June 3, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-9115-P
P.O. Box 8016
Baltimore, MD 21244

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 (Interoperability and Patient Access Proposed Rule)

Dear Administrator Verma:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Interoperability and Patient Access Proposed Rule, posted in March 2019.

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to also educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI's Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

PAI is committed to advancing policies that protect the ability of patients to receive high-quality care and is supportive of the Centers for Medicare and Medicaid (CMS) phasing in policies that advance interoperability and patients’ access to their health information. We agree with the Agency that “patients should have the ability to move from health plan to health plan, provider to provider, and have both their clinical and administrative information travel with them throughout their journey,”
and that for provider health IT “should be a resource . . . to deliver high quality care, creating efficiencies and allowing them to access all available data for their patients.” Interoperability and the unimpeded flow of information, for both physicians and their patients, is critical to ensuring the delivery of coordinated, high-quality, and necessary health care.

**Overview**

In the current healthcare system, patient health information is dispersed across settings, physicians, and plans. These barriers include patient matching and interoperability; lack of standardization; information blocking; lack of adoption/use of health IT among post-acute providers (PAC) providers; and privacy concerns regarding HIPAA. As a result, both patients and their physicians lack access to a comprehensive patient medical record that provides them a holistic view into the patient’s health and would allow both parties to make more informed care decisions.

CMS has issued this proposed rule to address these barriers to interoperability and outline standards for the exchange of patient health information across Medicare and Medicaid programs. PAI commends the agency for recognizing these longstanding challenges and barriers and proposing policies in this rule that would help advance health information among physicians, facilities, patients, and payers. PAI is supportive of the Agency’s core policy to support patient access to all information relevant to a patient’s health, care services, and plan, provider, and treatment options which recognize issues surrounding patient confidentiality. Furthermore, we believe it is important to empower patients to make more informed decisions. Matching claims and encounter data would allow physicians to get a more holistic look at patient health profiles and make decisions based on the totality of the care patients are receiving across the spectrum of medical and health care services.

We believe in giving patients more visibility into their medical records and making their information more transparent to them so they can truly be partners in their own medical care and treatment.

In this proposed rule, CMS describes policies in the following areas: patient access through application programming interfaces (APIs); health information exchange and care coordination across payers; API access to published provider directory data; care coordination through trusted exchange networks; improving the care experience for dual-eligible beneficiaries by increasing the frequency of federal-state data exchanges; public reporting and prevention of information blocking; provider digital contact information; revisions to the conditions of participation (COPs) for hospital and Critical Access Hospitals (CAHs); and advancing interoperability in innovative models. The policies in this proposed rule would apply to Medicare Advantage (MA) Organizations (MAOs), Medicaid managed care plans and state agencies, CHIP entities, and QHP issuers in FFEs (collectively referred to in this document as “payers”).

In this letter, PAI provides input on the specific proposals in this rule. We urge the Agency to take the following into consideration as it proceeds with implementation of any policies:

- Bi-directional information exchange is critical to interoperability and ensuring greater coordinated and better communicated patient care.
- Importance of making available all relevant patient health information to provide a patient and their physician with a complete health profile to make more informed care decisions,
including social determinants of health factors, pharmacy data, lab/diagnostic testing data and information, claims data, individual-specific medical data, and general plan data.

- Greater standardization of data elements, collection methods, and sharing processes to support increased health information exchange and interoperability.
- Protection to ensure that the burdens, cost, and other impacts of these policies required of payers not be passed downstream to physicians and patients.

**Information Types**

CMS identifies two types of information to support patient access to their health information records: individual-specific information, including current and past medical conditions and care received; and general plan information, including plan provider networks, formulary, and coverage policies. PAI believes these two types are information are invaluable, and more specifically, we believe it is important to also include historical information, including past medications and surgeries, as well as allergies and lab information as part of the individual-specific information type.

Additionally, there is a third type of patient information that is overlooked but also essential: pharmaceutical and pharmacy data. This data is currently only available at high costs which serves as a barrier to access. The addition of pharmacy health information data would provide a more comprehensive view into a patient’s health and support care coordination.

**Application Programming Interfacing (APIs)**

CMS notes three important attributes of APIs:

- Standardization – the APIs would use modern computing standards (e.g., RESTful interfaces and XML/JSON) and present the information using recognized content standards (e.g., standardized vocabularies). Both the technology itself and that data must be standardized;
- Technical transparency – the APIs would need to make publicly accessible the specific business and technical documentation necessary to interact with the APIs; and
- Pro-competitive implementation – APIs are implemented in a manner that promotes efficient access to, exchange of, and use of health information (e.g., proactively advising enrollees they can use other APIs).

PAI believes that APIs contribute to the goal of interoperability. Currently, there is substantial variation in how patients’ protected health information (PHI) is collected and shared; thus, PAI is supportive of standardization and transparency, which are critical to ensure that APIs can be used to access necessary information. PAI is also supportive of pro-competitive implementation so as not to impose any constraints on patients’ access to their information or physicians need for access to make informed and accurate medical decisions.

**API Standards**

CMS is proposing the adoption of content and vocabulary standards for representing electronic health information, and technical standards for the API by which the information must be made available. The Agency is proposing to align these standards with those proposed as part of the Office
of the National Coordinator’s (ONC’s) 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Proposed Rule (ONC Proposed Rule). The Agency is also proposing that entities can use updated versions of required standards if required by other applicable law, if not prohibited under other applicable law, and if the updated version does not disrupt an end user’s ability to access the data available through the API.

PAI is supportive of streamlining and aligning the proposals in this proposed rule with those in the ONC Proposed Rule. We believe that greater standardization and alignment of requirements of payers and third-party entities and making sure data requirements, as well as data standards, are consistent with the technology being presently used by physicians. It is important that standards be updated regularly for both payers and other entities, without additional costs to users including physicians and patients.

Data Made Available Through APIs
CMS is proposing that payers make the following information available to their current and past enrollees: adjudicated claims (including charge amount); encounters with capitated providers; provider remittances; enrollee cost-sharing; clinical data, including laboratory results (where available); and provider directories and formularies, prescriptions. Generally, this data must be made available within one business day after the plan receives it. CMS notes that payers may want to consider whether contracts with their providers should include a timing requirement for timely submission of claims and encounter data so payers can comply with API requirements proposed under this rule.

While PAI is supportive of the policy to make the data available as soon as possible, we caution against inappropriately and unjustly penalizing physicians and other providers for claims that are submitted within a reasonable time when they are using health IT and electronic health records (EHR) technology. Additionally, we believe it would be helpful to make available any social determinants of health (SDOH) data that a plan may be collecting, as well as prior authorization requirements, as these are also relevant to patient health and care decisions.

Restricting Access to APIs
Based on objective, verifiable criteria applied fairly and consistently across all applications, CMS is proposing to allow payers to decline or terminate a third-party application’s connection to their API. While PAI understands that there may be some circumstances when payers may want to restrict access to APIs, we are concerned that a “fairness” standard would be interpreted differently by payers, third-party applications, and users, such as physicians. PAI encourages the Agency to establish a clearer standard of acceptable circumstances when API access can be restricted and that this standard should be clearly communicated to physicians, patients and third parties accessing and using the data.

Health Information Exchange and Care Coordination Across Payers
CMS is proposing that when a patient requests their information to be shared with another plan (e.g., when switching plans), each plan would be subject to the following requirements: 1) accept the data
from another plan that covered the enrollee with the past five years; send data at any time during enrollment and up to five years later to another plan that currently covers the enrollee; and 3) send data at any time during enrollment or up to five years after enrollment ended to a recipient identified by the enrollee.

PAI is supportive of this care coordination across payers and recommends that the Agency ensure that the physician(s) currently treating the patient also be notified automatically of the hand-off between the plans.

As part of this health information exchange and care coordination across payers, it is important that, when information is being transferred to a new plan, this transfer does not have a negative impact on the care a patient is receiving or the patient’s existing coverage. The data elements to be shared should be clearly presented and shared, with a specific focus on how insurer-specific information (e.g., risk adjustment, risk evaluation, patient authorization or formulary access, etc.) are transferred. Consideration should also be given to coverage continuity (e.g., patient not having to go through step-therapy again, or ensuring that the current treatment is not impacted immediately due to coverage changes like rate increases and there is a grace period to ensure that the patient continues receiving their care as documented in the patient’s medical file and data shared by the previous plan).

