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May 1, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: 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 [CMS-9115-P]

Dear Administrator Verma,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 36,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease, Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy. All of these disorders require coordination of care between neurologists and primary care physicians. Further, many neurologic disorders, especially at early stages, require care coordination, including multiple visits with various providers. Issues associated with data blocking and EHR interoperability can add additional challenges.

The AAN is committed to efforts that will streamline EHR interoperability and reduce data blocking. Challenges associated with interoperability and data blocking are two of the most critical elements forcing clinicians to spend more time on low-value clerical work and less time on direct patient care. Consistent policies are needed across the board to incentivize and facilitate the exchange of data across systems. Many EHRs do not support the robust use of application program interfaces (APIs) for data exchange or are hindered by APIs that are implemented in proprietary ways that inhibit data exchange. The AAN is appreciative of the Centers for Medicare and Medicaid Services' (CMS) commitment to promoting interoperability and decreasing data blocking and believes that many of the provisions contained within this proposed rule are necessary steps toward a health system in

which patients and providers are empowered through comprehensive access to needed data. Although support is warranted for many of these proposals, the AAN cautions CMS that the six-month implementation timeline for many of these changes is likely to impose a significant burden on providers and may be too rapid for system-wide change.

Data Sharing Requirements

The AAN supports CMS's efforts to advance the use of standardized, Fast Healthcare Interoperability Resources (FHIR) based APIs for patients to gain access to their health information. Patient access through open APIs to data including claims data, laboratory results, medications, and clinical notes is critically important to care coordination and to improving a patient's overall understanding of their health and course of treatment. Although the AAN supports improved access to this data, the AAN requests further clarification on how data that predates this rulemaking will be treated. Will patient data from legacy systems be required to meet the updated FHIR standard? The AAN is concerned that a requirement to update legacy EHI data to the new standard may be significantly burdensome on providers and practices. The AAN supports a requirement for vendors to implement these new standards, including potential legacy EHI, in a manner that should not place additional burden on provider and end-user configuration.

The proposed rule requests comment on the "utility to providers of obtaining all of their patients' utilization history in a timely and comprehensive fashion."[1] The AAN supports this and believes that it is of paramount importance that comprehensive patient information is available when it is needed.

The proposed rule also requests comment on the "potential unintended consequences that could result from allowing a provider to access or download information about a shared patient population from payers through an open API."[2] The AAN applauds the transparency intent of this request and agrees that this information should be available for import into a provider's EHR. However, we caution that this should limit a providers' liability, in that clinical decision support tools used for population management, may vary by the end user. This information should be intended for educational purposes and not intended for direct patient care interventions until safeguards are in place on how providers can reasonably interpret and accommodate this information into their clinical decision making. This should not substitute for information relied upon by a patient, their caregivers, and other medical providers involved in their care, but rather serve as supplemental information.

Additionally, the AAN is concerned with impact of open API disclosure of highly sensitive patient data, such as genetic testing results. The AAN firmly believes that discretion is of the utmost importance in cases in which the results of high-risk genetic tests are conveyed to patients. In cases in which test results implicate a very high-rate of developing a degenerative disease for which there is no cure or effective treatment, like Huntington's disease, the AAN believes an exception to data sharing requirements is appropriate to ensure that patients and their families are not exposed to this information through an open API without appropriate counseling.

[1] 84 Fed Reg. 7639
[2] Ibid

API Security and the Transfer of Protected Health Information

The AAN is concerned with the security framework related to third-party applications. The AAN is unclear on what the security framework will be for third-party APIs, to prevent unauthorized disclosures, after protected health information (PHI) is transmitted. The AAN understands that HIPAA covered entities are not responsible for the security of PHI after PHI has been transferred to a third-party application at the direction of a patient,[3] but requests clarification on the responsibilities of third-party applications to ensure that sensitive patient information remains protected. The proposed rule indicates that there is no existing federal regulatory framework, aside from FTC enforcement to address unauthorized disclosures of PHI.[4] Given the sensitive nature of PHI and the paramount importance of trust between patients and providers, the AAN implores CMS and the FTC to ensure that there are clear security guidelines for third-party APIs and that there is robust enforcement to ensure that third-party applications are responsible stewards of patient data. Even in cases in which a disclosure may not be a HIPAA violation, there are likely to be significant negative impacts on a provider's reputation related to an unauthorized disclosure.

