Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1694-P,
P.O. Box 8013,
Baltimore, MD 21244-8013

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Dear Administrator Verma,

On behalf of the CARIN Alliance, we thank you for the opportunity to comment on the proposed rule for the Hospital Inpatient Prospective Payment Systems. We appreciate your consideration of our comments.

The CARIN Alliance is a multi-sector group of stakeholders representing numerous hospitals, thousands of physicians, and millions of consumers, individuals, and caregivers. We are committed to enabling consumers and their authorized caregivers easy access to their personal health information. Specifically, we are promoting the ability for consumers and their authorized caregivers to gain digital access to their health information via open APIs.

Shift from "Meaningful Use" to "Promoting Interoperability"

The CARIN Alliance appreciates, and thanks you for, CMS's efforts to promote the exchange of health information and the enablement of access by consumers. As you know, many stakeholders have struggled to realize the benefits of electronic health information technology in the last several years. Over the last several years the proliferation of electronic health records has brought positive changes to the health care ecosystem. However, providers have noted the increased reporting burdens they operate under and the challenges they face when interfacing with some systems. Similarly, many patients have not achieved their goals of easily moving their health information through the system electronically. Vendors have felt that innovation has been stifled because of their required architecture.

CMS's reframing of the EHR Incentive Program away from a "meaningful use" reporting structure, with "all or nothing" thresholds and a broad set of measures, towards a system that will

prioritize liquidity of data, provider ease and innovation, patient empowerment, and seamless transfer of information is a material enhancement to the program. We have great hope that this shift will be more than nominal and that CMS and ONC, as regulators, will truly allow for increased information transfer, reduced provider burden, and technological innovation. Thank you for your efforts to transition the EHR Incentive Program towards more innovation and the prioritization of patient access and interoperability.

CMS' continued requirement to implement the APIs associated with the 2015 edition by 1/1/2019

We appreciate CMS's continued requirement to implement the APIs associated with 2015 Edition Certification. We note our joint appreciation that CMS is moving forward with the requirement to implement 2015 Edition Certified Electronic Health Record Technology (CEHRT) for the reporting year starting on January 1, 2019.

Specifically, the CARIN Alliance notes that, to improve on interoperability and access for consumers, ensuring the consistency of data access is important. We suggest that, as detailed below, CMS require, as part of the "Provide Patients With Electronic Access to Their Health Information" measure, that the patient access capabilities, including the API should remain available in production once initially enabled, especially for the 2020 reporting year, even if the reporting period is 90 days as proposed.

CMS proposes that for reporting years 2019 and 2020, providers will be required to attest to using 2015 Edition CEHRT for any continuous 90-day period during each year. The CARIN Alliance recognizes that various stakeholders throughout the health care community have various reasons to both support and oppose the 90-day reporting period. The Alliance has no position on such a policy.

However, although measurement is limited to 90 days, CMS should clarify that, as part of the current PIP information block attestation that the consumer-facing API remain enabled, once it has been turned on. Note that we are not suggesting that providers must report thresholds for API outside of the reporting period. Rather, we suggest that CMS provide guidance to providers that API access, once enabled, must stay on. If it does not, they may not attest to compliance with information blocking sections currently mandated. We note that temporary outages for upkeep, maintenance, or for purposes of protecting information security, (i.e., cybersecurity issues) should not be considered "information blocking" for attestation purposes. Both HHS and CMS have underscored the priority of making more data available to consumers through the MyHealtheData initiative. As part of this initiative, patients and consumers are encouraged to access their health information, including their longitudinal health record and information about their claims through BlueButton 2.0. Prioritizing API access, and the development of consumer facing apps, should be an ongoing activity.

Additionally, we urge CMS to conduct an educational campaign for providers and consumers about the importance of the ability to access health information and to encourage providers to

maintain API access throughout each reporting year. The educational campaign should also focus on new responsibilities to keep health information private and secure.

Next, we appreciate CMS's focus on providing patients access to their electronic health information through the weighting structure outlined in the Promoting Interoperability scoring structure. At forty out of a possible one-hundred for reporting year 2019, it is clear that CMS is working to prioritize consumer access to their information. We strongly support this recommendation and encourage CMS to finalize this scoring structure in the final rule.

We are similarly appreciative of the ongoing prioritization of this metric in future reporting years. We would encourage CMS, though, to maintain the weighting at forty out of one hundred for future reporting years. While we recognize the balance that needs to be achieved in weighting, we also believe this this is a critical measure that should be prioritized.

