

PUBLIC POLICY RESILIENCE INSTITUTE (PPRI)

Nonpartisan policy research and implementation accountability

Public Comment on Proposed Rule

Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (Proposed Rule)¹

45 C.F.R. Parts 170 and 171

Submitted via Regulations.gov

Acronyms

ASTP/ONC — Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology

EHI — Electronic Health Information

VDT — View, Download, and Transmit

WCAG — Web Content Accessibility Guidelines

DSI — Decision Support Intervention

LEP — Limited English Proficiency

CFR — Code of Federal Regulations

Fed. Reg. — Federal Register

Cover Sheet

Position: Support with conditions (guardrails)

PPRI supports deregulatory streamlining and modernization only where it reduces unnecessary compliance burden without shifting burden onto patients—particularly older adults, people with disabilities, individuals with limited English proficiency (LEP), and those who rely on caregivers or authorized representatives to access and use electronic health information (EHI).¹ PPRI's support is therefore conditional: if the final rule removes certification-era safeguards, ONC should adopt specific, testable substitute requirements so that deregulation does not create a measurable access, safety, or accountability gap.

Public-information assurance

PPRI's comments rely solely on publicly available information and the proposed rule text. PPRI does not use or rely on nonpublic information.

Disclaimer: This submission reflects policy analysis and recommendations based on publicly available information and the proposed rule text. It is not legal advice and does not create an attorney-client relationship.

Perspective: PPRI provides governance- and implementation-focused policy analysis informed by service delivery and administrative practice, relying solely on publicly available information.

Summary of conditions for support

PPRI recommends ONC finalize deregulatory revisions only if ONC retains or replaces measurable safeguards in five areas:

- Accessibility baseline for patient access (retain WCAG conformance or adopt a functionally equivalent, testable baseline).³
- Inclusive design accountability (replace removed transparency with a binding, testable substitute mechanism—e.g., a standardized public attestation, testing cadence, and remediation pathway—rather than relying solely on general statements that other laws apply).⁴
- Predictive DSI (AI) accountability (retain minimum transparency and monitoring expectations proportional to risk).⁵
- Privacy/security assurance (if ONC removes privacy/security certification criteria and framework, replace with an assurance floor that is explicit, enforceable, and testable, so baseline security and auditability expectations do not become optional or unevenly implemented).⁶
- Administrative/adjudicative access impacts (explicitly assess how final changes affect people who must obtain records for benefits-related determinations and similar processes).

Comment

1) General support—provided ONC prevents burden-shifting

PPRI supports deregulatory actions that reduce duplicative compliance costs and improve interoperability and patient access in practice.¹ However, ONC should not remove ex ante safeguards in ways that relocate cost, delay, or usability barriers to patients and caregivers. A certification program should preserve real-world access—not only theoretical access.

2) Patient access and accessibility: retain a measurable baseline

A. VDT: retain WCAG conformance or a functionally equivalent testable baseline

ONC proposes removing the WCAG conformance requirement from the View, Download, and Transmit to 3rd party (VDT) certification criterion at 45 C.F.R. § 170.315(e)(1)(i).³ PPRI recommends ONC retain WCAG conformance or adopt a functionally equivalent, testable accessibility baseline paired with a clear remediation pathway. Patients should not bear the burden of accessibility failures through workarounds, delays, or reliance on third parties to obtain usable records.

B. Accessibility-centered design: replace removed transparency with a lightweight accountability mechanism

ONC proposes removing the health IT accessibility-centered design certification criterion at 45 C.F.R. § 170.315(g)(5).⁴ PPRI recognizes ONC's point that other legal obligations remain in force; however, those obligations do not replace the value of a measurable certification-era signal. If ONC removes this criterion, ONC should adopt a binding, lightweight substitute that preserves transparency and accountability—such as a standardized public accessibility attestation describing (1) the standard used, (2) testing cadence, (3) an accessibility support/escalation contact, and (4) a defined remediation timeline for material accessibility defects.

3) Predictive decision support (AI/ML): retain minimum guardrails proportional to risk

ONC proposes removing specified transparency and risk management elements for predictive Decision Support Interventions (DSIs), including provisions identified in 45 C.F.R. § 170.315(b)(11)(iv)–(vi).⁵ PPRI supports innovation and burden reduction where appropriate, but ONC should retain fit-for-purpose minimum guardrails for predictive DSIs used in clinical settings: (1) intended use and limitations, (2) monitoring and feedback loops, (3) auditability, and (4) clear human override pathways. These guardrails remain narrow, testable, and consistent with a risk-based approach.

4) Privacy/security: if ONC removes criteria, replace with an assurance floor

ONC proposes removing all privacy and security certification criteria at 45 C.F.R. § 170.315(d) and removing the Privacy and Security Certification Framework at 45 C.F.R. § 170.550(h) (as of the effective date of a subsequent final rule).⁶ PPRI recommends ONC pair any such removal with an alternative assurance floor that is explicit and testable (not merely discussed in preamble), so that API-era interoperability does not

proceed without baseline security and auditability expectations that purchasers and the public can reliably assess.

5) Administrative and adjudicative access impacts: address foreseeable access barriers (neutral, non-agency-specific)

PPRI urges ONC to explicitly assess how changes to patient access functionality, accessibility baselines, and privacy/security certification expectations affect individuals who must obtain and submit medical records for benefits-related determinations and other administrative or adjudicative processes. These processes rely on timely, usable records access. Accessibility regressions and “portal/app-only” practical pathways can create predictable delays and increased reliance on third-party assistance.

Recommendation: ONC should include an implementation monitoring plan tracking patient-access failures, accessibility regressions, and complaint trends across affected populations, and should define corrective actions when barriers increase.

Conclusion

PPRI supports modernization and burden reduction consistent with the proposed rule’s stated objectives.¹ PPRI recommends ONC finalize deregulatory changes only with the conditions above to ensure burden reduction does not become burden shifting, and to ensure patient access remains measurable, equitable, and reliable.

Respectfully submitted,

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PPRI provides the following citations to enable rapid verification of the specific provisions addressed in this comment.

Footnotes (PPRI public comment style)

1. Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity, 90 Fed. Reg. 60970 (Dec. 29, 2025) (proposed rule).

2. Id. at 60971 (discussion of Executive Order 14192).

3. Id. at 60990–60991 (proposed removal of WCAG conformance requirement for VDT) (referencing 45 C.F.R. § 170.315(e)(1)(i)).

4. Id. at 60997 (proposed removal of accessibility-centered design certification criterion) (referencing 45 C.F.R. § 170.315(g)(5)).

5. Id. at 60987 (predictive DSI provisions; discussion of removing source attribute transparency and intervention risk management requirements) (referencing 45 C.F.R. § 170.315(b)(11)(iv)–(vi)).

6. Id. at 60988–60990 (proposal to remove privacy/security certification criteria and framework) (referencing 45 C.F.R. § 170.315(d) and § 170.550(h)).