

August 31, 2018

The Honorable Seema Verma
Administrator, Centers for Medicare and Medicaid Services
Attention: CMS-1689-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations” (CMS-1689-P, RIN 0938-AT29)

Submitted electronically to <http://www.regulations.gov>

Dear Administrator Verma:

On behalf of the Premier healthcare alliance serving more than 4,000 U.S. hospitals and health systems and approximately 165,000 other providers, we appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule on the “CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations,” which was published in the July 12, 2018 *Federal Register*.

Premier healthcare alliance, 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. Innovatix, which is part of Premier, is one of the nation’s largest non-acute care group purchasing organizations that delivers savings and value to infusion and other provider organizations. Together, Premier and Innovatix serve more than 4,800 home infusion locations. Additionally, Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our owner hospitals, health systems and infusion providers which have a vested interest in Medicare’s home health prospective payment system (PPS) and home infusion therapy requirements. Below, the Premier healthcare alliance provides detailed comments with suggested modifications to the policies proposed by CMS.

Our comments focus on the following two sections of the proposed rule:

- VI. Medicare Coverage of Home Infusion Therapy Services
- VIII. Requests for Information
 - A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

MEDICARE COVERAGE OF HOME INFUSION THERAPY SERVICES

We have serious concerns with Section VI of the proposed rule entitled “Medicare Coverage of Home Infusion Therapy Services” in that it oversteps Congressional intent in passing the services payment structure in section 50401 of the *Bipartisan Budget Act of 2018 (BBA)* (Pub. L. 115-123) and section 5012 of the *21st Century Cures Act of 2016 (CURES)* (Pub. L. 114-255). Unfortunately, the rule in its current form does not recognize the extensive services required to properly provide home infusion to vulnerable Medicare beneficiaries and will create access issues that Congress and the infusion community have long been seeking to address. **We urge CMS to amend the definition of an “infusion drug administration calendar day” to eliminate the requirement that a skilled professional be in the home for reimbursement to occur and define the term as “the day on which professional services are provided to the individual through the administration of a home infusion drug.”**

Background

Historically, though unique home infusion services have long been recognized and distinctly paid for by other healthcare payors, including commercial insurers, Medicare Advantage plans, the Veterans Administration and the TriCare programs, neither Medicare Part B nor D has covered the service component of providing home infusion drugs. Necessary services may include, but are not limited to, drug preparation, care management, lab review, a visit by a home care nurse to set up the infusion treatments, training caretakers on proper administration and maintenance of equipment, checkup visits, maintaining accreditation standards, and 24/7 on-call services.

Since 2003 and passage of the *Medicare Modernization Act* (P.L. 108-173), the average wholesale price (AWP) for Part B durable medical equipment (DME) drugs typically covered the costs associated with home infusion services. However, CURES significantly changed the DME infusion drug payment rate to an “average sales price plus 6%” (ASP+6) methodology to more accurately reflect the true costs of these medications starting in 2017 and created a new services benefit to go into effect four years later in 2021. To address the unintended consequences associated with the misalignment in start dates of the two provisions, Congress passed Section 101 of the *Medicare Part B Improvement Act of 2017/ the Medicare Home Infusion Therapy Access Act of 2017* (H.R.3178/ S.1738) as part of the *Bipartisan Budget Act of 2018* (P.L. 115-123). Unfortunately, the home infusion provisions in the proposed rule are a significant departure

from the intent of the legislation and will result in similar unintended consequences if not addressed, including patient access issues and higher costs to the Medicare program.

CMS should recognize extensive professional services beyond nursing services are necessary for home infusion.

In the BBA and CURES, the home infusion services benefit was intended to reimburse providers for their “professional services, including nursing services.” This language set forth a structure for CMS to reimburse providers for their “professional services,” such as drug preparation, clinical care planning, care coordination, nursing and other associated professional work. This language was meant to include nursing services as a subset of professional services but was not meant to limit the benefit to nursing services only.

Yet, CMS proposes to interpret “professional services, including nursing” as “skilled services,” and pulls a definition of skilled services from a section of the Code of Federal Regulations that concerns skilled nursing facilities (SNFs) (42 C.F.R. 409.32), though the statutory language did not indicate that the nursing services must be “skilled services” and did not point to a specific provision of the CFR. The legislation only stated, “including nursing services” with no reference to the word “skilled.” Home infusion requires a range of professional services, starting with pharmacy and care intake, drug delivery and care coordination, and remote and direct patient monitoring. Additionally, these professional services must be performed in compliance with state pharmacy laws and with sterile dose preparation requirements established by the United States Pharmacopeia (standards <797> and in the near future <800> where applicable) and requires maintenance of a rigorously controlled “clean room” environment. Home infusion services, in addition to nursing services, need to be recognized to ensure consistent and appropriate home infusion care for beneficiaries.

“Infusion Drug Administration Calendar Day” should not require a nurse or other skilled professional to be present in the patient’s home for reimbursement.

CMS proposes that “payment for an infusion drug administration calendar day is for the day on which home infusion therapy services are furnished by skilled professional(s) in the individual’s home on the day of infusion drug administration.” Congress did not include this physical presence requirement in the BBA or in CURES. Rather, they recognized that while important home infusion services do occur in the home, many do not. Requiring home infusion services to occur “in the home” for a reimbursement to occur misinterprets the fundamental practice of home infusion and will lead to inadequate reimbursement for providers.

In fact, a nurse is often not present for each administration of the home infusion drug and does not need to be for proper administration of the therapy. Only a single nurse visit per week might be needed in connection with drugs that can be self-infused or infused by the patient’s non-professional caretaker on each of the remaining six days. Yet, the home infusion professional

services that allow that drug to be infused are needed every day the drug is infused, regardless of the presence of health care personnel. The services that occur outside the home include drug preparation and dispensing, clinical care planning and implementation, and care coordination. CMS should align the Medicare program with virtually all other payors for home infusion (commercial plans, Medicare Advantage Plans, the Veterans Administration, or others) that do not have such a requirement for a professional to be physically present in order to reimburse for the beneficiary's home infusion. CMS should amend the definition of an “infusion drug administration calendar day” to eliminate the requirement that a skilled professional be in the home for reimbursement to occur and define the term as the “day on which home infusion therapy services are furnished on the day of infusion drug administration.”

