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AMERICAN MEDICAL
ASSOCIATION

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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:     Draft 2020-2025 Federal Health IT Strategic Plan

Dear Dr. Rucker:

On behalf of the physician and medical student members of the American Medical Association
(AMA), I am pleased to offer our comments to the Office of the National Coordinator for Health
Information Technology (ONC) on the Draft 2020-2025 Federal Health Information Technology (Health
IT) Strategic Plan (Plan).

The Plan outlines an ambitious set of priorities. The AMA supports ONC's vision to use information to
better engage with patients, lower costs, deliver high quality care, and improve health. While we also
support the Plan's four goals—promoting health and wellness, enhancing the experience and delivery of
care, building a data—driven ecosystem, and connecting health care and data through health IT—the
combination of six principles, 13 objectives, and 60 individual strategies may prove difficult to manage,
particularly if the goals conflict with the measures ONC includes in Appendix B to evaluate the Plan's
success. ONC suggests the implementation of its Plan is geared to support and enable the measures
themselves. Are the *measures* the Plan's overarching driving factor? If so, how will the measure of
supporting "new business models" align with the principle of "putting individuals first" when doing so
may conflict with corporate interests? Put differently, who will decide which individual interests are more
important than business models and what happens when stakeholders disagree? How will these dynamics
impact benchmarking and success over time? It is also unclear how ONC will coordinate this Plan across
12 federal departments and agencies, each with different priorities and constituencies (for example, the
U.S. Department of Commerce prioritizes business needs whereas the Federal Trade Commission
prioritizes consumer protections). As an overarching consideration, **the AMA recommends ONC
further elaborate on how various metrics, priorities, and goals will be harmonized such that there is
a clear direction and hierarchy over the next five years.**

The AMA is also providing comments on several of the Plan's goals, objectives, and strategies. We look
forward to continuing to work with ONC over the next five years on the implementation of its Federal
Health IT Strategic Plan.

*Goal 1: Promote Health and Wellness*

AMA comment:

The AMA agrees health IT should be used to empower individuals, address patients' full range of health needs, promote healthy behaviors, and facilitate the improvement of health for individuals, families, and communities. To facilitate this, digital health technology must capture, manage, and communicate information in a similar format using common terminology. This is particularly important as physicians incorporate patient generated data and remote monitoring information into their decision-making processes. The farther away from the physician/patient encounter a device is located (e.g., a blood pressure monitor located in a patient's home), the greater the need for semantic and syntactic interoperability. More focus is needed on capturing and communicating high-quality data remotely and supporting trust in those data. To support this level of interoperability, expert-curated standards, terminologies, classifications, and clinical guidance are essential. For use cases involving patient-generated and -sourced data, **ONC should promote the private sector development and use of implementation guides (IG).** Standards development organizations (SDOs), using a ballot process, are well positioned to assist in building the necessary consensus.

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

AMA comment:

The successful development and application of technologies, such as machine learning, improved patient matching, patient safety solutions, and mechanisms for data governance and provenance, will require physician expertise. **The AMA recommends creating an additional strategy to promote physician engagement in solution development.** We also seek further clarity on what "implement mechanisms of data governance and provenance" means. Is this directly related to the Trusted Exchange Framework and Common Agreement (TEFCA) or would this be applicable across the entire federal strategy?

*Objective 2c: Reduce regulatory and administrative burden on providers*

AMA comment:

A successful strategy will require involvement of physicians and other clinicians. This is evidenced by the Current Procedural Terminology® (CPT®) Editorial Panel and the AMA/Specialty Society Resource-based relative value scale (RBRVS) Update Committee's (RUC) efforts to reduce documentation requirements. Ultimately, CPT Editorial Panel/RUC recommendations were adopted by the Centers for Medicare & Medicaid Services (CMS). Those efforts are expected to reduce physician burden. **The AMA recommends ONC promote physician engagement to maximize regulatory and administrative reduction strategies.**

