment.

Adopt Standards in Digital Health to Increase Interoperability and Protect Data Integrity

The issue of data is an important topic. At present, there is a growing need for data security and safe interoperability in the digital health space. UL is pleased to see Objective 2A in the plan and encourages ONC to continue to look at new ways to make sure that the sharing of data is safe and secure. UL also commends ONC on including Objective 2B in the plan. UL feels that in this field, technical standards are key to achieving a truly interoperable HIT system.

There is a significant focus in the field of cyberphysical systems on reducing the threat surface (i.e. opportunities to attack these systems) and addressing security and safety aspects of system design as forethought rather than an afterthought. As such, UL believes that data integrity and security must be a primary concern in the digital health field. UL is working with AAMI to collaboratively create and publish the AAMI/UL 2800 series of standards for safe interoperability of medical devices (including Mobile Medical Application software), with the intent of becoming internationally adopted. More



information on this standard can be found below. The goal here is to make sure that data is safe, preserved, and exchanged correctly across interoperable devices to protect patient safety. UL believes standards should be included and recognized within any HIT legislation.

The use of consensus standards and the principles around their introduction was set out in the National Technology Transfer and Advancement Act (NTTAA), enacted more than 15 years ago. This states that federal agencies should utilize standards developed by private sector voluntary consensus standards bodies in lieu of developing unique proprietary, non-consensus, standards. The NTTAA goes on to direct Federal agencies to consult with standards development organizations (SDOs), and participate in standards development. Voluntary consensus standards reflect the interest of diverse stakeholders. They help to support and guide technical specifications and resulting conformity assessment. UL believes that standards have a dual function to meet evolving regulator needs: (1) They provide the reference for specifications and processes, allowing the industry to have a common set of standards upon which to develop products and support interoperability; and (2) They can help mitigate risk, while supporting safety and quality. Standards, however, should not impair or become obstacles to developing new and better technologies. UL supports regulator engagement with private sector SDOs to meet agency needs.

Health Information Technology Standards

UL is participating in the development of a safe and interoperable integrated clinical environment by working to demonstrate key aspects of safety assurance. We aim to facilitate interoperability that can be trusted from the perspectives of manufacturers, regulators, solution providers, healthcare providers, and patients. UL is engaged with multiple stakeholders from industry sectors relevant to health IT and mHealth. Stakeholders include: the healthcare and IT industry, medical device manufacturers, software and mobile application developers, healthcare provider organizations, standard development organizations, academia, and nonprofit stakeholders. UL has conducted significant research and been involved in case study work to support the pending development of a suite of consensus-based standards for interoperable medical device interface safety (AAMI/UL2800). This standard defines the safety and related specifications of interface(s) required when it is declared an interoperable medical device, thereby enabling manufacturers to design safer interoperable products and aid healthcare facilities in implementation. UL has facilitated the development of medical device interoperability safety based on sound research and concepts:

- Engaged in developing standards for “interoperable medical device interface safety,” which establish a link between the Medical Device domain and the HIT domain.
- The outcomes of these activities are intended to encompass safety concepts from a number of international medical device safety standards.
- These safety concepts are aligned with the essential requirements of multiple directives across several product safety engineering disciplines.

We are aligning with existing internationally accepted standards. The type of standards reflect the essential requirements of international directives so that essentially when these standards, like 2800, become adopted in regulatory processes they are effectively aligning with international philosophies.

Increase the Usage of Post-Market Surveillance

UL shares industry and government’s belief that providing new technologies to patients and doctors as quickly as possible is an important goal within healthcare. UL feels that this needs to be done with safety as a primary concern, even if pre-market regulations or testing requirements are modified. UL supports current activities that make post-market surveillance a critical aspect of ensuring patient safety as new technologies (e.g. EHRs, etc.) that are, as yet, largely unproven in the field are deployed. UL feels that without mechanisms in place for correlating adverse events to specific technology deployments, it will become virtually impossible to determine whether (a) the technologies are implicated as “root causes” of adverse events, and (b) whether current risk controls are sufficient to meet societally tolerable risk targets from a risk/benefit perspective relative to the use of these new



technologies. If the root cause of the potential hazard is related to a component that doesn't fall into the domain of regulated devices, then the traceability to that component becomes a challenge. UL supports the actions regulators are taking to increase the use and effectiveness of post-market surveillance so that new health information technologies can enter the market quickly, but still be tracked once in use.

Adopt Timelines for Regulations that Encourage Innovation

UL shares the desire of ONC to have clear timelines associated with the goals and objectives within the 2015-2020 plan, but would like to encourage ONC to consider quicker timelines for adoption and outcomes. In speaking with industry groups and manufacturers that UL advises, these timelines may be too long for industry to continue to invest in the necessary technology to support the objectives. UL believes that by speeding up the timelines for adoption of the objectives, that more innovation will come to the market. This would help support ONC's vision of having health information accessible when and where needed.

UL looks forward to the opportunity to work on these important issues. Please contact Abel Torres (abel.torres@ul.com) if you have any further questions.