Unintended Consequences: Patient Safety Risks and Higher Cost to Medicare

Unfortunately, payment under the proposed rule would be so limited that it could restrict the availability of services for Medicare beneficiaries. Beneficiaries requiring medications without adequate Medicare home infusion reimbursement rates may no longer have the option of receiving therapy in their homes. As a result, these beneficiaries may incur serious clinical consequences from being moved from their home into alternate site of care, such as a physician's office, skilled nursing facility (SNF) or a hospital. Beneficiaries who receive home infusion therapy are often susceptible to infection and other adverse clinical outcomes, which makes the outpatient care setting less optimal.

Primary Immune Deficiency Disorder (PIDD) is a clear example where home infusion is the most clinically appropriate option. PIDD is a chronic disorder in which part of the body's immune system functions improperly. Those with PIDD live their entire lives more susceptible to infections—enduring recurrent health problems and often developing serious and debilitating illnesses because their bodies cannot properly fight off infections. The infections may be in the skin, sinuses, throat, ears, lungs, brain, spinal cord, or in the urinary or intestinal tracts, and the increased vulnerability to infection may include recurring infections. These beneficiaries, who require subcutaneous immunoglobulin therapies, should not be forced into healthcare settings where they could be exposed to other patients with infectious conditions, when the home is a proven safe and optimal site of care. Additionally, the proposed rule, contrary to CMS' goal to reduce healthcare spending, would cost the Medicare program significantly more due to the increased treatment costs in institutional settings as compared to the home.

REQUEST FOR INFORMATION ON PROMOTING INTEROPERABILITY AND ELECTRONIC HEALTHCARE INFORMATION EXCHANGE THROUGH POSSIBLE REVISIONS TO THE CMS PATIENT HEALTH AND SAFETY REQUIREMENTS FOR HOSPITALS AND OTHER MEDICARE- AND MEDICAID-PARTICIPATING PROVIDERS AND SUPPLIERS

CMS is interested in feedback from stakeholders on how it could use the Conditions of Participation (CoPs), Conditions of Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities to advance electronic exchange of health information in support of care transitions between hospitals and community providers.

Premier strongly supports the development and implementation of an efficient and effective infrastructure for health information exchange across the care continuum. Hospitals, health systems and clinicians continue to make significant investments in certified electronic health records (EHRs). We appreciate CMS' desire to address interoperability and data exchange but **we are strongly opposed to using the CoPs/CfCs/RfPs to advance interoperability or electronic data exchange. CMS should not implement interoperability requirements in the CoPs/CfCs/RfPs as they are not the appropriate vehicle(s) to encourage interoperability or electronic data exchange given the significant consequences to providers (noncompliance could result in the inability of providers and clinicians to participate in the Medicare and Medicaid programs).** Furthermore, there are inconsistent definitions of interoperability and wide variation in measures/metrics for interoperability. CMS should address these discrepancies as part of its ongoing Promoting Interoperability efforts.

Furthermore, existing CMS and ONC efforts to achieve interoperability are evolving “works in progress”, still in their early stages of development and implementation and thus immature. CoPs/CfCs/RfPs are typically restrictive in acceptable approaches for meeting the condition, thereby limiting providers' flexibility to test and implement novel approaches. **Including requirements for interoperability and electronic data exchange in the CoPs/CfCs/RfPs/ would create an extreme penalty (i.e. potential exclusion from Medicare) for aspects that are currently penalized through other CMS requirements and reporting programs (i.e., the Promoting Interoperability Program, QPP, MIPS).** Furthermore, requiring providers to meet interoperability requirements via the CoPs/CfCs/RfPs, while also reporting Promoting Interoperability measures and participating in other contemplated Federal efforts, such as the Trusted Exchange Framework and Common Agreement (TECFA) would be unnecessarily and extremely burdensome and duplicative.

CMS invited stakeholder feedback on questions regarding possible new or revised requirements for interoperability and electronic exchange of health information. In the chart below (*CMS Proposal for interoperability-related CoPs/CfCs/RfP*), we provide brief responses to CMS' specific questions.

CMS also invited comments about how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers and to identify fundamental barriers to interoperability and health information exchange. Following the chart, Premier provides detailed suggestions about attaining interoperability goals and addressing barriers. **We believe that it is premature for CMS to consider imposing COPs/CfCs/RfPs until the barriers and challenges to exchange have been fully addressed.**

CMS Proposal for interoperability-related CoPs/CfCs/RfP	
CMS Question	Premier Response
<p>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?</p>	<p>As Premier explains in greater detail below, we are opposed to adding any requirement(s) for electronic exchange of medically necessary information within the CoP/CfC/RfP standard(s). Furthermore, CMS provides no clear definitions of several terms (i.e., “medically necessary”, “materially discourage” and “information blocking exceptions”; definitions are essential to responding to CMS’ questions. Furthermore, there are no details about ONC’s planned implementation of information blocking rulemaking (as required by Section 4004 in the 21st Century Cures Act). Thus, any efforts by CMS to address information blocking via CoP/CfC/RfP are inappropriate and premature. Adding interoperability requirements to the CoP/CfC/RfP would result in significant additional and duplicative administrative and reporting burdens. In particular, incorporating data into workflow and ensuring that data are available and accessible to clinicians and their patients in a usable and understandable manner is critical to achieving interoperability. CMS should focus its efforts on applying current policy levers; refining requirements for CEHRT; accelerating standards development and implementation; and allowing providers and clinicians greater flexibility to receive credit for using health information technologies beyond legacy EHR platforms.</p>
<p>Should CMS propose new CoPs/ CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient’s or resident’s (or his or her caregiver’s or representative’s) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient or resident access as well as interoperability?</p>	<p>Premier is opposed to any use of the CoPs/ CfCs/RfPs to ensure a patient’s or resident’s (or his or her caregiver’s) or representative’s right and ability to electronically access his or her health information without undue burden. Providers who qualify for the Promoting Interoperability program will have implemented patient portals and/or APIs that provide the level of access required by the certification criteria. Thus new CoPs/CfCs/RfP are not necessary. The current use of portals and the expected implementation of open, public and published APIs will likely satisfy the requirement regarding patient or resident access to health data. However, in order to fully realize the benefit of APIs, CMS and ONC must focus attention on requiring EHR vendors to publish and consistently implement and support open (non-proprietary) APIs to make health information more accessible to providers and their patients. Moreover, CMS must</p>

