

September 24, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
Submitted electronically to: <http://www.regulations.gov>

Re: CMS-1695-P, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma:

On behalf of the Premier healthcare alliance, we appreciate the opportunity to submit comments regarding the regulation proposed by the Centers for Medicare & Medicaid Services (CMS) for the Outpatient Prospective Payment System (PPS). Premier is a leading healthcare improvement company, uniting an alliance of approximately 4,000 U.S. hospitals and 165,000 other providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, advisory and other services, Premier enables better care and outcomes at a lower cost. Premier, a 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 primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the effective operation of the outpatient PPS. Below, the Premier healthcare alliance provides detailed comments with suggested modifications to the policies proposed by CMS.

OFF-CAMPUS PROVIDER BASED DEPARTMENTS (PBDs)

In the preamble of the proposed rule, CMS provides some history of Medicare inpatient and outpatient hospital payment systems, and the agency expresses concerns about expenditure growth in the outpatient department. The OPPS was enacted in section 4325(a) of the Balanced Budget Act of 1997 (Public Law 105-33). As enacted, Congress directed CMS to establish a

prospective payment system for covered outpatient department (OPD) services which included authority to develop a method for controlling unnecessary increases in the volume of covered OPD services under section 1833(t)(2)(F) of the Act. While CMS never established such a method, it has attempted to address expenditure growth through such policies as increased packaging and the development of C-APCs. These policies apply generally to all facilities furnishing covered OPD services.

Section 603 of the Bipartisan Budget Act (BBA) of 2015 amended the OPSS statute by adding section 1833(t)(21) of the Act which establishes the payment rules for off-campus provider-based departments (PBDs). New off-campus PBDs (i.e., generally those that opened after November 2, 2015) are paid differently from existing off-campus PBDs. In section 603, Congress amended the statute (viz., section 1833(t)(1)(B) of the Act) to exclude services furnished by these new off-campus PBDs from the definition of covered OPD services with the legal effect of precluding payment for those services under the OPSS. Congress directed the agency to provide for payment for these services furnished by these new facilities under another Part B payment system effective January 1, 2017. Grandfathered off-campus PBDs (i.e., those that are not new within the meaning of section 603) furnish covered OPD services and are paid under the OPSS. In doing so, Congress established different rules for the payment of services furnished by off-campus PBDs.

While these policies are aimed at preventing the conversion of physician practices to provider-based clinics, **Premier does not support “site neutral” provisions that do not recognize the key differences between physician practices and provider-based outpatient clinics that result in higher overhead expenses for provider-based outpatient clinics.** For example, hospital outpatient departments have costs associated with standby services incurred in 24-hour emergency department settings, which include around-the-clock availability of emergency services, cross-subsidization of uncompensated care, EMTALA and Medicaid, emergency back-up for other settings of care and disaster preparedness. Similarly hospital-outpatient departments have a wide range of staff and equipment, including clinics pharmacy, radiology and other diagnostic testing, care management, and access to a wide range of post-acute care services, which are not available in physician offices. Finally, hospitals have more comprehensive licensing, accreditation, and regulatory requirements than physician offices. For example, the provider-based facility payment to hospital outpatient departments supports the significant cost of providing ambulatory care services to hospital standards for quality and safety and meeting Centers for Medicare & Medicaid Services (CMS) conditions of participation. **At a time when providers are adopting population health strategies that seek to limit inpatient care when it is safe and medically appropriate, we are concerned that CMS’ over-reach is counterproductive and will have negative consequences for beneficiaries.** In lieu of expansive site-neutral payment policies, CMS should focus on methods to encourage providers to adopt risk-based alternative payment models.

