SUBMITTED ELECTRONICALLY

June 3, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: 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 (CMS–9115–P)

Dear Sir or Madam:

The Healthcare Leadership Council (HLC) is a coalition of chief executives representing all disciplines within the healthcare sector in the United States. It is the exclusive forum for the nation's healthcare leaders to work together to develop policies, plans, and programs aimed at making affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. As part of their mission, HLC members are committed to sharing with providers and the individuals they serve comprehensive access to health data consistent with applicable privacy and security protections. HLC therefore supports the efforts of the Centers for Medicare and Medicaid Services (CMS) in its Interoperability and Patient Access Proposed Rule (the Proposed Rule) to improve facilitated patient access to claims data and advance interoperability. We respectfully submit our comments below to the Proposed Rule. We also want to thank CMS for graciously extending commenters additional time to review and comment on the Proposed Rule given its complexity.

COMMENTS

Application Programming Interfaces

HLC applauds CMS's efforts to make available claims data from Medicare Advantage (MA) plans, Medicaid state agencies, Medicaid managed care plans, Children's Health Insurance Program (CHIP) agencies, CHIP Managed Care entities, and issuers of qualified health plans (QHPs) in Federally-Facilitated Exchanges (FFEs) (Covered Plans and Agencies) to members and others through interoperable Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interfaces (APIs). Individuals with access to their own health information are more engaged, can make more informed patient and family care decisions and can more easily share information among caregivers and providers. As we noted earlier this year in our joint report with the Bipartisan Policy Center entitled, "*Advancing Interoperability, Information Sharing, and Data Access: Improving Health and Healthcare for Americans,*" we believe that rapid adoption and implementation of FHIR-based APIs by providers, payers and other healthcare organizations will help to accelerate interoperability, data access and information sharing.

We are concerned, however, that Covered Plans and Agencies will not have sufficient time under the Proposed Rule to implement this mandate. Under the proposal, MA plans and QHP issuers in FFEs must implement an API by January 1, 2020, and Medicaid FFS, Medicaid managed care plans and CHIP managed care entities must implement an API by July 1, 2020. As CMS acknowledges in the Proposed Rule, the U.S. Core Data for Interoperability (USCDI) standard does not support all of the data elements that Covered Plans and Agencies will be required to share through the API. Although the Blue Button 2.0 project very recently demonstrated one method for using FHIR-based resources to exchange claims data, it will take time for Covered Plans and Agencies (and their selected health IT developers) to build APIs and map their data to the FHIR-based resources. With this Proposed Rule and the Office of the National Coordinator for Health Information Technology's 21st Century Cures proposed rule unlikely to be finalized until later this year, we believe it is unrealistic to expect Covered Plans and Agencies to adopt FHIR-based APIs so quickly. We urge CMS to give Covered Plans and Agencies sufficient time to develop and test their APIs, and ensure the security of the connections they are establishing.

We also want to make note of important privacy and security concerns related to using an API to provide access to third party applications of an individual's choice. The third party applications that individuals will use to access their claims data will typically not be subject to the Health Insurance Portability and Accountability Act's (HIPAA) Privacy and Security Rules because the third party developers do not offer their applications on behalf of covered entities or business associates. Although Section 5 of the Federal Trade Commission Act prevents these application developers from engaging in unfair or deceptive trade practices concerning the privacy or security of information they collect, HIPAA provides more prescriptive security requirements and privacy protections. Many individuals will not fully appreciate that the protections of HIPAA do not extend to the applications they are using to obtain claims data through the API, and that the level of security offered by third party applications varies significantly. While we are pleased

that the Office for Civil Rights (OCR) recently released guidance clarifying that healthcare providers and health plans are not responsible under the HIPAA Security Rule for verifying the security of an individual's chosen third party application, this "safe harbor" does not address the potential vulnerability of members' health information when sent to the chosen application.

HLC proposes that CMS and/or OCR work with the private sector to develop a privacy and security trust or certification framework for third party applications seeking to connect to APIs of healthcare providers and health plans. Such a program could foster innovation, while providing better assurance to members of the security of their health information.

Condition of Participation - Patient Event Notifications

HLC supports efforts to increase the exchange of admission, discharge and transfer information between hospitals and community care providers. We are concerned, however, that the Condition of Participation proposed by CMS is not the appropriate tool to achieve this goal. Under CMS's proposal, the new Condition of Participation would require hospitals to share patient event notifications electronically with licensed and qualified practitioners, members of patient care teams, and post-acute care services providers and suppliers that have an established care relationship with the patient. Notably, the proposal would only apply to hospitals that have adopted an electronic medical records system with the capacity to generate information for patient event notifications, and the potential consequence for non-compliance would be exclusion from the Medicare program.

