



March 13, 2020

Donald W. Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

Re: ONC 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker,

The American Osteopathic Association (AOA), on behalf of the more than 151,000 osteopathic physicians and medical students we represent, appreciates this opportunity to share input on the HHS Office of the National Coordinator (ONC) for Health Information Technology (HIT) 2020-2025 Federal Health IT Strategic Plan. The roadmap that ONC has set forth in its strategic plan will not only continue to advance interoperability, but will build on this effort to advance the use of health data in ways that support clinical practice and enhance population health.

As physicians who partner with our patients to develop care plans, being able to utilize interoperable HIT to understand patients' medical histories, view population health insights, and deliver the highest quality of care is deeply important to us. We believe that the goals and strategies outlined will support innovation and drive better health outcomes. However, we believe that elements of the plan relating to patient privacy and promoting the availability of innovative tools and data for use by clinicians can be strengthened. Please find our comments on these issues, as well as other elements of the plan, below.

Goal 1: Promote Health and Wellness

The AOA supports this goal of empowering patients with their health data and promoting healthy communities by leveraging HIT. As physicians practicing across all specialties and in diverse geographic settings, we recognize the importance of partnering with patients to promote healthy behaviors and wellness, as well as on social determinants of health that impact our patients' health. We support most of the objectives and strategies outlined in this section. However, we urge ONC to revise the third strategy under objective 1b to read, "Advance use of evidence-based digital therapeutics to help prevent, manage, and treat conditions through smartphones, tablets, and other personal devices." This will help clarify that technologies are not placing patients in charge of their own diagnosis and treatment, but are used in conjunction with care plans developed by our physician members with their patients.

While evidence-based digital therapeutic technologies may be used to manage and treat conditions, there is a difference between patients being engaged in their healthcare and well-being, and promoting self-diagnosis and treatment. We are concerned that promotion of digital therapeutics, in some cases, may delay or be used as a substitute, for proper evaluation and treatment by a physician. Should the ONC adopt the strategy as proposed, we recommend that policy development regulating digital self-management tools include appropriate patient education and guidelines for when to seek medical care from a physician.



Goal 2: Enhance the Delivery and Experience of Care

Objective 2a: Ensure safe and high-quality care through the use of health IT

While we support the overall intent of this objective, we believe it is too broad and could be improved by dividing it into two targeted objectives. The first objective could be, “leveraging data to promote safe, high quality care.” The second objective could be, “using HIT to transform clinical practice and promote access to high-value care.” Dividing the objective in this way would allow ONC to place greater emphasis on how HIT can be used to transform our healthcare system into one that reimburses for greater value.

As the healthcare system shifts towards value, it is important that ONC evaluate how data and HIT will be leveraged to better understand the value of services, drugs, or therapeutics, and ensure delivery of high-quality care. The strategic plan, as written, has limited detailed discussion of the movement towards value, even though it is referenced in a few strategies. We believe that using data to support the transition to a value-based healthcare system should be a greater focal point for the ONC. Under this framework, strategies 1, 2, 4, and 8 would align well with the objective focused on clinical practice, safety and high-quality care. The remaining strategies, which focus on use of data for analytical purposes, could be categorized under the “value” objective to support cost-efficient use of HIT resources and better benchmark patient outcomes.

Objective 2c: Reduce regulatory and administrative burden on providers

We applaud ONC for acknowledging the impact of regulatory and administrative burden and proposing strategies to enable physicians to spend more time with their patients. To truly make an impact, we recommend that the ONC take its efforts a step further to alleviate burden and promote coordinated, high-quality care by adding the following two strategies to this objective. First, as CMS and ONC work to achieve greater transparency and make more data available to both patients and providers, it would be useful to make claims data available to physicians at the point of care. This type of effort would follow in-line with a recent “Data at the Point of Care” pilot by CMS which makes claims data available to providers in their EHR workflows for use at the point of care. This type of effort should be expanded. Second, ONC should promote greater usability testing of products to ensure that HIT products and tools truly support clinical workflow and care delivery. This effort should entail development of more stringent standards for testing and usability.

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

Objective 3b: Support research and analysis using health IT and data at the individual and population levels

While it is critical that ONC support the use of new technologies that incorporate machine learning and predictive modeling, these technologies require unique considerations, as compared to EHRs, to ensure safety when used in clinical practice. Because these tools are being used more frequently to support clinical decision making, considerations that need to be accounted for include potential biases built into software or flaws that prevent them from being relevant to specific patient populations. We recommend that the ONC include the development of a new regulatory framework for these technologies among its strategies. The regulatory framework for these technologies should be informed by industry best practices and the best available data. They should also be continuously updated to minimize risk of adverse consequences when the technologies are deployed in clinical settings. ONC should also set standards to evaluate the impact of these technologies on care quality and patient outcomes.



Goal 4: Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure

Objective 4a: Advance the development and use of health IT capabilities

The AOA strongly supports this objective and its strategies. However, since the enactment of the HITECH Act of 2009 and implementation of meaningful use, the number of providers using HIT has grown to the extent that most providers now use certified EHR technology. This makes the priority of promoting adoption somewhat dated as it relates to EHRs. According to ONC's data, 96 percent of all hospitals use certified EHRs, and 80 percent of office based physicians use certified EHRs.¹ ONC could strengthen this goal by shifting focus towards supporting uptake of more advanced technologies that have proven potential to enhance patient care. However, federal agencies should be judicious in designing any incentive programs to ensure that they do not create unnecessary regulatory burden.

Objective 4d: Promote secure health information that protects patient privacy

While this objective is critical, it does not adequately address what happens to data when it enters third party applications (apps), or technologies that are not utilized by HIPAA covered entities or business associates. As the AOA noted in its comments to ONC on its proposed rule implementing the 21st Century Cures Act, when patients want to use a health management application, they are often required to agree to user "terms and conditions" which often contain language permitting the developer to pass along user information to third parties. A recent study examining the 24 top-rated Android apps for health medicine management found that 19 of the 24 apps shared user data with third parties. Of these apps that shared data, 66 percent of the third parties that these apps shared data with "provided services related to the collection and analysis of user data, including analytics or advertising, suggesting heightened privacy risks."²

While ONC recently released the final rule, we believe that it does not go far enough in regulating use of data by third party apps not covered by HIPAA privacy rules. We recommend that the ONC list an additional strategy under this objective to expand explicit protections for patient privacy and give patients greater control over what entities may have access to their data.

The AOA appreciates ONC's work to promote interoperability, innovation, and the use of data to improve healthcare. We believe ONC's efforts, with adoption of the above-mentioned recommendations, have the potential to transform the healthcare landscape to enhance the information available to providers, improve outcomes, and reduce provider burden. The AOA would welcome the opportunity to work with the ONC to further define objectives and strategies for policy development. If you have any questions about our comments or recommendations, please contact Lisa Miller, MS, Senior Director of Regulatory Affairs and Policy Engagement at lmiller@osteopathic.org or (202)-349-8744.

Sincerely,

A handwritten signature in cursive script that reads "Ronald R. Burns".

Ronald R. Burns, DO, FACOFF
President, AOA

¹ <https://dashboard.healthit.gov/apps/health-information-technology-data-summaries.php?state=National&cat9=all+data&cat1=ehr+adoption>

² <https://www.bmj.com/content/364/bmj.i920>