



June 20, 2023

2023

President

Robert Brodsky, MD
Johns Hopkins University
Ross Building, Room 1025
720 Rutland Avenue
Baltimore, MD 21205
Phone 410-502-2546

President-Elect

Mohandas Naria, DSc
New York Blood Center
310 E 67th Street
New York, NY 10065
Phone 212-570-3056

Vice President

Belinda Avalos, MD
Atrium Health
215 N. Pine Street, Unit 4703
Charlotte, NC 28202
Phone 980-442-2000

Secretary

Cynthia Dunbar, MD
NHLBI/NIH
Translational Stem Cell Biology Branch
Building 10-CRC, Room 5E-3332
10 Center Drive
Bethesda, MD 20892
Phone 301-402-1363

Treasurer

Joseph Mikhael, MD, FRCPC, MEd
Translational Genomics Research Institute,
City of Hope Cancer Center
445 N. Fifth Street
Phoenix, AZ 85004
Phone 602-343-8445

Councillors

Christopher Flowers, MD, MS
Alison Loren, MD, MS
Bob Löwenberg, MD, PhD
Charlotte Niemeyer, MD
Sarah O'Brien, MD, MSc
Betty Pace, MD
Jamil Shammo, MD
Wendy Stock, MD, MA

Executive Director

Martha Liggett, Esq.

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Health Data, Technology, and Interoperability: Certification Program
Updates, Algorithm Transparency, and Information Sharing Proposed Rule
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Submitted via: www.regulations.gov.

Re: Health Data, Technology, and Interoperability: Certification Program Updates,
Algorithm Transparency, and Information Sharing (HTI-1) RIN 0955-AA03

Dear ONC Staff,

The American Society of Hematology (ASH) appreciates the opportunity to provide comments on *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) RIN 0955-AA03*. We are pleased to share comments on several of the policies as proposed in the rule, including:

- Certification for Decision Support Interventions and Predictive Models; and
- Pharmacy Interoperability Functionality within the ONC Health IT Certification Program.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

Certification for Decision Support Interventions and Predictive Models

In this rule, ONC has proposed several changes to the functionalities of clinical decision support (CDS) interventions given that technology used to support clinical-decision making has rapidly evolved since the first set of requirements were established. As such, proposals to modify the standards that certified health IT developers must adhere to are as follows:

- Health IT Modules that enable or interface with predictive Decision Support Interventions (DSIs) allow a user to review predictive DSI “source attribute” information through the Health IT Module.
- Developers of certified health IT with Health IT Modules that enable or interface with predictive DSIs employ or engage in “intervention risk management” practices and that summary information regarding these intervention risk management practices be made available via a publicly accessible hyperlink.

ASH supports the development of these standards and offers the following comments for consideration. We believe that the use of decision support and predictive models has a future, if it is not already here, in the diagnosis and treatment of hematologic diseases. However, we also believe that while utilizing technology in this manner, it is imperative to establish effective guardrails to ensure safety of the patient, protect physician’s decision-making processes, and uphold physician autonomy.

ASH believes that health IT companies building predictive models must be transparent about the data being used to create the program, including how frequently a predictive model database is updated. Transparency about the data used and the frequency of updates is paramount to the clinical utility of the model’s decisions. Furthermore, it will be essential to promote transparency in the underlying logic of the model itself. Predictive algorithms can be quite complex; for clinicians and patients to trust and use them, steps must be taken to promote interpretability of the model. Explanations of how the models work in general, and when applied to specific clinical situations, will help clinicians understand and trust these promising new tools.

Additionally, the data must be of high quality and updated frequently to allow the predictive models and decision support to adjust to changes in treatment successes and failures, adjust to changes in practice patterns and to adjust to changes in advances in technology and development of new treatment regimens. Medical specialty societies such as ASH create evidence-based treatment guidelines for our members that often take years to develop. We suggest that decision support technology incorporate these types of guidelines into their databases. In addition, as algorithms are developed to support medical decision making, ASH recommends that predictive models are created through close collaboration of technical experts, physicians and other qualified healthcare professionals.

While ASH supports the use of predictive modeling and decision support tools, often collectively called artificial intelligence (AI), we have concerns when it comes to protecting physicians that use the technology. For instance, the Society believes that physicians should not be held responsible when the physician’s recommendation is overridden by AI and the treatment or course of action subsequently fails. Physicians should maintain their autonomy in medical decision making and may use AI as a tool in reaching a final decision, diagnosis, or course of action. The use of AI should never be punitive.

Finally, AI models and tools must be created with data that are inclusive and does not perpetuate health inequities. Bias in underlying data will introduce bias into algorithms and must be avoided. The information within a model must fit the population for which the model is being consulted. The data

cannot be a “one size fits all” as different population cohorts require different treatment considerations.

Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities Request for Information

The proposed rule includes several requests for information (RFI), one of which seeks information from the public on the issues related to establishing certification criteria that could support complementary and interoperable workflows between physicians and pharmacies. ASH believes that interoperability is key to decreasing physician burnout and reducing administrative burden. ASH supports the criteria that ONC have created for the certification of health IT modules used in real-time prescription benefit programs.¹ We offer the following additional items for consideration:

- Information on step therapy and pricing should be readily accessible. Having this information available while the patient is in the office or clinic creates a better opportunity to have conversations with their provider about the coverage of the therapy, rather after the patient visit has concluded.
- Information on prior approval, if needed, should be readily available when prescriptions are transferred to the pharmacy.
- If there is a preferred drug within a class or category of drugs, this information should be made available. This information can be helpful for providers and patients in making informed decisions about treatment options.
- Incorporating electronic prior authorization (ePA) into real-time prescription benefit functionality would benefit physicians and their staff by reducing burden and time consuming manual prior authorizations.
- Patients benefit from the use of ePA as well by having information immediately so that they can make decisions about their care and understand their responsibilities in paying for that care.

We appreciate that the ONC is working towards a more connected and streamlined healthcare technology system. We see this as an invaluable opportunity to alleviate physicians’ burnout and administrative burden to allow our members to spend more of their time on patient care.

Our Society thanks ONC for the opportunity to share these comments. Should you have any questions or require further information, please contact Suzanne Leous, ASH’s Chief Policy Officer, at sleous@hematology.org.

Sincerely,



Robert A. Brodsky, MD

¹ Federal Register, Vol. 88, No. 74, pg. 23849.