**Trusted Networks**

Trusted Networks would allow for broader interoperability, establish rules of the road for interoperability and allows for HIE among those within the network. CMS is proposing three requirements for trusted networks: 1) able to exchange PHI with applicable state and federal laws across jurisdictions; 2) capable of connecting inpatient and ambulatory EHRs; and 3) support secure messaging or electronic querying by and between patients, providers, and payers.

PAI agrees with the value of trusted networks. However, it would be shortsighted if trusted networks did not extend their reach beyond inpatient and outpatient EMRs. We believe that they should also extend to nursing homes, hospices, palliative care, and behavioral health EMRs, home health agencies, and labs, as well as other health information technology sources used by other clinicians and social service providers.

**Exchange of State MMA Data Files**

Currently, states are required to submit MMA files at least monthly, but CMS is proposing to require MMA files to be submitted to CMS daily. Relatedly, CMS is seeking input on the following: What else would be necessary for interoperability for dual eligibles for data sharing, care coordination, eligibility determinations, streamlining provider enrollment, etc.? What infrastructure support would be necessary? How to enhance processes to share Medicare data with states for care coordination and program integrity?

PAI is supportive of greater exchange of MMA data files, but this exchange of information needs to be bi-directional. Currently, although state agencies that are tied to Medicaid accept data, they do not readily share data with physicians or HIEs. We encourage the Agency to require that this data be shared and be made more publicly available similar to the other data addressed in this proposed rule.
Quality Payment Program (QPP) and Information Blocking

CMS is proposing to publicly report, using an indicator, when eligible clinicians submit a “no” answer in response to any one of the three information blocking attestation statements required under the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability category.

PAI does not support this proposal. The Promoting Interoperability MIPS category is continuously changing and was completely overhauled for the 2019 QPP participation year. This has caused confusion among physicians who must learn the new reporting requirements and track the changes. Until there is more stability in the QPP and MIPS program, we do not believe this information should be publicly reported.

Provider Digital Contact Information

To increase the number of providers with valid and current digital contact information available on the National Plan and Provider Enumeration System (NPPES), CMS is proposing, beginning in the second half of 2020, to publicly report the names and NPIs of those who do not have their information included in NPPES. CMS is seeking comments on where and with what frequency names should be posted, other enforcement efforts and authorities that could be leveraged (e.g., making it mandatory through MIPS), connecting it to prior authorization and submission of medical record documentation, etc.

PAI is supportive of the Agency adopting incentives to ensure that providers update their information in the NPPES. However, we have concerns of adding this as an additional requirement to already complex federal programs like the QPP, MIPS, etc. As discussed above, the QPP and MIPS program are constantly changing and the lack of continuity in the program makes it complex and confusing. Therefore, we do not think that the requirement should be tied to existing programs. Furthermore, we encourage the Agency to test a more convenient method and medium for accurately collecting this information prior to making it mandatory.

Conditions of Participations (CoPs) for Hospitals and CAHs

CMS is seeking input on revisions to current CoPs that would require hospitals that are electronically transferring medically necessary information to another facility, community provider, patient, or a specified third-party upon patient transfer/discharge. CMS is proposing a new electronic notifications requirement that would require the hospital to send an electronic patient event notification if a patient is admitted, discharged, and/or transferred to another facility or provider. The information included in the notification should include at a minimum provider name, sending institution name, and if not prohibited by other law patient diagnosis. This would be limited to those that currently have EHRs and technical capacity, and similar policies are being proposed for psychiatric hospitals and CAHs.

PAI is supportive of this policy. These notifications are tremendously helpful and valuable to physicians and ultimately patients and the care they receive. However, PAI does not believe this requirement should be limited, but rather all hospitals should be required (if not incentivized) to adopt and implement this technical capacity. PAI also urges that diagnosis information also be made
available as part of this notification. The policy should also be extended to similar, relevant notifications for outpatient setting patients (e.g., when they start receiving care from a new provider in the outpatient setting).

**Interoperability in the Center for Medicare and Medicaid Innovation (CMMI) Models**

CMS is seeking comments on the following general principles on interoperability for integration into new CMMI models: provide patients access to their own e-health information; promote trusted health information exchange; and adopt leading health IT standards and pilot emerging standards.

