Sent via online submission

Dr. Micky Tripathi, National Coordinator
Health and Human Services
The Office of the National Coordinator for Health Information Technology

Re: Office of the National Coordinator for Health IT Federal IT Strategic Plan

Dear Dr. Tripathi:

      My name is Kristen Engelen, PharmD, and am writing on behalf of RxLive, Inc ("RxLive") to submit comments on the Office of the National Coordinator for Health IT's ("ONC") Federal Health IT Strategic Plan (the "Strategic Plan"). I am both the Chief Pharmacy Officer at RxLive and serve on the Trusted Exchange Framework and Common Agreement's advisory committee. I lead a team of pharmacists and care coordinators who help in closing gaps in care via effective management of an empaneled patient population of more than 100,000 patients' medications. We use RxLive's proprietary technology to identify opportunities to reduce contraindications, allergic reactions to medication, and other adverse clinical events. To be fully effective, this technology must rely on a data fluid ecosystem and obtaining data from sources across the healthcare ecosystem. RxLive vigorously supports interoperability and the ONC's strategic objectives, which if implemented in regulation and throughout the health IT marketplace, would have a positive impact on patient care, outcomes and the quality of care provided.

      RxLive specializes in helping patients get their medications under control. As a practicing pharmacist with over 15 years of experience, this is impracticable without the right data. Patients cannot be relied on to remember, or even know, all of their allergies and medical history. Their records are also fragmented. As a consequence, patients often receive the wrong medication or wrong dosage, leading to preventable acute events like seizures and heart attacks. According to the Centers for Disease Control ("CDC"), adverse drug events is a national public health problem that causes 1.3 million emergency department visits per year across 350,000 individual patients.[1] However, new technologies and integration across the healthcare delivery system is playing a role in reducing these numbers. For example, last year, RxLive helped its customers get over 40,000 patients' medications managed, resulting in 500 avoided hospitalizations, $5M in savings, all while driving an average of 6%-8% improvement in medication adherence and driving $1/day savings per engaged patient in decreased pharmacy spend. However, like most clinicians attempting improve patient outcomes and bring down healthcare costs through innovation, we face significant impediments with respect to data access and interoperability.

    The Strategic Plan's goals to 1) Promote Health and Wellness, 2) Enhance the Delivery and Experience of Care, 3) Accelerate Research and Innovation, and 4) Connect the Health System with Health Data are all laudable and RxLive welcomes further focus on these objectives. Specifically, focusing on expanding access to new modalities like smartphones, expanding data classes to capture clinical and social determinants of health, supporting record linking solutions, and expanding access of health data to all populations will drive real clinical results. At RxLive, we see how access to critical clinical and administrative data can lead to better

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[1] https://www.cdc.gov/medicationsafety/adult_adversedrugevents.html

managed medication regimes, and thus, better outcomes for patients along with fewer hospitalizations and costs to the broader health system.

RxLive has found that challenges in interoperability and data access are frequently due to the business decisions of the data sources and not necessarily the lack of APIs or standards for said exchange. RxLive welcomes ONC's continued efforts to curtail such behavior through 1) advancing TEFCA to create a "universal governance, policy, and technical floor for nationwide interoperability" and 2) supporting efforts to combine clinical and administrative data streams, and 3) encouraging pro-competitive business practices for the appropriate sharing of electronic health information.

In furtherance of the above, RxLive encourages ONC to exercise its regulatory authority in conjunction with the Centers for Medicare and Medicaid Services ("CMS") to curtail one of the most pernicious restrictions that providers face today: unlawful use case limitations on EHI. Many healthcare providers, pharmacy benefit managers, and other major sources of health information continue to prohibit the use of EHI for specific purposes. Often, these clauses are facially explicitly anti-competitive (e.g. prohibiting competition with the data sources themselves) and appear to violate the 21st Century Cures Act's prohibition against information blocking. Use of EHI may also be restricted based on whether a provider wants to perform analytics to identify care gaps, support the administrative operations of their organization, apply artificial intelligence to identify clinical trends in a patient population, or even use such EHI in a different care setting (e.g. inpatient vs. outpatient). We encourage ONC to continue to collaborate with CMS to ensure healthcare providers and other data sources permit the use of EHI for any lawful purpose, so long as such use complies with HIPAA and any other applicable privacy laws.

We thank the ONC for the progress towards interoperability it has made for providers and patients alike. For the reasons stated above, we believe that these efforts would substantially improve patient care and data access. Specifically, it would enable pharmacists, physicians, and technology to collaborate more effectively in reducing the number of lives lost in the United States each year to preventable adverse drug events.

Sincerely,

Kristen Engelen, PharmD