

Sound Policy. Quality Care.

March 18, 2020

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

Don Rucker, MD National Coordinator for Health Information Technology Office of the National Coordinator for Health Information Technology U.S. Department of Health and Human Services 330 C Street, SW Washington, DC 20201

RE: 2020-2025 Federal Health IT Strategic Plan

Dear Secretary Azar and Dr. Rucker,

On behalf of the Alliance of Specialty Medicine (the "Alliance"), representing more than 100,000 specialty physicians from 15 specialty and subspecialty societies, we are writing to provide feedback on the Office of the National Coordinator (ONC) for Health IT's 2020-2025 Federal Health IT Strategic Plan. The Alliance is deeply committed to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. As such, we applaud ONC for its department-wide, outcomes-focused effort to continue to advance interoperability among health care providers, payers, and patients, and to help patients become more engaged partners in care through enhanced access to data. We are especially supportive of ONC's overarching goal of developing health IT policies through open, transparent, and accountable processes, and look forward to continuing to provide you with the specialty clinician perspective.

Below, we offer feedback on select goals and objectives outlined in the Strategic Plan:

Goal 1: Promote Health and Wellness

Objective 1c: Integrate health and human services information

The Alliance appreciates ONC's recognition of the need to better integrate health and human services data in order to provide more person-centered care and to improve our understanding and better address social determinants of health. The ongoing lack of real-time coordination and integration of data between not only various federal, state, and local agencies, but also between the government and specialty-led clinical data registries creates major inefficiencies and inhibits our ability to truly understand and improve upon existing gaps of care. We support this objective, but request that ONC

also consider strategies to better support data sharing with clinical data registries. The ability to easily merge administrative and clinical data sets is critical for providing a more complete picture of healthcare spending and utilization in relation to outcomes and for addressing ongoing gaps in the quality of care.

Goal 2: Enhance the Delivery and Experience of Care

Objective 2a: Ensure safe and high quality care through the use of health IT Objective 2b: Foster competition, transparency and affordability in health care Objective 2c: Reduce regulatory and administrative burden on providers

The Alliance supports efforts to optimize care delivery by applying advanced information technology capabilities, such as data sharing, machine learning and evidence-based clinical decision support. However, it is critical that widely-accepted standards are in place to promote interoperability and data sharing; to ensure these new technologies result in safer, higher quality, and more effective care; and to ensure the use of health IT strengthens, rather than erodes, the patient-clinician relationship. It is equally important that relevant clinical experts are involved with the design and appropriate application of these standards and new technologies. There are numerous studies in the medical literature that have shown how usability issues, including design problems related to data entry, defaults, displays, and alerts, have resulted in fatigue and frustration among clinicians and even patient safety issues. It is critical that federal efforts to promote the use of health IT keep patient safety and higher quality care—both in terms of clinical outcomes and patient and clinician satisfaction—front and center.

In regards to transparency, the Alliance supports efforts to ensure that data regarding the quality of healthcare is more timely, accessible, and easily understandable to both clinicians and patients. In regards to price transparency, we urge ONC to be mindful of the unique nuances that factor into healthcare decision-making and to work to ensure that patients understand their full range of care options and the potential implications of each of those options. We also believe that payers— not hospitals or physicians— should be responsible for releasing price information and presenting it in a way that is useful for the patient. Providers have very little direct influence over healthcare prices other than charge rates. Payers maintain control over negotiated rates, have full access to and control of patient cost-sharing information, and know details such as how much of a deductible a patient has already paid. Putting this burden on providers would further interfere with patient care as providers would have to spend time tracking down this information from payers. Finally, we urge HHS and its agencies to implement future price transparency initiatives carefully and gradually. For example, it should first test the feasibility and utility of making limited price data available, such as formulary driven prescription prices or elective procedures, which are more predictable and easier to capture.

