PREMIER TRANSFORMING HEALTHCARE TOGETHER®

June 3, 2019

Administrator Seema Verma
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Re: CMS-9115-P 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

Submitted Electronically: **https://www.regulations.gov/comment?D=CMS-2019-0039-0001**

Dear Administrator Verma:

On behalf of the 4,000 U.S. hospitals and health systems and more than 165,000 other providers and organizations in the Premier healthcare alliance, we are pleased to submit these comments in response to the Centers for Medicare & Medicaid Services (CMS) proposed rule on interoperability and patient access to health data. Premier, a 2006 Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Our comments reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in ensuring that HHS reduces provider and clinician administrative and reporting burdens.

Premier supports efforts to encourage value-based healthcare delivery that emphasizes integrated and coordinated care for patients, as well as to make the administrative aspect of healthcare delivery, such as information exchange for treatment, payment or healthcare operations purposes, more efficient. Premier also advocates for meaningful privacy and security rights for the protected health information (PHI) of our patients. The primary goal is to ensure provider access to accurate health information at the point of care to inform healthcare decisions and achieve best patient outcomes. This must be accomplished in a manner that minimizes administrative burdens on providers.

With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. In the comments below, we provide general comments about the CMS proposed rules and then offer recommendations and comments about specific sections.

GENERAL COMMENTS

CMS' proposed rules along with ONC's 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rules are a good start to further advance nationwide interoperability, data sharing and exchange. It is essential to address ongoing interoperability challenges so that providers can improve care delivery, patient safety and performance, and to drive operational efficiencies. Premier continues to advocate for, develop and implement innovative solutions to achieve open data access across health IT systems and technologies to support the industry's value-based care transition across the care continuum. Interoperability will enable systems to move beyond

13034 Ballantyne Corporate Place
Charlotte, NC 28277
T 704.357.0022
F 704.357.6611

444 North Capitol Street, N.W.
Suite 625, Washington, DC 20001
T 202.393.0860
F 202.393.6499

PREMIERINC.COM

simply recording data in electronic health records (EHRs) toward integrating and combining data to streamline analytics on supply chain, financial, public and population health and clinical care for evidence-based decision-making. Without connectivity across the care continuum, data collection is fragmented and does not provide the total picture necessary for healthcare providers to deliver informed, coordinated care. However, Premier continues to have concerns and offers general comments in the following areas:

- Ensuring increased provider data access and availability at the point of care and within workflow
- Reducing provider administrative and reporting burdens
- Privacy and security

Provider Data Access and Availability at the Point of Care and within Workflow

We are concerned that the proposed rules do not adequately ensure that providers have access to real time information on their patients at the point of care. Providers (i.e., clinicians, hospitals and health systems) need robust, scalable, and interoperable health IT systems and EHRs to improve clinical decision making and deliver improved outcomes. CMS should focus additional attention on the ongoing need for providers to be able to have real time access to data at the point of care and within workflow. While we support patient access to their data this should be in addition to ensuring (not instead of) providers having data access.

The movement towards value-based care and alternative payment models (APMs) has created an even greater imperative for health information exchange and interoperability. Advanced payment models such as ACOs and bundled payments involve participation by multiple providers, suppliers and sometimes payers who are at risk for coordinating the care of patients, requiring the ability to access and aggregate information from different EHRs, health information technology applications and across multiple facilities and care settings.

Data are essential to achieve the vision of a consumer-centered and healthcare provider-driven healthcare system. Premier wholeheartedly supports expanding patients' access to their healthcare data. We are concerned, however, that the proposed rules emphasize data access to patients and consumers without ensuring that providers have unfettered access to their patients' health data.

Healthcare providers need data at the point of care and within workflow to deliver informed, high-quality, safe, coordinated and cost-effective care. The inability to access and integrate timely and complete data across the care continuum from multiple sites of service, diverse providers and various data sources threatens quality of care, patient safety and efficiency. The lack of access to complete and timely data adds inefficiencies and costs to the healthcare system and hampers population health efforts, public health surveillance and reporting.

Healthcare providers (especially under risk-based care and advanced payment models) have inadequate and limited access to timely and complete Medicare, Medicaid, Children's Health Insurance Program (CHIP), Veteran's Affairs (VA) and TriCare data. Missing and lagged data prevent providers from treating and managing care for individuals, populations and communities.

Reducing Provider Burdens

We are pleased that CMS and ONC continue to articulate their commitment to reduce unnecessary regulatory data collection and documentation and reporting burdens and to reduce related costs for providers. Nevertheless, we believe that the proposed rules could compromise efforts to reduce provider burdens and could result in greater burdens and costs. For example, the proposed ONC information blocking rule creates related and potentially overlapping or conflicting requirements on providers such as those under Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Substance Abuse

Confidentiality Regulations (42 CFR Part 2 regulations). Vigilance around alignment of federal programs and their requirements is needed to help reduce provider burden and eliminate redundant and unnecessary reporting.

In addition, the additional Conditions of Participation (CoPs) that CMS proposes for hospitals, psychiatric hospitals and critical access hospitals (CAHs) would create additional burdens on providers, in spite of CMS' noting several challenges (i.e., identifying who has current relationships with the patient and their ability to receive event notifications (admissions, discharges and transfers (ADT)). CoPs create an extreme penalty (i.e. potential exclusion from Medicare). The proposed CoP would require hospitals to demonstrate that their EHRs are generating patient event notifications. Premier appreciates that CMS is seeking to improve interoperability; however, CoPs are not an effective lever to achieve interoperability. CMS could easily align and use existing mechanisms, such as ONC's CEHRT and the CMS Promoting Interoperability programs to achieve ADT functionality within certified EHRs. On the other hand, we are encouraged that in its proposed rules, CMS notes that it continues to consider creating a set of priority health IT activities as alternatives to the traditional Promoting Interoperability measures. To the extent that CMS allows providers greater flexibility to use various health IT technologies and activities, provider burdens can be reduced, duplicative reporting can be eliminated, and interoperability can be further advanced.

