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May 28, 2024

Comments from Wolters Kluwer on
the Draft Federal Health IT Strategic Plan 2024-2030

Below are Wolters Kluwer's comments to the Office of the National Coordinator for Health Information Technology (ONC) on the draft Federal Health IT Strategic Plan 2024-2030. Thanks for allowing us to provide our views.

As way of background, Wolters Kluwer is a leading global provider of clinical technology and evidence-based solutions that drive effective decision-making and outcomes across the healthcare continuum. Key solutions include UpToDate®, UpToDate® Lexidrug™, UpToDate® Patient Engagement, Medi-Span®, Sentri7®, Lippincott® Solutions, Ovid®, and Health Language®. Wolters Kluwer had annual revenue in 2023 of €5.5 billion.

Our initial comments recommend a shift in focus for federal health IT policy from interoperability to improving quality of care and lowering costs. Our subsequent comments are organized under broad topic headings that address: **Promoting the Practice of Evidence-based Medicine; Collection and Use of Health Data; Artificial Intelligence**; and **Patient Engagement and Health Literacy**. Under each topic, we provide our views on specific goals, objectives and strategies proposed in the Federal Health IT Strategic Plan 2024-2030 (the Plan), and where appropriate, recommend new policies that can help achieve them.

Shifting Focus of Federal Health IT Policy to Improving Quality and Lowering Costs

While we generally support the draft Federal Health IT Strategic Plan 2024-2030 ("the Plan"), we believe the broad focus of federal health IT policymaking over the next 5+ years should be to leverage technology to **improve quality of care** and **lower costs**.

At the time HITECH was passed, policymakers expected the wider use of health information technology to ultimately create substantial cost savings, improvements in care and the avoidance of unnecessary tests and preventable medical errors. To achieve these goals, federal regulators properly placed their initial focus on achieving widespread *adoption* of health IT by providers and facilities. These initial efforts were very successful, with 95% of hospitals and 88% of clinician practices using EHR technology as of 2021. When it then became clear that clinicians adopting new health IT were either unable to share data with systems made by different vendors, or purposely blocking data transfer to other providers to preserve a competitive advantage, federal policy shifted focus to *interoperability,* where it has largely remained since 2016.

As of early 2024, federal regulators have now created a solid foundation of new programs and policies to promote greater interoperability of health data and prevent information blocking. For example, to facilitate the exchange of health data, the United States Core Data for Interoperability (USCDI) was added to the ONC Certification program. Clinicians and hospitals now face Medicare payment reductions if they fail to exchange health data. The new Trusted Exchange Framework Common Agreement (TEFCA) was finalized and implemented, with 7 organizations chosen to serve as

qualified health information networks. The HHS Inspector General can now levy financial penalties on select actors who engage in information blocking, and ONC will soon finalize regulations to create provider disincentives to information blocking.

Given that adoption has largely been achieved and interoperability is being aggressively addressed, we believe federal health IT policies in the next 5 years should orient around the twin goals of **enhancing quality of care** and **lowering costs**.

Health IT is uniquely positioned to help achieve both because it facilitates harmonized decision-making where diagnosis and treatment are evidence-based (via clinical decision support software), care teams are aligned (via greater interoperability and exchange of health data) and patients are more active participants in their care (via shared decision-making, interactive messaging and customized treatment plans.) These elements are already included in the Plan, and we recommend the final version clearly spell out the shift in policy focus to quality and cost.

Promoting the Practice of Evidence-based Medicine

Medical decisions, diagnoses and treatment recommendations should reflect the best medical evidence, regardless of where a patient lives or their access to health facilities or resources. Health IT can play a leading role in enabling providers, patients, and other health IT users such as payers and pharmacy benefit managers to access the latest medical evidence anywhere via decision support software and medical knowledge databases. Federal policies that promote or encourage regular and routine consultation of such solutions will help improve quality of care and patient outcomes while also lowering costs. The relevant goals, objectives and strategies in the Plan that address the virtues of evidence-based medicine are discussed below.

A proposed strategy under Goal 2: Objective A of the Plan involves the federal government promoting "*the use of health IT and other modern technologies in clinical workflows so that health IT supports clinicians in providing high-quality, safe, efficient and evidence-based care.*" We strongly support this strategy. To help achieve this goal, federal regulators should continue encouraging and promoting the use of evidence-based clinical decision support (CDS) by providers in all sites of care. For example, CMS is already doing this via the addition of CDS-related Improvement Activities to the Merit-based Incentive Payment System (MIPS). To ensure the CDS provides evidence-based recommendations, providers should be encouraged to use CDS solutions developed by any entity with a strong track record of providing high-quality, up-to-date content. It is imperative the CDS be maintained and continuously updated to ensure the recommendations provided reflect current best practices.

