January 28, 2019

Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Donald Rucker, MD
National Coordinator for Health Information Technology
The Office of the National Coordinator for Health Information Technology
330 C Street SW, Floor 7
Washington, DC 20201

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: The Office of the National Coordinator for Health Information Technology Draft "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs"

Dear Secretary Azar, National Coordinator Rucker, and Administrator Verma:

UL appreciates the opportunity to provide comments with respect to the Office of the National Coordinator for Health Information Technology's (ONC) November 2018 ***"Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs"***.

UL is a global independent safety science company that has championed safety and innovation for more than 120 years. Guided by our mission, UL's 14,000 professionals 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 provide solutions and address the risks of increasingly complex technology and global supply chains.

As you may know, UL is an ONC-Authorized Testing Laboratory and ONC-Authorized Certification Body. In addition to our work in support of ONC, UL promotes the safety and usability of medical devices and electronic health records (EHR) through our industry-leading human factors research and design team, which supports public and private sector partners, including AAMI and NIST, to advance Health IT standards and associated usability test methods.

UL supports ONC's conclusion that EHRs should be better leveraged to improve patient care and safety. Critically, health IT usability via the incorporation of user-centered design principles and risk mitigations would not only ease workflow challenges and other issues related to clinician and health care professional burn out, but also ensure that health IT meaningfully improves patient safety.

UL LLC
1850 M St. N.W., Suite 1000, Washington, DC 20036-5833 USA
T: 202.296.1435 / F: 202.872.1576 / W: UL.com

The following comments focus on the **Clinical Documentation** strategy to *"leverage health IT to standardize data and processes around ordering services and related prior authorization processes"* and the **Health IT Usability and the User Experience** strategies to *"promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction"* and *"promote harmonization surrounding clinical content contained in health IT to reduce burden"* and the **Public Health Reporting** strategy to "*Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow".*

ONC's existing certification criteria for usability tests could be improved to better address the strategies and recommendations outlined in this report. Currently, EHR certification requires that developers conduct usability tests during design and development of the EHR. However, in order to promote user interface optimization, for example, usability tests could also be required in the implementation phase of the EHR for the following reasons:

- Many EHRs are customized during the implementation phase by the EHR vendor and provider, and therefore no longer reflect the same usability as they did during the development and design phases;
- Development and design phase testing might not take into account the full range of types of clinician using the EHR nor the type of training she or he has received to use it; and
- Development and design phase testing might not take into account the real-world situations in which a clinician operates.

Extending usability testing to account for the full EHR lifecycle would support ONC's Clinical Documentation and Usability recommendations in this report, including improving processes for medication and other service ordering, prior authorization, and documentation. Extending usability testing to the implementation phase of the EHR would also support the Public Health Reporting recommendation to improve interoperability between EHRs and PDMPs. Finally, ONC's recommendation to test interface design standards specific to health care delivery cannot be achieved without testing in the implementation phase.

Improving usability test case scenarios are critical to achieving the improvements described above. For example, test cases should focus on both clinician interactions with the EHR that pose a high risk to patient safety as well as routine events that may be low risk but offer significant room for error. For more details on ways that test cases can be improved, see the report *"Ways to Improve Electronic Health Record Safety"* authored by The Pew Charitable Trusts, the American Medical Association, and Medstar Health.[1]

UL recognizes that the adoption of certification criteria to more fully address EHR lifecycles, provider roles, and implementation currently exceed what is required under federal regulation. ONC should work with Congress to address these important issues or seek to leverage private sector conformity assessment to drive these efforts forward.

While the statutory requirements differ, it is worth noting that the U.S. Food and Drug Administration (FDA) has robust testing requirements in place for medical device manufacturers to demonstrate safety and usability throughout the product life cycle.[2] This type of rigorous usability testing for safety and effectiveness could act as a model for enhanced testing of electronic health records to ensure patient safety.

Thank you for your consideration of our comments and we welcome the opportunity to discuss these important issues in further detail. Please contact Abel Torres (Abel.Torres@ul.com) or Karen Grunstra (karen.grunstra@ul.com), UL Global Government Affairs, with any additional questions or concerns.

Sincerely,

Kevin Harper
Global Strategy & Innovation Manager
UL Life & Health Sciences
UL, LLC

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[1] *"Ways to Improve Electronic Health Record Safety".* The Pew Charitable Trusts, the American Medical Association, and Medstar Health. August 2018. Last accessed January 2019. https://www.pewtrusts.org/en/research-and-analysis/reports/2018/08/28/ways-to-improve-electronic-health-record-safety

[2] *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*. February 3, 2016. Last accessed January 2019. https://www.fda.gov/downloads/medicaldevices/.../ucm259760.pdf