Privacy and Security Issues

CMS acknowledges receiving many comments in the past raising concerns about the privacy and security risks created by an API connecting to third-party applications, and it understands that HIPAA-covered entities and business associates are responsible for protected health information (PHI). CMS requests comments on whether existing privacy and security standards, including those under HIPAA, are enough for these proposals or whether additional privacy and security standards should be required by CMS. We recommend **that CMS work with ONC to align criteria and tolerable risk levels appropriate to assessing risk to an API for providing patients' access to their health data.**

Premier is concerned that **CMS understates the risks and potential liabilities faced by HIPAA-covered entities and business associates**[1] and should acknowledge the complexities and implications for privacy and security, especially related to data access, exchange or sharing that occurs outside or beyond the scope of HIPAA.[2] [3] We **urge CMS to work with OCR to issue additional guidance on addressing variation in state and federal laws related to privacy and consent and to further clarify that covered entities are not responsible when connecting to a third-party application requested by a patient**. We note that the Office for Civil Rights (OCR) has recently issued new FAQs (frequently asked questions) to address how HIPAA Rules apply to covered entities and their business associates with respect to the right of access, apps and APIs. **We urge CMS and ONC to work with OCR to continue to develop informational materials and guidances to ensure that stakeholders are more fully informed once these rules are finalized and implemented.** We note that the OCR FAQs pertain to electronic protected health information (ePHI) and uses terms and terminology (such as "electronic health record (EHR) system developer") which differ from terms used in the ONC and CMS proposed

[1] Health Care Industry Cybersecurity Task Force (HHS), Report on Improving Cybersecurity in the Health Care Industry (2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

[2] Risky Business? Sharing Data With Entities Not Covered by HIPAA https://www.manatt.com/Insights/White-Papers/2019/Risky-Business-Sharing-Data-With-Entities-Not

[3] Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges https://ncvhs.hhs.gov/wp-content/uploads/2018/05/NCVHS-Beyond-HIPAA_Report-Final-02-08-18.pdf

rules. We recommend that CMS and ONC work with OCR to harmonize the use of terms where appropriate and develop additional FAQs where gaps exist.

We believe that **CMS understates concerns that unscrupulous actors could use direct-to-consumer applications to profit from obtaining and using or disclosing PHI without the individual's authorization**.[4] Furthermore, CMS has established specific processes for third party application developers to access patient data under CMS' Blue Button 2.0 initiative and to register a beneficiary-facing application.[5] We urge CMS to share best practices and lessons learned with the payers required to provide beneficiaries access to data under this proposed rule.

We recommend that CMS consider additional steps to help ensure the quality and reliability of the third party applications used by patients to access their data.[6] [7] Furthermore, HHS should consider the need for a formal vetting or certification process for third party applications.[8] [9] We note that CMS has implemented a process for reviewing requests from app developers seeking to access patient data from the CMS Blue Button 2.0 initiative and we recommend that CMS consider establishing a similar process for the applications contemplated in this proposed rule.

CMS notes that effective January 1, 2020, payers that would be regulated by the proposed rule would be required to provide current and former enrollees with certain information related to privacy and security of protected health information (PHI). Each payer would be required to provide educational resources on its website and through other normal communication channels with current and former enrollees seeking to access their health information held by the payer. **Premier supports CMS requiring payers to provide education and information for beneficiaries and enrollees abut PHI; but we believe the proposed required actions are inadequate** to ensure that patients, beneficiaries, enrollees and their caregivers will be able to understand the nuances of privacy and security of their health data, especially when such data is shared with third party health applications. We urge CMS to work with ONC and OCR to develop and implement a nationwide educational program for beneficiaries, enrollees and caregivers about privacy and security of their health information, especially focusing on the risks and challenges when connecting to third-party apps that are beyond the scope of HIPAA.

In the sections below, we offer comments on specific provisions in the proposed rule.

TECHNICAL STANDARDS RELATED TO INTEROPERABILITY

CMS proposes specific standards for Medicare Advantage (MA) organizations, state Medicaid and CHIP agencies, Medicaid and CHIP managed care organizations, and Qualified Health Plan (QHP) issuers in the federally-facilitated exchanges (FFEs) (referred to collectively in the preamble to the rule as "payers") and requires that these payers adopt and implement openly published application programming interfaces (APIs) ("open APIs"). CMS intends that enrollees in these plans will be able to use an application of their choice to access their own electronic health information and other information to manage their health. CMS identifies specific types of data to be made available (i.e., adjudicated claims (including cost);

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[4] Fougerouse PA, Yasini M, Marchand G, Aalami OO. A Cross-Sectional Study of Prominent US Mobile Health Applications: Evaluating the Current Landscape. AMIA Annu Symp Proc. 2018;2017:715–723. Published 2018 Apr 16.
[5] https://bluebutton.cms.gov/
[6] de la Vega R, Miró J. mHealth: a strategic field without a solid scientific soul. a systematic review of pain-related apps. PLoS One. 2014;9(7):e101312. Published 2014 Jul 7. doi:10.1371/journal.pone.0101312
[7] https://xcertia.org/the-guidelines/
[8] Larson RS. A Path to Better-Quality mHealth Apps. JMIR Mhealth Uhealth. 2018;6(7):e10414. Published 2018 Jul 30. doi:10.2196/10414
[9] Marceglia S, Fontelo P, Rossi E, Ackerman MJ. A Standards-Based Architecture Proposal for Integrating Patient mHealth Apps to Electronic Health Record Systems. Appl Clin Inform. 2015;6(3):488–505. Published 2015 Aug 5. doi:10.4338/ACI-2014-12-RA-0115

encounters with capitated providers; provider remittances; enrollee cost-sharing; clinical data, including lab results where available; provider directory; and formularies.

