



June 3, 2019

Seema Verma, MPH  
Administrator Centers for Medicare and Medicaid Services  
Attention: CMS-1693-P  
P.O. Box 8016  
Baltimore, MD 21244-8013

Re: CMS-9115-P

Dear Administrator Verma:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease.

We are writing to offer our comments to CMS regarding the proposed rule on 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 the Federally-Facilitated Exchanges and Health Care Providers. RPA believes the use of common data elements and improved accessibility to health information has the potential to transform care delivery and improve kidney patient outcomes. Unfortunately, digital records are only part of the equation. Previous efforts have addressed data structure but lacked focus on implementing technology consistently across electronic health records (EHRs). Efforts by others to establish governance models for trusted exchange practices lacked oversight to ensure a uniform understanding of shared medical information. This lack of coordination has been detrimental to providing optimal patient care across sites of service, including physician practices, dialysis units, hospitals and skilled nursing facilities. This lack of interoperability is particularly dangerous to the nation's nearly 750,000 end-stage renal disease (ESRD) patients.

ESRD patients need frequent, ongoing dialysis care. They typically have multiple chronic conditions that require numerous prescribed medications, treatment plans, and lab tests from multiple sources. Dialysis providers are challenged by incomplete transfer of pertinent clinical data from patient hospitalizations, impeding safe care transitions. Among ESRD patients, more than one in three hospital discharges were followed by a readmission within 30 days (35.4%), compared to 21.6% for patients with chronic kidney disease (CKD) and only 15.3% for older Medicare beneficiaries without a diagnosis of kidney disease

(i.e., those greater than 66 years old).<sup>1</sup> Furthermore, while the ESRD population constitutes approximately 1% of the total Medicare population, it has accounted for about 7.2% of Medicare fee-for-service expenditures. The disproportionate readmission rates of ESRD patients' calls into question the communication and care coordination occurring as patients return to outpatient dialysis facilities from acute hospitalization, as well as highlight the need for improved interoperability. The RPA appreciates CMS' efforts in developing these proposals to improve interoperability across sites of service and has included specific recommendations below.

RPA supports CMS's requirement of compliance with ONC content and vocabulary standards and technical standards for an application programming interface (API) to make electronic health information available to both patients and providers and recommend coordination of common content, vocabulary standards, and value sets whenever possible. We believe that this is best achieved by developing and maintaining a fully standardized set of clinical data models supported by both clinical and informatics consensus and review. We believe that joint development amongst consensus-based entities including standards development organizations that draw on the existing body of standards work is critical to maintaining these models. This provision would drive overall consistency in data and technical standards across the industry. We believe that adherence to technical standards is key to implementing interoperability at foundational, structural, and semantic levels.

Overall, RPA supports the move from the Common Clinical Data Set to the United States Core Data for Interoperability (USCDI). We believe that full interoperability cannot be achieved unless data classes are specified as standardized clinical data elements and value sets with terminology bindings to existing data standards. However, we support the inclusion of the quality measurement and registry communities in a regular review process for determining a core interoperable dataset for widespread use. RPA cautions that the USCDI was not developed for public health or registry reporting and that real-world testing must be done prior to future development of the USCDI.

- RPA supports the proposed requirement that payers provide patients with access to their health care data through an application programming interface (API). We agree with CMS that patients should have the ability to decide how their information will be used by consumer-facing apps, and we have listed below several ways CMS can incentivize app developers to keep patient health information private.
  - CMS should require payers to provide prior authorization requirements to patients and physicians.
  - While physicians must provide information to patients free-of-charge, CMS has not indicated that the same requirement applies to payers. It is unclear who will absorb costs associated with providing this information; requiring providers to do so will provide an unnecessary burden on physician practices.
  - CMS should ensure that beneficiaries should have assurances that information provided across settings (e.g., online web portals, smartphone apps, payer policy booklets, etc.) contain consistent information.
- RPA supports the proposal that certain payers make available provider directory information through an API to current enrollees, prospective enrollees, and the public.

---

<sup>1</sup> US Renal Data System: USRDS 2018 Annual Data Report: Atlas of Chronic Kidney Disease & End-Stage Renal Disease in the United States. Bethesda, Md., National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2018.