As CMS recognizes in the Proposed Rule, there is currently no certification criterion under the ONC Health IT Certification Program for sending electronic patient event notifications in the manner proposed by CMS. Although the HL7 Admission, Discharge, Transfer (ADT) message format has been adopted by certain health information exchanges (HIEs), the messages cannot be sent using Direct Messaging or other exchanges used for exchanging continuity of care documents. Hospitals that do not participate in an HIE that manages and directs the flow of ADT messages to the appropriate provider would potentially need to custom develop and maintain this functionality. Given the severity of the potential penalty for non-compliance, and the investment that some hospitals will need to make to comply with the requirement, we are concerned that CMS may actually discourage hospitals from adopting an electronic health record (EHR) that has the capacity to generate information for patient event notifications (a prerequisite for the Condition of Participation to apply in the first place).

Rather than adopt a Condition of Participation, HLC believes it may be more effective for CMS to look for ways to strengthen the business case for exchanging health information in an interoperable manner. CMS has already taken steps in this direction by promoting alternative payment models, shared savings programs and bundled payments. It is in these situations – where hospitals have the potential to receive increased reimbursement by effectively coordinating a patient's care with other providers – that interoperability solutions have thrived. We ask that CMS consider not making the patient event notification a requirement under the list of Conditions of

Participation, or in the alternative that it provide hospitals an extended period of time (at least three years) to adopt and test the patient event notification functionality before enforcing the Condition of Participation.

Patient Matching

HLC supports private sector efforts to improve patient matching algorithms and standardize data elements, as well as private sector efforts to develop unique patient identifiers (UPIs) to improve the accuracy of patient matching. In particular, we encourage CMS to support the standardization of patient demographic data by, for example, applying the U.S. Postal Service Standard to addresses.

The Pew Research Center (Pew) recently collaborated with Indiana University to test whether standardizing demographic fields (including address, phone number, name, and others) would yield improvements to patient matching. To conduct the research, Indiana University ran a matching algorithm across four different databases where the researchers already knew the true matches. Pew then standardized the data and re-ran the algorithm to determine whether standardization generated better matching results. The research indicated that use of the U.S. Postal Service standard for addresses can increase match rates by approximately 2-3 percent—which would make a meaningful difference. Standardizing last name alongside address showed further improvement in match rates (up to approximately 8 percent).

CMS requested information on whether to require program participants to use a patient matching algorithm or a solution with "proven" success validated by the Department of Health and Human Services (HHS) or a third party. HLC recommends that CMS examine how to benchmark different approaches to patient matching, measure the variation across matching algorithms and highlight current limitations. Benchmarking, however, on its own will not improve match rates. CMS should work with ONC to optimize the use of demographic data (including adoption of the U.S. Postal Service standard for addresses and the use of additional data elements).

CMS also requested information on whether to expand recent Medicare ID card efforts by requiring a CMS-wide identifier for all beneficiaries and enrollees in healthcare programs under its administration and authority. Implementing an agency-wide identifier may help CMS better serve beneficiaries and improve matching. This approach, however, is still insufficient to address patient matching on a nationwide scale.

Finally, CMS requested information on whether it should advance more standardized data elements across all appropriate programs for matching purposes by perhaps leveraging the USCDI proposed by ONC. We support the proposed inclusion of address in the USCDI, and again encourage CMS to work with ONC to advance the use of the U.S. Postal Service standard for addresses.

Incentivizing EHR use by Long Term Post-Acute Care Facilities

HLC commends CMS's vision to incentivize increased EHR adoption and information sharing with long term and post-acute care (LTPAC) clinicians and facilities. LTPAC clinicians and facilities play a critical role in carrying out care plans developed for Medicare beneficiaries after hospitalization, which can help prevent further hospitalization. Developing mechanisms that would improve the ability of LTPAC clinicians and facilities to send and receive information with hospitals and primary care providers, such as LTPAC-oriented USCDI content, is an important step towards achieving CMS's vision. We encourage CMS to consider ways to provide financial incentives to LTPAC clinicians and facilities to adopt and implement Certified Health IT, as these providers were not included in the EHR Incentive Program. We believe the best approach is one that 1) facilitates efforts by standards development organizations to develop health IT standards for LTPAC use cases and 2) rewards LTPAC clinicians and facilities who adopt these health IT standards.

Conclusion

HLC appreciates this opportunity to provide comments on the CMS Proposed Rule. Please contact Tina Grande at 202-449-3433 or tgrande@hlc.org if there are any comments or questions about this letter.

Sincerely,

Mary R. Grealy
President