Premier supports CMS' reference to and expected use of the API technical standards proposed in the separately published ONC proposed rule on interoperability**. We support CMS' proposal to align its requirements with the interoperability and data standards in the ONC proposed rule.**

We caution **against CMS separately adopting** the proposed ONC standards and/or as future standards on interoperability, content and vocabulary**.** Premier believes that separate standards adoption would risk misalignment of standards or versions of standards across HHS programs. We believe that **HHS should align and harmonize interoperability, health data exchange and access and data standards efforts across agencies.**

The clinical data requirement as proposed by CMS would effectively make any clinical data included in the USCDI (Version 1), proposed in the ONC proposed rule, available through the API if the data is received and maintained by the payer as part of its normal operations. CMS seeks comment on any barriers that may discourage payers from obtaining, maintaining and sharing these data. **Premier urges CMS to work with ONC to consider the potential unintended consequences (duplicative data; misaligned data; data discrepancies) if patients receive clinical data from both their providers and the payers.**

IMPROVING THE MEDICARE-MEDICAID DUALLY ELIGIBLE EXPERIENCE BY INCREASING THE FREQUENCY OF FEDERAL-STATE DATA EXCHANGES

We support CMS' proposal to update the frequency requirements (in 42 CFR 423.910(d) and conforming changes) to require that starting April 1, 2022, all states submit the required MMA file data to CMS daily (every business day for which a new transaction is available to transmit). We believe this alleviates the lag in data that results in the state or beneficiary paying premiums for longer than appropriate. Recoupment and redistribution of funds is a burdensome administrative process between the beneficiary, state, CMS, and SSA. It can take multiple months to correct and resubmit an improperly processed transaction, exacerbating the delays in appropriately assigning premium liability. This can impact beneficiaries' use of healthcare services and possibly result in detrimental health outcomes.

INFORMATION SHARING BETWEEN PAYERS AND PROVIDERS THROUGH APIS: REQUEST FOR INFORMATION

CMS anticipates that in the future payers and providers may seek to coordinate care and share information on an overlapping patient population in a single transaction and notes that such data sharing could facilitate better understanding of where patients are receiving care. Premier appreciates CMS and ONC efforts to ensure that data is made available to patients; however, it is critical that providers can also access data for their patients. Premier supports future rulemaking that would require payers to allow providers to request data on a shared patient population. Understanding their patients' healthcare interactions will help providers better coordinate and manage care. While access to a patient's full clinical data is essential, utilization and claims data from payers can provide a necessary first step in understanding a patient's ongoing healthcare interactions and needs. Moreover, having comprehensive data for a larger portion of the patient population will allow providers to better engage in population health activities.

We support CMS' proposal for collaboration and information sharing between payers and providers through APIs and **urge CMS to undertake additional efforts to help ensure that providers have access to information on their patients.**

CMS further seeks input on the usefulness to providers of obtaining all their patients' utilization history in a timely and comprehensive fashion. Timely and comprehensive information is essential to care coordination. Real-time access to data, including access to claims data that has not been adjudicated, can help providers identify earlier opportunities for intervention. For example, if a provider can access payer data the provider could be alerted when a patient has a claim submitted for a hospital stay. The provider can quickly intervene and assist in care transitions rather than learning of a patient's hospitalization much later.

We recommend that **CMS work with payers and providers to identify what specific data would be shared; the anticipated timing and schedules (real-time; prospective; retrospective) for data sharing; and the specific mechanisms and processes proposed for data transmission.** For example, providers need various data such as those required for verification of benefits and medical eligibility. Beyond identifying the current insurance status of patients, providers need to have data about the amount of coverage and co-pay at point of care for specific orders or referrals. Patients and their providers would benefit from data about out-of-pocket patient costs. Most major EHRs can identify patients' insurance status. Additional information (at the point of care) would be useful for providers such as the amount of coverage and co-pay for specific orders or referrals. Healthcare providers simply can't tell if or how much an order is covered in the patient's plan. **We recommend that CMS leverage ongoing work, such as TEFCA 2.0, Project Argonaut and the DaVinci project, and identify and implement high priority use cases to ensure increased data sharing between payers and providers.**

Providers, especially accountable care organizations (ACOs) and other APMs need more and timelier data on their patients. We support the recommendation to offer flexibility to APM participants. Providers depend on the timely transfer of patient information and coordination of patient care. Since Medicare beneficiaries have the right to seek care from any provider that accepts Medicare, it can be a challenge for ACOs to monitor the services received by their aligned patients. We recommend that CMS and ONC accelerate approaches to ensure ACOs have access to more timely and complete information on beneficiaries' care, such as through alerts or portals that provide ACOs access to claims information upon CMS receipt and prior to CMS processing.

Interoperability will enable systems to move beyond simply recording data in EHRs toward integrating and combining data to streamline analytics on supply chain, financial, public and population health and clinical care for evidence-based decision-making. Without connectivity across the care continuum, data collection is fragmented and does not provide the total picture necessary for healthcare providers to deliver informed, coordinated care. Further, the movement towards value-based care and alternative payment models has created an even greater imperative for health information exchange and interoperability. Advanced payment models such as ACOs and bundled payments involve participation by multiple providers, suppliers and sometimes payers who are at risk for coordinating the care of patients, requiring the ability to access and aggregate information from different EHRs, health information technology applications and across multiple facilities and care settings.

Data are essential to achieve the vision of a consumer-centered and healthcare provider-driven healthcare system. Healthcare providers need data at the point of care and within workflow to deliver informed, high-quality, safe, coordinated and cost-effective care. The inability to access and integrate timely and complete data across the care continuum from multiple sites of service, diverse providers and various data sources threatens quality of care, patient safety and efficiency. The lack of access to complete and timely data adds considerable inefficiencies and costs to the healthcare system and hampers population health efforts, public health surveillance and reporting. Furthermore, lack of provider

data jeopardizes the transformation to value-based care (VBC) and APM. Data access must be a high priority public policy focus because, despite progress, gaps and challenges remain. Legislative and policy actions are needed to remove barriers and obstacles hampering providers' ability to access and use data.

