Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1693-P,
P.O. Box 8013,
Baltimore, MD 21244-8013

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma,

On behalf of the CARIN Alliance, we thank you for the opportunity to comment on the proposed rule for the Physician Fee Schedule and Quality Payment Program. 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.

<u>**Shift from "Meaningful Use" to "Promoting Interoperability"**</u>

As we have previously noted, 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 we have previously communicated, and as you clearly 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. As you have rightly pointed out, now that the infrastructure of electronic health information systems is nearly universally adopted, a programmatic shift away from setup measurement towards data liquidity and interoperability is important.

As we have previously communicated, 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. Providers have felt constrained by reporting structures that they do not feel advance care coordination. Therefore, CMS's

reframing of the EHR Incentive Program away from a "meaningful use" or "advancing care information" towards a system that will prioritize liquidity of data, provider ease and innovation, patient access and empowerment, and seamless transfer of information is a material enhancement to the program. We have continued to believe, and hope, that this shift will be more than nominal and that CMS, as regulator, and ONC as facilitator, will truly allow for increased patient access and information transfer, reduced provider burden, and technological innovation.

Thank you, again, 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 appreciate the CMS's emphasis on moving to 2015 Edition product and avoiding the "fragmentation" that may result by continuing to allow eligible clinicians to use 2014 product.

Additionally, we appreciate CMS's ongoing efforts to provide certainty to providers in their scoring methodology for "promoting interoperability" within MIPS. Specifically, we recognize your "request (for) comments on our proposal to add §414.1320(e)(1) that for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year." You further note that requirements for both reporting periods and utilization of 2015 Edition product should be standardized between eligible clinicians and CAHs or qualifying hospitals.

As we noted in our comment on the IPPS proposed rule, we believed that although measurement is limited to 90 days, CMS should clarify that, as part of the Provide Patients Electronic Access to Their Health Information measure reporting that the consumer-facing API remain enabled, once it has been turned on. We appreciate your clarification in the IPPS final rule that CMS expects that providers will leave all functionality enabled once it is turned on, except when needed for maintenance.

Note that we remain consistent in that we are not suggesting that providers must report thresholds for API functionality 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 patient access measure as currently proposed. We again 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.

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. In particular, we believe that developing educational material, including use case briefs, for providers may help them understand the utility of information sharing and the requirements they have under HIPAA to facilitate electronic delivery of health information to their patients.

Expanding the Amount of Data Available via through the USCDI

As we commented through the IPPS process, we reiterate our desire to see a glidepath and progression to the inclusion of more data elements through the US Core Data Set for Interoperability. We believe that progress from the standard CCDS to a paradigm where clinicians and consumers may access other data elements is important. Those additional data elements could include: open notes, claims data, payment information, pharmacy data, long-term care data (using CMS' recently published data element library), real-time pharmacy benefit check, required SDOH elements as part of the accountable health community initiative and others. We also recommend CMS and the ONC take a leadership role in partnering with private industry to develop consensus-based implementation guides for how the standards should be implemented. Disjointed implementation of standards will exasperate the issues associated with interoperability. We encourage CMS and ONC to update certification references to the USCDI once in place. Doing so enables the entire industry to develop a roadmap for true interoperability across systems. Close coordination between ONC and CMS is necessary to avoid ambiguous or conflicting requirements.

As discussed above, we again note the need for a progression and glidepath of CCDS to USCDI for both vendors and covered entities. This need underscores the importance CMS and ONC coordination, as well as ample opportunities for input from all stakeholders.

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

As we noted through our comments on the IPPS NPRM, 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. The FIDO Alliance recently announced its 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.

Alignment between Medicaid and Medicare Programs

As noted throughout this comment, we appreciate CMS's efforts to move the EHR Incentive Program away from the traditional Meaningful Use approach. 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