While promoting the "greater understanding of applicable regulations and practices" may help reduce burden, there is opportunity to drastically reduce burden created by regulations. **The AMA recommends that federal departments and agencies examine all current and forthcoming policies through the lens of ROPI, or "return on physician investment."** In other words, it is not enough to educate individuals about requirements. We must question if it is the requirement or policy itself that adds burden, if the outcome is worth the effort, and what can be done to minimize physician burnout and frustration

with regulations. For instance, are CMS' Promoting Interoperability (PI) measures improving physicians' experience with health IT, interoperability and patient engagement? Is check-the-box measurement an effective approach? Are there other policies, i.e., information blocking regulations that achieve the same goal while being less prescriptive? Similarly, should the Administration continue to invest in legacy electronic health record (EHR)-centric programs, or should there be a new strategy that accommodates evolving consumer expectations and new digital health tools? More must be done to create a positive ROPI.

*Objective 3a: Enable efficient management of resources and a workforce confidently using health IT*

AMA comments:

The AMA appreciates ONC's strategies around data standards and secure access. We agree the use of common vocabulary sets are necessary to effectively share data between systems. **We also recommend the promotion of "data reuse" and "data repurposing."** Physician time is a valuable resource and should not be squandered. Physician data collection requirements should be limited to the information necessary for direct patient care or in instances where population health requires collecting additional elements, e.g., documenting patients' travel to monitor outbreaks. Additional uses for data, such as quality measurement and research, should be derived from information collected for patient care. Where possible, collecting data for secondary, tertiary, or supplemental needs should be eliminated. **ONC should create a strategy to reuse or repurpose data across the health care system.** This can lead to drastic reductions in burden and health care costs.

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

AMA comments:

The AMA supports the role of augmented intelligence (AI) in enhancing patient care, improving population health, reducing overall costs, increasing value, and the support of professional satisfaction for physicians. **The AMA recommends the adoption of a strategy that promotes the use of AI systems that advance the quadruple aim.** Specifically, AI systems should: (1) enhance the patient experience of care and outcomes; (2) improve population health; (3) reduce overall costs for the health care system while increasing value; and (4) support the professional satisfaction of physicians and the health care team. We emphasize that ethical use of AI tools (including the data sets on which they are built) must include mechanisms to address bias in product systems-design; failure to do so will contribute to inequitable health outcomes. Patients should also have the right to know whether their health data will be used to develop and/or train machines or algorithms. The opportunity to participate in data collection for such these purposes should be on an opt-in basis.

We also encourage ONC to work with other agencies, including their Office of Minority Health, to ensure that research and analysis protocols improve data collection and use of racial and ethnic data to improve demographic diversity. Research grounded in data gleaned from fully representative samples of diverse populations will enhance understanding of how discrimination and other stressors impact health outcomes. Utilizing an equity framework in research and analysis can also help restore trustworthiness in institutions that have exacerbated social and medical harms in past medical studies and interventions.

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

AMA comments:

The AMA generally agrees with these strategies. As stated in this letter, however, it is not clear how ONC will strike the necessary balance between promoting business models and protecting patient privacy. While these are not mutually exclusive, there may be an inherent push and pull between competing interests. It is not the federal government's role to promote economies that are funded through the monetization of patients' health data. We are concerned this could lead to consumers being viewed as products. We recommend reevaluating several of these strategies. **ONC should consider how to support innovation while ensuring patients and their families are not disadvantaged.**

The AMA strongly disagrees with the notion that providers will not adopt health IT without regulatory requirements or incentives. **We recommend removing the strategy to "support provider adoption and use of health IT by requiring health IT use to participate in federal programs, investing in health IT, and making resources available to support adoption and use."** Research shows that physicians want to adopt digital health tools, are willing to use them, and recognize their advantages.[1] Technology that detracts from patient care, is not well integrated into a physician's workflow, and exposes physicians to security risks <u>are the major impediments</u> to adoption and use. Recent research has shown that digital health tool adoption has risen significantly over the past three years. This is particularly true for tools that provide remote care.[2] The rise in adoption is occurring despite federal regulation or significant increases in payment or coverage. In other words, these tools are being voluntarily adopted based on their usefulness and support of patient care. On the other hand, health IT spurred by federal pressure, i.e., EHRs, are a primary cause of physician burden and burnout.[3,4] EHRs can also contribute to patient harm.[5] **We strongly suggest ONC and CMS reconsider stale federal policies requiring health IT use to participate in federal programs. Rather, HHS should adopt a new strategy to enable the use of a wide range of technologies.** As an immediate step, CMS should recognize the use of non-certified health IT across its PI programs.