Additionally, given the lack of a regulatory framework, the AAN is concerned that CMS is placing the burden on providers to ensure that patients are informed of potential risks. Ensuring that necessary precautions are taken so that PHI remains secure should be the responsibility of application developers, rather than providers. While the AAN understands the importance of informed consent, a disclosure of this sort may add additional burden and liability onto the provider and may lead to more patients declining to share their information. This would work counter to CMS's goal of promoting exchange of data and has the potential to detrimentally impact providers' relationships with their patients.

Proposal to publish the names of providers who engage in data blocking

The AAN agrees that it would benefit patients to know if their provider has negatively attested to data blocking attestation statements under the Quality Payment Program (QPP) or the Medicare Fee-for-Service Promoting Interoperability Program. Motivating clinicians, hospitals and critical access hospitals to refrain from data blocking is needed when building an interoperable health system. The AAN is skeptical of the practical impact that public shaming of providers, by publishing their names, will advance the goal of promoting interoperability. Additionally, the AAN believes that the burden of complying with any future requirements related to data blocking ought to fall predominantly on EHR vendors, rather than on providers.

Provider Digital Contact Information

The AAN strongly supports CMS making provider contact information digitally available through a common directory.[5] A centralized directory of provider electronic addresses maintained via the National Plan and Provider Enumeration System (NPPES) will greatly

[3] 84 Fed Reg. 7621
[4] Ibid
[5] 84 Fed Reg. 7648

enhance provider communication and care coordination between referring providers and specialist providers, like neurologists. The AAN understands that many providers have already voluntarily submitted digital contact via the NPPES, but it is critical that this directory is both comprehensive and up-to-date. While the AAN understands that an enforcement mechanism may be needed to promote participation, the AAN is skeptical of the practical impact that publicly naming providers will have on NPPES participation. Additionally, the AAN believes that the NPPES data fields should be updated to account for multiple practice and billing locations. The AAN also supports aligning the NPPES with the Provider Enrollment, Chain, and Ownership System (PECOS), both of which request overlapping information related to providers enrolling in Medicare. The AAN also requests that CMS examine the possibility for establishing a hardship exception for solo-practices.

Hospital Patient Event Notifications

The AAN strongly supports CMS's proposal to require eligible hospitals and critical access hospitals to deploy patient electronic event notifications.[6] These event notifications will enable improved care coordination by informing providers when their patients receive care in a hospital setting. While the AAN supports this provision, the AAN asks that providers not be penalized if their EHR system is unable to receive these alerts, until this capability becomes a part of EHR certification.

Request for Information on Advancing Interoperability Across the Care Continuum

CMS includes a request for information (RFI) in the proposed rule that seeks input on potential strategies for advancing interoperability across care settings to inform future rulemaking.[7] The AAN encourages CMS to implement strategies that would reduce administrative burden and incentivize the use of qualified clinical data registries (QCDRs), like the AAN's Axon Registry. As such, the AAN recommends that CMS explore strategies that would promote full credit under the MIPS Promoting Interoperability category to eligible clinicians and groups using certified electronic health record technology (CEHRT) to participate in a QCDR.

Patient Matching Request for Information

The AAN supports efforts to improve patient matching and to establish a comprehensive standard for identifying and matching patient records. The AAN understands that a universal patient identifier has been statutorily banned[8] but believes some standard should be in place to allow for the matching of patient records across systems. In the absence of a universal patient identifier, the AAN recommends using 2-3 unique patient data elements for the purpose of matching patients.

Trusted Exchange Network

[6] 84 Fed Reg. 7618
[7] 84 Fed Reg. 7653
[8] 84 Fed Reg. 7656

The AAN supports CMS's proposal to require MA plans, state Medicaid and CHIP programs, Medicaid and CHIP managed care organizations and Qualified Health Plan issuers to participate in a trusted exchange network. The AAN supports using the Trusted Exchange Framework and Common Agreement (TEFCA) standard as the approach for the trusted exchange network.

Conclusion

Addressing the ongoing challenges related to interoperability and data blocking is a top priority for the AAN. The AAN appreciates CMS's continued engagement and commitment to addressing these challenges. The AAN believes that the policies outlined in this proposal are a significant step toward a more interoperable health IT landscape. The AAN is committed to continued engagement with the administration as the health care system works to combat information blocking and improve the exchange of information.

Thank you for the opportunity to provide comments on this proposed rule. Please contact Matt Kerschner, the AAN's Government Relations Manager, at mkerschner@aan.com or Daniel Spirn, the AAN's Senior Regulatory Counsel, at dspirn@aan.com with any questions or requests for additional information.

Sincerely,

Ralph L. Sacco, MD, MS, FAHA, FAAN
President, American Academy of Neurology