- We recommend extending this requirement to qualified health plans (QHPs) in federally-facilitated exchanges (FfEs).
- We also urge CMS to require payers to update their provider directories in real-time and expeditiously correct errors, and strongly encourage CMS to implement and enact enforcement actions for payers that demonstrate noncompliance.
- RPA appreciates the importance of trusted exchange networks (TEN) for information exchange but recommends that CMS include language in its final rule preventing insurers from requiring TEN participation as a term of network contracts.
- RPA urges CMS to move away from additional punitive levers related to information blocking and increase its efforts to provide positive incentives that will continue to increase rates of interoperability and patient access.
- RPA agrees with the general goal of including digital health contact information in a national provider directory.
  - CMS should encourage the development of this directory through positive incentives as opposed to public shaming, Medicare enrollment/revalidation, or Medicare reporting programs.
  - The directory should be accessible only to the provider and payer community (as opposed to public) or, alternatively, should utilize an industry solution that is selected via a transparent process with input from cross-industry stakeholders.
- RPA agrees with CMS that coordination of care across institutional and non-institutional settings of care, as well as timely, electronic exchange of health information to support patient admission, discharge, and transfer (ADT) is a desirable goal. As kidney patients are seen in multiple locations, including physician office practice, dialysis units, hospitals and skilled nursing facilities, this data exchange is critical to optimal patient care management.
  - However, the proposal is vague and, as drafted, could place substantial burden on physician practices.
  - We advocate for common data element definitions (and curation of those data elements), to enable sharing of data.
  - Furthermore, CMS should not include technology in regulatory standards that have not been field-tested.

Additionally, RPA has identified the following four areas of concern related to physician contracting requirements, privacy, payer-to-payer exchange of clinical data, and payer overreach into a physician's electronic health record (EHR).

### *Physician Contracting Requirements*

As this rule will impose additional requirements on payers to provide certain types of information to patients and exchange information with other entities (e.g., other payers and trusted exchange networks), we are concerned that payers may "pass down" similar requirements onto their network physicians through burdensome or coercive contractual requirements. For example, as explained in more detail below, a payer may force a physician to participate in the same exchange in which the payer participates so that it has access to the physician's clinical information. This would likely lead to physicians who

contract with multiple Payers needing to comply with multiple network requirements and take on costs and administrative burdens associated with each network.

CMS anticipates—and in fact encourages—that payers will impose contractual requirements on physicians. Recognizing that payers’ ability to provide data quickly will depend on providers submitting the data on a timely basis, CMS “urges payers to consider whether their contracts with network providers should include timing standards regarding the submission of claims and encounter data to comply with API requirements.” This suggestion fails to consider potential downstream consequences, including whether such tactics will narrow a payer’s provider network. Narrow network plans have become increasingly common in private health insurance markets, including Medicare Advantage. RPA and the American Medical Association (AMA), along with others, have raised concerns that narrow physician networks create challenges for patients seeking care and pose potential patient protection issues. Payers have much more leverage in a physician-payer relationship than a physician—particularly a small physician practice—and they will point to CMS’ comments to coerce physicians. If a physician refuses, a network narrows. To guard against this, **CMS should prohibit payers from using these proposals to place additional contractual demands on physicians and impose meaningful penalties for payer noncompliance with this new prohibition.**

### *Privacy*

RPA strongly appreciates CMS’ acknowledgement that “unscrupulous actors” could use apps to profit from an individual’s information in ways that the individual did not authorize or understand. Unfortunately, stories and studies abound about how smartphone apps share sensitive health information with third parties, often without the knowledge of an individual. If beneficiaries access their and their family’s health data—some of which are likely sensitive—through a smartphone, a patient should have a clear understanding of the potential uses of that data by app developers. Otherwise, most patients will not be aware of who has access to their medical information, how and why they received it, and how it is being used (for example, an app may collect or use information for its own purposes, such as an insurer using health information to limit/exclude coverage for certain services, or may sell information to clients such as to an employer or a landlord). The downstream consequences of data being used in this way may ultimately erode a patient’s privacy and willingness to disclose information to his or her physician.

To assist in preventing this scenario, the RPA has identified an opportunity for CMS to empower patients with meaningful knowledge and control over how apps use their health data. **CMS should require that payers’ APIs check an app’s attestation to:**

- **Industry-recognized development guidance** (e.g., Xcertia’s Privacy Guidelines);
- **Transparency statements and best practices** (e.g., Mobile Health App Developers: FTC Best Practices and CARIN Alliance Code of Conduct); and
- **A model notice to patients** (e.g., U.S. Office of the National Coordinator for Health Information Technology’s [ONC’s] Model Privacy Notice).

