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June 3, 2019

Administrator Seema Verma  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-9115-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

***RE: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organizations and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in Federally-Facilitated Exchanges and Health Care Providers Proposed Rule [CMS-9115-P]***

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the proposed rule “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organizations and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in Federally-Facilitated Exchanges and Health Care Providers,” 84 *Fed. Reg.* 7610 issued by the Centers for Medicare & Medicaid Services (CMS).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 154 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America’s medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Together, these institutions and individuals are the American academic medicine community.

The AAMC applauds CMS for its efforts to advance interoperability, support the access, exchange, and use of electronic health information, and prevent information blocking. We share CMS’s commitment to ensuring that patients and clinicians have the increased ability to access electronic health information to make informed health decisions through secure and seamless exchange of electronic health information. The focus of efforts to improve interoperability should be on what is needed for high quality clinical management of patients receiving care from providers as they move

through the health care system. At the same time, it is critical to also protect the privacy and security of patient health information.

Many of the AAMC's member institutions were early adopters of electronic health record (EHR) technology; they have helped to pioneer its development and use and are committed to providing quality care using these systems. While we support CMS's efforts, the AAMC would like to highlight provisions in the proposed rule that we support, aspects that could be strengthened, and areas of concern that could increase burden and health care costs. These include:

- **Conditions of Participation Requirements to Send ADT Notifications:** Given the immaturity of the infrastructure of interoperability, unanswered questions, and significant implementation issues, the conditions of participation should not be used as the mechanism to ensure hospitals provide the admission, discharge and transfer electronic notifications. CMS should consider other approaches to encourage these notifications, such as setting forth requirements related to the exchange of this information in the Promoting Interoperability Program.
- **Patient Information in Apps:** EHR API vendors that are certified by ONC should certify that the apps meet established best practices and privacy guidelines and provide a model notice to patients regarding how their information might be used by the app.
- **Information Blocking and Public Reporting:** CMS should ensure hospitals and physicians have the opportunity to make corrections if data is inaccurate and would erroneously publicly report the hospital or physician as an information blocker. During this time of great transition to interoperability, public reporting should not be used until there is stability in the transformation.
- **RFI: Collection of PAC standardized elements:** While the AAMC supports enhanced coordination between acute-care hospitals and post-acute providers, CMS should not require that hospitals and physicians collect the PAC standardized data elements in their EHRs.
- **RFI: Advancing Interoperability in Innovative Models:** CMS should consider making interoperability-related activities, like participating in a trusted exchange, encouraged but voluntary aspects within the broader model requirements to ensure adequate participation.
- **RFI: Patient Matching:** Considering that there is a long road ahead to solve patient matching, CMS should refrain from implementing new requirements on providers to use a specific algorithm and instead focus on bringing together experts to develop solutions, including the potential for a successful patient-matching algorithm.

#### REVISIONS TO THE CONDITIONS OF PARTICIPATION FOR HOSPITALS AND CAHS

The CMS proposed rule would require as part of the Medicare Conditions of Participation (CoPs) that hospitals send electronic notifications when a patient is admitted, discharged, or transferred to another health care facility or to another community provider. Hospitals would be required to send these notifications to other facilities, licensed and qualified practitioners, other patient care team members, and post-acute care (PAC) services providers and suppliers with an established patient relationship with the patient relevant to his or her care. The hospital must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis).

The AAMC strongly supports efforts to achieve interoperability and to share meaningful, actionable information to improve patient care within and across settings while also protecting a patient's privacy. **However, the AAMC does not support changing the conditions of participation to require these electronic notifications. The conditions of participation are not the right vehicle to encourage interoperability given the significant unintended consequences if the CoPs are not met, particularly since there are still numerous operational challenges that need to be resolved to achieve interoperability across the continuum of care. We recommend CMS consider other approaches to achieving this goal, such as setting forth requirements related to the exchange of this information in the Promoting Interoperability Program.**

Prior to implementing any requirement to send electronic notifications, there are several questions that would need to be answered and operational considerations to be addressed. First and foremost, there must be a process in place for the patient's privacy to be protected if that patient does not want any or all physicians and providers to receive these notifications. It is also important to recognize that not all EHRs are able to generate these messages and there is no requirement in ONC certification that the EHRs have this functionality. It would be a major undertaking for hospitals that are not connected to Health Information Exchanges (HIEs) to identify which providers and practitioners have an "established patient relationship" and to generate these messages for those providers. While the burden would be eased if a provider is connected to a health information network that can provide these notifications, it is important to recognize that many providers are not connected to HIEs currently.

