Executive Summary of AMA Comments on ONC's Proposed Rule

The American Medical Association (AMA) has submitted comments to the Office of the National Coordinator for Health Information Technology (ONC) on the Interoperability, Information Blocking, and the ONC Health Information Technology (Health IT) Certification Program proposed rule.

The following outlines its principal recommendations on ONC's proposed rule:

- The AMA supports ONC's proposal to require all certified health IT systems to comply with the U.S. Core Data for Interoperability version 1 (USCDI v1). The AMA urges ONC to prioritize its effort to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.

- The AMA supports ONC's proposal for certified health IT developers to adopt and implement new requirements around application programing interface (API) design, function, and use. This will enhance interoperability and reduce implementation complexity and cost. We support requiring the adoption of Fast Healthcare Interoperable Resources (FHIR) Release 4 and compliance with HL7 U.S. Core FHIR Implementation Guides.

- The AMA appreciates ONC's efforts to address excessive fees charged by electronic health record (EHR) vendors to connect their products with other health IT systems, health information exchanges, and third-party applications. ONC's proposal fee policy attempts to address most scenarios, but the resulting framework is complex and has limited usefulness for physicians. We suggest a more practical approach that includes a tiered fee structure for APIs. For instance, ONC could establish categories where the technology requirements designate the fees.

- Data segmentation is critical for health information exchange, regardless of where the data resides, how it is used, or with whom it is exchanged. Patient consent and privacy, data provenance, governance, and state and federal law compliance must be inherent in technology development. The AMA supports Consent2Share (C2S) as a Base EHR requirement and encourages ONC to increase C2S adoption.

- The AMA supports the need to limit information blocking. Practical regulation is required to establish guiderails for electronic health information (EHI) and exceptions for information blocking practices. However, ONC's EHI and information blocking proposals are too vague. A logical, objective approach is necessary to reduce confusion. ONC should align its information blocking requirements with the certified capabilities of health IT vendors—i.e., the USCDI and APIs. Information blocking should be evaluated through the lens of access, use, and exchange of the USCDI.

- The AMA supports the use of APIs and consumer-facing applications (apps). ONC's proposal includes numerous policies that seek to promote app developers' access and use of EHI. However, the AMA has serious concerns with apps being provided equal protections and benefits with those of patients. Concerningly, apps frequently do not provide patients with clear terms of how that data will be used—licensing patients' data for marketing purposes, leasing or lending aggregated personal information to third parties, or outright selling it. These practices jeopardize

patient privacy, commoditize an individual's most sensitive information, and threaten patient willingness to utilize technology to manage their health. Patients should be the primary authority in designating rights to access, exchange, and use of their data. ONC should require that all certified APIs include mechanisms to strengthen patients' control over their data.

- The AMA recognizes the potential benefits of bulk data access for public and population health and quality improvement. However, we have concerns with the potential pitfalls of entities having unprecedented access to patient information. Important parameters must still be established to maintain patient privacy, data security and usability, and adherence to federal and state law. We urge ONC to take a methodical approach in its promulgation of information blocking and EHI regulation.

- The AMA supports maintaining the Health Insurance Portability and Accountability Act's (HIPAA) minimum necessary standard. However, the proposed rule conflates payers' needs with clinicians' needs to access, exchange, or use health information. Physicians must be permitted to retain their professional judgment to protect their patients' rights or privacy, including their designation for what constitutes minimum necessary.

- AMA research has shown that cyberattacks are inevitable and increasing, and numerous agencies across the federal government recognize cybersecurity as a patient safety issue. ONC's policy allowing an actor (e.g., a consumer-facing app developer) the ability to *read, write,* and *modify* a patient's entire medical record invites cyber-attacks. ONC should do more to ensure EHR vendors develop and test to industry protective measures, prescribed standards, and security protocols.

- The AMA has concern with ONC's interpretation of Health Information Networks (HINs) and other terms. ONC's definitions are inconsistent. This creates separate interpretations, adds subjectivity, and introduces unnecessary vagueness and inconsistency. We strongly recommend that the definition of HIN be narrowed to include only entities that are an actual network (or formalized component of an actual network) and have an actual operational role and responsibility for the network.

- The AMA supports many of the proposals for certified EHR technology (CEHRT). However, ONC's physician adoption timeline is incredibly ambitious and usurps CMS' authority to determine EHR adoption. To prevent significant confusion for physicians about program requirements, we strongly recommend ONC refrain from adjusting the 2015 Edition Base EHR definition and recommend naming a new Edition.

The AMA proudly supported several health IT provisions in the 21st Century Cures Act (Cures). The iterative introduction of information technology in health care has been around for decades. The passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act quickened the pace of EHR adoption and use. Early after its passage, the AMA recognized the potential to improve patient care and reduce costs through the digitization of health information. However, the AMA also had the prescience to identify unintended consequences of hastily deploying health IT without a well-thought-out plan and priorities. Lacking fundamental elements to facilitate safe, effective, and interoperable EHRs, patients and physicians would be negatively impacted. Health IT would stray from being a clinical benefit to a burden. Our concerns have largely been proven right.

The passage of Cures provides an opportunity to correct the course of health IT. Congress wisely included provisions addressing physician burden, EHR usability and vendor practices, interoperability, information blocking, and patient information empowerment. ONC has taken up this charge and proposed a sweeping set of changes to health IT certification as well as a thorough interpretation of congressional intent. **Several of the proposed changes, especially around health IT vendor practices and EHR performance, are welcome and respond to concerns raised by the AMA and clinical community.**

The AMA has also identified proposals that could prove problematic and run counter to the goals Congress set out to achieve in Cures. **ONC's broad interpretation of legislative language, compressed development and adoption timelines, complex regulatory requirements, and a misplaced emphasis on data quantity will dramatically impact patient privacy and safety, data security, and further exacerbate physician burden and concerns with health IT.** Without addressing these issues, the U.S. Department of Health and Human Services (HHS) may fail at meeting the goals set out by Congress in Cures.

The AMA's full comment letter can be found here.