	<p>provide clear definitions of terms such as “electronically access his or her health information without undue burden”; “health information” and “undue burden” as used within their question(s).</p>
<p>Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?</p>	<p>Premier is opposed to any use of the CoPs/CfCs/RfPs for interoperability and electronic exchange of health information. CMS needs to allow sufficient time and experience with existing (and planned) CMS Medicare and Medicaid policies and ONC activities (i.e., 2015 CEHRT criteria for interoperability) and regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act).</p>
<p>What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?</p>	<p>As Premier explains in greater detail below, we are opposed to any use of the CoPs/CfCs/RfPs as a mechanism to address interoperability and electronic exchange of health information. Rather than expanding the CoPs/CfCs/RfPs, CMS should provide greater flexibility and offer alternative approaches and mechanisms to give credit to providers and clinicians for their use of diverse health information technology activities, beyond legacy EHR platforms.</p>

<p>Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?</p>	<p>As Premier explains in greater detail below, we are opposed to any use of the CoPs/CfCs/RfPs as a mechanism to require hospitals and other participating providers ensure interoperability and electronic exchange of health information. Rather than implement yet another set of additional requirements, CMS should: allow providers to gain experience with current and planned policies intended to help achieve interoperability (i.e., TEFCA and use of 2015 CEHRT) before considering other policy levers. CMS must address the multiple barriers described in our letter which, if ignored, will continue to impede nationwide interoperability.</p>
<p>Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?</p>	<p>Premier is opposed to any use of the CoPs/ CfCs/RfPs as a mechanism to require hospitals and other participating providers ensure interoperability and electronic exchange of health information. However, CMS must allow/permit the use of non-electronic forms of sharing medically necessary information when the receiving provider, supplier, or patient/resident cannot receive the information electronically.</p>
<p>Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?</p>	<p>Premier is opposed to any use of the CoPs/ CfCs/RfPs as a mechanism to require hospitals and other participating providers ensure interoperability and electronic exchange of health information. Following this chart, we provide a more detailed description of recommendations for achieving interoperability and a discussion about existing barriers and challenges faced by hospitals, clinicians and other providers and suppliers in meeting existing CMS and ONC program requirements for interoperability and health information exchange.</p>

<p>What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?</p>	<p>Premier is opposed to any use of the CoPs/CfCs/RfPs as a mechanism to require hospitals and other participating providers ensure interoperability and electronic exchange of health information. CMS should continue to allow exceptions under the QPP, including those related to CEHRT hardship or small practices.</p>
---	---

In the discussions below, we identify fundamental barriers to interoperability and health information exchange and offer comments and recommendations about how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers.

Premier Recommendations about Achieving Interoperability

Premier has identified a number of ways for CMS (working with other agencies) can help promote interoperability. In the discussion below, we address several issues and offer specific recommendations:

- Use and Adapt Existing Policy Levers
- Implement 21st Century Cures Provisions
- Update and Maintain Certified EHRs
- Information Blocking
- Timelines and Reporting Requirements
- Offer Providers Maximum Flexibility
- Security

Use and Adapt Existing Policy Levers

Providers and clinicians continue to make progress exchanging and sharing information.^{1 2} However, the current and future policy landscape for interoperability and EHRs remains unclear. CMS and ONC should allow providers time to gain experience with the various existing policy, technical and programmatic updates expected over the next few years before considering other

¹ Sharing Health Information for Treatment. <https://www.aha.org/guidesreports/2018-03-01-sharing-healthinformation-treatment>

² Expanding Electronic Patient Engagement. <https://www.aha.org/guidesreports/2018-03-01-expanding-electronicpatient-engagement>

avenues to promote interoperability. CMS must align and use existing mechanisms and policy levers (such as the Promoting Interoperability Programs, MIPS, QPP, CEHRT, and HIPAA) to help achieve interoperability. CMS needs to work with ONC and other federal agencies (such as NIST) to implement relevant 21st Century Cures Act (Cures) provisions, including information blocking, APIs, the EHR Reporting Program, the Trusted Exchange Framework and Common Agreement (TEFCA) and the U.S. Core Data for Interoperability (USCDI). We anticipate that the required use of 2015 CEHRT and APIs will help improve interoperability and believe that forthcoming API, interoperability and CEHRT rules by ONC will also help address CMS' goal to promote interoperability and reduce provider burdens. **Providers and clinicians must be given sufficient time to implement and adapt to these changes and CMS and ONC must evaluate their impact before considering other mechanisms or processes to attain interoperability.**

Furthermore, existing policy levers unfairly target and penalize providers (i.e., hospitals, health systems and clinicians). EHR vendors are currently not required to demonstrate interoperability, usability or their platforms' conformance to standards. 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 and ONC must address improving the functions and capabilities of EHRs, including: information exchange across EHRs; accurately identifying (matching) patients across EHRs; and ensuring that data are easily incorporated into workflow. The ability to transmit data into and obtain from EHRs is critical and EHRs must be required to demonstrate this capability as part of CEHRT testing (as is required under Cures Section 4005 for clinical registries). CMS and ONC must recognize these types of impediments, barriers and challenges to interoperability and address them directly.