Providers need real-time access to data for care delivery and coordination across diverse and disparate sites of care, clinicians, facilities, and organizations and within different health information systems and EHRs. Federal efforts are needed to require seamless and unfettered provider data access at the point of care and within the workflow. Public sector efforts need to support enhanced and accelerated data and interoperability standards development and consistent implementation.

CARE COORDINATION THROUGH TRUSTED EXCHANGE NETWORKS

CMS proposes that the payers that would be regulated under this proposed rule must participate in "trusted exchange networks" in order to improve interoperability. In January 2018 ONC released a draft Trusted Exchange Framework and Common Agreement (TEFCA) for public comment. The first Draft TEFCA described a high-level proposed network of networks. However, it was difficult to determine to what extent the proposed architecture was reasonable and scalable across use cases, permitted uses and stakeholders. In previous comment letters, Premier urged ONC to further clarify and address the multiple dimensions of and approaches to data access, exchange and sharing and describe how the TEF will accommodate currently envisioned and future stakeholders, health IT technologies, public policies, permitted purposes, queries and use cases.

We note that ONC released TEFCA 2.0 on April 2019 and comments are due June 19, 2019. At a minimum, CMS **needs to clarify if and how their proposed requirement for payer participation in trusted exchange networks relates to the final TEFCA,** before stakeholders can offer substantive comments about the CMS proposed requirement for payers to participate. While CMS enumerates several attributes of such trusted exchange networks,[10] it does not identify which networks would meet these criteria. We recommend that CMS provide examples of existing networks that meet its criteria. Furthermore, we believe that it **is premature for CMS to make this a regulatory requirement until the TEFCA is finalized.**

We urge CMS to work with ONC to accelerate efforts to launch the Trusted Exchange Framework and to require specific interoperability standards (transport, syntax, and sematic) along with technical implementation specifications for health IT systems, EHRs and health information networks. Lacking such standards, stakeholders will not have the data for true coordinated, high quality, cost-effective healthcare. CMS needs to work with ONC and specify policy actions that will be taken to advance the development, adoption and use of industry-recognized data definition and data normalization standards, including the implementation and use of vocabularies, code sets, and value sets. We are cautiously optimistic that once finalized the TEFCA will help achieve nationwide interoperability as envisioned by the Interoperability Roadmap and the 21st Century Cures Act.

PUBLIC REPORTING OF PROVIDERS

CMS proposes to publicly report information on eligible clinicians' attestations under the QPP on the Physician Compare website, and to report similar information on attestations of hospitals and CAHs under the Medicare Promoting Interoperability Program on a CMS public website. In order to comply with MACRA requirements, information blocking prevention provisions were implemented by CMS through the

[10] Is capable of exchanging PHI, (defined at 45 CFR 160.103) in compliance with all applicable state and federal laws across jurisdictions; Can connect to inpatient electronic health records and ambulatory electronic health records; and Supports secure messaging or electronic querying by and between providers, payers and patients.

adoption of attestation requirements, consisting of three statements about a provider's use of CEHRT. To satisfy the Promoting Interoperability requirements, providers (i.e. clinicians, hospitals and critical access hospitals) must attest "yes" to each of the statements. CMS is proposing to utilize an indicator that would publicly report information on providers' attestations on Physician Compare or Hospital Compare. CMS intends to determine the best display and wording after testing and sharing with stakeholders through the Physician Compare Initiative page and other communication channels. CMS reiterates that the proposal depends on the technical feasibility of using these data for public reporting. **Premier is concerned that the CMS proposed rule lacks sufficient details about CMS' intentions to display these data**.

Premier does not oppose requiring provider attestations; however, CMS needs to allow more time for provider experience with CMS' attestation requirements prior to publicly reporting a clinician, hospital or CAH that provides a "no" to any 3 of the CEHRT attestation statements. The current attestation requirements have been in place for only two years. In addition, it is unknown how the proposed CMS and ONC rules may impact the existing attestation questions. We suggest that CMS reevaluate the attestation questions based on the proposed rules commenting processes. Furthermore, the final rules could inform CMS about more concrete assessments that would be better suited for public reporting. For example, one of the existing attestation questions requires timely access by patients and timely exchange of information; however, timely is not defined and is likely to vary based on the stakeholder's perspective. As a result of the implementation of the final rules, it may be better to assess timeliness of response.

The proposed rule notes that additional information would be provided "outside the rulemaking process through usual communication channels" but fails to provide sufficient detail about what CMS intends to do to post this information. Premier urges CMS to delay implementation of public reporting until stakeholders have had the opportunity to help determine the best displays and wording through testing. **Furthermore, CMS' effective date should allow sufficient time for providers to gain experience with the ONC final rules, especially the information blocking provisions.**

CMS should assess the impact of the final rules and make necessary updates to the attestation requirements through future rulemaking. If CMS revises the attestations or incorporates other methods for assessing information blocking, we believe that a period of non-enforcement is needed to allow providers to adjust to the new requirement. We support CMS' proposal to provide a 30-day preview period for providers to review their information before it is posted. CMS should follow the approach it has traditionally followed for public reporting, that is, allowing providers a preview of their results and providing results on all providers in the downloadable database for at least one year prior to including indicators on the Compare provider profiles. This approach allows providers to gain familiarity with reporting prior to public display.

