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Dr. Micky Tripathi
U. S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street SW
Washington, DC 20201

Dear Dr. Tripathi:

The Office of the National Coordinator for Health Information Technology (ONC) on April 5 implemented rules on “information blocking” that generally require healthcare providers to provide patients with access to their electronic health information (EHI) immediately. On behalf of AMGA and its members, I am writing to provide you with an update on the initial effects of these new requirements. Our members are reporting this “immediate resulting” requirement is causing patient harm by releasing clinical data to patients before their physicians can review and interpret the results.

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. AMGA strongly supports transparency and the need for patients to have access to their data and clinical information. However, we are concerned—and have heard reports from our members—about the unintended consequences of immediately providing patients with access to the data and information at the same time as their providers. By providing immediate access to clinical findings absent any context or explanation, the rules are causing patient harm, hindering effective communication between patients and their care providers, and complicating care coordination efforts. AMGA recommends that ONC move quickly to revise the rules to prevent patient harm and foster improved communication by expanding the definition of harm and allowing for some delay in the release of the laboratory and other results.

Key Recommendations:

- ONC should expand the definition of harm to account for emotional distress.
- Providers should be able to hold select results for 24 to 72 hours to deliver them in a more compassionate way.

Concerns with Immediate Resulting

AMGA and its member support the concept of providing timely access to results and other information to patients. Due to concerns that physicians were delaying the release of information and results, many of our members tie physician compensation to the timely release of information to patients. How quickly physicians and care teams inform patients of their laboratory result or other findings factors into how our medical group and health system members evaluate the performance of their physicians and other clinicians. In some cases, those providers who are consistently late in releasing or providing results to their patients face financial penalties. The information blocking regulations, however, go beyond supporting the concept of sharing information and instead are adding confusion to the doctor-patient relationship. AMGA members report concerning and disturbing instances where immediate resulting has caused patient harm. Examples include:

- A patient portal automatically alerted a patient of a Huntington's disease diagnosis.
- A patient learned of a miscarriage via a phone alert before the physician had reviewed the results.
- Patients are routinely receiving pathology reports that either confirm a cancer diagnosis, or, absent a conversation with their doctors, lead them to believe they have cancer.
- Patients are receiving positive test results for infectious diseases, including HIV.

These examples demonstrate the immediate need for ONC to revise the regulations. AMGA is pleased to offer recommendations to amend the definition of patient harm so the regulations support transparency and information sharing, while also ensuring patients receive results in context and as part of a care plan.

Supporting Counseling and Providing Context

AMGA has two chief concerns: the limited definition of harm and the unduly restrictive limitation on when a provider may delay a specific result from automatic release. The final rule allows providers to delay a result if the provider believes releasing the information will result in patient harm. AMGA agrees that such an exception is warranted. However, this exception largely is restricted to physical harm. Namely, that withholding the results of a particular test would substantially reduce a risk to the patient or another person's life or physical safety. AMGA recommends that ONC expand the definition of harm to cover emotional harm.

The current limits on the type of harm that would allow a clinician to withhold results does not account for the nuance that often occurs in the practice of medicine. In several instances, the final rule acknowledges the importance of patient counseling and context, but presumes that this occurs when a test is ordered or as part of a care plan that is developed before a patient would receive results. Our members report that this does not represent their experiences. While a provider may prepare a patient, patients often are not able to interpret a result correctly, despite any pre-test counseling. An "abnormal" result may not be a cause for concern and had the result been provided in context, patients would not be unduly stressed or worried about a particular result. More disturbing, however, is that patients are receiving cancer diagnoses via automatic resulting. Unless a provider honestly believes this will result in physical harm, – i.e., suicide – the regulations do not allow for a delay in providing the result. Nobody should receive such a diagnosis from a computer.

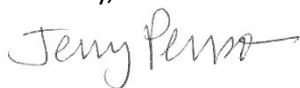
The timing of how patients are receiving results also is contributing to patient confusion. Often, patients will receive a result, have questions or be concerned about a result they do not understand, and reach a clinician who is on-call or covering for the patient's regular provider. Members report this is a frequent occurrence over the weekends, when a patient might automatically receive a result on a Friday and attempt to reach their provider over the weekend. Importantly, most of the lab results that are causing confusion or concern typically are not an emergency. A short delay in their release will not change the diagnosis or prognosis of the patient. In emergency situations, our providers have protocols in place to ensure the patient receives instructions on what immediate steps to take.

In guidance issued subsequent to the final rule, ONC indicated it would likely be considered interference for information blocking purposes if a healthcare provider organization implemented a policy that "imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results." ONC should reconsider this guidance. Even a brief hold on select results would prevent unnecessary confusion or distress. AMGA recommends a hold of 24 to 72 hours on results if a clinician believes that providing them immediately will unduly confuse or distress a patient.

AMGA appreciates the need for patients to have timely access to their test results. Our members strive to deliver such results as quickly as possible. The technology that enables such rapid results, however, is no substitute for the compassion and expertise of a provider. The best care will be provided when our physicians use technology to support effective communication with their patients. Unfortunately, our members experience to date with the immediate resulting requirements indicate that the rule has the unintended consequence of removing a patient's care team from the equation.

AMGA and our members thank ONC for consideration of our comments. Should you have questions, please do not hesitate to contact AMGA's Senior Director of Regulatory Affairs, Darryl Drevna at 703.833.0033 ext. 339 or ddrevna@amga.org.

Sincerely,



Jerry Penso, M.D., M.B.A.
President and Chief Executive Officer