The problems are further exacerbated by the fact that CMS provides no definition of an "established patient relationship" in the proposed rule, making it difficult for hospitals to know which clinicians and providers should receive these notifications. The list of physicians and other providers with an "established care relationship" could be extensive if left undefined. Identifying providers with "established care relationships" is especially complicated for academic medical centers that treat patients from many different jurisdictions throughout the country. Privacy considerations also are of concern as it is possible that these notifications may be sent electronically to physicians and providers that the patient does not want to receive these notifications. **Given these challenges, we recommend that for purposes of electronic notifications the term "established patient relationship" be defined as the principle physician identified by the patient and any institution (e.g., nursing home) that the patient identifies.**

The challenges with exchanging electronic health information are significant in the patient discharge and transfer areas because many post-acute providers and behavioral health providers have not been able to adopt health information technology (HIT) to the same extent as acute care hospitals. These providers were not considered part of the EHR Incentive Programs under the Health Information Technology and Clinical Health (HITECH) Act and therefore did not have the same ability and financial assistance to adopt HIT as acute care hospitals. Thus, it is likely that the acute care hospitals would be unable to meet the requirements to share the information if the post-acute and behavioral health care providers are unable to accept that information electronically. In addition, small physician practices may not have the resources to invest in expensive EHR systems that can receive the transmitted messages. All parties to the exchange need to have compatible technology for the exchange to be successful.

If the conditions of participation were modified to require these electronic notifications, a survey team would need clear guidance on how to assess providers to ensure that they are transmitting and receiving patient information from/to other providers. In addition, health care providers would need a clear understanding of the expectations and how a determination would be made of whether they are complying with the requirement. It is unclear as to how providers would prove during a survey process that they are “interoperable,” particularly given the fact that the surveyors would only visit the facility they are assessing. It is unclear how surveyors would be able to determine compliance.

**Given the immaturity of the infrastructure of interoperability, unanswered questions, and significant implementation issues raised above, the conditions of participation should not be used as the mechanism to ensure hospitals provide these notifications.** Hospitals that are found to be out of compliance with the conditions of participation face the possibility of being removed from participating in the Medicare and Medicaid programs. This would result in major harm to patients, providers, and communities. This penalty is too extreme, particularly given the fact that there are still so many barriers to achieving interoperability.

To address the challenges with interoperability, the AAMC recommends CMS explore other mechanisms to encourage providers to exchange information (e.g., message notifications), such as setting forth requirements related to electronic notifications in the Promoting Interoperability Program. Under the Promoting Interoperability Program, CMS currently requires hospitals to attest that they did not “knowingly and willfully take action to limit or restrict the compatibility or interoperability of their certified EHR and that they have implemented the technology to support “secure and trusted bidirectional exchange” of information. Those failing to attest face hefty financial penalties under the Inpatient Prospective Payment System (IPPS) and CAH programs. They would be subject to a 75% reduction to the market basket update applied to Medicare inpatient reimbursement.

We believe that a more fruitful approach would be for CMS and ONC to focus their efforts on creating the infrastructure for exchange of health information and establishment of consistent standards across vendor platforms. We recommend that CMS and ONC continue to work on implementation of the Trusted Exchange Framework and Common Agreement (TEFCA) to create the infrastructure to support interoperability.

#### PATIENT ACCESS THROUGH APIS

In the rule, CMS expresses its desire to ensure that patients have access to their own health information through the use of apps. While we support patient access to information, we are concerned that a patient may not understand that their information obtained through these apps may be shared with third parties that are under no obligation to keep that information private. Health information is very personal and there is a potential for the information shared in apps to be used in ways that impact employment, access to affordable health insurance, or other areas.

As proposed, the CMS and ONC rules require that health information be shared through apps; yet they do not establish any patient privacy and security protections or any standards regarding how the information from the app may be used. Before finalizing these rules, patients and policymakers should have a comprehensive dialogue regarding the potential consequences of the impact of using

apps and develop approaches that protect a patient's privacy and security. Patients and consumers should have access to better information and tools to assess apps with which they will share their health data. They also should understand what rights and protections they have for their private health data when they choose to share it through an app.

