

October 4, 2024

Micky Tripathi, PhD, MPP
National Coordinator
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW, 7th Floor
Washington, DC 20024

Submitted electronically via <http://www.regulations.gov>

Re: RIN 0955-AA06 HTI-2 NPRM

Dear Assistant Secretary Tripathi,

The Society of Gynecologic Oncology (SGO) appreciates the opportunity to provide comments on the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology's (ASTP/ONC) Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule.

The SGO is the premier medical specialty society for healthcare professionals trained in the comprehensive management of gynecologic cancers. Our more than 3,000 members include physicians, advanced practice providers, nurses, and patient advocates who collaborate with the SGO's foundation, the Foundation for Women's Cancer, to increase awareness of gynecologic cancers and improve the care of those diagnosed with gynecologic cancers. Our mission focuses on supporting research, disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations dedicated to gynecologic cancers and related fields, all with the ultimate vision of eradicating gynecologic cancers.

Protecting Care Access Exception

The proposed rule proposes an exception for providers whereby they will not be considered an information blocker when there is a good faith belief that sharing electronic health information (EHI) related to reproductive health may result in potential exposure to legal action.

Following the *Dobbs v. Jackson Women's Health Organization* decision, reproductive health data is increasingly being weaponized by state officials and others.¹ States are targeting individuals who receive or facilitate access to reproductive health care, often identifying them through medical records requests. Confusion surrounding information blocking regulations, and associated exceptions, further facilitates unrestricted access to EHI. Currently, there are no exceptions specifically designed to address concerns about the legal risks (e.g., investigations, court actions, or liability) that could arise from the access, exchange, or use of specific EHI.

Given the very nature of the types of care our members provide, which includes helping patients make difficult decisions about their reproductive health due to cancer, we strongly recommend that the ASTP/ONC finalize this proposed exception. Gynecologic oncologists need the ability to make care decisions and share or not information as needed, without fear of being accused of

¹ *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022)

information blocking, and without fear of legal action being taken against them for providing care that is lifesaving to their patients. If finalized, the exception will provide gynecologic oncologists and other practitioners with the necessary protection to allow withholding of healthcare information when that information may be used as a means to bring legal action against either the practitioner or the patient under circumstances regarding reproductive healthcare.

Requestor Preference Exception

There may be instances when a requestor (patient) has specific preferences as to the types of information immediately available to them. Many patients value the release of the health care records and test results as soon as those items are available, however, some patients may choose to have life-changing test results or other information withheld until such time that their provider is able to review and discuss directly with the patient. Due to current information blocking regulations which mandate that all EHI information is immediately available, patients and practitioners do not have a choice when information is disclosed. This proposed change gives the patient and the provider a choice without the risk of a practitioner being in violation of the information blocking rules.

Additionally, the exception as proposed will allow patients to inform their practitioners of the types of information they would like released immediately, and the types of information they would like withheld. The SGO supports this proposal given the sensitive nature of the care gynecology oncologists provide, and the life-changing effects certain diagnoses have on our patients. We believe that the physician and the patient should have the option to review together life-changing diagnoses, associated treatments, and medical interventions needed.

However, while endorsing this proposed exception, we also provide the following comments to ensure that the exception, if finalized, operates as it should. Honoring a patient's request to delay or limit the release of results or reports is only possible if the technical capability exists. Meaning that the electronic health record interface or patient portal would need to be designed to allow the patient to electronically select which laboratory test results they want delayed within their EHR portal or medical record application. If the EHR lacks this technical capability, the request to withhold information cannot be fulfilled. Therefore, we urge ASTP/ONC to establish a certification criterion that would require health IT developers to provide the technical capability to delay certain medical information, allow patients to control alerts for new results or reports, and specify how and when medical information is available. Without the necessary technical capability, patients' preferences cannot be fully honored, and those who fear receiving life-changing information may still experience harm.

ASTP/ONC proposes a *request* condition where, for this exception to apply, that patients must express their preferences in writing. ASTP/ONC states that this requirement is intended to prevent inappropriate use of the exception or retroactive attempts to "justify" an actor's decision to meet their patient's preferences. However, requiring patients to express their preferences in writing may undermine the flexibility and responsiveness that are crucial to the physician-patient relationship. In many cases, patients may not have the capacity or resources to provide written consent, especially in urgent or sensitive situations. Verbal communication often serves as the most immediate and effective means of conveying preferences, particularly in environments where patients are vulnerable or when language barriers exist. By insisting on written documentation, ASTP/ONC's proposal risks alienating those very patients it aims to protect, potentially leading to unmet needs and compromised care. The SGO suggests if the written request language is finalized that there be certain situations and conditions when a preference provided verbally is acceptable, particularly in the case of urgent situations.

Improving Prior Authorization and Benefit Transparency

The SGO continues to support policy changes and the exchange of health information that streamlines the prior authorization (PA) process and ensures timely access to patient care. Delays in receiving PA requests often lead to patient anxiety, delays in care delivery, and place significant emotional burden on the patient. The care we provide for our patients is at times very urgent and waiting for a PA decision is not practical, but the ASTP/ONC proposal to add payer and physician application programming interfaces (APIs) into the base electronic health record definition will create processes that allow for more timely PA interactions between providers and payers. Requiring EHR developers to include this API interfaces to into EHR program software will help achieve this goal.

The SGO also supports the addition of electronic prescribing and real-time prescription benefit (RTPB) technology into the base EHR definition, as well as certification criteria requiring support of the National Council for Prescription Drug Programs (NCPDP) electronic PA and RTPB standards. Increasing physician access to these high-value functionalities will address well-known transparency issues and administrative burdens related to drug prescribing and PA. Gynecologic oncologists often need to urgently administer life-saving chemotherapy drugs to patients and we support policy changes that allow them to do just that. Requiring certified EHRs to support these critical functionalities will improve the transparency and efficiency of drug prescribing and the PA process, and benefit both physicians and patients.

In closing, the SGO thanks the ASTP/ONC for the opportunity to provide these comments. Should you have any questions or require further information, please contact Kay Moyer, Director of Regulatory Affairs, CRD Associates, kmoyer@dc-crd.com.

Sincerely,



Amanda Nickles Fader, MD
President, Society of Gynecologic Oncology
amanda.fader@sgo.org