June 20, 2023

Micky Tripathi
Director, Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (RIN 0955-AA03)

Dear Director Tripathi:

On behalf of the Connecting for Better Health coalition, we write in response to the Office of the National Coordinator for Health Information Technology's (ONC) proposed rule "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" (HTI-1) published on April 18, 2023. We are generally supportive of the proposed rule and welcome the opportunity to provide comment and recommendations.

Connecting for Better Health is a coalition representing diverse health care organizations and leaders including consumers, providers, and health plans, that supports the advancement of health data exchange policy in California. Our vision is that every Californian and their care team have the information and insights they need to make health care seamless, high quality, and affordable. Ensuring that certified electronic health technology is interoperable, and advances health equity, is key to ensuring that actors in California are able to support data sharing that can improve care for the whole person.

We respectfully provide the following comments to ONC:

**We support ONC's effort to define and regulate Decision Support Interventions.** We support ONC's proposal to establish a Decision Support Interventions (DSI) certification criterion. We agree that algorithmic transparency promotes the exercise of a provider's judgment at the point of care, which can help avoid errors and mitigate algorithmic biases. Relatedly, we support ONC's proposal to require certified Health IT Modules with predictive DSIs to enable users to review information that may be pertinent to health equity concerns, to require developers to employ
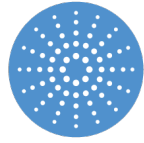
risk management practices for DSIs, and to require that risk management practices be made public. These proposals would address pressing concerns that artificial intelligence algorithms can reinforce biases related to socioeconomic status, race, ethnicity, gender, sexuality and other identities and conditions. Recent advances in artificial intelligence stand to benefit providers and patients by enhancing the information a provider has at the point of care to improve patient outcomes; however, they also stand to potentially harm patients by reinforcing implicit and explicit biases that do not reflect our country's diverse population and that may only increase health inequities. Public transparency requirements for source attribute information are an important measure to avoid exacerbating these inequities. If patients understand how their data is used, they can better hold their providers (and their technology) to higher standards of care, which benefits the entire health system.

**We support ONC's proposal to make changes to the information blocking rule's infeasibility exception.** We support ONC's proposal to clarify when actors can claim the infeasibility exception to the information blocking rule. The addition of further definition to the "uncontrollable events" condition and to the second condition that actors exhaust the manner exception. This proposal strikes the right balance by allowing for an exception to the information blocking rule in instances where an actor is unable to meet their legal obligations due to an uncontrollable event and the actor has exhausted the manner exception and cannot technically share its information. This proposal would both support the infeasibility exception of a causal link between the uncontrollable event an inability to share information, and conversely, the need for requesters of information to ensure that their products are built using interoperable, standard-based methods that can technically receive information in standards-based manners.

**We support ONC's proposal to permit providers to rely on the Trusted Exchange Framework and Common Agreement (TEFCA) in support of their compliance with the federal Information Blocking Rule.** We support national efforts to streamline the exchange of health care information. Deeming TEFCA participation as substantial compliance with Information Blocking rule, as the proposal does through the TEFCA Manner Exception, could serve as a powerful incentive for providers to engage in a national system for sharing health information in addition to state-specific efforts like California's Data Exchange Framework.

**ONC should include electronic prior authorization within HTI-1 for EHR certification, once CMS has finalized its rule.** We recommend that ONC incorporate a likely Centers for Medicare and Medicaid Services (CMS) final rule on electronic prior authorization (ePA) (CMS 0057-P) in HTI-1,
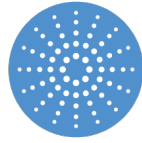
once that rule is finalized. Electronic prior authorization stands to benefit providers, payers, and ultimately patients by streamlining the prior authorization process utilizing electronic health record data. Contingent on the final rule promulgated by CMS, ONC should work to collaborate with CMS, stakeholders, and standard-setting agencies like HL7 to ensure robust testing of the proposed HL7 Implementation Guides, and ensure alignment between payers and EHR vendors and the standards required of these stakeholders.

**We support ONC's proposal to require that health IT developers support patient preferences, and we recommend that ONC support a maturity model for DS4P to support this and other segmentation efforts.** ONC has proposed a patient-requested restrictions criterion in HTI-1. This criterion would support instances, including those required under HIPAA, where patients request a restriction on uses and disclosures of their information. We support this proposal, as it will further patient privacy preferences. However, in light of both this proposal, as well as efforts at both the federal and state levels to place prohibitions on certain uses and disclosures of reproductive health care and other information, we recommend that ONC also consider supporting a maturity model for DS4P to support these complementary efforts, and to assist certified EHR technology vendors in establishing new, more granular standards. States such as California currently have bills introduced (AB 352) that would both require vendors to ensure their products can segment data, as well as require that providers and other organizations prevent certain uses or disclosures of reproductive health care and other information across state lines. To do this work effectively, developers, providers, and other actors will need to be able to adequately and consistently flag these data to ensure they are not shared. However, a common vocabulary is required to ensure that all actors are utilizing the same syntax and semantics in flagging and segmenting these types of data. For example, there are numerous ways to describe an abortion, whether utilizing more general terms (abortion or termination) and/or more precise terms to describe the methods (dilation and extraction or dilation and evacuation). Without a common approach and set of terms and definitions, actors will be left to develop such standards on their own.

We appreciate the opportunity to submit these comments. If you have any questions, please contact Robby Franceschini, Director of Policy at BluePath Health, at robby.franceschini@bluepathhealth.com.

Sincerely,
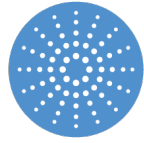
Timi Leslie

Director, Connecting for Better Health

Founder and President, BluePath Health