Controlling Unnecessary Increases in the Volume of Outpatient Services

Beginning with 2019, CMS proposes to use its authority under section 1833(t)(2)(F) of the Act (i.e., to control unnecessary increase in the volume of covered OPD services) to pay the same amount for an outpatient Clinic visit (G0463) at an off-campus PBD excepted from section 603 of the BBA that it currently pays for the same service in an off-campus PBD that is not excepted from section 603 of the BBA—40 percent of the OPPS rate. CMS believes capping the OPPS payment at the PFS-equivalent rate would remove the payment incentive that it believes is increasing utilization in the OPD to control the volume of unnecessary services. CMS would not apply a budget neutrality adjustment to its proposed policy, making the argument that budget neutrality is only required for “adjustments” but not for “methods” to control unnecessary increase in the volume of covered OPD services under section 1833(t)(2)(F) of the Act.

CMS’ Proposal Is Not A Method to Control Unnecessary Increases in Volume.

CMS proposes to reduce the payment under the OPPS for one code billed by some hospital outpatient departments. CMS asserts that this policy proposal to reduce payment rates for an outpatient clinic visit furnished at section 603 grandfathered off-campus PBDs is a “method” to control unnecessary increases in the volume of covered OPD services within the meaning of section 1833(t)(2)(F) of the Act. The proposal is not a method; it is a payment adjustment to one code billed by section 603 grandfathered off-campus PBDs.

Paragraph (2)(F) of section 1833(t) of the Act must be read in the context of paragraph (2) of section 1833(t) (as well as the remainder of section 1833(t) of the Act). Paragraph (2) of section 1833(t) sets forth general criteria for the Secretary to take into account when establishing the OPPS. The introductory language in paragraph (2) states as follows: “(2) SYSTEM REQUIREMENTS.—Under the payment system—” which indicates that when developing the OPPS for covered OPD services furnished by hospital outpatient departments, CMS must include certain congressional priorities for the system.

These requirements (which are set forth in section 1833(t)(2)(A) through (H) and as modified in succeeding paragraphs of section 1833(t)) apply generally to all covered OPD services furnished by all hospital OPDs. Unless the statute specifically permits a distinction to be made among facilities (i.e., a special rule for certain types of providers), then the statute must be read as requiring the system to apply to all hospital outpatient facilities and to the covered OPD services they furnish. Thus a method under section 1833(t)(2)(F) must apply generally to covered OPD services for which payment is made under the OPPS. As an example of discretion granted by the statute on this issue, the language of section 1833(t)(2)(E) establishes the authority of the agency to establish adjustments for various purposes, including “...adjustments for certain classes of

hospitals.” There is no such discretion afforded to the agency under section 1833(t)(2)(F) of the Act. That section clearly states as follows:

“(F) the Secretary shall develop a method for controlling increases in the volume of covered OPD services;”.

A method to control increases in the volume of services is one that applies system wide. In the 2018 proposed rule, CMS cites the example of the sustainable growth rate under the Medicare physician fee schedule (PFS) that was also enacted in the Balanced Budget Act of 1997 (83 FR 37138). The PFS sustainable growth rate (SGR) replaced the Medicare volume performance standard; both were intended as a control on the rate of expenditure growth from one fiscal year to the next. Though different in their design, the method applied generally to physicians’ services for which payment was made under the PFS. The SGR specified the growth rate “for all physicians’ services for a fiscal year”¹ pursuant to a specific statutory formula.

Similarly, under the Medicare Maryland hospital all-payer waiver under section 1814(b)(3) of the Act, per capita inpatient and outpatient hospital growth is limited to a certain percentage per year (i.e., the long-term growth rate of the state’s economy). There are no special payment rules for a particular hospital service nor are there distinctions made based on whether a facility is an off-campus facility or not. CMS’s proposal is not a method within the language and intent of section 1833(t)(2)(F); it is merely a payment adjustment for certain hospital outpatient facilities for a single outpatient code.

