June 3, 2019

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services, Attention: CMS-4180-P
P.O. Box 8016
Baltimore, MD 21244-8013

Dear Regulations Staff:

Re: CMS-9115-P: 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

Point-of-Care Partners (POCP) is pleased to provide the Centers for Medicare and Medicare Services (CMS) with comments on the subject proposed rule.

POCP is uniquely positioned to comment on this proposed set of requirements. We are a nationally recognized consulting firm in the areas of electronic prescribing (ePrescribing); standards to support payers, prescribers and pharmacies; specialty pharmacy automation; electronic exchange of health and administrative data; interoperability of electronic health records (EHRs); and electronic medication management. POCP also provides related management and strategic consulting services in those areas to a wide range of stakeholders.

Since 2006, POCP has been a leader in the development of standards and transactions being adopted under the Health Insurance Portability and Accountability Act (HIPAA) and Medicare Part D. We have testified frequently before the National Committee on Vital and Health Statistics (NCVHS), as well as provided technical assistance to both CMS and the Office of the National Coordinator for Health Information Technology (ONC). This year, we testified before the United States Senate Special Committee on Aging and the Health Information Technology Advisory Committee (HITECH).

Most recently, POCP has been at the forefront of the development of standards for electronic prior authorization (ePA) and the Real-Time Pharmacy Benefit Check (RTPBC). We currently are helping to lead the Da Vinci project, which is a multi-stakeholder effort for use of HL7's FHIR (Fast Healthcare Interoperability Resources) standard to facilitate the exchange of clinical and administrative data among payers in support of value-based care. FHIR also shows promise for the development of application programming interfaces (APIs) for patients to access their data and better understand their financial liability for their health care and treatments.

Our comments are provided below.

1. Implementation date. This draft rule is closely linked to the one (RIN 0955–AA01) that was issued simultaneously by the Office of the National Coordinator for Health Information Technology (ONC). The two proposed rules are linked both by having similar requirements and similar goals to improve interoperability. Yet they have different compliance dates: January 1, 2020 for CMS and up to several years later for various portions of the ONC draft regulation. This is confusing to developers, payers and

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providers—especially in light of the scope of the changes that are proposed (e.g., requiring widespread adoption of FHIR) and the time that stakeholders will need to address them.

Many payers and electronic health record (EHR) developers will consider the implementation date of 2020 to be too aggressive. It will not give enough time for payers, in particular, to adapt to the requirements. Payer systems are designed to import data for the purposes of claims processing. They are not set up to export data or use the FHIR standard. Similarly, many EHR developers will need time to build to the requirements; vet, connect with and test various application program interfaces (APIs); and adjust their products' workflows to accommodate the incoming payer data.

- **Recommendation 1a:** We recommend that the implementation dates for the ONC and CMS draft rules are synced in the corresponding final rules.
- **Recommendation 1b**: We recommend that ONC and CMS work with the industry to adopt the most aggressive schedule feasible for payers and EHRs, no later than January 1, 2022 for both to maintain forward momentum.

2. Payers must make data available through FHIR APIs. Both proposed rules call for use of open application programming interfaces (APIs) based on the Health Level 7 (HL7) FHIR (Fast Healthcare Interoperability Resources) standard. Many EHRs already have developed APIs using FHIR, but it's now part of the certification process. It's worth noting that EHRs that have developed APIs have entire programs and app stores, meaning they certify those to whom they grant access and, in many cases, charge them a fee. While patients should surely have access to their data – and be able to direct it to a provider of choice – it is unclear in the proposed rule how payers will be allowed to grant this access.

- **Recommendation 2a: The final rule should include mechanism(s) for CMS and ONC to continue their subject matter and financial support of payer programs to grant patients and their providers access to their data, such as through consensus-building projects like Da Vinci, while continuing to support the necessary training and technical support needed for HL7 and FHIR to gain adoption at the pace that is required by the proposed regulations.**

3. Use of standards. The draft rule proposes the use of FHIR for application programming interfaces (APIs). It also proposes that API developers must use standards for privacy and security under the Health Insurance Portability and Accountability Act (HIPAA) and electronic prescribing under Medicare Part D (as appropriate), as well as those required under ONC's certification process.

That said, there are many other transaction, data and content standards that will be needed to handle the range of personal health information that will be shared among patients and payers under the proposed rule. Some are already well established in the marketplace, others are works in progress, such as the Real-Time Medical Benefit Check transaction, which will provide patients at the point of care with accurate, real-time information on copayments; costs for drugs, devices and procedures that will be covered by insurance; and potential out-of-pocket costs.

The proposed rule does not address use of such standards. This makes it challenging for EHR developers to allow APIs access to their systems and incorporate API-provided information into clinical and pharmacy workflows. Without using named standards, APIs run the risk of being one-offs to import and export data, negating the value of requiring FHIR as the ubiquitous standard.