PAI is supportive of testing newer and additional interoperability policies through CMMI models. Additional waivers may be necessary as well under these models to truly test innovative approaches to integrating and advancing interoperability (e.g., waivers of timeliness requirements or use of specific editions of CEHRT). We caution against making these mandatory under new models as they may deter some physicians and practices from participating in and transitioning away from fee-for-service (FFS) into value-based payment arrangements.

**Request for Information (RFI) on Sharing Information Between Payers and Providers**

CMS is seeking comment for consideration in future rulemaking on the following policies related to payer-provider information exchange:

- Feasibility of providers being able to request and download information on shared patient populations
- Whether this can be accomplished by leveraging the APIs proposed in the rule
- Patient notice and consent requirements, as well as legal and regulatory requirements
- Whether or how data transfer could be cumulative over time between various providers
- Value of obtaining comprehensive patient utilization history in a timely manner
- Potential unintended consequences that could result

PAI agrees with the Agency that effective care coordination between payers and physicians could help physicians understand the totality of their patients’ needs, manage their care, and better understand where their patients are receiving care. HIEs, where available, are a valuable solution to interoperability, bi-directional information exchange, and care coordination among all interested stakeholders (physicians, patients, payers, etc). The Agency should consider leveraging existing infrastructure and HIEs to support interoperability. Additionally, there needs to be more coordination and cooperation between state and federal agencies on how HIT and related funds are allocated for data submission and use. Additional funding and support is also necessary on the physician and provider side to adopt and implement capabilities that would allow them to connect to interoperable systems.
Patient notice and consent requirements are often barriers to health information exchange which can hinder performance under value-based payment arrangements. These will need to be addressed as any policies are considered.

While an open API approach could be utilized to help support bi-directional data exchange, there are shortcomings to this option. PAI believes that this is only one solution and should not be considered the only solution. We urge against imposing the adoption costs of these solutions on physicians and practices. For smaller practices and individual physicians, costly solutions can be burdensome and an obstacle to their ability to contribute to greater health information exchange and care coordination for their patients.

Furthermore, physicians who make data available to other parties should be able to charge fees in certain circumstances, similar to fees that are being permitted under the ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule for API suppliers and data providers.

**Patient Matching RFI**

One of the current barriers to interoperability and patient care is patient matching, which can help centralize patients’ medical record in a single file/resource. CMS is seeking input on opportunities for patient matching that can contribute towards coordinated care efforts.

PAI believes that patient matching is critical so both patients and their physicians can have access to a holistic view into the patient’s health and would allow both parties to make more informed care decisions. Matching claims and encounter data would allow physicians to get a more holistic look at patient health profiles and make decisions based on the totality of the care patients are receiving across the spectrum of medical and health care services. We believe in giving patients more visibility into their medical records and making their information more transparent to them so they can truly be partners in their care.

However, a key component to patient matching is standardization of data elements and a greater focus on data matching. PAI believes that streamlining the reporting requirements, collection standards, identifying common data elements for state, federal, and other programs, and identifying specific data fields would support better patient matching. However, these efforts should be done with stakeholder input, especially those who must enter the data and who must rely on the data for care delivery. The delivery of health care services is a cross-sector model and it is important that the different requirements from each of the sectors be incorporated and aligned within the EHR and health IT elements of the delivery model.

**Conclusion**

Overall, PAI supports CMS’ efforts to streamline and reduce unnecessary burdens placed on physicians related to EHRs, interoperability, and health IT. These adjustments must benefit all physicians and providers equally and should not be designed or structured simply for large health systems. These adjustments also should not disadvantage or be detrimental to small practices, but rather incentivize them to engage in interoperability activities. Lastly, it is important that physicians
and other clinicians not be penalized or held accountable for the actions of vendors, plans, and other third parties that are responsible for complying with the policies resulting from this proposed rule. We welcome the opportunity to work with the ONC to further implement and advance strategies and efforts to reduce burden in a meaningful and impactful way. If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI’s Executive Vice President and CEO, at k2strategiesllc@gmail.com.

Sincerely,

Robert W. Seligson, MBA, MA
President, Physicians Advocacy Institute