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June 3, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human
Services
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Washington, D.C. 20201

Don Rucker, M.D.
National Coordinator for Health
Information Technology
U.S. Department of Health and Human
Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via www.regulations.gov

Dear Administrator Verma and Dr. Rucker:

Established in 1943, the AAAAI is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. We appreciate the opportunity to provide combined comments on the Centers for Medicare & Medicaid Services' (CMS) rule, *"Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers,"* and the Office of the National Coordinator for Health IT's (ONC) rule, *"21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program."*

AAAAI supports the comments of the American Medical Association (AMA) on each of the aforementioned rules.

General Comments

A/I professionals lead in the diagnosis, treatment and ongoing management of asthma, allergy and immunology conditions. By itself, asthma – a chronic disease that affects the airways in the lungs – affects more than 25 million Americans at a total cost of \$56 billion per year. Asthma causes 14.2 million missed days of work and 10.5 million missed

(more)

days of school, and results in 479, 300 hospitalizations, 1.9 million emergency department visits, and 8.9 million doctor visits.¹

With this in mind, it goes without saying that a robust network that allows both patients ***and*** providers to effortlessly exchange health information is essential to improving the lives of patients with A/I conditions.

Unfortunately, CMS' EHR Incentive program left physicians with electronic health record (EHR) systems that are not interoperable thus constraining provider-to-provider communication and effective care coordination; reduce the likelihood that physicians can achieve much needed efficiencies to adequately engage in emerging delivery and payment models; limit their ability to meaningfully engage with patients about managing serious, chronic health conditions, such as asthma and primary immune deficiency diseases, which is a cornerstone to the A/I specialty; lack formal or structured mechanisms for reporting and addressing health IT-related patient safety events, and ultimately, fail to support the delivery of high-quality, efficient clinical care and decision making.

While we laud the Administration for its efforts to address key aspects of interoperability, these proposals do not tackle challenges that providers have raised about health information technologies for several years, and in fact, create a whole new host of challenges that will have significant, unintended consequences for patients and providers. To that end, we strongly urge the Administration to delay these proposed requirements, or at a minimum, issue the provisions as interim final and continue to accept comments from the public. Again, we support the comments of the AMA specific to the aforementioned rules.

Information blocking: Provider-to-provider health information sharing

The Administration's requirements slant toward patients access to health information; however, it is providers of healthcare – such as A/I practitioners – that are clamoring for more robust data about their patients to more effectively and efficiently diagnose, manage and treat A/I disease and conditions. All too often, patients and their caregivers are expected to share their “health story” as they seek treatment, but key details are frequently missing or forgotten that may be critical for the new and/or consulting provider as he/she takes responsibility/accountability for the patient's care. Health information networks should be established to support provider-to-provider health information sharing, regardless of EHR system or vendor.

Clinical Data Registries

AAAAI established a clinical data registry (CDR) to improve the practice of A/I. Practitioners can use the registry to push and pull data and information on A/I diseases and conditions a real-time basis, improving the delivery of A/I at the point of care. However, registry users face significant challenges when attempting to connect the registry to the EHR system. We are deeply disappointed that the Administration has encouraged and promoted the use of clinical data registries through its Quality Payment Program (QPP), yet registries continue to face extreme difficulty, excessive costs, and are often blocked when attempting to connect to EHR systems.

¹ https://www.cdc.gov/asthma/impacts_nation/asthmafactsheet.pdf

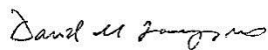
Moreover, AAAAI is greatly concerned about the definitions of both “health information exchange” and “health information network,” that would include CDRs, thus implicating them in the data blocking restrictions. Holding registries accountable for ensuring that patient-specific data is easily and regularly accessible to the patient or a third-party requestor is unreasonable, particularly when registries are not the originating source of data and is frequently de-identified and cannot easily be linked back to an individual. Again, this is even more frustrating given app developers and other entities are not required to meet such requirements.

Patient Safety

While outside the scope of this rule, patient safety remains a high priority for A/I providers. We are concerned that there are no formal or structured mechanisms in place to report HIT-related patient safety events, nor assurances that identified patient safety hazards will be adequately addressed in a timely fashion. For those A/I providers practicing in hospital and academic institutions, we urge CMS to work with the Center for Clinical Standards and Quality (CCSQ) to modify Conditions of Participation (CoP) related to a hospital’s quality assessment and performance improvement (QAPI) activities to clarify that HIT-related adverse patient events are to be included as part of the existing adverse event reporting structure. CMS should improve the Medicare CoPs to ensure patient safety events associated with HIT and EHR products are addressed appropriately, and in a timely fashion, at no cost. For A/I providers in private practice that have secured CEHRT independent from a hospital system, an HIT patient safety reporting program should be established.

We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,



David M. Lang, MD FAAAAI
President