EHR adoption among hospitals, clinicians and providers who were not eligible to receive incentives to implement certified health information technology, including post-acute care, long-term care, rehabilitation, and psychiatric hospitals, lags significantly. **CMS should focus on approaches to incentivize the use of health IT in order to drive interoperability for providers and clinicians not previously eligible for incentives (i.e., community health providers, clinical subspecialties, post-acute care and long-term care providers).**³ The absence of incentives for these settings and providers has stalled adoption of health IT; without adoption in all settings interoperability along the continuum is not feasible.

Implement 21st Century Cures Provisions

Implementation of several Cures provisions is long overdue. CMS must work with ONC and other agencies to align and harmonize administrative and reporting programs, such as CMS'

³ Interoperability 2017 https://klasresearch.com/images/pages/events/Cornerstone_Interop_White_Paper_2017.pdf

Promoting Interoperability Program, ONC's CEHRT program, and TEFCA in order to reduce provider burden, eliminate redundant and unnecessary reporting, and further interoperability. Premier expects that existing and contemplated policies and rules (such as those related to TEFCA and implementation of several provisions in the 21st Century Cures Act) may contribute to progress on exchange of health information and interoperability. However, final proposals about TEFCA and USCDI are pending, the timeline for their releases remains uncertain, and their impact cannot be assessed until rules are promulgated, implemented and enforced.

CMS and ONC must provide more clear and detailed information about their processes and timelines to implement Cures provisions and how they will harmonize and align Cures provisions with the Promoting Interoperability Programs. ONC's forthcoming proposed rules (i.e., APIs, registries, certification and information blocking) will likely impact the envisioned Promoting Interoperability Program. However, lacking detailed information about CMS and ONC actions, stakeholders are unable to provide more responsive comments to this RFI. Premier expects to have the opportunity to comment further once ONC issues proposed rulemaking required under Cures and once CMS articulates how those rules will impact its programs, including the Promoting Interoperability Program. CMS and ONC must assure that future versions of CEHRT support and are aligned and harmonized with CMS' programmatic and reporting requirements.

Regarding APIs, it is essential that ONC and CMS operationalize the goal of 21st Century Cures mandating that health information "can be accessed, exchanged, and used *without special effort* through the use of application programming interfaces (APIs)." ONC and CMS must clarify that such certified EHRs must support an industry-recognized standard and the APIs must be open, public and published.

Providers must have reliable, robust and transparent information about EHRs' usability, functions and level of interoperability. To help providers select and measure performance of EHR products, Cures (Section 4002. Transparent Reporting on Usability, Security, and Functionality) requires the establishment of an Electronic Health Record (EHR) Reporting Program that includes product features and capabilities (such as a product's security, usability and interoperability).⁴ Premier urges CMS and ONC to accelerate the implementation of this Cures' provision and also include information about EHR vendors' material limitations and types of costs associated with its API functionality and app integration capabilities, in order to assure an open marketplace, ongoing innovation and a robust app ecosystem.

Cures (Section 4005 Clinical Registries) requires EHRs to be technically capable of transmitting to, receiving and accepting data from registries as a condition of certification in accordance with standards recognized by ONC. This includes clinician-led data registries that are certified to be

⁴ ONC Report to Congress April 2016. Report on the Feasibility of Mechanisms to Assist Providers in Comparing and Selecting Certified EHR Technology Products https://www.healthit.gov/sites/default/files/macraehrpct_final_4-2016.pdf

capable of receiving, accepting and transmitting data to certified EHR technology. It is essential that CMS work with ONC to ensure that this provision be implemented as soon as possible.

Update and Maintain Certified EHRs

Furthermore, ONC must continue to address CEHRT usability, interoperability, functionality and capabilities and ensure that CEHRT and EHR testing processes are aligned with CMS' requirements. ONC's efforts and activities should include the following:

- Ensure that providers, such as health systems, hospitals and clinicians (in addition to patients), can access EHR data using any application of their choice that is conformant with/configured to meet the technical specifications of the ONC-recognized API standard within the CEHRT
- Ensure that providers (health systems, hospitals and clinicians) can readily extract data from and insert data into their EHRs (ability for EHRs to send and receive data)
- Minimize the need for manual data collection, abstraction, calculation and/or reconciliation within Federal reporting and administrative programs (i.e., Promoting interoperability; MIPS; QPP)
- Require CEHRT to use standardized data elements, definitions, and formats so that data and information can be more easily documented, collected, accessed, extracted and used
- Require EHR vendors to implement EHR platforms and systems using consistent, replicable, scalable and supported data and interoperability standards
- Assure that CEHRT requirements easily support and are harmonized with CMS administrative and reporting requirements
- Address CEHRT usability, interoperability and ability to support clinical workflow
- Harmonize CEHRT with the CCDS and the future USCDI

Information Blocking

There are numerous challenges and barriers related to effective data sharing, especially with different EHRs.⁵ CMS must clarify terms and definitions relating to interoperability and information blocking and ONC must issue proposed rules about information blocking. However, **CMS should not use the CoPs/CfCs/RfPs to address real or perceived instances of information blocking.** Current EHRs do not allow for the easy use, exchange or sharing of data. Legacy EHR vendors are restricting data flow and are preventing competition and limiting innovation by implementing proprietary and/or restrictive vetting processes that govern if and how a third-party product or application can integrate with the EHR.^{6 7 8 9}

⁵ Castillo et al. Vendor of choice and the effectiveness of policies to promote health information Exchange BMC Health Services Research (2018) 18:405 <https://doi.org/10.1186/s12913-018-3230-7>

⁶ <https://code.cerner.com/apps>

⁷ <https://open.epic.com/>

⁸ <https://www.healthcareitleaders.com/blog/4-takeaways-from-the-epic-app-orchard-developer-conference/>

⁹ <http://www.modernhealthcare.com/article/20170222/NEWS/170229974>

CMS efforts to address provider information blocking must be coordinated with ONC efforts and Cures' requirements to address EHR vendor information blocking. Providers and clinicians depend on their EHR vendors to implement timely and appropriate software and system upgrades and changes to accommodate new ONC and CMS requirements and should not be penalized for EHR vendors' business practices or reluctance to implement new CEHRT requirements.