A proposal to cap payment rates for a particular code when furnished by a particular type of provider is a payment adjustment for that service when furnished by that provider. Thus, **CMS’s rationale for applying its proposed payment adjustment in a non-budget neutral manner is flawed.** An adjustment by any other name is still an adjustment. CMS itself acknowledges that its proposed change is an adjustment as it arrived at the payment amount by applying the PFS relativity adjuster to the full OPPS payment amount (see 83 FR 37142, “For a discussion of the PFS relativity adjuster that will now also be used to pay for all outpatient clinic visits provided at all off-campus PBDs...”). Its proposal is not a method within the meaning of the statute as enacted and subsequently implemented by the agency for close to 20 years. **Thus, the provisions of section 1833(t)(9)(A) and (B) apply to the proposal, and the policy, if finalized, must be implemented in a budget neutral manner.**

CMS’ Proposal Contravenes Section 603 of BBA 2015

As noted above, section 603 of BBA 2015 established authority for CMS to set different payment rates for outpatient services furnished by “new” off-campus PBDs with certain exceptions (e.g., emergency department services are still paid at OPPS rates). Congress could

¹ See section 1848(f)(2) of the Act, as amended by section 4503(a) of the Balanced Budget Act of 1997.

have applied this authority to establish different (i.e., lower) payment rates for all off-campus PBDs; however, congressional policy was to exempt existing off-campus PBDs from the application of section 603 payment policies. Section 1833(t)(21)(B)(ii) of the Act clearly exempts those off-campus PBDs that billed for covered OPD services under the OPSS before November 2, 2015.

Under the payment methodology CMS adopted to implement section 603, payment for an outpatient clinic visit (G0463) furnished by a “new” off-campus PBD is equal to 40 percent of the payment rate under the OPSS for that clinic visit when paid as a covered OPD service. CMS proposes to pay that exact same rate for that service when furnished by an off-campus PBD that was exempted from the application of section 603 by Congress. This is in direct conflict with the statute and with congressional intent of the enactment of section 603.

CMS is exceeding its statutory authority in proposing a policy that directly contravenes the BBA 2015 and is attempting to usurp Congress’s role in setting Medicare policy on this issue. Had Congress intended to grant the agency the discretion to apply service-specific payment reductions for exempted off-campus PBDs under section 603, it would have done so. However, Congress clearly identified the class of facilities to which the payment rules of section 603 shall apply. CMS may not propose policies under pre-existing provisions of the OPSS statute to undermine congressional intent in this area and to grant to itself authority to effectively legislate on this issue.

Premier opposes the administration’s proposal to pay physician fee schedule rates, instead of outpatient rates, for all outpatient clinic visits and new lines of services in off-campus provider-based departments and continues to believe that CMS does not have the statutory authority to implement such a proposal. In addition, we feel strongly that the proposal will undermine high quality, cost effective care.

Expansion of Clinical Families of Services at Excepted Off-Campus PBDs

In the CY 2017 OPSS rule, CMS proposed, but did not finalize, a policy that excepted PBDs could continue to be paid at OPSS rates for items and services in each of the 19 proposed “clinical families of services” if that PBD furnished and billed for a service in that clinical family of services prior to November 2, 2015. While CMS did not finalize this policy in CY 2017, CMS noted that it would continue to monitor the volume of services at excepted PBDs to determine if service line expansion should be addressed in future rulemaking.

For CY 2019 rulemaking CMS is again proposing this concept to start January 1, 2019. Under the current proposal, if an excepted PBD furnishes services in new clinical families of service, such services must be billed with the PN modifier and would be paid at 40 percent of the OPSS rate. To establish which clinical families of services will be excepted at a PBD, CMS is proposing that hospitals determine whether the PBD furnished a service in the clinical family during a baseline period from November 1, 2014 through November 1, 2015. If it did furnish a service in the clinical family during that time period, all services in such family would continue

to be paid at the full OPPS rate. However, items from clinical families of services not billed during the baseline period would be paid at the non-excepted rate of 40 percent of the OPPS rate.