REVISIONS TO THE CONDITIONS OF PARTICIPATION FOR HOSPITALS AND CRITICAL ACCESS HOSPITALS (CAHS)

CMS is interested in feedback from stakeholders on requiring Admission, Discharge, Transfer (ADT) notifications as part of the Hospitals Conditions of Participation (CoPs), to advance electronic exchange of health information in support of care transitions between hospitals and community providers. We support the overall intent, high-level approach, and policy goals of data sharing and exchange and CMS' efforts to improve care coordination via ADT notifications to providers and care managers. We share CMS' desire to address interoperability and data exchange but **Premier does not support using the hospitals' CoP to advance interoperability or data exchange because CoPs are not the appropriate vehicle.**

Premier appreciates that CMS is seeking comments about its proposal to require ADT event notifications as part of hospitals' CoP; however, **CoPs are not an effective lever to spur interoperability or access to data.** The CoPs create an extreme penalty (i.e. potential exclusion from Medicare) and are typically restrictive in acceptable approaches for meeting the condition, thereby limiting providers' flexibility to test and implement novel approaches. **We strongly recommend that CMS focus its attention on existing interoperability-related policy levers and activities underway and planned over the next few years.**

We do not agree with CMS' assumption that certified EHRs will be able to handle ADTs just because these systems may be able to handle other Health Level 7 (HL7) functionality like immunization registries. While it's true the HL 7 ADT is widely adopted, the challenge is the HL7 protocol cannot be sent through Direct Messaging, Care Equality and other exchanges used for the CCD/CCDA discharge. We recommend the agency conduct further analysis of the existing functionalities and how these align with the proposed future requirements.

CMS fails to recognize that event notifications are occurring.[11] [12] [13] We urge CMS to work with ONC and other federal partners and private sector stakeholders to ensure accelerated, efficient, non-duplicative and less burdensome health data exchange requirements. Requiring providers to develop one-off technical or data use agreements between individual data sharing/trading partners is costly, inefficient and burdensome. CMS' efforts toward nationwide interoperability should **focus on incentivizing providers to leverage existing national, regional and/or state exchanges and networks and business relationships to share and exchange data, including ADT notification.** CMS should not expect providers to support – legally, organizationally, technologically, or technically – thousands of point-to-point interfaces for ADT notifications or any other use cases.

Use Existing Policy Levers

As previously stated, Premier does support adding ADT event notifications requirements to the CoPs. Rather than expanding the CoPs, **CMS should leverage other existing policy levers and give credit to hospitals for their ongoing interoperability and health information technology activities**. CMS acknowledges that there is no criterion under the ONC Health IT Certification Program that certifies health IT to create and send electronic patient event notifications. We urge CMS to work with ONC to develop such a requirement. CMS should align and use existing mechanisms (such as the Promoting Interoperability Programs, Certification Criteria (CEHRT), Trusted Exchange Framework and Common Agreement (TEFCA), and the US Core Data for Interoperability (USCDI). Moreover, **CMS should focus on current approaches to incent the use of health IT that drive interoperability for hospitals**.

- *ADT functionality within the base EHR definition and the USCDI.* **CMS should work with ONC to add ADT functionality to the base EHR definition; specify and add standardized data classes and elements to the USCDI.** ONC standards should require EHRs to send ADT messages outside of the EHR system. CMS needs to work with ONC to advance the development, adoption and use of industry-recognized data definitions and data normalization standards, including the implementation and use of vocabularies, code sets, and value sets for ADT events. Currently, many providers and clinicians are unable to incorporate electronic information received into their EHR due to the limitations of the EHR itself (i.e., incongruent implementation of standards, misaligned standards, semantics, and inconsistent implementation of standards specifications) all hindering data flow and impeding useable and understandable data across EHRs and other health information technologies and systems. **CMS should work**

[11] eHI's 2019 Survey on HIE Technology Priorities. https://www.ehidc.org/resources/2019-survey-hie-technology-priorities
[12] https://www.directtrust.org/directtrust-success-stories/
[13] https://www.healthshareexchange.org/sites/default/files/pdf/hie_value_prop_report_final.pdf

with ONC to ensure that EHRs can collect the data elements needed to support event notifications. Furthermore, ONC should ensure that standardized ADT data classes and data elements are included within the USCDI. Prior ONC efforts to implement ADT notifications identified challenges, such as variability in message content and poor or missing data; lack bidirectional communication between hospital administrative/registration systems with EHRs; attribution of patents to specific providers; and significant costs associated with establishing ADT feeds.[14] Moreover, the proposed rule lacks specificity or clarity about how surveyors would determine compliance for this provision, although it appears that CMS is proposing that hospitals would need to demonstrate the functionality of their EHRs to send notifications.

- *Require EHR vendors to demonstrate ADT functionality as part of CEHRT*. **CMS should work with ONC to ensure that base EHRs have implemented and support standardized ADT data elements**. ONC should, via the conditions and maintenance of certification, require EHRs to demonstrate specified and standardized ADT functionality. This would help ensure that the system's notification function is fully operational; the system uses adopted content exchange standards; and the system sends standardized ADT data elements. By requiring that event notifications be part of CEHRT, providers would know that their EHRs were be configured to send the notifications and would ultimately comply with CMS/ONC specific requirements.
- *CMS has previously sought public comment on the future direction of the Promoting Interoperability Programs (PI).* The PI program is one of the more appropriate vehicles for driving innovative approaches to interoperability. One activity CMS has noted that it is considering is identifying a set of priority health IT activities as alternatives to the traditional program measures. Premier healthcare alliance is supportive of CMS' efforts to identify a set of priority health IT activities, such as ADT notifications as alternatives to the traditional program measures. Allowing hospitals to meet CMS' goals of care coordinating care and achieving interoperability through providers' existing health information technology activities would allow hospitals greater flexibility in their approaches to improving care delivery and assuring patients' access to their data. **Premier suggests that at a minimum, CMS should recognize ADT event notifications as a high priority health IT activity as a means of meeting CMS' Promoting Interoperability requirements.**
- *Incentivize Participation in the Trusted Exchange Framework and Common Agreement (TEFCA).* Premier believes that existing and contemplated polices and rules such as those related to the TEFCA will go a long way to making progress on exchange of health information and interoperability. As we have previously stated, Premier recommends that **CMS work with ONC to accelerate efforts to launch the TEFCA**. ONC's TEFCA proposal recognized that many providers participate in several networks and exchange organizations, (who do not necessarily share data with another). Healthcare organizations are currently burdened with creating many costly, point-to-point interfaces between organizations. The proposed TEFCA could significantly reduce the need for individual interfaces, which are costly, complex to create and maintain, and an inefficient use of provider and health IT developer resources.[15] **We also recommend that CMS work with ONC to identify ADT notification as a high priority use case for the TEFCA and incentive providers using TEFCA for ADT notifications.**

