Advancing High Performance Health

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Information Blocking: Expand the Definition of "Patient Harm" to Include Psychological and Emotional Harm

Overview

The Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology (ASTP/ONC) currently defines patient harm narrowly at 45 CFR § 171.201. This strict definition creates unintended consequences that can traumatize patients when life-altering diagnoses are delivered through automated systems without clinical context or support.

Expanding the Preventing Harm Exception to allow for up to a 72-hour pause to address potential psychological or emotional harm would uphold the Department of Health and Human Services' (HHS') commitment to patient access while aligning with the principles of patient-centered care.

AMGA's Policy Recommendations

AMGA urges ASTP/ONC to explicitly recognize mental and emotional harm as legitimate grounds for applying the Preventing Harm Exception by:

1. Expanding the harm definition in 45 CFR § 171.201(d) and subregulatory guidance to include mental or emotional harm when based on individualized clinical judgment.
2. Codifying a safe harbor for good-faith clinician discretion, allowing providers to delay release of sensitive results for up to 72 hours to ensure results are reviewed, interpreted, and communicated with compassion.
3. Collaborating with electronic health record (EHR) developers and clinicians to incorporate features that promote patient understanding of released test results, such as embedded plain-language explanations, educational resources, and automated follow-up scheduling tools.

This framework would preserve the intent of 45 CFR § 171.201 while recognizing that serious psychological trauma can be as consequential to patient well-being as physical harm.

Background

The 21st Century Cures Act (2016) established information blocking provisions to promote patient access to electronic health information (EHI). The Preventing Harm Exception at 45 CFR § 171.20 permits healthcare actors to temporarily delay information access when they hold "a reasonable belief that the practice will substantially reduce a risk of harm to a patient or another natural person." However, the current regulation limits what constitutes actionable "harm" by referencing the HIPAA Privacy Rule at 45 CFR § 164.524(a)(3)(i-iii), which primarily focuses on:

- **Physical safety risks:** When access is "reasonably likely to endanger the life or physical safety of the individual or another person."
- **Substantial harm to others:** When information references another person and access would cause them "substantial harm."
- **Harm to the patient from a representative:** When a legal representative's access would cause "substantial harm to the individual or another person."

Because 45 CFR § 164.524(a)(3)(i) excludes psychological and emotional considerations from the HIPAA standard of "physical safety," healthcare providers cannot delay release of results, even when severe emotional distress is foreseeable and preventable through brief clinical intervention.

This rigid interpretation has had real-world consequences. AMGA members report cases in which patients have learned of devastating diagnoses through automated portal notifications before any provider contact could occur, including:

- Cancer diagnoses delivered via electronic portal message without oncology consultation
- Miscarriage confirmations received through lab results before provider follow-up
- Infectious disease diagnoses such as HIV/AIDS released without counseling resources
- Genetic testing results indicating serious hereditary conditions without prior genetic counseling

Even less severe examples underscore the need for flexibility. Patients frequently misinterpret abnormal but clinically insignificant results, leading to unnecessary emergency visits, or are reassured by partial results and leave care prematurely. Others receive potentially alarming pathology reports late on a Friday evening, without access to clinical guidance until the following week.

These incidents demonstrate how the current "immediate release" requirement, though well-intentioned, can inflict preventable psychological trauma and disrupt continuity of care.

Conclusion

AMGA strongly supports the principle of patient access to health information but urges ASTP/ONC to ensure that such access does not come at the expense of patient well-being. Revising 45 CFR § 171.201 to include mental and emotional harm would preserve the intent of the 21st Century Cures Act while reflecting core ethical, clinical, and regulatory principles. The medical maxim *primum non nocere*—"first, do no harm"—applies equally to psychological and physical well-being. Delivering life-changing diagnoses without clinical support violates the ethical obligation to minimize suffering and protect patients from avoidable distress. True patient-centered care requires ensuring that information is conveyed in ways that support comprehension, coping, and informed decision-making—not through impersonal automated systems.

Recognizing mental and emotional harm would also improve quality of care, as brief, clinically justified delays allow providers to deliver context, reassurance, and appropriate referrals—reducing unnecessary emergency department visits, panic responses, and care discontinuity. This more compassionate approach protects patients with limited health literacy, language barriers, or preexisting mental health conditions from disproportionate distress when sensitive results are released without explanation.

AMGA respectfully requests that ASTP/ONC prioritize this regulatory revision in forthcoming rulemaking to ensure that policies on information blocking reflect the realities of clinical practice and uphold the core tenets of "first, do no harm."