

February 27, 2026

Michael Lipinski

Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW, Washington, DC 20201

Re: [HHS-ONC-2025-0005] Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity

Dear Mr. Lipinski:

The American Association for Justice (AAJ), formerly known as the Association of Trial Lawyers of America (ATLA), hereby submits comments on the Department of Health and Human Services' (HHS) proposed rule *Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity*.

AAJ was established 80 years ago to safeguard victims' rights, strengthen the civil justice system, promote injury prevention, and foster transparency. We work to ensure that all impacted individuals retain their ability to hold the parties responsible for causing harm accountable under the law.

As AAJ's member attorneys represent families across the country whose lives have been forever impacted by medical negligence and errors in the healthcare system, we strongly believe that federal protections must safeguard the integrity of information concerning a patient's health. These electronic health records (EHRs) and the accompanying audit trail are vital sources of evidence—and often effectively the *only* objective witness—in determining the truth when people are hurt in our healthcare system. Accordingly, it is essential that both transparency and accountability concerning patient health information are preserved.

It is for this reason that AAJ opposes HHS' proposed rule, which would undermine the security of patient health information and eliminate several requirements under the Office of the National Coordinator's (ONC) Health IT Certification Program altogether. While the goal of the program that HHS now seeks to modify is to ensure the quality, security, and interoperability of EHRs, the reality is that the proposed rule—rather than promoting innovation, as HHS claims—would be a significant step in the opposite direction, as it would reduce transparency and erode accountability in our healthcare system at the expense of patient safety.¹

¹ [Certification of Health IT](https://healthit.gov/certification-health-it/), Assistant Sec'y for Tech. Pol'y, (Jan. 21, 2026), <https://healthit.gov/certification-health-it/>.

I. The proposed rule revokes requirements to ensure the integrity of EHRs and protect patient safety.

The proposed rule would effectuate sweeping changes to ONC’s Health IT Certification Program, wiping out over half of the program’s existing technical mandates and weakening others.² The technical standards that would be eviscerated by the proposed rule are foundational to the integrity of patient health information and the associated audit trail—and gutting these protections as HHS now proposes to do would usher in a wave of obfuscation that would severely undercut patients’ rights to know the truth about their health.

A. The proposed rule removes protections to prevent tampering with and otherwise improperly altering patients’ health records.

In its proposed rule, HHS proposes to rescind two certification criteria governing who is allowed to edit audit logs and when they are allowed to do so,³ which are essential to ensuring the integrity of medical records by preventing tampering with or unauthorized editing of records. Specifically, the technical standards that HHS seeks to revoke require that EHR platforms must be able to record actions and edits to electronic health information (EHI), indicate when an audit log is enabled or disabled, and record the encryption status of EHI on the platform.⁴ These regulations further mandate that EHR platforms are set by default to record actions and edits in an audit log, and that the disabling of any capabilities listed in these regulations must be recorded.⁵

If these technical standards are abolished as HHS now urges, HHS runs the risk of allowing for EHR software that permits flexible editing histories. As a result, medical providers would be permitted to give patients medical records without any trace of edits or changes that may have been made. Providers would likewise no longer be required by law to establish a virtual “chain of custody” of health records to patients. Because it is critical that patients have access to accurate health records—especially when hurt when receiving medical care—HHS must reject this proposal to compromise the integrity of patient health information and transparency in medical recordkeeping.

² Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity, 90 Fed. Reg. 60970, 60973 (proposed Dec. 29, 2025) (to be codified at 45 C.F.R. §§ 170 and 171).

³ *Id.* at 61018.

⁴ *See* 45 C.F.R. § 170.315(d)(2)(i)(A-C) (2025); *see also* 45 C.F.R. § 170.315(d)(10) (2025); “Auditing actions on health information.

(i) By default, be set to record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1).

(ii) If technology permits auditing to be disabled, the ability to do so must be restricted to a limited set of users.

(iii) Actions recorded related to electronic health information must not be capable of being changed, overwritten, or deleted by the technology.

(iv) Technology must be able to detect whether the audit log has been altered.”

⁵ *Id.* at (d)(2)(i-v).

B. The proposed rule eliminates technical mandates intended to ensure the safe use of artificial intelligence (AI) and prevent software errors in medical decision-making.

This proposed rule would also extinguish two requirements of the ONC Certification Program that are key to safeguarding patients from errors arising from the use of AI in medical decision-making.⁶

One of the certification criteria that HHS seeks to eliminate governs the use of Decision Support Interventions (DSI) and AI on EHI platforms. DSIs are “technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis.”⁷ This technical standard mandates that only certain users can configure medical interventions based on select data, and that the source attributes must be included for all suggested interventions.⁸

While DSIs help medical providers to provide efficient care to patients, the fact remains that—without the safeguards that HHS now suggests doing away with—patients are at risk of adverse outcomes. Source attribution is a necessary component in understanding why a DSI may be recommending a particular treatment for a patient, and without this data, a patient who has been injured will be unable to know why his caregivers decided to either follow or disregard a DSI in determining his course of treatment. As a result, eradicating this requirement would subvert patients’ ability to access information that is needed to gain a full picture of the decisions that were made by their healthcare providers.

The second certification criterion HHS proposes to revoke regulates user-centered design processes.⁹ This technical standard dictates that design processes—such as those meant to prevent user errors—must go through a certain testing protocol that includes the submission of test data to the ONC.¹⁰ Nullifying this requirement under the proposed rule would invite the risk of untested and defective software reaching the market and creating the potential for adverse patient outcomes due to software errors, posing additional risks to patient safety and further reducing transparency when it comes to patients’ health records.

⁶ 45 C.F.R. § 170.315(b)(11) (2025); 45 C.F.R. § 170.315(g)(3) (2025).

⁷ Off. of the Nat’l Coordinator for Health Info. Tech., Decision Support Interventions (DSI) Fact Sheet: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule 2023).

⁸ 45 C.F.R. § 170.315(b)(11)(iv).

⁹ 45 C.F.R. § 170.315(g)(3).

¹⁰ *Id.* at § (g)(3)(iv-v)

II. The proposed rule fails to define provider chat platforms as EHI, causing these chat logs to be improperly excluded from patient medical records.

In addition to the wholesale elimination of provisions that are important for the integrity of EHRs and patient safety as outlined above, the proposed rule fails to revise the definition of EHI to include provider chat platforms. As a result, the proposed rule would not capture large swaths of information, further detracting from the ability of patients and their families to learn what happened when people are hurt in our healthcare system.

Because the proposed rule does not define provider chat platforms as EHI, the information that healthcare professionals store in these tools—including TigerText, Doximity, and Spok¹¹—would not be available to patients. Importantly, these platforms—which are increasingly used by medical professionals—contain private patient information, deliberations on care, and the decision-making processes that physicians engage in while caring for patients. In the interest of transparency and accountability, HHS should update its definition of EHI to include these communications.

For all of these reasons, AAJ urges HHS to reject the proposed modifications to the ONC Certification Program. While a strong audit trail standard that prioritizes the preservation of patient information is essential to the integrity of our healthcare system, this proposed rule represents a decisive move in the opposite direction.

We thank you for the opportunity to submit comments. If you have any questions, please reach out to Elli Schank at elli.schank@justice.org.

Respectfully submitted.



Bruce Plaxen
President
American Association for Justice

¹¹ *AI That Orchestrates Care Across The Hospital*, tigerconnect, <https://tigerconnect.com/?nab=0> (last visited Feb. 25, 2026); Doximity, <https://www.doximity.com/> (last visited Feb. 25, 2026); Spok, <https://www.spok.com/> (last visited Feb. 25, 2026).