ADT Event Notification Challenges

CMS fails to recognize or consider the significant complexities and challenges associated with ADT event notification. These include conformance to standards, lack of consistency of data elements, limits to the

[14] https://www.healthit.gov/sites/default/files/hie adt_supplemental_program_white_paper_final_october202017.pdf
[15] https://www.healthit.gov/sites/default/files/draft-guide.pdf

amount and consistency of patient data available and patient matching challenges. There is a lack of common patient identifiers as well as inconsistency with patient demographic information to match patients with the providers that should receive an alert. It is not practical for hospitals to establish one-to-one connectivity with all other providers with whom a patient may have a relationship. However, CMS' proposal would require hospitals to consider such connectivity in the absence of an intermediary. Below, we provide more detail on these challenges.

Accurately identifying the patient-provider healthcare relationship is essential to successful ADT event notifications. There may be many providers (i.e., attending; referring; consulting; admitting; surgeon; primary care physician) with a potential interest in a patient's status; however, **it is necessary to prospectively determine and confirm which providers have appropriate and existing relationships with patients (patient attribution and attribution verification**). CMS' proposal fails to adequately address the need to confirm patients' relationships with their providers.

It is also essential to determine what types of notifications providers wish to receive; and the transport method by which they prefer to receive ADT notifications (how those notifications should be (technologically) sent. It is critical to verify that clinicians can receive and use ADT alerts. Post-acute care (PAC) and other providers, were not provided financial incentives under the HITECH Act, and there has been no other comparable mandate to adopt CEHRT. As a result, many PAC providers are not using EHRs or are using EHRs that are not designed for interoperability with a hospital CEHRT through which an event notification would be received.[16] Furthermore, recipients need flexibility to determine what they want to be notified about (e.g., admissions only, discharges only); how often they receive the notifications (e.g., real time, daily, twice a day); and how to receive notification (e.g., direct secure message).

CMS' proposal fails to recognize and identify the infrastructure elements required to send, receive and distribute ADT notifications. Successful ADT notifications require an infrastructure, numerous synchronized processes and adoption of data and interoperability standards. Premier recommends that CMS work with ONC to leverage best practices and lessons learned from prior and ongoing efforts to operationalize nationwide ADT event notifications.[17] [18] ADT notifications require the technological ability to acquire data feeds and a rules engine to support alerting routing and delivery; and a "master patient index" function to create and verify patient panels. Additionally, **CMS needs to clearly depict applicable ADT use case(s),** such as the following:

- Patient is admitted to the hospital for inpatient treatment;
- Patient is admitted to the hospital for emergency department treatment;
- Patient is discharged from the hospital;
- Patient is transferred from one care setting to another (e.g., to a different location (unit, bed) within the hospital or to another facility outside of the hospital); and/or
- Patient's demographic information is updated (e.g. name, insurance, next of kin, etc.) by a hospital

While intermediaries, such as health information exchanges or other data sharing entities may help provide an infrastructure to obviate the need for point-to-point connectivity, there may be multiple

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16 https://wyatthitechlaw.com/2019/04/09/cms-proposed-rule-on-hospital-ehr-electronic-patient-event-notifications/

17 Improving Hospital Transitions and Care Coordination Using Automated Admission, Discharge and Transfer Alerts
A Learning Guide Presenting lessons learned by the 17 Beacon Community Awardees of the Office of the National Coordinator for Health Information Technology in the U.S. Department of Health and Human Services May 2013.
https://www.healthit.gov/sites/default/files/onc-beacon-lg1-adt-alerts-for-toc-and-care-coord.pdf

18 Regional ADT Exchange Network Infrastructure Models Prepared for the Office of the National Coordinator for Health IT by Audacious Inquiry, LLC March 17, 2017
https://www.healthit.gov/sites/default/files/regionaladt_exchange_network_infrastructure_models.pdf

intermediaries providing similar services (in a geographical area) and that can be a barrier to widespread ADT notifications. There are inconsistencies (processes, practices, conditions and terms of agreements; technologies; and data and interoperability standards implemented) across intermediaries. Significant challenges exist regarding data elements, such as variability in EHR vendor implementation of data standards; insufficiencies in interoperability standards; lack of attention to semantic interoperability standards; and inconsistent use of terminologies and formats. Information that is electronically exchanged from one provider to another should adhere to the same standards, and these standards should be implemented uniformly (within EHRs), for the information to be understandable and usable, thereby enabling interoperability.

ADT messages are typically sent when a patient is admitted to a hospital, transferred to another facility, or discharged from the hospital. Alerts are then generally sent to update physicians and specific care team members (with confirmed relationships with the patient) on a patient's status. Nationwide ADT notification and interoperability requires the development, adoption and consistent implementation of data and interoperability standards, including those for ADT notifications.

Not all EHRs can easily create, send and/or receive ADT messages; nor can all providers easily receive ADT notifications. **CMS did not address the need for provider flexibility when ADT event notifications cannot be received electronically**. Exceptions would need to be available for providers, such as smaller rural providers; critical access hospitals, small practices, post-acute care providers and other community providers for whom incentives have not been available to encourage their adoption and implementation of EHRs. EHRs do not uniformly collect, define or present data. Specialized technologies and solutions (beyond EHRs) as well as robust business and operational rules are needed to successfully ensure that the right provider or case manager receives the right ADT event notice on those patients with whom there is an existing relationship in a format that the intended recipient can receive. Patient or enrollee rosters/panels need to be supplied and reconciled regularly.