Premier is discouraged to see this concept proposed again. We do not believe CMS has taken into consideration the realities of care delivery indicated by the narrow list of clinical services within the 19 families. We are concerned that limiting the expansion of services in PBDs will create a barrier for providers trying to meet the changing medical needs of a community, adapt to changing technology or evolve with the practice of medicine in future years if decisions about service lines are restricted by regulations.

Excepted PBDs must be able to expand the items and services that they offer in order to meet changes in clinical practice and the changing needs of their communities without reductions in its reimbursement. Given the rapid pace of technological advances in medicine, the treatments and services offered by outpatient departments today will inevitably evolve into newer, innovative and more effective care in the future. Especially with the concerted effort to move more and more services out of hospitals and into outpatient settings. CMS policy must not hamper access to innovative technologies and services. Nothing in the law requires that CMS treat expanded services in an excepted PBDs in this way. In fact, the plain language does not address expansion at all. CMS must ensure that patients continue to have access to the services they need at the facilities where they seek treatment. **We believe that CMS should not place any restriction on expansion of services lines for excepted PBDs.**

Application of the 340B Drug Payment Policy to Non-excepted Off-Campus PBDs

Under section 603 of the BBA 2015, generally off-campus provider-based departments (PBDs) of hospitals that open after November 2, 2015 (with limited exceptions) are not paid under the OPPS for “applicable items and services”² they furnish. This is because section 603 excludes most of the items and services furnished by these “non-excepted off-campus PBDs”³ from the definition of covered OPD services. Section 603 directs CMS to pay for these items and services when furnished by non-excepted off-campus PBDs under an “applicable payment system” under Part B, and it specifically excludes the OPPS. The applicable Part B payment system for drugs and biologicals is determined pursuant to 1842(o)(1)(C) of the Act. Section 1842(o)(1)(C) specifies the Part B payment methodology for a drug or biological when that drug or biological is not paid “on a cost or prospective payment basis as otherwise provided in this part”.⁴ Thus, because applicable items and services furnished by non-excepted off-campus PBDs are not

² Applicable items and services exclude items and services furnished by a dedicated emergency department.

³ CMS generally refers to off-campus PBDs subject to section 603 as “non-excepted off-campus PBDs.”

⁴ The reference to “this part” in the quoted material is a reference to Part B of the Medicare program.

covered OPD services for which payment is made under the OPSS, the statute clearly requires payment to be made for those drugs when furnished by those facilities pursuant to the rules established under section 1842(o)(1)(C). Pursuant to section 1842(o)(1)(C), CMS makes payment for drugs and biologicals furnished non-excepted off-campus PBDs section 1847A (the average sales price (ASP) methodology), meaning generally that payment is calculated as 106 percent of the ASP for the drug or biological.

Separately, in the OPSS rulemaking cycle for 2018, CMS established a 340B payment policy under the OPSS whereby the agency pays hospital outpatient departments for drugs and biologicals acquired under the 340B drug discount program (other than drugs on pass-through payment status and vaccines) at ASP minus 22.5 percent. CMS cited a provision within the OPSS statute as its authority to make this adjustment; specifically, CMS asserts that section 1833(t)(14)(A)(iii)(II) permits it to adjust the payment amount for a specified covered outpatient drug that is furnished as part of a covered OPD service. CMS believes this adjustment authority was intended by Congress to grant the agency discretion to reduce payment amounts for separately payable drugs and biologicals under the OPSS when those drugs or biologicals are acquired through the 340B program. This policy applies to hospital outpatient departments, including those off-campus PBDs that are exempted from the payment rules of section 603 of BBA 2015. **Premier continues to oppose this policy as Section 603 neither amended nor made any reference to the 340B drug discount program under the Public Health Service Act; the 340B drug discount program is a very important tool for hospitals to provide access to discounted drugs for vulnerable low-income patients.**

CMS proposes to pay the adjusted payment amount of ASP-22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program when they are furnished by non-excepted off-campus PBDs of a hospital effective January 1, 2019. CMS proposes to exempt rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment consistent with the policy it applies for on-campus PBDs and excepted off-campus PBDs. CMS believes the proposed policy would better reflect the resources and acquisition costs that non-excepted off-campus PBDs incur for drugs and biologicals acquired under the 340B program. CMS cites section 1833(t)(21)(C) of the Act as its authority for applying the 340B policy to non-excepted off-campus PBDs.