Furthermore, the Office of Civil Rights (OCR) should provide additional guidance clarifying and ensuring that providers have flexibility to address any potential security vulnerabilities and threats from consumer-facing apps. ONC, CMS, FTC and OIG should align and clarify their rules, regulations and guidances to ensure that all stakeholders understand their responsibilities in the context of the evolving app ecosystem. Again, we strongly urge CMS, FTC, OIG, and ONC to consider how policy related to security, APIs and information blocking will consider issues involving the use of APIs. Furthermore, we believe that CMS and ONC continue to underestimate the potential security risks and vulnerabilities and application "vetting and registration" burdens that CMS expects to providers to assume as they fulfill CMS and ONC requirements to implement consumer-facing APIs.¹⁰

As noted in Cures, ONC must implement updated maintenance of certification requirements and rules about information blocking, and APIs. We urge CMS to work with ONC to ensure that CMS' Promoting Interoperability measures and requirement are fully aligned with CEHRT. Cures require EHR vendors to:

- Attest, as a condition and maintenance of certification that it: (a) did not engage in information blocking, (b) provided assurances that it will not engage in information blocking or take any action that may inhibit the exchange, access and use of electronic health information unless for a legitimate purpose specified by the Secretary of HHS, and (c) did not prohibit or restrict communication regarding the usability, interoperability or security of HIT;
- Demonstrate that it does not prohibit or restrict information regarding: (a) users' experiences when using HIT, (b) its business practices related to exchanging electronic health information, and (c) the manner in which a user has used the technology;
- Attest that it published application program interfaces (APIs) and allows health information from such APIs to be accessible, exchanged and used without special effort through the use of APIs or successor technologies or standards, including providing access to all data elements of a patient's EHR to the extent permissible under applicable privacy laws; and
- Attest that it has successfully tested the technology for interoperability in the setting in which it will be marketed.

¹⁰ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-16766.pdf>

We expect that promulgation and enforcement of fair and equitable information blocking rules can go a long way to helping address vendors' practices that might interfere with, prevent, and materially discourage the access, exchange, or use of electronic health information.¹¹ As previously noted, OCR should provide additional guidance allowing providers to assess and verify the security of patient-facing apps without risk that such practices would be considered information blocking.

Timelines and Reporting Requirements

Providers face extreme and unnecessary burdens due to frequently changing CEHRT and CMS administrative and reporting requirements. Providers need a clear and defined level of predictability so that they can respond approximately to proposed changes and anticipate their implementation. Changes to the Promoting Interoperability and CEHRT programs typically result in significant time for EHR vendors to develop and launch software revisions/updates and then providers require sufficient time to budget and plan for and then operationalize EHR changes. Having additional certainty will bring stability as providers continue pushing forward on data exchange and pursue solutions that require interoperability. CMS must recognize the true financial impact and administrative burden incurred by hospitals and health systems in implementing CMS (and other agencies') administrative and reporting requirements. We believe CMS has significantly underestimated these burdens in the impact analyses.

Offer Providers Maximum Flexibility

CMS notes that a focus on interoperability and simplification will help reduce healthcare provider burden while allowing clinicians and providers increased flexibility to pursue innovative health information technology activities and applications that improve care delivery and increase the likelihood of achieving nationwide interoperability. Thus, CMS is exploring the creation of a set of priority health IT activities that would serve as alternatives to the traditional EHR Incentive Program measures.

We support CMS efforts to introduce additional flexibility to allow providers a wider range of options to "get credit" for various health information technology activities. Providers' use of patient portals and other health information technologies (such as portals and open APIs) should fully satisfy CMS' requirements that providers ensure a patient's or resident's (or caregiver/representative) right and ability to electronically access his or her health information as well as to meet overall interoperability requirements. Future recognition of certain health IT activities, like participation in the Trusted Exchange Framework and Common Agreement (TECFA) as an alternative to traditional program measures provide hospitals, health systems, clinicians and other providers greater flexibility and promote innovative uses of health IT. Other

¹¹ ONC Report to Congress April 2015. Report on Information Blocking.
https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

use(s) of health information technology beyond CEHRT (such as other systems, applications and modules) should also qualify providers' successfully fulfilling CMS promoting interoperability requirements. Providers should be able to report and receive credit for health information technology activities that are most appropriate to their setting, patient population, and clinical practice improvement goals.

Premier urges CMS to focus attention on allowing providers' maximum flexibility to obtain credit for their innovative use of health information technologies. As the 2015 CEHRT requires providers to implement open APIs that allow patients' access to their health information, we strongly believe that providers should be able get "credit" for interoperability when using these APIs. Providers should also get credit for their use of health information technologies and applications beyond certified EHRs as providers need solutions outside their EHRs to support value-based care and population health management programs and initiatives.^{12 13}

CMS must allow providers' flexibility when information cannot be sent or received electronically. Exceptions need to be available for providers, such as smaller urban and/or rural providers; community-based providers; and small practices and other providers for whom incentives have not been available to encourage their adoption and implementation of electronic health records. Furthermore, data must be able to flow across the continuum of care, including to and from post-acute care and long-term care providers. Many subspecialties, long term, post-acute care and skilled nursing facilities often do not have EHRs, or at least do not have CEHRT. Connecting providers along the care continuum is essential to achieving nationwide interoperability; CMS should focus efforts on incentivizing and encouraging adoption of CEHRT in these and other settings.

Security

CMS emphasizes patient engagement in their health care and patients' electronic access of their health information through use of APIs. The CMS Blue Button 2.0 initiative enables Medicare beneficiaries to connect their Medicare claims data applications, services, and research programs they trust (<https://bluebutton.cms.gov/>). CMS has developed app criteria that need to be met and verified by the CMS Blue Button API team, including how an application is registered with CMS. Yet, there are no guidances or "rules of the road" regarding compliance with CEHRT 2015 (for open APIs) nor for Promoting Interoperability measures that require the use of APIs to share data with apps of the patients 'choosing.

