Advancing High Performance Health

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Dr. Thomas Keane
Assistant Secretary for Technology Policy; National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
ASTP/ONC
330 C Street SW
Washington, DC 20201

Dear Dr. Keane:

On behalf of AMGA and our members, I am writing to reiterate our deep concerns with the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology's (ASTP's) interpretation of the "immediate resulting" requirement under the information blocking regulations. While AMGA strongly supports transparency and timely patient access to electronic health information (EHI), the automatic release of sensitive test results before physicians can review, interpret, and integrate them into a broader diagnostic and care plan continues to cause patient harm, disrupt the physician-patient relationship, and complicate care coordination.

Founded in 1950, AMGA represents more than 450 multispecialty medical groups and integrated delivery systems representing approximately 177,000 physicians who care for one in three Americans. Our members work diligently to provide innovative, high-quality, patient-centered care in an efficient and cost-effective manner.

Considering Sec. Robert F. Kennedy Jr.'s recent announcement directing the department to emphasize enforcement action against healthcare entities that engage in information blocking, AMGA recommends the department revisit the regulatory requirements at 45 CFR §171.201 to expand the definition of patient harm to account for mental or emotional harm.

Concerns with Immediate Resulting

Our members have consistently reported troubling cases in which patients received life-altering information—such as cancer diagnoses, miscarriages, or positive tests for infectious diseases—through an automated portal notification before their physician could provide context or compassionate counseling. These experiences demonstrate the rigid requirement for "immediate" release does not reflect the realities of clinical practice.

We ask ASTP to reconsider its interpretation that any delay, even for a matter of hours, constitutes "interference" absent an immediate threat of physical harm. Emotional and mental

harm caused by patients learning devastating diagnoses without provider support is real, profound, and should be recognized in federal regulation.

AMGA would welcome the opportunity to share additional real-world examples from our members to illustrate these challenges, including:

- Patients who misinterpreted abnormal but clinically insignificant lab results, leading to unnecessary emergency department visits.
- Patients who, reassured by a single normal test result, left an emergency department before a full evaluation, diagnosis, and follow-up plan could be completed.
- Patients who received pathology reports suggesting malignancy late on a Friday evening, with no access to their treating provider until the following week.
- Patients who learned of sensitive genetic or prenatal findings through a portal alert rather than from a trusted clinician.

To address these concerns, AMGA urges ASTP to take the following actions:

1. Codify through formal notice-and-comment rulemaking a revision to 45 CFR §171.201 to expand the Preventing Harm Exception to account for mental or emotional patient harm in instances related to the release of sensitive results and/or life-altering diagnoses.
2. Clarify through sub-regulatory guidance the agency's interpretation of the Preventing Harm Exception to account for mental or emotional patient harm in such cases.
3. Codify through formal notice-and-comment rulemaking a safe harbor for good-faith clinician discretion, allowing clinicians to delay release of sensitive results for up to 72 hours to ensure results are reviewed, interpreted, integrated, and then communicated with compassion.
4. Collaborate with electronic health record (EHR) developers and clinicians to incorporate innovative solutions that support patient understanding of released test results, such as embedding plain-language explanations, patient education links, and automated follow-up scheduling tools.

We respectfully request a meeting with ASTP leadership to discuss these concerns and recommendations in detail and to provide an opportunity for frontline providers to share their real-world experiences. AMGA and our members remain committed to advancing patient access while ensuring information is delivered in a way that promotes understanding, minimizes harm, and strengthens the patient-provider relationship.

Thank you for your consideration. Please contact Darryl Drevna, AMGA's senior director of regulatory affairs, at 703.833.0033 ext. 339 or ddrevna@amga.org to arrange a meeting.

Sincerely,

Jerry Penso

Jerry Penso, MD, MBA
President and Chief Executive Officer, AMGA