As noted above, section 603 of BBA 2015 directs CMS to make payment for applicable items and services furnished by non-excepted off-campus PBDs under an "applicable payment system" under Part B (other than OPSS). In the case of drugs and biologicals that are applicable items and services furnished by non-exempt off-campus PBDs, under the terms of the statute (i) they are not covered OPD services, and (ii) they are not paid for under a cost or prospective payment basis. Thus, by law, payment for these drugs and biologicals is determined pursuant to the rules of section 1842(o)(1)(C) which mandates that payment is to be made for these drugs and

biologicals when furnished by these facilities pursuant to the rules of section 1847A (ASP methodology). Section 1847A requires that must generally be made at ASP+6 percent. There is no provision within section 1847A that permits the agency to set payment rates for these drugs and biologicals when furnished by these facilities at ASP-22.5 percent.

CMS cites section 1833(t)(21)(C) of the Act as its authority for applying the 340B policy to non-excepted off-campus PBDs. The agency does not have the discretion to interpret the phrase “applicable payment system” in section 1833(t)(21)(C) to mean whatever it wants to accomplish its own policy goals. While Congress gave the agency some discretion in implementing section 603, Congress clearly intended the agency to use the existing Part B payment systems as in effect on the date of enactment of BBA 2015. Had Congress intended to vest authority in the agency to develop its own payment system, the statute would have had to specify that policy directly. Thus, where a payment system was specifically established by legislation and is in effect for drugs and biologicals that are not covered OPD services under the statute, CMS must use that payment system which in this case is the ASP methodology under section 1847A of the Act. Congress sets major policy changes through legislation; the creation of a new Part B payment system would be a major change in Medicare Part B payment policy. The payment provision of section 603 does not vest that degree of discretion in the agency, and the agency’s proposal usurps Congress’ role of establishing Medicare payment policy through legislation. Additionally, the language of section 1833(t)(21)(C) does not grant CMS any adjustment authority which is the language in section 1833(t)(14)(A)(iii)(II) of the Act which CMS asserts granted the agency the authority to establish its 340B payment policies for 2018.

CMS should not finalize this policy as Congress has not granted the agency the authority to implement such a policy, therefore, we are strongly opposing this proposal.

PACKAGED ITEMS AND SERVICES

CMS is interested in comments on reorganizing or establishing more granular APC groupings to provide incentives for increased use of non-opioid alternatives. Premier has been active in seeking solutions to the opioid epidemic. Because we play a major role in the supply chain by contracting with supplies for hospitals and other providers, we work closely with virtually all the drug and device manufacturers in the nation. As a means to help our members find solutions to the opioid epidemic, we have created a evidence-based, pain management portfolio of product options for our members to consider. One issue that has impacted the uptake of these products is inadequate reimbursement for these products compared to opioids. **We are supportive of CMS’s efforts to promote the use of evidence-based alternatives to opioids, including innovative medical devices, as a way to fight this crisis.**

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

Measure Removal Factors

In alignment with proposals for other quality programs in 2019, CMS proposes an eighth removal factor, “the costs associated with a measure outweigh the benefit of its continued use in the program.” CMS also indicates that using the proposed Factor 8 would be on a case-by-case basis and states that if CMS concludes that the beneficiaries justify the reporting burden it can decide to retain a measure. **Consistent with inpatient PPS, Premier supports the adoption of the 8th removal factor; however, CMS should provide information on how it evaluates the cost and benefit when proposing to remove or retain a measure.**

CMS is also proposing to reword factor 7 to state, “collection or public reporting of a measure leads to negative unintended consequences *other than* patient harm” to align with the other quality reporting programs. **We support the rewording of factor 7 as we feel that this allows for consistency in measure evaluation methodology across programs.**

Removal of Measures

Ten measures are being proposed for removal from the OQR program for 2020 and 2021 payment determination. Measures proposed for removal based on the proposed cost/benefits of factor 8 would not be finalized for removal if that factor is not adopted in the final rule.