Approaches could include requiring EHR API vendors that are certified by ONC to certify that the apps meet established best practices and privacy guidelines and to provide a model notice to patients regarding how their information might be used by the app. Labeling is an approach that could be used to enable patients to better understand the security of a given app. The ONC and CMS should consider leading an effort for such a labeling standard or could partner with a non-governmental entity to maintain a labeling system. For example, the ONC could look to the Patient Privacy Rights group's "Information Governance Label" as an example of a check list for assessing an application's information security.<sup>1</sup>

#### INFORMATION BLOCKING AND PUBLIC REPORTING

The Medicare Promoting Interoperability Program requires hospitals and CAHs to submit attestations related to information blocking. Similarly, the Quality Payment Program requires eligible clinicians and groups to make similar attestations. CMS proposes to publicly report information on these attestations on an unspecified CMS public website for hospitals and CAHs, and on Physician Compare for eligible clinicians and groups. Specifically, CMS would publicly indicate that the hospital, CAH, or eligible clinician/group is deemed an "information blocker" if the hospital, CAH, or eligible clinician/group submits a "no" response to any of the three attestation statements regarding information blocker.

CMS will make all public reported data for physicians available for review and correction under the Quality Payment Program (QPP) targeted review process. Hospitals and CAHs would have a 30-day preview period to review information before it is publicly posted. CMS proposes to only make changes to the information reviewed on a case-by-case basis. **During this time of significant transition to interoperability, CMS should not use public reporting as a mechanism to encourage interoperability.** If CMS chooses to publicly report, **the AAMC asks that CMS ensure that prior to posting hospitals and physicians have the opportunity to review data and make corrections to any inaccuracies.**

#### PROVIDER DIGITAL CONTACT INFORMATION

The 21<sup>st</sup> Century Cures Act requires the Secretary to create a provider digital contact information index. CMS proposes to meet this requirement through an update to the National Plan and Provider Enumeration System (NPPES) to capture digital contact information for individuals and facilities. Since June 2018, the NPPES system has been updated to be able to capture pieces of digital contact information, including Direct address and a range of other endpoints for secure information exchange (e.g., a FHIR server URL or a query endpoint associated with a Health Information Exchange). Despite this capability, CMS has found that many providers have not yet submitted digital contact information, and that the information submitted is frequently out of date. To remedy this CMS

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<sup>1</sup> Patient Privacy Rights (PPR) "Information Governance Label" available at [https://docs.google.com/document/d/1-62rk2oN\\_BYop7Vag1cLbEmAybEJ\\_cgpn2e07BH8\\_bM/edit](https://docs.google.com/document/d/1-62rk2oN_BYop7Vag1cLbEmAybEJ_cgpn2e07BH8_bM/edit) (last visited May 31, 2019)

proposes to publicly report the names and NPIs of providers who do have digital contact information stored in the NPPES beginning in the second half of 2020.

We support the goal of including digital health contact information in the national provider directory. As a first step **CMS should undertake additional provider education efforts to ensure providers are aware of the ability to maintain digital contact information in the NPPES. CMS also should encourage submission of that information through other positive incentives rather than by “shaming” providers publicly. If CMS decides to publicly report this information, providers must have an opportunity to review its accuracy and correct it before the public reporting.**

#### RFI ON ADVANCING INTEROPERABILITY ACROSS THE CARE CONTINUUM

As part of its work under the IMPACT Act, CMS has defined certain standardized patient assessment data elements and their associated health IT vocabularies across post-acute care (PAC) settings. To enable bidirectional exchange of this health information, CMS seeks public comment on whether hospitals and physicians should adopt the capability to collect and electronically exchange a subset of the same PAC standardized patient assessment data elements (for example, functional status, pressure ulcers/injuries) in their EHRs. CMS is seeking comment on whether to move toward the adoption of PAC standardized data elements through the expansion of the USCDI process. The Agency is interested in (1) whether the full set of the standardized patient assessment data elements from the IMPACT Act would be appropriate or whether a subset of those elements would be preferable and (2) what implementation timeline would be most appropriate for requiring adoption of these data elements in the provider and hospital systems under the ONC Health IT Certification program. They also seek comment on the administrative, development, and implementation burden that may be associated with adopting these new data elements.

**The AAMC supports enhanced coordination between acute-care hospitals and post-acute providers to improve overall quality of care, collaboration and reduce total health spending. We also support alignment of data elements to the extent possible. However, we do not support requiring that hospitals and physicians collect and electronically exchange the PAC standardized data elements in their EHRs.**

Typically, the acute care hospital setting focuses on a different level of patient care and different treatment goals than the post-acute care settings. For example, in the acute care setting, the hospital may not be focusing on whether a patient can ambulate a certain distance if the patient is confined to his or her bed for medical reasons. The hospital will focus on interventions for the patient that will enable the patient to be discharged to a lower acuity setting and will develop a comprehensive discharge plan. There will be collaboration between the levels of care through effective discharge planning and transition services. When the patient transitions to a post-acute care setting (e. g skilled nursing facility, inpatient rehabilitation facility, or home health), the patient may have different needs requiring different functional goals. Therefore, the PAC data obtained while the patient was in the acute setting could be very different than the patient’s presentation at the post-acute care setting.