Finally, the Alliance very much appreciates ONC's goal of reducing regulatory and administrative burden. Activities such as clinical documentation, prior authorization, and even quality reporting divert clinician time and attention away from the patient. We have long urged federal agencies, such as CMS, to simplify and streamline federal documentation and quality reporting requirements. In that vein, federal strategies to advance health IT should consider how best to incorporate technologies into existing workflows, reduce reporting requirements, and minimize burden. More specifically, ONC policies should aim to:

- Improve the functionality and intuitiveness of EHRs to ensure the safe use of these technologies
 and to reduce the time, effort, and expense to clinicians of entering data and merging it with
 other more robust sources of data, such as clinical data registries.
- Reduce the time, effort and expense of meeting regulatory reporting requirements, such as through the promotion of automated data extraction, harmonizing reporting requirements

across federal agencies, and minimizing the impact of unnecessary and misapplied regulations, such as prior authorization requirements, that can interfere with care more than improve it. Prior authorization, in particular, is a significant and growing challenge for specialty physicians and their patients. According to a recent survey of specialty physicians, the Alliance found that nearly 90% have delayed or avoided prescribing a treatment due to the prior authorization process and that 82% reported that prior authorization either always (37%) or often (45%) delays access to necessary care. CMS' recent efforts to adopt standards that would support real-time electronic prior authorization for prescription drugs are encouraging. As those policies continue to evolve, we request that HHS collect data on the scope of prior authorization practices (i.e., denial, delay, and approval rates) and work to ensure that prior authorization practices do not create inappropriate barriers to care for patients.

• Foster a greater understanding of applicable regulations, including requirements related to data sharing, by providing clinicians with timely and clear guidance and other tools so that compliance is achieved efficiently and effectively.

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

The Alliance agrees with ONC that an integrated ecosystem that collects data from multiple sources is critical for health IT tools to unlock the power of data. We also support ONC's goal to "put research into action" by strengthening feedback loops between scientific and healthcare communities in order to efficiently translate evidence into clinical practice and improvement. "Big data" presents a significant opportunity in regards to research, direct clinical decision making, and improving the quality of health care. However, we continue to face significant challenges related to the collection, organization, and application of these data. We note with disappointment that, to date, the Administration, and particularly CMS, has remained virtually silent on supporting the exchange of Health IT for purposes of research and clinical registries. As such, we respectfully remind the Administration that uniform data collection will strengthen the role of research and registries when implementing current or developing future policy initiatives, including quality metrics and cost reporting. ONC must work with diverse stakeholders to continue to improve harmonization of data elements and standards, including the creation of a common vocabulary set to improve the consistency, integrity, and quality of data, and to enable data to be effectively shared between systems. As noted earlier, ONC and CMS also should bolster secure access to large datasets of health information for quality improvement and outcomes research—particularly for use by specialty societies and their clinical data registries.

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

Objective 4b: Establish transparent expectations for data sharing
Objective 4d: Promote secure health information that protects patient privacy

In general, the Alliance supported provisions in the 21st Century Cures Act to promote the seamless exchange and integration of health information through the use of shared data standards and common terminologies and by addressing activities, such as information blocking, that impact access to, exchange and use of electronic health information. We believe that, if applied appropriately, these policies have the potential to enhance the trustworthiness of health IT and to promote a more systematic collection of standardized clinical and other health data, which will ultimately improve the quality of patient care.

However, as we expressed in our comments to ONC last year, we have serious concerns about the potential implications associated with making data so easily accessible and transferable, including risks related to information overload (on the part of both the patient and the clinician), threats to data security and privacy, and increased physician burden. It is critical that HHS and its agencies and offices carefully re-evaluate current regulatory policies, including the reach of HIPAA, in the context of modern data exchange to ensure privacy and security protections for health information keep up with the pace of technology. Current health privacy and security laws may not be sufficient to protect against the misuse or inappropriate disclosure of health information in the world of enhanced data access envisioned by HHS. We support ONC's proposed strategies of integrating privacy and security considerations into the design and use of health IT and implementing such mechanisms as appropriate to the sensitivity of the data. This will help to ensure that new or updated protections do not create another layer of regulatory burden for clinicians. It is also important that federal agencies provide clear guidance to clinicians about their obligations under this shifting landscape and that regulations evolve to reflect the additional demands that will be placed on clinicians as a result of enhanced data access. Similarly, HHS and its agencies must help to educate patients and caregivers on how their health data may be used in this rapidly changing environment so they can make informed decisions about data exchange and secondary uses of their data.

The Alliance shares ONC's vision of a future where patients are more active and well-informed healthcare decisionmakers and clinicians can provide more appropriate and efficient care as a result of better access to information at the point of care. However, getting there will require some major shifts in regulations, expectations, and care delivery. Given the significance and complexity of these changes, we strongly recommend that ONC work with other HHS offices and agencies to accomplish these goals through a transparent, stakeholder-informed process that is both thoughtful and gradual.

Should you have any questions or require additional information, please do not hesitate to contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
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North American Spine Society