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Comments from Wolters Kluwer on the
Draft 2020-2025 Federal Health IT Strategic Plan

Below are comments from Wolters Kluwer on the draft of the 2020-2025 Federal Health IT Strategic Plan recently released by the Office of the National Coordinator for Health Information Technology (ONC). We appreciate the opportunity to comment.

As way of background, Wolters Kluwer is a leading global provider of information, business intelligence and point-of-care solutions for the healthcare industry. Key solutions include UpToDate®, Medi-Span®, Lexicomp®, Facts & Comparisons®, Pharmacy OneSource®, Health Language®, Emmi® and POC Advisor®. Wolters Kluwer had annual revenue in 2019 of €4.6 billion.

We generally support the draft Federal Health IT Strategic Plan (“the Plan”) as outlined by the ONC. The Plan appropriately focuses on achieving a fully connected, interoperable digital health system that enables patients and their caregivers to access and use electronic health information. We were pleased to see the Plan give prominence to goals, objectives and strategies that seek to empower and engage patients in their own care.

The Plan emphasizes the need for continued innovation in health IT through such applications as advanced clinical decision support and artificial intelligence. The Plan also envisions greater use and application of health data to clinical decision-making and meeting patient’s unmet needs. Finally, recognition is also made that to achieve the Plan’s vision of using health information to improve quality and lower costs, the federal government must work in partnership with the private sector and be judicious in issuing new mandates and requirements.

Our comments and observations on specific aspects, goals and objectives of the Plan are below.

Added Challenge – Care Variability

The Plan identifies a number of challenges in health care that must be considered when developing and implementing strategies to advance the use of health IT, including increased health care spending, poor health outcomes, access to care and access to technology. We recommend adding the challenge posed by care variability, which has become a major problem in the United States and around the world.

Research has shown that the same condition may be treated differently depending on a patient’s zip code, resulting in poor clinical outcomes and skyrocketing expenses.¹ Another landmark study looked at 30 different conditions treated in the U.S. and concluded that only 55% of patients received an evidence-based recommended course of treatment.² Besides poor quality

¹ Dartmouth Atlas Project <http://www.dartmouthatlast.org/> See also NHS Atlas Series <http://www.england.nhs.uk/rightcare/products/atlas>

² The Quality of Health Care Delivered to Adults in the United States. McGlynn, EA, et al. N Engl J Med 2003; 348:2635

outcomes, unwanted variation in care is also expensive, with one source estimating that 38% of total U.S. health care spending is on clinically ineffective care.³

Health IT is uniquely positioned to help alleviate the poor outcomes and high costs that result from care variability because it helps facilitate harmonized decision-making where diagnosis and treatment decisions are evidence-based (via use of clinical decision support software), care teams are aligned (via greater interoperability and exchange of health information) and patients are more active participants in their care (via shared decision-making, interactive messaging and tailored treatment plans). As such, we think the challenge of care variation should be added to the final version of the Plan.

Opportunities in a Digital Health System – Patient Empowerment

We were pleased to see the prominence the Plan gives to patient empowerment in the “Opportunities in a Digital Health System” section, and we agree that federal policy over the next 5 years should help encourage patients to take a more active role in their care. The section outlines a number of ways that health IT can empower patients, including giving them the ability to review quality and price information. We note the Plan cites the low levels of patient health literacy in the preceding section on “Challenges,” but makes no reference to the opportunity for health IT to improve patient health literacy. We recommend adding this to the “Opportunities” section in the final version of the Plan.

Opportunities in a Digital Health System – New Technologies and Available Data

We strongly agree the development and deployment of new technologies such as artificial intelligence, machine learning and remote monitoring technologies is a significant opportunity over the next 5 years. The ability of the health care system to properly collect, organize, analyze, interpret and apply “big data” is properly characterized in the Plan as both a challenge and opportunity.

Goal 1 – Promote Health and Wellness

One of the strategies listed under Objective 1a in this section calls for building “the evidence case on the use of health information, including on the types of information that will benefit individuals most and the best ways to present information to patients and caregivers.” The health IT industry has invested (and will continue to invest) significant time and resources in the development of user-friendly application programming interfaces (API) and in the presentation of clinical content that is understandable to, and actionable by patients. Does ONC envision that the federal government will begin building its own evidence base, or is this a strategy that would continue to rely on the private sector? In the final version of the Plan, please clarify this point.

We referenced above the importance of improving health literacy and believe that the strategies listed under Objectives 1a and 1b would all be more successful if medical content were translated into more patient-friendly terms. The private sector should continue to take the lead, but the federal government can help facilitate and encourage excellence in this area. To that end, ONC or CMS might consider staging a competition similar to the Artificial Intelligence Health Outcomes Challenge that rewards the best apps or solutions that improve patient literacy.

³ The Price of Excess: Identifying Waste in Health Care Spending. PriceWaterhouseCoopers’ Health Research Institute 2008

Also, under Objective 1a, we agree promoting greater portability of health information and access to smartphone and other technologies are two key strategies for improving individual access to their health information. For both to be successful, HHS will need to continue offering guidance on the permissible sharing of patient information that promotes improved outcomes and cost savings while not running afoul of HIPAA. Specifically, guidance as to what constitutes sensitive information and at what level sensitive information should be tagged (e.g. document level, header level, data element level) will be important to understand as the private sector continues to develop consumer facing applications. Continued guidance from the Federal Trade Commission's authority for securing patient health privacy is also advisable.