Completing the PAC standardized data elements is a resource intensive activity that will require additional clinical staff time and changes in clinical protocols if required in the hospital setting. For patients with a short hospital length of stay, the time frame for completion of assessments likely would be very limited and would require increased staffing which would have a significant financial

and resource impact on hospitals. While we believe the need for comprehensive discharge information is critical for both patients and providers, the requirement that the PAC standardized data elements be collected for hospital inpatients would most likely require providers to reprioritize and reorganize their daily operations and divert resources that would be better used elsewhere.

#### RFI ON ADVANCING INTEROPERABILITY IN INNOVATIVE MODELS

CMS seeks information from stakeholders on how it can best use the Center for Medicare and Medicaid Innovation (CMMI) authority to tests ways to promote interoperability across the health care spectrum. Some ways CMS might focus on interoperability in future model development include piloting emerging standards, leveraging non-traditional data in model design, and leveraging technology-enabled patient engagement platforms. In addition to these, CMS seeks comments on three general principles for integration into new models: (1) Provide Patients Access to Their Own Electronic Health Information (EHI), (2) Promote Trusted Health Information Exchange, and (3) Adopt Leading Health IT Standards and Pilot Emerging Standards.

##### ***Provide Patient Access to Their Own Electronic Health Information***

CMS seeks feedback on whether models should require providers and other health care entities with direct patient interactions to provide patients access to the patients' own EHI and, upon patient's authorization, to third party developers via APIs.

The AAMC urges CMS to align patient access requirements with other federal laws (e.g., HIPAA) and regulations requiring health care providers to provide patients access to their own EHI. The AAMC is concerned that requiring this through model participation may create confusion, as the providers and health care entities with direct patient interaction are not always the entity that is directly contracting with CMS to participate in the model. For example, accountable care organization (ACO) entities are intentionally separate and distinct entities from providers. Providers participating with the ACO should be able to meet requirements for providing patients access to their EHI broadly but might not be able to do so in a manner tailored to the provider's participation in the ACO (e.g., segmenting out data only as it related to the patient's care provided from the ACO). It is unclear whether CMS envisions that providers and other health care entities must be able to segment patient's EHI specific to the model. If model-specific data segmentation for patient access is what the agency envisions, the AAMC would caution CMS to consider making such a requirement voluntary to ensure provider participation in the broader model test.

Similarly, it is unclear whether CMS envisions that providers with direct patient interactions be required to *encourage* a patient's authorization to share their data with third party developers via APIs or simply be required to *facilitate* such access if the patient so authorizes. The latter is a reasonable requirement for supporting patient access to their EHI whereas the former could at worst run afoul of federal privacy laws and requirements and at best cause patient distrust in the provider or the provider's broader participation in the CMMI model.

##### ***Promote Trusted Health Information Exchange***

CMS seeks feedback on whether it should require model participants, where appropriate, to participate in a trusted exchange network that is able to exchange protected health information (PHI)

in compliance with all applicable state and federal privacy laws, connects to both inpatient EHRs and ambulatory EHRs, and supports secure messaging or electronic querying by and between patients, providers, and payers.

The AAMC advises CMS to be cautious in how it might apply criteria for appropriateness for a requirement for model participants to participate in a trusted exchange network. CMS should balance the requirement with consideration for whether such a requirement is likely to limit the regions in which potential model participants provide care (due to the lack of a health information network in their region or area) or otherwise chill interest in participating in the model. The AAMC is concerned that such a requirement to participate in innovate models, which in the past have been voluntary based on an institution's readiness for change and ability to direct time and resources to the effort, may discourage participation. **CMS should consider making additional requirements, such as participating in a trusted exchange, voluntary within the broader model requirements to ensure adequate participation in the model test.**

#### *Adopting Leading Health IT Standards and Pilot Emerging Standards*

CMS anticipates that CMMI will take on a leadership role in developing new (or less mature) FHIR and supporting more innovative interventions undertaken by states as part of the design and testing of innovative payment and service delivery models. The AAMC supports this principle, so long as CMS balances burden of such requirements for participation in models to ensure robust participation in models going forward.