*Objective 4b: Establish transparent expectations for data sharing*

AMA comment:

The AMA agrees there is a need to develop resources and guidance for physicians to better understand and comply with regulations. The AMA has developed a reference manual that compiles legal

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[1] AMA/ Kantar TNS Survey. "Physicians' motivations and requirements for adopting digital health". (2016). Available at https://www.ama-assn.org/press-center/press-releases/survey-finds-physicians-enthusiastic-about-digital-health-innovation.

[2] AMA Digital Health Research. "Physicians' motivations and requirements for adopting digital health / Adoption and attitudinal shifts from 2016 to 2019". (2019). Available at https://www.ama-assn.org/system/files/2020-02/ama-digital-health-study.pdf.

[3] Melnick, E. R. et al. "The Association Between Perceived Electronic Health Record Usability and Professional Burnout Among US Physicians". (2019). Available at https://www.sciencedirect.com/science/article/pii/S0025619619308365.

[4] Shanafelt, T. D. et al. "Relationship Between Clerical Burden and Characteristics of the Electronic Environment with Physician Burnout and Professional Satisfaction". (2016). Available at https://static1.squarespace.com/static/527a6f47e4b06d382162aed0/t/5831e9442994ca3ef536c769/1479665990345/MCP+2016+EHR+burn.pdf.

[5] The Pew Charitable Trusts. "Medical Groups Ask Medicare to Encourage Safety in Use of Health Record Systems". (2020). Available at https://www.pewtrusts.org/en/research-and-analysis/articles/2020/01/03/medical-groups-ask-medicare-to-encourage-safety-in-use-of-health-record-systems.

requirements medical practices must follow for patient record access and sharing. The Patient Records Electronic Access Playbook focuses on dispelling myths around the Health Insurance Portability and Accountability Act (HIPAA) and helping physicians and their practices understand their obligations to provide patients with access to their health information. The AMA and ONC have previously collaborated to include similar resources in ONC's Health IT Playbook. **We recommend ONC expand its strategy to support the development and incorporation of resources created by medical professional societies.**

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

AMA comment:

The AMA appreciates ONC including an entire section on patient privacy. **We firmly believe that the federal government can and should simultaneously promote patient access and data privacy to truly benefit patients.**

Privacy is a core component of the health care system and patients have become accustomed to the protections afforded to them by longstanding state and federal privacy laws, including HIPAA. Many patients will not realize that HIPAA does not apply to health data shared by covered entities with applications (apps) and app developers—there are almost no restrictions on how it can be used, disclosed, and sold. Furthermore, we continue to learn of ways that apps collect and exchange data without the knowledge or meaningful consent of individuals. This threatens patient trust in the health care system and the goal of the 21st Century Cures Act (Cures) to promote an app-based economy in health care while protecting privacy.

**Privacy protections are of critical importance to the success of Cures' implementation, as reflected by the numerous references to privacy throughout the legislation.** Congress specified in Section 3002 of Cures that the Health Information Technology Advisory Committee (HITAC) should recommend to ONC policies to advance electronic access, exchange, and use of health information, specifically including privacy as a priority target area. In its Annual Report to Congress for Fiscal Year 2018, the HITAC identified privacy and security of health data as "important considerations" in advancing and maintaining trust in interoperability. Specifically, the HITAC determined that "lack of user awareness and education about privacy and security protections" as a "key gap" in policies aimed at achieving interoperability objectives and benchmarks. The HITAC recommended "educational approaches, technological mitigators, and potential regulatory solutions that offer improved privacy and security protections." The AMA commends ONC on promoting several aspects of this recommendation into its five-year strategy. However, we believe more must be done in the short- and near-term to provide patients meaningful awareness of how apps will use their data.

