



June 5, 2015

The Honorable Johnny Isakson
U.S. Senate
Washington, DC 20515

The Honorable Ron Wyden
U.S. Senate
Washington, DC 20515

Dear Senate Finance Committee, Chronic Care Working Group:

UL appreciates your work on the Chronic Care Working Group and for the attention you are bringing to the important issues surrounding our nation's medical service delivery and development. As advances are made in telehealth and remote patient monitoring, we believe that finding ways to improve patient safety while also encouraging innovation should be a paramount concern. UL feels that telehealth and remote monitoring technologies are key to delivering quality care for chronic conditions and believe that these services must be deployed safely. UL believes this can be effectively done through the use of voluntary private sector systems certification programs for software and integrated clinical environments, and urges the committee to consider this approach.

Issue 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 established with certain technologies associated with electricity, transportation, and telecommunications. 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 and Health IT products.

At present, regulation and certification of medical devices is done on a component by component basis. Increasingly, there is a need for a certification process that allows for full systems to be certified as interoperable or for components to be certified as safe and effective when integrated into these systems. As more devices, software, and other technologies are connecting together and as integrated clinical environments are being developed, there needs to be a way to ensure that different elements can "plug and play" with other elements, regardless of vendor. Accredited third parties can help to certify that integrated clinical environments and full systems are interoperable and certify safety beyond individual intended use. This would help to simplify the approval process for the regulators, specifiers, and for manufacturers as the third party will coordinate the certification of all system elements.

While there are clear processes to approve individual medical devices, there is an increasing need to bring a similar level of safety to systems comprised of multiple connected devices. Within an integrated clinical environment, for example, many unregulated components may interact with regulated components within a system, but the potential impacts and unintended consequences of those interactions are not well understood from a safety perspective nor are they tracked under post-market surveillance processes if they are an unregulated component. The goal of UL's proposals is to ensure that all critical components of a system are certified for compliance with at least a minimal set of safety and security requirements.



Proposal

UL believes that developing an optional and voluntary certification program for health systems that utilizes accredited third parties to ensure integration of all components of a health system would add value to all players within the health care space and increase patient safety. UL proposes the following three concepts:

1. For systems comprised of components from disparate vendors, a regulatory mechanism to partner with private sector labs (paralleling OSHA's Nationally Recognized Test Labs (NRTL) program or the ONC-ACB/ATL programs) should be established with specific focus on safety aspects of medical systems (i.e. electrical safety, safe interoperability, and cybersecurity)
2. When the combination of components results in a system with an intended use that is unique, relative to the intended use of any individual component, the intended use of the combination should be verified relative to its baseline of safety, security, and effectiveness.
3. Third Party verification and certification of the intended use and safety of the combination should be recognized by the regulators, who would retain oversight and quality control of the Third Party verification and certification process.

Benefits

The use of accredited third-party organizations to conduct optional certification of systems and integrated clinical environments is a means of improving and helping to safeguard the public by preserving device safety and accelerating time to market. When traditional medical devices are connected into integrated care settings, this type of program would help to improve safety and security by verifying that anything that connects to such a network meets minimum industry consensus safety and security requirements. This is especially important as many unregulated devices are now connecting to traditionally regulated medical devices, which could pose safety and security concerns.

Additionally, by using a third party program, manufactures can obtain the benefit of coordination across multiple vendors so they are not individually looking up the standards each component meets (see appendix for more information on standards). A third party can quickly and efficiently both certify that components meet necessary standards and also certify that systems are in-turn comprised of components that satisfy the minimum safety and security requirements. This allows healthcare delivery organizations to quickly implement integrated solutions so that patients have access to the clinical services and devices they require without sacrificing safety or quality. This also allows regulatory agencies to focus on and administer the more challenging elements of its regulatory responsibilities to create a true public-private partnership. Additionally, the voluntary nature of such a program would fall in line with many of the software certification guidances and policies that have been put forward.

Conclusion

UL commends the Finance Committee for their work on chronic care and considering telemedicine as a part of this. Moving forward, telehealth systems will continue to be an important aspect of how health care is delivered and UL believes that patient safety must be a paramount concern and is well protected through the use of third party certification for integrated clinical environments. UL looks forward to the opportunity to work with the Finance Committee on these issues.

CONTACT: Rachel Urban
Global Government Affairs Specialist, Life and
Health Sciences
UL LLC
Rachel.Urban@ul.com

Abel Torres
Global Government Affairs Manager, Life and
Health Sciences
ULL LLC
Abel.Torres@ul.com



Appendix: Application of Standards

Standards come in many forms, from those that may be set by individual companies, governing their own internal processes, to those that may be set for global adoption through balanced stakeholder consensus processes. The standards alluded to in the proposals above are of the latter type. UL has a long history of following the American National Standards Institute (ANSI) consensus process, where we bring together key stakeholders from across industry, including producers, consumers, regulators, etc., to develop standards that meet the needs and expectations of these varied groups. Such standards often then become the de facto norm for topics such as safety and security in the given geography where they have been adopted. Many of UL's standards, over the years, have supported legislation and codes like the National Electrical Code in the US, as well as legislation in other geographies, such as European Norms for alternative energy systems' safety.

The proposals above can add additional safety and guard rails to the industry, which benefits both traditional manufactures and health IT or software producers alike. For example, internationally, there are many standards that are used for the quality testing of medical devices. Some key standards include the following: The International Organization for Standardization, ISO, developed a standard for medical device quality systems (ISO 13458), that is used for device and system approval around the world. The IEC 62304 standard provides for managing medical device software development lifecycle processes, with a focus on safety. ISO 14971 and IEC 80001 have begun to pave the way for managing risk related to medical devices, but there are still some gaps with regard to interoperability-related risks, which is why the AAMI/UL 2800 standards are also currently under development. Tracking approvals and certifications to these standard for different components of a system can be a time consuming process. By developing a public private partnership that utilizes third parties, the agencies can help ensure compliance to these standards without repetitive approval work.