One measure is proposed for removal beginning with the 2020 payment determination:

- OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) is proposed for removal because costs outweigh the benefits.

Nine measures are being proposed for removal beginning with 2021 payment determination:

- OP-5: Median Time to ECG (NQF #0289) is proposed for removal because costs outweigh the benefits. In addition, while the measure does not meet the definition of topped out, CMS does not consider these differences between the 75th and 90th percentiles (less than 2 minutes) to be meaningful in helping beneficiaries make informed care decisions as performance variation has been minimal.
- OP 31: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536) is proposed for removal because costs outweigh the benefits. After initially adopting OP-31 as a mandatory OQR Program measure for the 2016 payment determination, CMS subsequently delayed data collection and then made the measure voluntary with only 1.2 percent of facilities reporting the measure on a voluntary basis.
- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and OP-30: Endoscopy/Polyp

Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659) are proposed for removal because costs outweigh the benefits.

- OP-9: Mammography Follow-up Rates is proposed for removal under factor 3 (the measure does not align with current clinical guidelines or practice), nor does it consider more recent guidelines and literature on the clinical benefits of diagnostic digital breast tomosynthesis (DBT).
- OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513) and OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT are each proposed for removal because the measures are topped out (factor 1).
- OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data and OP-17: Tracking Clinical Results between Visits are proposed for removal based on factor 2, in that performance or improvement does not result in better patient outcomes. These measures assess functionality of health information technology and do not address patient outcomes.

We support the removal of the ten measures from the OQR program and continue to encourage CMS to implement stakeholder feedback in a more timely manner. Premier has raised issues with the burden of reporting OP-31 for several years. In addition, we have recommended the removal of OP-9 and OP-14 since 2015. Additionally, we urge CMS to consider the removal of several other measures that have been recommended for removal by the NQF Measures Application Partnership (MAP), such as, OP-8: MRI Lumbar Spine for Low Back Pain, OP-10: Abdomen CT – Use of Contrast Material and OP 22: ED Patient Left Without Being Seen.

Future Considerations

CMS indicates it is moving toward greater use of outcome measures and away from the use of clinical process measures and requests comment on future measure topics for the OQR program. Premier continues to support the reduction of measurement burden. **While we agree outcome measures are of higher value to quality programs, there is still value in process measures.** Many process measures address topics where there is insufficient evidence or standardized data to assess an outcome.

Notice of Participation Form

CMS proposes to remove the requirement that hospitals submit a notice of participation form for participation in the OQR Program. Submission of any OQR Program data would indicate a hospital's status as a program participant. Under the proposal, a hospital would still need to (1) register on the QualityNet website before beginning to report data; (2) identify and register a

QualityNet security administrator; and (3) submit data. **Premier supports the removal of this requirement and urges CMS to consider a similar policy in other quality reporting programs.**

Frequency of OQR Program Specifications Manual Release

Instead of updating the OQR Program Specifications Manual every six months CMS proposes to update the manual every six to 12 months depending on the need for an updated release. The agency believes the twice a year update is unnecessary and confusing to program participants. It notes that the schedule would consider the CMS policy of providing at least 6 months' notice for substantive changes in measure specifications. **Premier supports this proposal and believes CMS should only make changes to the specification manual on an annual basis. In the event of a substantial measure change, CMS should consider suspending the measure.** Constant updates to the specification manual increases the burden of reporting the measure as systems must be reprogrammed or medical record reviews must be conducted again.