Looking to the future, the CDS Hooks standard could also be added to ONC's Certification Program. CDS Hooks enables improved and broader use of health data with CDS engines to support a growing list of use cases within the clinical workflow. The use of CDS Hooks can accelerate improved adherence to clinical guidelines and medical evidence, and reduce medication errors and variability in care. As we previously expressed in comments to ONC, the addition of CDS Hooks to the Certification Program only makes sense if use of the standard is tied to one or more use cases and all provider types/roles. Interventions facilitated by CDS Hooks that can help drive lower costs, decrease medical errors, and reduce variability in care include:

- Preventive care reminders;
- Evidence-based treatment suggestions (e.g. "we noticed this patient has high BP and we would suggest medication XYZ");
- Evidence-based treatment alternatives (e.g. "instead of medication XYZ that you ordered, you might consider medication ABC because it may be more effective and/or safer for this patient");
- Appropriate use of diagnostic tests;
- Real-time prescription benefit checks;
- Prior authorization facilitation;
- Pharmacogenomic-informed medication recommendations

In addition, we strongly support the strategies proposed in the Plan that emphasize the importance of using evidence-based medicine to address explicit and implicit bias in the delivery of patient care (Under Goal 3: Objective C) and to increase the data linkages across diverse data sets to help ensure the completeness of evidence-based information (Goal 4: Objective E).

While commonly used in medicine, the direct relevance of race or ethnicity to medical care is limited. Non-genetic factors such as social drivers of health and the effects of racism are typically the sources of differences in health conditions and outcomes between race- and ethnicity-defined groups. CDS that avoids inappropriately including race or ethnicity in its recommendations will promote high-quality care for all patients. For example, CDS guiding the management of patients with lung or kidney disease should use race-neutral equations for estimating pulmonary and kidney function, respectively, to help avoid inappropriately undertreating some Black patients.

Collection and Use of Health Data

The Plan makes numerous references to the collection and use of health data, and appropriately so in our opinion. Now that health IT enjoys widespread adoption, and interoperability and data sharing are on their way to becoming standard practice, the quantity and quality of health data will increase substantially over the next few years. This will help improve many aspects of the health care system, including in areas such as diagnosis, medical research, patient engagement, quality-based payment, new drug discovery, population and public health. Our comments below pertain to several goals, objectives and strategies that discuss the use of health data.

As part of Goal 1: Objective B, the Plan offers a strategy to "*build on the collection of evidence needed to improve the use of EHI so that data classes and data elements that improve clinical and social determinants are standardized and included in health and human services systems*." We agree and have no suggested changes.

We also take this opportunity to once again urge ONC to be more aggressive in building out the USCDI, particularly in the *Laboratory* and *Medications* data classes. For both these data classes, it is critical to provide clinicians with granular data on their patient's tests and medications, not only to facilitate smooth continuity of care but to also safeguard patient safety. Both classes are also foundational to ONC's efforts to improve public health, health equity and the care rendered to underserved communities. As we noted in recent comments to ONC, many of the *Laboratory* and *Medications* data elements in these classes that could be added to USCDI as soon as version 5 are either at Level 2 for adoption and/or supported by FHIR/US CORE. They would therefore represent a modest

implementation burden for stakeholders. Examples include *Laboratory Results: Date and Time Stamps; Laboratory Test Performed Date; Laboratory Test/Panel Code;* and *Medication Date Prescribed*.

Notwithstanding our comments above, we commend ONC for launching the USCDI+ initiative, which seeks to add new data classes and elements to the USCDI that facilitate data transfers and exchanges for use cases of importance to federal agencies. We note the projects currently underway with USCDI+ align nicely with several goals and objectives proposed in the Plan, including public health (Goal 1: Objective C) and oncology, clinical care and research (Goal 3: Objective A).

Other strategies proposed in the Plan that emphasize the important role for health data include advancing the use of standardized social determinants of health data to reduce disparities, expanding health IT use beyond hospitals and physician offices (Both under Goal 2: Objective B, with pharmacies also added to the latter as a site for expanded health IT use), merging clinical and administrative data to improved decision-making (Goal 2: Objective C), and the importance of integrating disparate data sets (Goal 3: Objective B). We support all these strategies.

In our earlier comments related to the importance of evidence-based medicine, we voiced support for the proposed strategy to "*increase data linkages across diverse data assets so that health IT users have more complete, evidence-based information to inform decisions*" (Goal 4: Objective E). This strategy is equally important from a data collection and use perspective. We also draw attention to and express our support for all the important strategies included under Goal 3: Objective A, which touch upon the importance of sharing health data to drive research, both at the individual and population levels; linking health and human services data; harmonizing common data elements to facilitate interoperability; and fostering data governance to reinforce privacy protections for large data sets. All of these strategies are important and we support them.