We urge CMS to work with ONC and clarify what processes and criteria will be developed for patient-facing apps required under this Promoting Interoperability measure. CMS and ONC must also address "app acceptance" (i.e., who will conduct apps review and vetting; how apps will be

¹² Sage Growth Partners (SGP). Are EHRs up to the task? March 2018 <http://sagegrowth.com/index.php/2018/03/ehrs-task-sage-growth-partners-report/>

¹³ Stalled Progress on the Path to Value-Based Care. <http://quanumsolutions.questdiagnostics.com/2018survey>

assessed for potential security vulnerabilities). Furthermore, CMS and ONC must clarify how activities undertaken by providers and MIPs eligible clinicians to secure their EHR platforms and other health IT systems to protect them from cyber-attacks, will be evaluated once the ONC rules about information blocking are promulgated and enforced. We believe that CMS' responses to commenters in the final IPPS rule¹⁴ about APIs, consumer-facing apps, information blocking and potential security risks, fails to acknowledge the increasing cybersecurity risks and vulnerabilities faced by the entire health system.^{15 16 17} Existing applicable laws and guidances appear to be woefully inadequate.

Barriers and Challenges to Interoperability and Recommendations to Address Them

There are several major barriers and challenges impeding interoperability that should be addressed by CMS, ONC and other Federal agencies prior to any further consideration of adding interoperability requirements to the CoPs/CfCs/RfPs, including the following:

- Non-competitive EHR marketplace
- Limited EHR functions
- Heightened need for open, non-competitive APIs
- Value-based care and advanced payment models require data beyond EHRs

Premier urges CMS and ONC to consider these ongoing challenges and barriers when developing future policies and expectations of providers. Following our discussions of barriers and challenges, Premier offers several recommendations and action items for how CMS and ONC can address these barriers.

Non-competitive EHR marketplace

A major challenge contributing to this ongoing shortfall in achieving nationwide interoperability is the increasingly non-competitive health information technology marketplace dominated by a relatively small number of legacy EHR vendors^{18 19} along with ongoing clinicians' dissatisfaction with existing EHRs.^{20 21} As the EHR market has matured, the number of EHR vendors has narrowed significantly. In March of 2015, 10 EHR vendors accounted for about 90

¹⁴ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-16766.pdf>

¹⁵ <https://www.csoonline.com/article/3260191/security/healthcare-experiences-twice-the-number-of-cyber-attacks-as-other-industries.html>

¹⁶ <https://www.phe.gov/preparedness/planning/CyberTF/Pages/default.aspx>

¹⁷ <https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf>

¹⁸ <https://www.definitivehc.com/hubfs/infographics/electronic-health-systems-ehr.pdf?t=1528465230285>

¹⁹ <https://www.kaloramainformation.com/Content/Blog/2017/04/28/The-State-of-the-EMR-Market-in-2017>

²⁰ <https://www.healthcare-informatics.com/article/ehr/cmios-parse-complexities-md-dissatisfaction-ehrs>

²¹ Mark W. Friedberg, Peggy G. Chen, Kristin R. Van Busum, Frances Aunon, Chau Pham, John P. Caloyeras, Soeren Mattke, Emma Pitchforth, Denise D. Quigley, Robert H. Brook, F. Jay Crosson, Michael Tutty Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. https://www.rand.org/pubs/research_reports/RR439.html

percent of the hospital EHR market, based on meaningful use attestation data from CMS.²² According to the ONC's Health IT Dashboard, three companies had 60 percent of the market share combined. A report from KLAS found that two companies each held about one-quarter of the acute care hospital EHR market share in 2016.^{23 24} A Black Book survey of 3,000 hospital EHR users finds that two-thirds of hospitals don't use patient information from outside their own EHRs because it's not available within their workflows.²⁵ Furthermore, an average hospital has 16 disparate EMR vendors in use at affiliated practices and 75% of the hospitals are dealing with 10+ disparate outpatient vendors.²⁶ A recent CMS report²⁷ discusses ACO challenges associated with health IT, multiple EHRs, interoperability, data analytics and the impact of health IT on health care cost, utilization, and quality. While providers and clinicians have experience sharing and exchanging health information with other providers and with patients, there are obstacles out of the providers' control that hinder or prevent achieving interoperability.²⁸

Stimulus funding (government supported \$30B) flowed to EHR vendors, while the penalties and burdens for not implementing certified technology and achieving interoperability remains with providers, creating provider dependence on EHR vendors. EHR vendors are not yet accountable for demonstrating and assuring interoperability, while providers remain dependent on their vendors. Legacy EHR platforms impede and/or do not allow real time data flow to/from EHRs and clinical workflow. Furthermore, EHR vendors retain practical control over clinical data, limiting third party app development and innovation and provider data access.

EHR market dominance and related "power" position makes application (app) developers and providers subject to EHR vendor business practices and generally unwilling/unable to challenge EHR vendors. Providers and clinicians continue to incur ongoing high costs for EHR platforms and systems interfaces, data, applications and implementations and application integration while facing unrelenting administrative and reporting burdens and excessive EHR costs. Provider dependence on EHR vendors results in a lack of data flow, higher costs, inflexible products, challenging implementations and diminished innovation. Furthermore, in spite of multiple private- and public-sector initiatives to improve the interoperability landscape, the GAO has identified several ongoing challenges to achieving nationwide interoperability nationwide.²⁹ There still is much work to be done to assure that providers and clinicians can easily use, share

²² <https://www.beckershospitalreview.com/healthcare-information-technology/50-things-to-know-about-the-ehr-market-s-top-vendors.html>

²³ <https://medcitynews.com/2017/05/epic-cerner-ehr-market-share/>

²⁴ <https://www.beckershospitalreview.com/healthcare-information-technology/epic-cerner-hold-50-of-hospital-ehr-market-share-8-things-to-know.html>

