June 20, 2023

U.S. Department of Health and Human Services (HHS) Office of the Secretary
Office of the National Coordinator for Health Information Technology (ONC)
Attention: Micky Tripathi, PhD, MPP, National Coordinator for Health Information Technology

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Notice of Proposed Rulemaking

Dear Dr. Tripathi:

The American Psychiatric Association (APA), the national medical specialty society representing over 38,000 psychiatric physicians and their patients, appreciates the opportunity to comment on the HTI-1 NPRM, particularly in light of the co-occurring mental health and substance use disorder crises facing our health system and the importance of high-quality shared data to improve mental health outcomes. We appreciate the work that the Office of the National Coordinator for Health Information Technology (ONC) invests in understanding the current landscape of clinical care and information technology (IT) solutions as well as work envisioning the future of interoperability. In particular, **APA applauds ONC's creation of an Insights Condition, updates to the real-world testing and patient-requested restriction certification criteria, and advancement of data segmentation strategies for user-centered interoperability.** These standards will improve the accountability and transparency of health IT products to customers, regulators, and policymakers, facilitating meaningful improvement and evolution in analytic capabilities and health outcomes. APA encourages health IT developers to embrace this transparency and accountability and we look forward to supporting ONC in implementing these approaches to support a more interoperable health data landscape.

Implementing interoperable health IT requires that health IT vendors participate in co-designing solutions with clinicians and patients; commit to responsible, consistent design and deployment of standardized tools; and act in good faith to create, the evolution of an interoperable health care data environment. ONC's development of the Insights Condition and additional certification criteria demonstrate commitment to tracking and enforcing adherence to interoperability objectives. In this process, we encourage ONC to identify key elements of the future, ideal state of interoperable health data – including patient-requested restrictions, outcomes measurement tracking and reporting, and seamless integration of external data sources including

prescription drug monitoring programs (PDMPs) and health information exchanges (HIEs) – and collaborate closely with technology and clinical stakeholders to identify maturity models to work toward achievement of these objectives. **We also recommend that ONC expand its current governance structure beyond subject matter experts to include, and support, patients and non-expert clinicians in product testing and reviewing Insights Condition and real-world testing results** to help ONC identify opportunities for enforcement actions and policymaking.

APA has found that, even among users of the same electronic health record (EHR) vendor across different facilities, capabilities and interfaces vary widely. Common clinical data, like measurement-based care tools (e.g., PHQ-9, GAD-7) are often housed in unstructured formats, confounding data-sharing efforts with large amounts of free text, while other measurement-based care tools critical for psychiatric care are not available at all. Tools that have now become considered standard from a population health perspective, like food and housing security screenings, aren't even available in some certified EHRs. Data from outside entities, like PDMPs, HIEs, or other health systems, are often not integrated into the EHR and have to be accessed through a distinct web-based portal with a unique login. In addition, upgrades, when they become available, cost facilities and customers significant money to acquire and come with disruptions to usability and service. **We recommend that ONC use data derived from the Insights Condition, real-world testing criterion, and stakeholder feedback to develop and publicize a gaps analysis of which USCDI elements included in certified EHR technology (CEHRT) are interoperable and usable to hold developers accountable for achieving ONC's interoperability goals.**

Recognizing the significant market of non-certified, specialty-practice EHRs – given the often-unsustainable cost of obtaining and maintaining CEHRT to small or independent practices – and the imperative to improve behavioral health care and outcomes, **we recommend that ONC provide technical assistance to smaller, uncertified, behavioral health-specific health IT firms in achieving interoperability objectives**. Conversations across these parties must demonstrate use cases for shared and integrated data, glidepaths to interoperability, and accountability for vendors that fail to work toward interoperability. **The APA offers the expertise of psychiatrists in partnership with ONC to develop education and support around these objectives that will resonate with clinicians and clinical decision-makers to advance behavioral health outcomes and equity.**

Please see APA's comments on specific elements of the HTI-1 NPRM below.

USCDI v3 adoption
We appreciate ONC's work to solicit updates to and maintain the relevance of the United States Core Data for Interoperability (USCDI) standards, reflecting evolving capabilities across the health data landscape. In particular, the inclusion of social determinants of health (SDOH) data in USCDI is a crucial step toward achieving health equity and outcomes improvement. However, data content and formats may need to be revised and standardized to make these data useful, usable, and used. For example, if social determinants of health goals, as proposed, are in free text formats, it is not possible to link them to metrics or treatment plans. ONC should work with vendors and clinicians to establish standards and formats for these fields that are clinically viable. **ONC should consider predicating certification criteria and compliance on a**

standardized format for data access, use, and exchange as the presence of the required data is not adequate to generate interoperability between platforms and data fields.