Under Objective 1c in this section, we were intrigued by ONC's mention of "capturing and integrating social determinants of health data into EHRs to assist in care processes, such as clinical decision support..." As ONC is aware, the health care system is only now able to exchange rudimentary social determinants of health (SDOH) data on patients. Integrating such data into electronic medical records (EMR) so that it can be used to assist in care processes will be major undertaking, but it is a goal worthy of inclusion in the Plan and we fully support it. ONC and CMS may also want to consider development of a measure framework for the more common SDOH data elements such as food insecurity, access to housing, social isolation or English language proficiency. Such a measure framework could then be used to identify high-risk patients and connect them with community resources and programs.

Goal 2 – Enhance the Delivery and Experience of Care

Under Objective 2a, we strongly support the strategy that calls for optimizing "care delivery by applying advanced capabilities like machine learning, evidence-based clinical decision support, and smart dashboards and alerts." In the final version of the Plan, we recommend ONC edit this sentence to also call out "surveillance software." The phrase would encompass the full range of such software, including remote monitoring, syndromic surveillance and real-time bedside monitoring of patients for conditions such as sepsis, C. difficile or worsening kidney function. The latter are already making a major contribution to the prevention and mitigation of such conditions and should be included in any care optimization strategy.

Perhaps the most important function of the EMR is to utilize surveillance decision support to detect patients at risk of dying. Since sepsis is the most common medical emergency that develops in the hospital with a risk of death, sepsis surveillance is worthy of mention in the Plan, as are hemodynamic shock and acute respiratory failure. The COVID-19 crisis is a stark reminder of the importance of surveillance, as the rapid spread of the virus is driving increased hospital census, reduced clinical staff and less frequent patient monitoring. Now more than ever, there is an increased need for real-time surveillance to monitor COVID patients that are at risk of ARDS and respiratory distress.

On a related note, we were also pleased to see in the recently released *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* that CMS is seeking to reduce burden and increase value by **promoting higher-value functionality**, such as widespread interoperability and **clinical support tools** (emphasis added). We strongly support this goal and look forward to seeing how it will be implemented in future rulemaking.

Objective 2a also includes several strategies aimed at optimizing the use of data. We support use of electronic clinical quality measures and agree the use of data derived from such measures will help improve clinician performance and be of critical use in clinical research. Similarly, we support the strategies related to interoperability and data sharing, and the use of

real-time data to customize care through patient-centric precision medicine. We also recommend that the ONC consider emphasizing the importance of best practices for data governance through the use of a reference data management strategy that can be deployed throughout an organization to ensure traceability.

We were also pleased to see, and fully support the Plan's reference to fostering competition, transparency (particularly price transparency) and affordability in health care (Objective 2b) and the proposed strategy to encourage pro-competitive business practices. We have already shared our grave concerns with ONC on the imposition of unreasonable, one-sided business and legal contract terms on third-party application developers seeking access to their customers' data through an API Technology Supplier's app program.

We generally support the ONC Cures Act final rule issued on March 9th and believe it addresses many of the anti-competitive practices that third-party app developers have been experiencing. While we recognize the health care system is currently focusing its time and resources in combatting the COVID-19 pandemic, we urge ONC not to delay implementation of the information blocking ban, as some stakeholders are advocating.

Goal 3 – Build a Secure, Data-Driven Ecosystem to Accelerate Research and Innovation

The Plan appropriately places significant emphasis on the use of health data to improve care, lower costs and inform clinical research. In addition to the data-related strategies contained in Objective 2a cited above, we also support several of the strategies under Objective 3a, including bolstering secure access to large datasets of health information for use in quality improvement and outcomes research, enabling individuals to securely provide data via apps, and fostering data governance that supports a secure, unified platform for researchers, innovators, patients, providers and payers. We were also pleased to see ONC finalize the US Core Data for Interoperability (USCDI) as the new data element standard. This is the first step to improved harmonization of data elements and to enable data sharing between systems.

A data-related strategy under Objective 3b that we also support is the increased use of new technologies like machine learning and predictive modeling to harness the power of integrated data for improved quality, research and clinical decision-making.

Goal 4 – Connect Health Care and Health Data through an Interoperable Health IT Infrastructure

We agree with the Plan's strategy under Objective 4a to require use of health IT in federal programs, investing in health IT, making resources available to support adoption and use, and reducing switching costs between EMR and other health IT products and systems. We also support strategies under Objective 4b that address information blocking and other actions taken by health IT developers that limit access, exchange and use of electronic health information, and the promotion of data liquidity by eliminating unnecessarily restrictive data sharing practices. We note that while the Cures Act Final Rule provided more clarity on the exceptions to the information blocking ban, future guidance will still be needed once enforcement of the ban goes into effect.

Thanks again for the opportunity to comment. If you have questions about any of our comments, please contact Bob Hussey (bob@bobhussey.com or (612) 281-8741), who can arrange contact with the relevant Wolters Kluwer staff.