²⁵ <https://www.prnewswire.com/news-releases/epic-systems-and-meditech-rise-atop-black-book-2018-survey-of-inpatient-ehr-client-satisfaction-joining-cerner-and-cpsi-300633557.html>

²⁶ <https://www.healthcareitnews.com/news/why-ehr-data-interoperability-such-mess-3-charts>

²⁷ <https://innovation.cms.gov/Files/reports/nextgenaco-firstannrpt.pdf>

²⁸ Castillo et al. Vendor of choice and the effectiveness of policies to promote health information Exchange BMC Health Services Research (2018) 18:405 <https://doi.org/10.1186/s12913-018-3230-7>

²⁹ United States Government Accountability Office ELECTRONIC HEALTH RECORDS Nonfederal Efforts to Help Achieve Health Information Interoperability. September 2015 <https://www.gao.gov/assets/680/672585.pdf>

and exchange information and efficiently add functionality and capabilities to their EHR platforms (such as via APIs).

Limited EHR Functionality

Providers need robust, scalable, and interoperable health IT systems and electronic health records (EHRs) to deliver high quality and cost effective care and to improve clinical decision making and deliver improved outcomes. Hospitals and health systems report that barriers to the sharing and effective use of received patient information continue to exist at many levels, from timing of receipt and formatting of the information to technical issues in the exchange transaction or the EHR itself.³⁰ 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. Value-based care (VBC), advanced payment models and population health management (PHM) approaches focus on prevention and care coordination functions often lacking in legacy EHRs.^{31 32}

Without connectivity across the care continuum, data collection remains 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, systems, applications and across multiple facilities and care settings. Current legacy EHRs' limit clinical decision making and quality patient care as they thwart innovation, collaboration and free exchange of information critical in delivering informed, safe and coordinated care.

EHRs are increasingly limited in their ability to meet providers' growing needs for core value-based care functions. Providers need to be able to add enhanced capabilities and functionality (i.e., risk stratification, case management, referral management, care coordination, decision support, data analytics, clinical surveillance, registries, enterprise analytics, and patient engagement) to their EHRs and not be restricted or hampered by their EHR vendors' practices when doing so. Increasingly, EHRs cannot provide access to complete patient data at the point of care, a limitation that continues to hinder providers' confidence that all the information necessary to make informed decisions is available when and how it's needed.

Open, Publicly Available and Non-competitive APIs

One of the potential solutions to address the problem of limited EHR functionality, is open APIs. CMS and ONC have focused on enabling consumer and patient access to health information. Blue Button 2.0 provides patients access to their Medicare claims data and the 2015 CEHRT

³⁰ [Sharing Health Information for Treatment. https://www.aha.org/system/files/2018-03/sharing-health-information.pdf](https://www.aha.org/system/files/2018-03/sharing-health-information.pdf)

³¹ <https://assets.sourcemediacom/a4/a3/98a6529b44e9ab724f84f89b4d2b/philips-wellcentive-realizing-the-value-in-value-based-care-wp-final.2.pdf>

³² <https://klasresearch.com/report/population-health-management-2017-part-2/1230>

requires for EHRs to implement APIs for consumer-facing apps. However, such efforts are inadequate to achieve full scale interoperability.

We are concerned that serious challenges and barriers prevent providers from accessing and using EHR data. APIs have the potential to allow access to EHRs and health data; however EHR vendor implementation of APIs is inconsistent. Furthermore, providers and app developers face significant costs when trying to add functionality into or “on top of” EHRs. Thus, EHR vendor business practices are stifling innovation. Premier believes that CEHRT, via APIs must support health care providers’ access to health information in order to help achieve widespread interoperability,

CMS has implemented the Blue Button 2.0 as a way to promote interoperability by allowing beneficiaries to access their claims data via an API and to share their data with applications of their choosing. To further promote interoperability and data access, we urge CMS to develop and implement a similar (access to claims data) functionality for providers by allowing providers to access and download their patients’ Medicare claims via an API.

Premier believes that providers and clinicians need their EHR vendors to provide public, open and fully accessible APIs to make health information more accessible to providers so that providers can connect applications to their EHRs and enhance their functionality. As previously noted, ONC’s 2015 CEHRT requires EHRs to allow patients to access their clinical data via APIs. ONC should implement similar CEHRT requirements for APIs for provider facing apps. Allowing data to be accessible through fully open, standardized and consistently implemented APIs will spur novel approaches to data integration and use, leading to a more open, innovative and competitive health IT market. Providers and other stakeholders must be able to connect and exchange data and information with other current, new and emerging health IT systems, modules and applications, medical devices and sensors across the care continuum, care settings, facilities and delivery systems/networks, without unfair and unnecessary restrictions placed on them by EHR vendors. EHR vendors (business practices) should not require providers to obtain permission to connect applications of the providers’ or clinicians’ choosing to the EHR platform.

Providers need maximum flexibility under Federal reporting programs (such as quality, payment and public health) to obtain credit for their innovative use of diverse health information technologies and activities. As the 2015 CEHRT requires providers to implement open APIs that allow patients’ access to their health information, providers should be given “credit” for interoperability when using these APIs. Providers need access to data and technology solutions outside their EHRs to support value-based care and population health management programs and other initiatives^{33 34} and should be able to get credit for their use of health information technologies and applications beyond certified EHRs.

³³ Sage Growth Partners (SGP). Are EHRs up to the task? March 2018 <http://sagegrowth.com/index.php/2018/03/ehrs-task-sage-growth-partners-report/>

³⁴ Stalled Progress on the Path to Value-Based Care. <http://quanumsolutions.questdiagnostics.com/2018survey>

There is an increasing demand for a growing range of health IT products, services, and applications, beyond the capabilities and functions of legacy EHR platforms. While CEHRT 2015 requires the use of APIs to give patients access to their health information through mobile applications of their choice, much work remains for ONC to develop certification requirements and implement specific CEHRT criteria for APIs. Additionally, ONC should ensure that providers can easily access their EHR data via APIs.