These data are also often not adequately nuanced in the medical record to be useful: EHRs often do not include socioeconomic status, education, occupation, living conditions, or access to transportation or other social services. EHRs also do not consistently capture or convey information related to health-related social needs coordination, such as communication with social workers or community support services. Coordination of these services is vital in the care of patients with mental health and substance use disorders. Future efforts can expand the specificity of SDOH-related items in the medical record.

Future standards should also incorporate foundational capabilities for structured measurement-based care modalities (both patient- and provider-reported outcomes measures) to work toward interoperable clinical registry capabilities. Measurement-based care tools in EHRs and other health IT products should enable tracking of patient progress on both individual and population bases and should reflect change over time rather than just point-in-time assessment. These features are critical to the effective integration of mental health care into certified EHRs for care delivery, quality improvement, and reporting purposes. In addition to core behavioral health assessments, like the PHQ-9 depression scale and GAD-7 anxiety scale, ONC should consider requiring certified vendors to develop standard report templates that can be updated with measurement tools to enable tracking of scores for other patient-oriented outcome measures – including for outcomes that are relevant to patient care regardless of the condition, such as pain-related measures and measures of functioning and quality of life over time – rather than leaving those capabilities up to individual vendors and customers. Lack of access to standardizable assessment formats confers burden to customers to create modules critical to high-quality, patient-centered care while stymying efforts at value-based care, quality measurement and improvement, and care coordination.

Finally, USCDI v3 includes many data elements often considered sensitive, such as social determinants of health, mental/cognitive status, sexual orientation, and gender identity. Sharing of such data without guardrails can pose significant patient safety issues for some individuals. **The APA commends ONC for considering polices that support data segmentation and urges ONC to work closely with clinical, patient, technology, and policy partners to advance these priorities in tandem.**

Discontinuing year-themed editions
APA does not support the discontinuation of year-themed editions. If year-themed editions are discontinued, updates should be released no more frequently than every two years with two years for implementation after the changes are finalized and supporting implementation guides are published. Customers bear the cost and operational burden of updates to health IT, and upgrades carry significant risk of temporary loss of usability, access, and data. APA does not support increasing the rate of changes to certification criteria by adopting iterative rather than batched, version-based specifications. It should not be the clinician's responsibility to pay for and opt into the most up-to-date version of an EHR as resource-constrained clinicians who decline specific updates – that may be unaffordable or seem irrelevant to the clinician's practice – may risk falling out of compliance with certification.

Even when vendors are delivering the upgrade remotely, there is significant personnel time required at the practice level to adjust, test, train staff, and effectively deploy these changes. Project plans and organizational change management processes can take many years, and frequent one-off changes disrupt the ability to appropriately plan for and deploy substantive updates that can enhance usability and care quality. For example, an APA member reported that a relatively straightforward update requested by their state health department resulted in hundreds of hours of staff time to implement the change and, eight months later, the change is not fully implemented. Any policies that increase the frequency of updates need to come with a plan for offsetting the operational and financial cost of those updates, including obligating certified vendors to maintain their certified status on behalf of the customer and provide extensive operational support to maintain access, usability, and compliance during updates. **Further, the final rule should clarify who bears the regulatory and financial obligation to maintain the most recent certification criteria in the technology in use by practices – the developer or the customer.**

Decision support interventions
The APA supports ONC's proposal to ensure transparency of the algorithms that train predictive Decision Support Interventions (DSI). In the final rule, we request that ONC clarify:

1) Whether transparency would only be required for the demographic and social determinants of health data used to inform the predictive DSI or whether ONC will implement full data source and algorithmic transparency; and

2) How this information would be made available and accessible to patients, including who would deliver the information, along with how developers will be required to develop necessary patient education about the meaning and importance of the information to accompany any disclosures.

Patient-requested restrictions certification criterion
If the patient-requested restriction criterion is adopted, APA does not support a standards-agnostic approach and requests that ONC maintain a standards-based (FHIR) criterion. Lack of standardization has the potential to worsen disparities and clinician burden as patients treated by resource-rich health systems with vendors who can innovate in this space without adding clinician burden may be able to reap benefits that those treated by health care providers in more resource-constrained areas cannot. Further, we appreciate the efforts to strengthen patient-requested restrictions capabilities in certified health IT, but we recognize that nuanced, robust capabilities to identify, tag, and retract data are not universally present in current technologies and that there is no consensus on a conceptual semantic model that defines "sensitive data." Accordingly, we suggest adoption of a maturity model that facilitates the standards-based development and implementation of incremental approaches to achieving this outcome with minimal disruption to, and cost of, services. While technological advances such as large language models offer the downstream possibility of identifying, tagging, and segmenting data according to patient preference across the medical record, federal investment and collaboration is critical to the comprehensive and effective development and implementation of these strategies incorporating user-centered design, extensive testing and validation, and patient and clinician education around the capabilities, limitations, burden, and risks of these approaches. **APA recommends that ONC convene**

experts from clinical, patient advocacy, technology, and ethics backgrounds to define a maturity model and set rules for any automated methods for segmentation.

Additionally, confusion around information-blocking regulation compliance and limited information-blocking exceptions can lead to the oversharing of sensitive personal health information. Members of Shift, the independent health care task force for equitable interoperability, report inadequate exceptions and operationalization or comprehension of the exceptions to adequately protect information related to reproductive health care and other sensitive data use cases. Current standards have not yet been piloted with a multi-step approval process in mind and would need additional development. Standards for multi-party approvals would need to be newly applied to the patient-requested restrictions use case, and reference implementations could then be developed incrementally.

Real-world testing
APA supports updating the real-world testing Maintenance of Certification criterion to address the potential for the criterion to be skipped for certain developers. To strengthen the usefulness of collecting these data from developers, we recommend that ONC clearly lay out a plan for how these findings will be applied in the policymaking and certification process while holding developers accountable for addressing flaws. The criterion would also be strengthened by requiring the input of patients, clinicians, and other actual users of these products rather than just testing in the intended *setting* of service by superusers.

For this criterion to meaningfully further ONC's objectives, ONC should also consider assessing and facilitating the accessibility of the real-world testing results to customers when shopping for a health IT vendor. APA frequently hears from members about how vendors do not live up to their promises of user-friendliness and interoperability. ONC can put in place strategies for helping customers shop for the highest-quality health IT products while enforcing mitigation of issues in existing technology.

Insights Condition
APA supports ONC's implementation of the Insights Condition to obligate vendors to provide information on the usefulness, usability, and quality of health IT products. We encourage ONC to go further in making use of this initiative to significantly improve the interoperable health data landscape. Data from the Insights Condition, much like the real-world testing criterion, should be used to publicly and iteratively inform quality improvement and enforcement processes in certified health IT products. In the final rule, ONC should define a clear and accessible pathway for public access to these data as well as how identified issues will be mitigated by the vendor. Methodological transparency is also essential to inform customers, regulators, and policymakers about what the Insights Condition was testing, how testing was performed, and what the reporting tells us about achievement of interoperability objectives. ONC should also ensure that no additional operational burden is conferred to customers or users of the product to conduct this testing, or the burden could significantly outweigh the benefits.

Information-blocking

APA supports the expansion of the infeasibility exception to include records that the third party is requesting in order to modify electronic health information. APA recommends that ONC maintain this approach while increasing interoperability by allowing third parties to suggest, or annotate, changes to a medical record without the authorization to modify the record without clinician approval. For example, while it is recommended that ONC work toward increased interoperability between health IT products and external data hosts, like PDMPs, HIEs, or immunization registries, all processes should require a preapproval step that allows the third parties to suggest revisions to the medical record rather than overwrite existing inputs. **In the final rule, ONC should clarify this exception in plain language with examples for clinicians and clinical decision-makers to better understand.**

Finally, there is widespread confusion about what is and is not allowed under information-blocking regulations. This can cause information to be shared inappropriately or inappropriately restrict sharing of information based on fear of noncompliance. Absent the technical capability to comply with federal or state law and regulation, or to meet patients' preferences to withhold EHI, current information-blocking exceptions are insufficient to accurately protect patients from the disclosure of sensitive personal health information while facilitating appropriate data-sharing. **The APA urges ONC to create plain-language guides and technical assistance materials that clearly identify reasonable and necessary activities that do not constitute information-blocking in instances of an actor withholding the access, exchange, or use of sensitive EHI and that illustrate compliant data flows that reflect current law and patient preference.**

Thank you for your review and consideration of these comments. If you have any questions or would like to discuss any of these comments further, please contact Abby Worthen (aworthen@psych.org), Deputy Director, Digital Health.

Sincerely,

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