- **Recommendation 3a**: **CMS should require API developers to use FHIR, where applicable.**

- **Recommendation 3b: CMS should acknowledge existing mandates for HIPAA privacy and security and other named standards where they are fit for purpose and have successful adoption and consider naming additional standards to further support the scope of the proposed requirements**.

4. Focus on standards and not versions. While the proposed rule specifies several required standards, it does not specify the versions. The proposal is to give technology suppliers flexibility to evolve versions as the technology advances. We understand the reason for not mandating a particular version; otherwise, ongoing rulemaking would be needed as versions change. The unintended consequence, however, could be a free-for-all with different vendors supporting different versions. It will be challenging enough for technology suppliers to support the mandated API's and standards. That challenge will be multiplied if multiple versions of standards need to be supported as well.

In addition, the required support of all these standards and versions perpetuates the need for clearinghouses and integration vendors. Not everyone will be able to transition to new standards at once due to the breadth of such an undertaking and the large number of distributed systems. There will be a need for translation by clearinghouses for some time into the future.

- **Recommendation 4a: CMS cite the use of specific standards. If not, the final rule should acknowledge the role of--and use of—clearinghouses and integration vendors.**

5. Patient access to data. A main objective of the proposed rule is to provide patients access to their health information. While this is a laudable goal, providing patients with their information through a plethora of available APIS could have unintended consequences. For example, this has the potential to create a massive surge in codified, structured, and unstructured data available to patients, providers, and other stakeholders. How will data be normalized from multiple disparate sources and for categories of stakeholders? This requirement does not address the need for patients and their caregivers to understand the claims and encounter data they will be given. Health literacy generally is very low.

In addition, payers would be required to implement and maintain an open API that allows third-party applications (with approval from the patient). This can be very confusing, especially if the patient wants to use several APIs, one that requires an opt-in mechanism and others requiring opt outs. Regular mail and/or emails also are options, but they need to be tracked and maintained. This needs to be fleshed out in the final rule to ensure consistency across APIs.

- **Recommendation 5a: CMS should institute a comprehensive patient education program to explain the initiative and how to interpret the administrative and encounter data they will be receiving.**

- **Recommendation 5b: The final rule should specify how patient consent is to be obtained and managed. In the case of opt-in or opt-out, only one method should be specified to create consistency across APIs and reduce beneficiary confusion and frustration.**

6. Drug Benefit Data, Including Pharmacy Directory, and Formulary Data. The draft rule proposes that drug benefit data, including pharmacy directory information and formulary or preferred drug list data, be available through an API to beneficiaries. While formulary or preferred drug list data might be useful to some patients, it is likely to be confusing to most.

It also is unnecessary for several reasons. For example, formulary information already is being made available to the provider as part of electronic prescribing workflow, where it can be discussed with the patient as part of the care process. Such information on the patient level is unnecessary in view of the required use of the Real-Time Pharmacy Benefit transaction, which provides additional, real-time data on costs for individual patients.

Similarly, the role of clearinghouses and intermediaries is critical in pharmacy directory information, as it ideally should be provided to prescribers as part of the prescribing process to determine which pharmacy is the optimal candidate for the prescription. The information provided under the pharmacy directory requirement needs further clarification. Does it include specialty pharmacies? How and when would it be updated?

- **Recommendation 6a:** CMS should consider making drug benefit data, including pharmacy directory information and formulary or preferred drug list data, available to the public on its website.

- **Recommendation 6b**: CMS should work with the industry to define the best options to make the data, including pharmacy directory information and formulary or preferred drug list, broadly available in a standardized format.

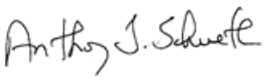
7. Admissions, Discharges and Transfer notifications. The proposed rule seeks to modify Medicare's Conditions of Participation (CoP) for hospitals and critical access hospitals by requiring these participants to send electronic notifications to designated providers when patients are admitted, discharged, or transferred (ADT) to healthcare facilities or providers. In order to provide for seamless transitions of care for patients, CMS should support ambulatory and other facilities to ensure their readiness to accept the notifications.

- **Recommendation 7a**: CMS should work with the industry to ensure the ambulatory community's readiness to identify the initial critical notifications that are actionable from acute care, LTPAC, payers and all members of a patient's care team, including initial testing that verifies the receiving provider can identify, verify, and communicate with the sending facility.

Conclusion. Point-of-Care Partners is pleased to offer comments on the proposed regulation. Please do not hesitate to ask for clarifications or additional information. You can reach me at tonys@pocp.com.

Thank you for the opportunity to comment on this draft regulation.

Sincerely,



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