Expanding the Amount of Data Available via through the USCDI

At various points, through multiple rulemaking activities, ONC has required data in the Common Clinical Data Set (CCDS) to be made available electronically. ONC is also progressing the definition of the US Core Data Set for Interoperability in support of the 21st Century Cures Act's trusted exchange framework. This progresses the CCDS to expand over time to include non-clinical data as well relevant to both clinicians and consumers. While we note that the CCDS is an ONC construct only and incorporated by reference in CMS rules and guidance via references to use of 2015 Edition, and specific 2015 functionality in current Patient Access specification sheet, we encourage CMS and ONC to update certification references to the USCDI once in place. Close coordination between ONC and CMS is necessary to avoid ambiguous or conflicting requirements.

With this recommendation in hand, we note the need for a progression and glidepath of CCDS to USCDI for both vendors and providers. This need underscores the importance CMS and ONC coordination, as well as ample opportunities for input from stakeholders.

Viability of two-factor authentication as it relates to providers and patients

Two-factor authentication is an opportunity to better identify individuals across systems. The CARIN Alliance believes the health care industry would benefit from a universal two-factor authentication open standard called FIDO. The FIDO Alliance recently announced it will become ubiquitous at no additional cost across multiple internet browsers for both desktop and mobile. The CARIN Alliance believes this open standard can be adopted by the health care industry to better secure individuals who authenticate across systems using industry-leading universal two-factor authentication. The open standard will dramatically increase security across systems and lower the operational burden associated with identifying individuals within and across systems. We urge CMS to work with ONC to encourage the use of two-factor authentication for use of apps associated with the open APIs.

Should participation in the TEFCA count as a future reporting measure?

CMS is requesting specific feedback on whether participation in the TEFCA should be included in a future, activity-focused, reporting measures. The CARIN Alliance asks that CMS define more precisely what "participation" means and exactly how it would be measured. We note that EHR vendors may need to enable participation in multiple networks, while providers need to activate their participation. Additionally, we note that it would be the provider that in most cases would need to agree to terms that flow-down from the TEFCA and not only their EHR vendor.

While there is concern among some of our members about using TEFCA participation as a reporting measure, adoption of the TEFCA or a similar trust agreement could be considered as an "activity" in future years. This would require that both a provider and their EHR vendor agree to TEFCA provisions but, in our recommendation, would not be limited exclusively to the TEFCA. An activity that outlined ways that the TEFCA or other agreements support new technologies and data liquidity would likely increase sharing and advance interoperability.

Should hospitals who provide patients open, persistent API access to their data receive credit in a future reporting activity-based measure?

The CARIN Alliance appreciates the move away from numerator and denominator measurement towards activity-based reporting. On this specific issue, we ask for additional clarification that this measure is distinct from Provide Patient Access measure. If this is a separate way for achieving the 40% score, many providers might appreciate the opportunity to earn their score through this method. If this is a separate, "extra-credit" item, we encourage you to move this proposal forward.

Next, we ask for additional clarification on the issue of "open, persistent API access." Specifically, is this different from the Provide Patient Electronic Access to Their Health Information measure and the information blocking attestation? Additional clarity on these points will be appreciated.

Could hospitals receive credit for participating in a pilot program to test bulk data queries for population health data in a future reporting measure?

We appreciate CMS's thinking about how to test bulk data queries. While CARIN is primarily focused on empowering individual consumers to access their data, we believe that there is great good that can be accomplished through bulk queries that enable population health management.

If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?

We appreciate the opportunity to comment on this issue and the clear priority of advancing electronic exchange evidenced in this concept. We do not believe that including this as a

CoP/CfC/RfP is necessary. As discussed above, we believe there are other mechanisms in place—and additional mechanisms in process—that will accomplish the goals of information sharing.

Alignment between Medicaid and Medicare Programs

As noted throughout this comment, we appreciate CMS's efforts to move the EHR Incentive Program away from a numerator and denominator approach towards activity-based measurement. However, we are concerned that Medicaid Eligible Providers and Hospitals will be left with requirements that are separate from Medicare providers. Specifically, we are concerned that Medicaid EPs will not be required to maintain the same level of API access. Allowing for some variability in the programs, while strongly promoting API access, is important.

Conclusion

We appreciate the efforts of CMS to advance consumer access to their health information, through the new Promoting Interoperability Program, BlueButton 2.0, and MyHealtheData. Allowing providers and vendors to innovate, while promoting patient access and uniform access to patient-focused APIs is critical. At a high level, we reiterate our desire for consistency, uniformity, and transparency around API development such that APIs don't further create "walled gardens" in health IT. We applaud your work to develop activity-based metrics that encourage consumer engagement.

Again, we appreciate your work here and your consideration of our comments. If you have any questions or additional follow-up, please contact me at david.lee@leavittpartners.com.

Thank you for considering our comments and recommendations.

David Lee
Leavitt Partners
On behalf of the CARIN Alliance