Extension of Reporting Period for OP-32: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy

CMS proposes to change the reporting period for the claims-based measure OP-32 from one year of data to three years of data based on findings that while 1 year of data provided sufficient reliability, three years of data increased the reliability and precision of the measure. This proposed change would be implemented for 2020 payment determination. In addition, the longer period is estimated to increase the number of HOPDs with eligible cases by an additional 235 facilities. **We agree with CMS that a three-year performance period may be better suited for this measure.** CMS should rely on experience from other quality performance programs (e.g. HVBP, HRRP) for determining when and how to apply a longer performance period. CMS should seek stakeholder feedback on developing a methodology and release a methodology report for public review and comment.

AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM

Measure Removal Factors

CMS is proposing several changes to the removal factors for the ASCQR program to better align with the OQR program:

- Effective with the 2019 OPSS/ASC final rule, current factor 2 (availability of alternative measures with a stronger relationship to patient outcomes) would be removed because it

is duplicative with current factor 6 (another available measure is more strongly associated with desired patient outcomes for a particular topic).

- In order to align the removal factors with those of the OQR Program, CMS proposes a new factor 2 (performance or improvement on the measure does not result in better patient outcomes).
- Also proposed is a new removal factor 8 (the costs associated with a measure outweigh the benefit of its continued use in the program).

Premier supports the proposed changes to the ASCQR removal factors. As previously mentioned, we feel the alignment of the removal criteria should be maintained across programs as this allows for consistency in measure evaluation methodology across programs.

Removal of Measures

CMS is proposing to remove eight measures from the ASCQR program for 2020 and 2021 payment. Measures proposed for removal based on the proposed cost/benefits factor 8 would not be finalized for removal if that factor is not adopted in the final rule. Several of the proposed changes to the ASCQR are parallel to the changes proposed in the OQR program.

One measure is proposed for removal beginning with 2020 payment determination:

- ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) is proposed for removal because costs outweigh the benefits.

Seven measures are being proposed for removal beginning with 2021 payment determination:

- ASC-1: Patient Burn (NQF #0263); ASC-2: Patient Fall (NQF #0266); ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); and ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265) are proposed for removal because they are topped out (Factor 1).
- ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659) are proposed for removal because costs outweigh benefits.
- ASC-11: Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery (NQF #1536) is proposed for removal because costs outweigh benefits

We support removing these measures from the program.

Possible Future Validation of ASCQR Program Measures

CMS seeks public comment on the possible future validation of chart-abstracted ASCQR Program measures. It believes that the program may benefit from providing more reliable estimates of national performance on measures, and that ASCs may also benefit from the opportunity to better understand their data and examine potential discrepancies. CMS believes that the OQR validation process may be a good model for this purpose. Within the OQR validation process CMS selects 450 hospitals at random and another 50 hospitals using targeted criteria for validation. Selected hospitals have 45 days to submit medical record documentation for validation. The data validation requirement is met if the hospital achieves at least a 75 percent reliability score as determined by CMS. The agency believes it would be beneficial to begin with one measure and recommends ASC-13: Normothermia Outcome due to its large sample size. **Premier supports the implementation of a measure validation program similar to OQR for ASCQR. In addition, we support beginning with only one measure to allow participants time to understand the program and its implications to payment.**

Extension of Reporting Period for ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

CMS is proposing to change the reporting period for ASC-12 from one year of data to three years of data beginning with 2020 payment determination because it is estimated that the longer reporting period would increase the number of ASCs with eligible cases by 10 percent, adding 235 ASCs to the measure calculation. **We agree with CMS that a three-year performance period may be better suited for this measure.** CMS should rely on experience from other quality performance programs (e.g. HVBP, HRRP) for determining when and how to apply a longer performance period. CMS should seek stakeholder feedback on developing a methodology and release a methodology report for public review and comment.