Another challenge is normalizing the data so that recipients can integrate data into their workflows. It is also necessary to obtain and confirm the delivery preference for each provider and to determine the electronic endpoint and "transport" method by which the provider can receive ADT notifications (e.g. via Direct Secure Messaging, via Health Level Seven (HL7)) for their patients. Additionally, not all providers want to receive notifications whenever every patient is admitted to a hospital, transferred, or discharged; thus, frequency and type of notifications must be determined.

Furthermore, **CMS proposed changes to the hospitals' CoP fails to recognize and significantly underestimates the burdens of adjudicating the privacy and security challenges about sharing information in accordance with applicable state and Federal laws and regulations** (such as HIPAA and 42 CFR Part 2 (confidentiality of substance use disorder patient records). Premier continues to advocate for statutory and regulatory reform of to make substance use data more readily available to providers who are already subject to HIPAA patient privacy protection regulations. Part 2 reform is essential to achieving nationwide interoperability and data exchange across the care continuum.

RFI ON ADVANCING INTEROPERABILITY ACROSS THE CARE CONTINUUM

Premier supports CMS' goal of advancing interoperability across the care continuum. Ensuring interoperability across EHR systems and settings of care can unlock barriers to data sharing and care coordination between health systems, physician group practices, independent physicians, and post-acute care settings. Ongoing measurement to understand the current status of HIT adoption by providers and the ability of providers to share information across the continuum will be important in understanding the effectiveness of interoperability initiatives.

Incentivizing HIT adoption

CMS seeks to develop standards and measures for advancing interoperability across care settings. As CMS notes in the RFI, post-acute care (PAC), behavioral health (BH), and home and community-based services (HCBS) providers were not eligible for the Medicare and Medicaid EHR adoption incentives created by the HITECH Act. Given the cost of EHR systems and lack of actualized support for interoperability from the vendor community, investment in health IT has been limited among PAC, BH, and HCBS providers. Long term (LT) and PAC often do not have EHRs, or at least do not have CEHRT. We also note that 42 CFR Part 2 will complicate information exchange with behavioral health programs that are part of the continuum. If CMS is serious about promoting interoperability within the care continuum, we recommend that CMS focus on the adoption of CEHRT in these settings and look towards fee schedule rules to encourage such adoption. Connecting the care continuum is an important endeavor, but the Promoting Interoperability (PI) Program and these measure proposals will be insufficient in accomplishing such a goal. **Premier recommends that measures used to evaluate PAC, BH, and HCBS interoperability begin on a reporting-only basis for an extended period.** As a result of these initial challenges, penalties for failure to adopt heath IT are not appropriate for these providers.

CMS needs to incentive PAC, BH, and HCBS providers to more readily adopt health IT in support of wider efforts to standardize patient data, improve care quality and reduce costs. To provide these incentives the **Innovation Center should develop a pilot program to provide a prospective payment for PAC, BH, and HCBS investment in health IT resources to advance interoperability.** CMS has previously structured a similar prospective payment to "improve system linkages" for prescription drug plans (PDPs) in the CMMI Enhanced Medication Therapy Management demonstration model that began in 2017. The demonstration should support investment in health IT, while evaluating outcomes through measurement of interoperability and patient outcomes.

Adoption occurring in non-acute care settings is often supported by partnering health systems that were both eligible for HIT adoption incentives and subject to penalties under the meaningful use – now Promoting Interoperability – program. CMS currently provides Stark Law and Anti-kickback statute waivers to support these efforts for providers' participation in Innovation Center programs. These **waivers should be further expanded beyond the Medicare Shared Savings Program and Innovation Center initiatives to permit collaborative investments by health systems and physician groups** into interoperable EHR systems in PAC, BH, and HCBS settings.

Cross-continuum data standards

Measuring interoperability across settings will provide valuable insight into providers' ability to share information that supports care coordination. To support this end, CMS requests feedback on whether physicians and hospitals should adopt the capability to collect and electronically exchange a portion of the standardized PAC assessment data elements mandated by the IMPACT Act. **CMS should focus on developing cross-continuum standards, rather than extending the collection of standards developed for siloed settings of care to additional providers.** The IMPACT Act mandated the establishment of standardized patient assessment data elements across PAC settings. However, this assessment is still effectively siloed since it applies only to PAC. Extending these data collection requirements to hospitals and physicians represents a workaround to interoperability that does not consider how care is provided across settings.

A holistic approach is needed for data standards whereby standards are developed for use across care settings, though provider types vary in the level of acuity and types of conditions they are clinically

appropriate to serve. There are at present a limited number of common data elements across inpatient, outpatient, and PAC care; however, these elements could serve as a starting point for cross-continuum patient assessment. For example, medication reconciliation is currently collected in the inpatient setting and has been included in the IMPACT Act-mandated PAC assessment. Interoperable sharing of medication reconciliation information is particularly relevant to improving care coordination and preventing adverse drug reactions. Developing data standards that consider how medication reconciliation occurs in various settings and what information is shared across settings will enhance interoperability in this area. **As the proposed USCDI and data standards are developed, adopted and implemented, CMS and ONC should consider how data will be collected and exchanged across care settings.**

Medically necessary access to behavioral health records

We note that 42 CFR Part 2 regulations continue to inhibit information flow. Access to a patient's entire medical record, including addiction records, ensures that certain providers and organizations, when medically necessary, have all the information necessary for safe, effective, high quality treatment and care coordination that addresses patients' health needs. Premier has previously submitted comments about the need to align HIPAA and 42 CFR Part 2; this alignment is essential to advance and maximize the benefits of interoperability with BH providers. **We again, strongly recommend that Part 2 requirements should be aligned fully with the HIPAA requirements that allow the use and disclosure of patient information for treatment, payment, and healthcare operations.** The current Part 2 requirements focus on patient privacy but run counter to the goals of interoperability and care coordination. Failure to integrate services and supports can lead to risks and dangers to individual patients, such as contraindicated prescription medicines and problems related to medication adherence.