Finally, on the issue of data privacy, which is referenced in several strategies throughout the Plan, including those found in Goal 4: Objective D, the issue of data segmentation for privacy will be an important one during the next few years. We support a patient's right to control their personal health data, and to be capable of tagging discrete data they consider particularly sensitive and limiting the sharing of such data to specific individuals or entities. At the same time, as we shared in past comments to ONC, we are greatly concerned about the impact such segmentation might have on decision support and patient care. CDS relies on having access to the full and complete record of a patient's health history to generate accurate recommendations on future treatment. Being able to utilize only part of that record will impair such recommendations and possibly create threats to patient safety. We appreciate that ONC, CMS and HL7 are working on solutions that weigh these competing demands, and look forward to reviewing the various approaches as they are presented.

Artificial Intelligence

Like health data, the Plan also makes numerous references to the use of artificial intelligence (AI) in health care. We agree the use of AI to expand the value and range of existing health software and to create entirely new solutions to improve the health care workflow will be profound over the next several years. Below are our comments on the goals, objectives and strategies in the Plan that address the use of AI.

A proposed strategy under Goal 2: Objective A states that "*the federal government plans to increase transparency and understanding of health data that goes into algorithm-based decision support*

tools so that health care providers have confidence that decision support tools facilitate more accurate and safer treatment options." We strongly agree with this approach, which will be particularly important when providers use generative artificial intelligence (GenAI) in clinical decision-making.

In the context of clinical decision-making, the use of GenAI holds great promise to achieve optimum quality of care while lowering costs by helping improve the accuracy of diagnosis, make treatment plans more effective, reduce unnecessary tests and treatments, and boost clinician productivity. Such a broad range of capabilities can make significant contributions to a patient's health and wellbeing, but such tools used at the point of care also pose risks to patient safety if they are not properly developed, tested or maintained.

We agree with ONC that transparency will be the key to fostering trust in GenAI tools used by providers and patients in medical decisions. The policy prescription we propose builds off ONC's recently finalized HTI-1 rule, and specifically the new Decision Support Interventions criterion. To account for the growing use of GenAI in clinical decision-making, ONC should add new source attribute information and intervention risk management (IRM) disclosures related to GenAI-enabled software.

For example, source attributes should clearly identify what clinical content was used to enable the GenAI application, including prompt design, model fine-tuning and grounding; how that content was created and curated; how often the model's evidence base is updated; and what safeguards are in place to ensure the model's output is accurate, unbiased and adheres to evidence-based medicine principles. An example of a GenAI-related IRM disclosure is how the certified developer manages/mitigates biases and hallucinations within its model.

Related goals, objectives and strategies that also discuss the important part AI will play in the coming years, and which we strongly support, include education, outreach and transparency about the use of AI technologies (Goal 1: Objective B); promoting the safe and responsible use of AI tools (Goal 2: Objective D); addressing and mitigating bias and inaccuracies in AI model output (Goal 3: Objective B); and addressing algorithmic discrimination in health IT (Goal 3: Objective C).

Patient Engagement/Health Literacy

We are pleased that patient engagement is part of the Plan, as it was in the 2020-2025 version, and federal regulators place such importance on improving health literacy. We strongly support the strategy under Goal 1: Objective C that envisions the "*use health IT to distribute health education and disease prevention measures to communities so that public health professionals and communities promote health literacy and achieve a more equitable care experience for all*." We recommend expanding this strategy to include health plans and their member communications.

However, we would be remiss by not pointing out that a key factor in the success of any patient engagement/health literacy campaign is to ensure that materials and communications are provided in a language that can be understood by patients with limited English proficiency.

For example, the problem of low medication adherence rates is one that can be significantly improved by patient engagement that takes language into account. Numerous studies looking at medication adherence have shown that almost half of patients are not taking their medications as directed, thereby undercutting the efficacy of the drug therapy and putting patient health at risk. There are multiple reasons for this adherence problem, including cost, but lack of understanding, low health

literacy and communication barriers also play a role. Recognizing the importance of providing patient medication information (PMI) to patients with limited English proficiency, large states such as California, Texas and New York require pharmacies to have such information available in translated form.

With an estimated 22% of the US population speaking a language other than English at home, according to the US Census, future federal efforts to improve patient engagement and health literacy must require that support materials and/or communications be available in languages other than English. A case in point is FDA's current proposed rule creating a new PMI document. Unfortunately, the rule did <u>not</u> propose to require availability of the document in multiple languages. We shared our grave concern about this oversight with FDA in comments submitted in late 2023, and sincerely hope it will be rectified in the final PMI rule.

Thanks again for the opportunity to share our views. If you have questions or want to discuss our response in more detail, please contact Bob Hussey at bob@bobhussey.com or (612) 281-8741 who can connect you with the appropriate staff at Wolters Kluwer.