#### RFI ON POLICIES TO IMPROVE PATIENT MATCHING

Congress has encouraged CMS to examine options to improve patient matching as a means of promoting exchange of patient health information. CMS has asks in this proposed rule for feedback to specific questions on possible policies it could implement to improve patient matching.

Achieving interoperability and information sharing will require the ability to match patient's data across health settings and health IT systems accurately. Patient matching is a quality of care and patient safety issue because inaccurate patient matching can lead to inappropriate and unnecessary care; an unnecessary burden on both patients and providers to correct misidentification; and finally, a time consuming and expensive burden on health systems to detect and reconcile duplicate patient records and improper record merges. **The AAMC appreciates CMS's request for information on creative, innovative, and effective approaches to patient matching within and across providers. Progress on patient matching is critical to EHR interoperability and helping patients receive appropriate and needed care when they seek it.**

#### *Requiring Use of a Patient Matching Algorithm with a Proven Success Rate*

Considering that there is a long road ahead to solve patient matching, at this time CMS should refrain from implementing new requirements on providers to use a specific algorithm. Instead, CMS should convene experts to develop solutions, including the potential for a successful patient-matching algorithm.



***Requiring a CMS-wide Identifier for All Beneficiaries and Enrollees in Health Care Programs under CMS Administration and Authority***

The AAMC understands the challenges and promise of a unique, universal identifier to improve patient matching, but we are concerned that a CMS-wide identifier would only cover a portion of the United States patient population. Considering the majority of Americans obtain private employer-based coverage, it is unclear whether the administrative undertaking of a CMS-wide identifier would provide commensurate benefit towards patient matching.<sup>2</sup> The AAMC advises that CMS consider other options that could be implemented more broadly to improve patient matching, like advancing more standardized data elements.

***Advancing More Standardized Data Elements Across Programs for Matching Purposes***

Providers, software developers, and other healthcare organizations should collaborate on the identification of a common set of data elements that should be collected by providers using federally adopted standards to support patient matching. A recent study by experts from Indiana University and supported by The Pew Charitable Trust found that the standardization of patient addresses using the United States Postal Service's format showed promise for improving the success of a matching algorithm.<sup>3</sup> **CMS should consider steps it could take to improve standardization of address data**, including updating policies that govern how digital systems exchange information to support use of the Postal Service format or coordinating use of the Postal Service's address validation API, used by the shipping industry to improve the delivery of mail and packages, for use in the healthcare sector to improve patient matching.<sup>4</sup>

Similarly, as more and more demographic data elements are captured in the EHR, the ONC should look at whether these elements could be used to improve patient matching. For example, it is believed that more than half of patient records include an electronic mail (e-mail) address and mother's maiden name. If these elements are already in the EHR, they should be used for patient matching. E-mail may be especially promising as an additional element for matching, as it is collected in an effort to provide patient access to patient-facing records portals.

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<sup>2</sup> United States Census Bureau, "Health Insurance Coverage in the United States: 2017," September 12, 2018. Retrieved from: <https://www.census.gov/library/publications/2018/demo/p60-264.html>

<sup>3</sup> Shaun J Grannis, et al., *Evaluating the effect of data standardization and validation on patient matching accuracy*, JAMIA. March 8, 2019. Retrieved from: <https://academic.oup.com/jamia/article-abstract/26/5/447/5372371>.

<sup>4</sup> United States Postal Service, "Address Information API," documentation available at <https://www.usps.com/business/web-tools-apis/address-information-api.htm> (last visited May 6, 2019).

Administrator Verma

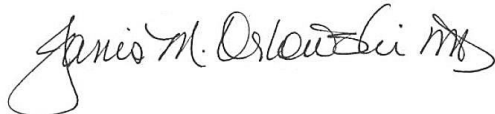
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**Conclusion**

The AAMC welcomes engagement on these issues and appreciates the opportunity to comment. We look forward to continuing work with CMS on these issues. If you have any questions, please contact Gayle Lee at (202) 741-6429 or [galee@aamc.org](mailto:galee@aamc.org) and Phoebe Ramsey at (202) 448-6636 or [pramsey@aamc.org](mailto:pramsey@aamc.org).

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski M.D.". The signature is written in a cursive style with a large, looping initial "J".

Janis M. Orlowski, M.D., M.A.C.P.  
Chief Health Care Officer

cc: Ivy Baer, AAMC  
Gayle Lee, AAMC  
Phoebe Ramsey, AAMC