To this end, we urge ONC and CMS to create pro-consumer policies that promote accountability on the part of app developers and provide patients with information about what apps do with the health data they receive. **For example, we recommend that an additional strategy be added to promote an app/EHR transparency framework.** Such a framework would require certified EHR vendor application programing interfaces (APIs) and payer APIs to check an app's "yes/no" attestations to the following:

- Whether the app provides patients with a model privacy notice;
- Whether the app was developed using consensus-driven privacy guidelines; and
- Whether the app adheres to industry-developed best practices around data use.

This framework would help apps to establish a practice of transparency as Congress works on federal privacy legislation. It would still allow apps to connect to EHRs if the apps answer "no" to the questions; in other words, it would not impose any burden or special effort on patients or physicians seeking to access or exchange health information. App attestation responses should be made public to provide basic accountability and a resource for patients seeking apps that will protect their privacy. Furthermore, the framework would help the Federal Trade Commission with investigations or enforcement actions related to deceptive or unfair trade practices if the app strays from its attestations.

We strongly support ONC's recognition of data security, yet there are no security guidelines available for physicians as they on-board third-party apps onto their systems. Data security is a complex issue and many small and medium practices lack resources. There is a dearth of tools available to help medical practices prepare for new security risks. **ONC should develop a strategy—in coordination with impacted stakeholders—to address security concerns with APIs and apps.** For example, ONC should work with appropriate federal agencies to develop API threat surveillance and mitigation guidelines that vendors could utilize when deploying API-enabled EHRs. Additional requirements will be needed to mitigate security concerns that arise with the on-boarding of third-party apps onto clinician and other providers' systems. Failure to do so could introduce significant cybersecurity threats to our health care system. Multiple stakeholders, including HHS' own cybersecurity advisory group, have raised the above privacy and security concerns.

Additionally, as more sensitive data is exchanged, health IT data segmentation capabilities should be prioritized. Protecting shared sensitive data is an issue that can no longer be neglected. Standards and functionalities that enable data segmentation, tagging and privacy labeling are critical to ensuring the privacy of patient data and trust between patients and physicians. Segmentation of patient data will also be critical as we transition to a health information exchange framework and as the nation seeks to leverage health IT in addressing the opioid addiction crisis. **The AMA recommends ONC include a strategy to promote the concept of "sharing with protections."**
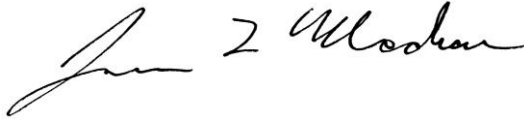
A privacy strategy should also promote equity and justice for all individuals, not only those with the skills and resources needed to protect themselves from discrimination based on digital phenotyping. Health care information is one of the most personal types of information an individual can possess and generate—regardless of whether it is legally defined as "sensitive" or protected health information under HIPAA. Accessing, processing, selling, and using it without the patient's best interest at heart can cause irreparable harm. Patients should be protected from discrimination, stigma, discriminatory profiling, and exploitation occurring during collection and processing of data, and resulting from use and sharing of data, with attention paid to minoritized and marginalized (vulnerable) communities. **The AMA recommends ONC include a strategy to protect patients from discrimination, stigma, and exploitation and promote equitable access to tools and resources that protect their health information.**

The AMA supports ONC's vision to use information to better engage with patients, lower costs, deliver high quality care, and improve health. We look forward to continuing our work with ONC, in coordination with other federal agencies, on the implementation of its Federal Health IT Strategic Plan. If

you have any questions, please feel free to contact Matt Reid, Sr. Health IT Consultant, Federal Affairs, at matt.reid@ama-assn.org or 202-789-7419.

Sincerely,

James L. Madara, MD