Suggested priority actions for CMS and ONC include the following:

- Allow providers to connect apps of their choosing to EHRs via open, public and publishable APIs, without obtaining the EHR vendors' permission
- Harmonize definitions and requirements for health information technology (i.e., base EHR; CEHRT; USCDI, TEFCA; health information technology; modules/functions) across Federal administrative, reporting, quality and payment programs
- Recognize, designate, support and enforce consistent, scalable and fair EHR use of an industry standard for the required open APIs (i.e., HL 7 FHIR; SMART on FHIR; or successor standard)
- Accelerate efforts to ensure that APIs are standardized, openly published, and consistently implemented to ensure provider data access and use at the point of care and within clinical workflow
- Develop and implement a transparent, open national testing and vetting/approval infrastructure and processes for APIs and apps to encourage innovation, assure consistent interoperability specifications and implement fair and equitable app dissemination
- Assure that an app once "approved" is able to be reused in all certified EHR platforms
- Clarify and clearly define "without special effort"
- Extend and accelerate open API standards for: bulk data export; clinical decision support; and bi-directional data flow (read-write into and out of EHRs)
- Align and harmonize TEFCA and USDI with current and future CEHRT and Promoting Interoperability requirements

Significant challenges exist regarding standards: variability in EHR vendor implementation of standards; insufficiencies in interoperability standards; lack of attention to semantic interoperability; and inconsistent use of terminologies and formats. Information that is electronically exchanged from one provider to another must adhere to the same standards, and these standards must be implemented uniformly, in order for the information to be understandable and usable, thereby enabling interoperability.³⁵

³⁵ ELECTRONIC HEALTH RECORDS Nonfederal Efforts to Help Achieve Health Information Interoperability Report to Congressional Requesters. United States Government Accountability Office. September 2015 <https://www.gao.gov/assets/680/672585.pdf>

Additional recommendations and actions items regarding CEHRT include the following:

- Provide transparent and publicly accessible information about their products and services, including capabilities, functions, security, APIs, fees and costs, usability, and interoperability
- Demonstrate/attest that they allow third party applications, modules, systems and products to seamlessly and securely connect to and integrate with their EHRs
- Attest that they do/will not unintentionally or deliberately restrict providers from integrating with or connect to their EHRs to applications, services, and modules of the providers' choosing
- Support workflow processes and incorporate user-centered design principles
- Demonstrate interoperability (i.e., ability to send and received structured and unstructured data) and use standardized data elements, definitions, and formats so that data and information can be more easily documented, collected, accessed, extracted and used in accordance with CEHRT criteria
- Facilitate providers' need to easily extract data from and insert data into their EHRs (bi-directional data flow)
- Ensure availability and accessibility of health data (including structured and unstructured clinical data) for an individual patient, panel of patients, or a population of patients

CMS and ONC must require EHR vendors to publish public and open APIs so that providers can seamlessly integrate third party applications and health information technologies and applications with EHRs. EHRs must demonstrate their ability to meet Promoting Interoperability measures and CEHRT criteria and related requirements in advance of establishing any expectations that providers do so. Furthermore, CMS must work with ONC to clarify the glide path from the current common core clinical data (CCDS) and the 2015 CEHRT to future versions of CEHRT and the proposed USCDI. ONC and CMS must clearly delineate how future versions of CEHRT, CCDS and/or the USCDI will be recognized and implemented within Federal administrative, reporting, quality and payment programs. ONC and CMS must assure that any future requirements will not unfairly burden providers. CMS, ONC and other Federal agency reporting and administrative requirements must be aligned and harmonized.

Summary

Value-based care (VBC) and advanced payment models (APM) require data-driven, technology-enabled data exchange, data sharing and interoperability across the continuum of care -- beyond EHRs. The ecosystem is moving toward population health management, accountable care organization (ACO) development, APMs and other initiatives that demand more robust data and analytics capabilities and diverse health IT tools and functions.

The movement towards VBC and the advent of APMs has created an even greater imperative for health information interoperability. Advanced payment models 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 across disparate sites of care, facilities, organizations and different HIT systems and EHRs.

Actionable insights drawn from clinical, financial, and socioeconomic data are critical for succeeding with population health management and value-based care. Identifying, intervening and managing patient care requires a combination of risk stratification, case management, referral management, care coordination, data analytics, and patient engagement functions and capabilities that require systems and applications in addition to EHR platforms.

Data analytics are key to success under value-based payments and alternative payment models. Successful quality improvement by healthcare providers requires effective use of clinical, financial and other data. Access to data will inform risk modeling, help providers identify patients who may benefit from targeted interventions, enable more effective patient engagement initiatives, design and evaluate quality improvement initiatives, identify and close clinical care gaps and implement workflow efficiencies to control costs.

Premier supports efforts to transform healthcare through the power of data and health information technology (IT). As discussed above, there are many obstacles, barriers and challenges—many outside of the control of hospitals, health systems and clinicians, —that impede and prevent their ability to seamlessly exchange information. It is essential that CMS and ONC first address and resolve ongoing interoperability barriers and challenges so that providers can improve care delivery, patient safety and performance, and 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. Premier healthcare alliance appreciates that CMS is seeking comments about interoperability and patient access; however, **we stress that the CoPs/CfCs/RfPs are neither appropriate nor effective levers to achieve interoperability, spur innovation, or ensure provider and patient access to data.**

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit comments on CMS-1689-P. Premier looks forward to working with CMS and other stakeholders to develop reforms that meet the agency's goals and are appropriate for beneficiaries and providers.

Ms. Seema Verma
August 31, 2018
Page 23 of 23

If you have any questions regarding our comments or need more information, please contact Aisha Pittman, senior director of policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

A handwritten signature in black ink, appearing to read "Blair Childs". The signature is fluid and cursive, with a large initial "B" and "C".

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance