

June 3, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Don Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)
21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Ms. Verma and Dr. Rucker:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P) and the Office of the National Coordinator's (ONC) proposals in support of 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. ASN represents more than 20,000 physicians, scientists, nurses, and other health professionals dedicated to improving the lives of more than 40,000,000 Americans with kidney diseases.

ASN supports this overall proposed rule set to promote electronic data exchange and stop data blocking to improve health care quality by ensuring that patients have timely access to important health information and have the ability to share it confidentially with the physician of their choice. While ASN has some concerns about specific provisions, the society commends your leadership through these proposed rules.

In service of the goals of these proposals, ASN has several issues it encourages CMS and ONC to resolve in final rulemaking or during a period of delayed implementation. Some of these issues are affected by only one proposal and others are impacted by the set of proposals. ASN requests that CMS and ONC address these issues as to their

final effect as a whole.

1. Definitions

Several terms are in need of more clarity regarding what is included and what is not. The two most significant terms are “electronic health information (EHI)” and “updated certified criteria.”

A clear definition of EHI is critical to prevent unintended data blocking. ASN is very concerned regarding how “open ended” this definition is and what it means to clinicians as they prepare their notes. What constitutes “everything” in a patient’s EHI and is that the same as “everything” in a patient’s electronic health record (EHR)? Greater specificity in this area is critical so that clinicians know what is expected of them—particularly in light of the severity of penalties for data blocking.

2. Implementation Timeline

ASN joins a growing chorus in the healthcare community that has expressed concerns that the timeline is too compressed and may cause significant unintended consequences that could be avoided through stepwise implementation. The society is supportive of the overall direction of these changes and believes the most successful path to implementation may incorporate a slower timeline than originally proposed.

Most notably, the compliance deadline for EHR systems is the same as for clinicians. ASN believes it makes more sense to accomplish EHR compliance before mandating usage by already overburdened clinicians who will need time to prepare their practices through training and administrative planning. The society urges CMS and ONC to adjust the timeline to allow software and EHR providers to complete their tasks before clinicians attempt to utilize the system.

ASN will plan efforts to educate its members about the coming changes, but ASN also urges CMS and ONC to develop resources to help clinicians prepare well in advance of the new requirements.

These adjustments to the timeline will help clinicians provide a smoother transition to full patient access to their own healthcare data.

3. Burden and Information Overload

Of concern to ASN is the proposal to require that clinicians close out an encounter in the patient record within one day. With highly complex patients, such as those with advanced kidney diseases, the need for additional labs, robust feedback, and second opinions that go into treatment decisions often cannot be completed in a day. An artificial deadline may result in physicians entering information to meet the one-day requirement that leads to less informative and less comprehensive records and communications sent to other providers. ASN encourages the agencies to not adopt this mandate.

ASN encourages CMS and ONC to closely monitor the financial impact of these proposals. There are several areas in which burdensome costs could be passed on to physician practices. Examples of potential financial burdens crosscut both the implementation stage of the proposals as well ongoing compliance. As EHR vendors update systems to be FHIR (Fast Healthcare Interoperability Resources) compliant, there is a concern that those changes and the addition of data segmentation and consent management software could represent substantial costs for some practices. There are also the potential costs associated with data use overages. ASN is concerned that API (Application Programming Interface) development/vendor costs and data overages will be passed on to physicians with no way to recoup these costs.

It is also unclear if the burden will be on the physician to prove, and how, that they were not blocking information. ASN requests that CMS and ONC share more information concerning how they will monitor compliance with these new regulations and urges CMS and ONC to take steps to minimize any additional reporting burdens for healthcare professionals.

4. **Dialysis Facilities**

Inclusion of dialysis units, most often separate from larger healthcare systems or physician practices, is not specifically mentioned in the rule. Dialysis patients can receive very segmented care partly because of EHR interoperability. As a result, it is important that bidirectional sharing occur between other healthcare settings and dialysis facilities. ASN believes that interoperability can promote safer care for dialysis patients. The society realizes that the proposed rule references dialysis facilities only as a possible inclusion in future innovation models. However, ASN encourages CMS and ONC to consider including dialysis facilities in the finalized rule.

5. **Privacy and Security**

The society requests that safeguards be firmly in place for HIPAA standards that protect the patient and their clinician from unregulated and poorly designed APPs (software applications). Patients need these protections and clinicians cannot assume the liability for APPs that mishandle confidential patient information. ASN appreciates the set of frequently asked questions (FAQs) from the Office for Civil Rights (OCR) that was prepared during the comment period to address these specific issues and urges CMS and ONC to monitor implementation of the rule set to determine if the steps taken by ONC are sufficient to address these concerns.

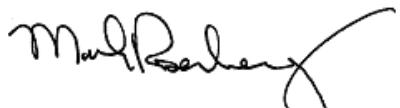
6. **Imaging**

ASN is concerned that the proposed rules do not properly address imaging study requirements. EHR systems often contain metadata around the available imaging studies, however, the imaging studies themselves are frequently stored in separate systems known as picture archiving and communication systems

(PACS). Providers should be responsible for sharing this imaging data, regardless of the technology supplier they choose. The society recommends making PACS vendors subject to EHR certification rules, specifically for API access requirements.

ASN stands ready to assist CMS, ONC, and the society's members in this important effort in any way possible. If you have any questions, please contact Rachel Meyer, ASN Director of Policy and Government Affairs, at rmeier@asn-online.org or (202) 640-4659.

Thank you,

A handwritten signature in black ink, appearing to read "Mark Rosenberg".

Mark E. Rosenberg, MD, FASN
President