RFI ON ADVANCING INTEROPERABILITY IN INNOVATIVE MODELS

Providers are extensively innovating through participation in APMs. Success in these models often rely on timely data exchange and care coordination. As such, **Premier supports the inclusion of interoperability requirements and piloting data standards as a part of larger care redesign efforts within APMs**.

Expanding APMs access to claims data

Interoperability can be advanced in the near term through the expansion and acceleration of provider access to patient data in APMs. Continuous quality and process improvement is dependent upon access to data that is recent and actionable. Providers have expressed concern that data access in some APMs, such as Bundled Payments for Care Improvement Advanced, has become more restrictive in comparison to earlier models. CMS should build upon previous data sharing advances to ensure that providers have the information necessary to redesign care. Additionally, CMS can advance electronic real-time availability of patient claims through the development of a provider portal, APIs or analogous mechanisms. Premier appreciates CMS's efforts to make claims data available through APIs; however, insight into data in advance of claims processing (i.e. at the time of claims receipt rather than after payment) will further support care coordinate, case management and quality improvement.

Expanding access to clinical data

APMs will be greatly enhanced with expanded with access to clinical data. Currently, APMs are limited through reliance on claims data; however, interoperable health records can advance sharing of documentation, test results, and other clinical data to support care coordination, quality, and process

improvement. **CMS should ensure that the intent of the CMS and ONC interoperability rules are not inadvertently hindered by APM program policies.**

CMS seeks input on requiring APMs to provide patient access to electronic health information or to third party APIs at the request of patients. Premier supports ensuring patients receive data; however, we caution placing such requirements on APMs currently. APMs are a collection of aligned providers working together to improve care. Accordingly, patients may access electronic health information directly from providers rather than through an APM. Moreover, placing additional interoperability requirements on APMs could lead to duplicative penalties, at the provider level and at the APM level. In recognition that APMs do have the ability to influence provider behavior, CMMI could continue to require that APMs monitor their aligned providers to ensure they are meeting interoperability standards. Currently, APMs are required to ensure that their aligned providers have adopted certified EHR technology. CMS could implement similar requirements that require the APM to ensure that its aligned providers are meeting certain interoperability requirements. CMMI could also reward APMs (e.g. rewards for quality measurement) that advance interoperability for their aligned beneficiaries.

CMS also seeks comment on Innovation Center model participants being required to participate in a trusted health information exchange or pilot emerging health IT standards. Premier believes APMs offer opportunities to voluntarily test the trusted health exchange, health IT activities, and/or emerging standards. **CMS should incent voluntary testing rather than requiring APMs to test as the providers aligned with an APM will represent varying degrees of readiness.** New APMs are focused on standardizing care process across providers and identifying opportunities to reduce costs; it may be difficult for these APMs to also test an emerging standard that has not been widely deployed.

Facilitating post-acute care, behavioral health, and HCBS provider participation in APMs

CMS acknowledges in the RFI that PAC, BH, and HCBS providers have relatively low rates of health IT adoption due to the omission of such providers from Medicare and Medicaid EHR adoption incentive payments. Simultaneously, participation by these providers in APMs is presently low. Unfunded mandates requiring providers to meet rigorous patient information standards will further increase barriers to participation in APMs and prevent opportunities for care redesign. As mentioned previously, **the Innovation Center should develop through a pilot program, or integrated within other APMs, a prospective payment for investment in health IT resources to advance interoperability in PAC, BH, and HCBS.** CMS has previously structured a similar prospective payment to prescription drug plans (PDPs) in the CMMI Enhanced Medication Therapy Management demonstration model that began in 2017. The demonstration should support investment in health IT, while evaluating outcomes through measurement of interoperability and patient outcomes. Further, CMS should continue to provide Innovation Center **waivers to the Stark law and Anti-Kickback statute to permit collaborative investments by health systems and physician groups in interoperable EHR systems**.

RFI ON POLICIES TO IMPROVE PATIENT MATCHING

CMS requests information on whether to require that program participants use a patient matching algorithm or solution with a “proven” success validated by HHS or 3rd party. **CMS should examine how to benchmark different approaches to patient matching to provide better information on the variation across matching algorithms and to highlight current limitations.** However, benchmark—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 address and the use of additional data elements).

CMS requests information on whether to expand recent Medicare ID card efforts by requiring a CMS-wide identifier for all beneficiaries and enrollees in health care programs under its administration and authority. Implementing an agency-wide identifier may help CMS better serve beneficiaries and improve matching. However, this approach is still insufficient to address matching on a nationwide scale. A unique identifier would still face limitations in matching patients to information prior to enrollment in federal health insurance programs, and they are still susceptible to errors (e.g. typos that exist today with the use Social Security Numbers).[19] If CMS pursues broader use of a CMS-wide identifier, the agency should still push forward with optimizing the use of demographic data (including adoption of the U.S. Postal Service standard for address and the use of additional data elements).

CMS requests information on whether it should advance more standardized data elements across all appropriate programs for matching purposes, perhaps leveraging the USCDI proposed by ONC. **CMS should work with ONC to advance both the use of the U.S. Postal Service standard for address and the addition of other elements—like email address—to the USCDI.**

CONCLUSION

The Premier healthcare alliance appreciates the opportunity to submit comments on the Interoperability and Patient Access proposed rule. Premier shares the vision of achieving interoperability and the establishment and adoption of standards and functions of health IT that will enable an interoperable, learning health ecosystem. Premier hopes our comments are helpful as you continue this important work. Premier stands ready to actively participate in CMS' efforts to achieve nationwide interoperability.

If you have any questions regarding our comments or need more information, please contact me or Meryl Bloomrosen, Senior Director, Federal Affairs, at meryl_bloomrosen@premierinc.com or 202.879.8012. We look forward to continued dialogue. Thank you again for providing us the opportunity to offer comments.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance

[19] https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/10/patients-want-better-record-matching-across-electronic-health-systems