The app could be acknowledged or listed by the API developer in some special manner (e.g., in an “app store,” “verified app” list). We would urge CMS to limit its BlueButton 2.0 app listings to those apps that have replied “yes” to all three attestations.

We recognize that a “yes” attestation would not ensure apps implement or conform to their attestations. However, app developer attestations would be a powerful resource for the Federal Trade Commission (FTC) in its enforcement of unfair and deceptive practices. In other words, an app developer would be strongly motivated to attest “yes” and to act in line with their attestations. We do not believe that

requiring an API check for an app developer attestation would be a significant burden on health IT developers. We also specifically note that this proposal does not ask CMS to regulate apps or app developers; rather it regulates the type of API technology that Payers must adopt.

CMS can implement this requirement even if ONC does not since CMS' proposal does not require Payers to use Health IT Modules certified by ONC. We firmly believe these sorts of "checks" on an app will provide a needed level of assurance to patients and would be greatly welcomed by users.

#### *Payer-to-Payer Exchange of Clinical Data*

CMS is proposing to require payers to coordinate care between plans by exchanging a set of clinical information (the U.S. Core Data for Interoperability, or USCDI) with another payer upon a beneficiary's request. We support the proposal to the extent that it will promote continuity of care and prevent new prior authorization or step therapy requirements. However, we have significant concerns about whether excessive data access will lead to increased prior authorization and patient profiling—limiting coverage and access to care.

Historically, payers have only had access to clinical information when necessary for payment and allowing EHRs automated access would potentially grant the payer access to information in the EHR beyond what it needs for a particular transaction. This could have negative downstream consequences for patients and physicians. For example, a payer could determine that the patient had already received imaging or another service from another plan and automatically deny coverage of that imaging service or require unnecessary prior authorization requirements that delay needed care. Even when patients already have coverage, there are examples of payers making coverage decisions based on patient information that neither the patient nor the patient's physician knew the payer was receiving. These concerns are heightened for chronic illness patient populations such as those with CKD or ESRD, who due to the multiple comorbidities and polypharmacy burden associated with their conditions will be both more likely to be the subject of inappropriate payer conduct and more vulnerable to its effects.

Payers must be prohibited from using this information to discriminate against a beneficiary—both newly covered and those in the application process. **CMS should require that payers (a) attest that USCDI exchange between plans cannot be used as a basis to deny or delay coverage, increase rates, or implement step therapy; (b) display information to that effect on their website and in coverage documents; (c) cannot require an applicant or enrollee to request that a previous payer send the information to the payer as part of the enrollment process; and (d) provide language to that effect on enrollment forms and websites.**

#### *Unfettered Payer Access to an EHR*

We have concerns about how payers will obtain the clinical information necessary to comply with CMS' requirement that a payer provide a beneficiary's full USCDI to another Payer at his or her request. The ultimate source of the USCDI's clinical data is a clinician; a Payer will not necessarily have a beneficiary's complete USCDI at any given point.

We anticipate that some commenters will suggest that payers be allowed to pull information out of a provider's EHR via API to promote payer compliance with this requirement while reducing burden on the patient and physician. In fact, some payers are already automatically accessing a physician's EHR for other purposes, either as an elective offering or through contractual requirements. We envision payers viewing this requirement as a logical use case for "tapping into" a physician's EHR. However, physician

practices may not understand that access to this data could lead to selective, discriminatory reimbursement models and intrusion on physician medical decision-making power (e.g., lower reimbursement rates for certain types of care that a physician deems necessary or in the best interest of the patient). Furthermore, physician practices could be priced out of markets because a payer determines that they are a “second- or third-tier” option based on the totality of the information in the EHR.

Accordingly, **CMS should clearly state that (a) payers are not entitled to receive information from a health care provider if such information is protected by federal, state, or local privacy law; (b) physicians may use their best judgement in responding to a request from a payer for clinical information to the extent allowed by law; and (c) payers may not condition provider participation in a plan based on whether a physician will grant the payer electronic access to the practice’s EHR to fulfil requests for the USCDI.**

RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation’s kidney patients, and we stand ready as a resource to CMS in its future work. Thank you for considering these suggestions and please let us know if you have any questions. Any questions or comments regarding this correspondence should be directed to RPA’s Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at [rblaser@renalmd.org](mailto:rblaser@renalmd.org).

Sincerely,

A handwritten signature in black ink that reads "Jeffrey A. Perlmutter" followed by a stylized flourish.

Jeffrey A. Perlmutter, MD  
President