REQUEST FOR INFORMATION ON PROMOTING INTEROPERABILITY AND ELECTRONIC HEALTHCARE INFORMATION EXCHANGE

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
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	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

<p>in section 4004 of the 21st Century Cures Act?</p>	<p>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 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</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>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>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 on Achieving Interoperability

Premier has identified a number of ways that CMS (working with other agencies) can help promote interoperability. In the discussion below, we address a number of 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.^{5 6} 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 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 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,

⁵ Sharing Health Information for Treatment. <https://www.aha.org/guidesreports/2018-03-01-sharing-healthinformation-treatment>

⁶ Expanding Electronic Patient Engagement. <https://www.aha.org/guidesreports/2018-03-01-expanding-electronicpatient-engagement>

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).**⁷ 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' 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

⁷Interoperability 2017 https://klasresearch.com/images/pages/events/Cornerstone_Interop_White_Paper_2017.pdf

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).⁸ 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 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

⁸ 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/macraehrpt_final_4-2016.pdf

- 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.⁹ 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.^{10 11 12 13}

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

⁹ 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>

¹⁰ <https://code.cerner.com/apps>

¹¹ <https://open.epic.com/>

¹² <https://www.healthcareitleaders.com/blog/4-takeaways-from-the-epic-app-orchard-developer-conference/>

¹³ <http://www.modernhealthcare.com/article/20170222/NEWS/170229974>

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.¹⁴

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.

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.¹⁵ 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.

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

¹⁵ ONC Report to Congress April 2015. Report on Information Blocking.
https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf

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 TECFA as an alternatives to traditional program measures provide hospitals, health systems, clinicians and other providers greater flexibility and promote innovative uses of health IT. Other 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.^{16 17}

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 healthcare 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 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 rule¹⁸ about APIs, consumer-facing apps, information blocking and potential security risks, fails to acknowledge the increasing cybersecurity risks and

¹⁶ 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/>

¹⁷ Stalled Progress on the Path to Value-Based Care. <http://quanumsolutions.questdiagnostics.com/2018survey>

¹⁸ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-16766.pdf>

vulnerabilities faced by the entire health system.^{19 20 21} 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^{22 23} along with ongoing clinicians' dissatisfaction with existing EHRs.^{24 25} 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 percent of the hospital EHR market, based on meaningful use attestation data from CMS.²⁶ 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

¹⁹ <https://www.csoonline.com/article/3260191/security/healthcare-experiences-twice-the-number-of-cyber-attacks-as-other-industries.html>

²⁰ <https://www.phe.gov/preparedness/planning/CyberTF/Pages/default.aspx>

²¹ <https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf>

²² <https://www.definitivehc.com/hubfs/infographics/electronic-health-systems-ehr.pdf?t=1528465230285>

²³ <https://www.kaloramainformation.com/Content/Blog/2017/04/28/The-State-of-the-EMR-Market-in-2017>

²⁴ <https://www.healthcare-informatics.com/article/ehr/cmios-parse-complexities-md-dissatisfaction-ehrs>

²⁵ Mark W. Friedberg, Peggy G. Chen, Kristin R. Van Busum, Frances Aunon, Chau Pham, John P. Caloveras, 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

²⁶ <https://www.beckershospitalreview.com/healthcare-information-technology/50-things-to-know-about-the-ehr-market-s-top-vendors.html>

the acute care hospital EHR market share in 2016.²⁷ ²⁸ 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.²⁹ Furthermore, an average hospital has 16 disparate EMR vendors in use at affiliated practices and 75 percent of the hospitals are dealing with 10+ disparate outpatient vendors.³⁰ A recent CMS report ³¹ 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.³²

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.³³ There still is much work to be done to assure that providers and clinicians can easily use, share and exchange information and efficiently add functionality and capabilities to their EHR platforms (such as via APIs).

²⁷ <https://medcitynews.com/2017/05/epic-cerner-ehr-market-share/>

²⁸ <https://www.beckershospitalreview.com/healthcare-information-technology/epic-cerner-hold-50-of-hospital-ehr-market-share-8-things-to-know.html>

²⁹ <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>

³⁰ <https://www.healthcareitnews.com/news/why-ehr-data-interoperability-such-mess-3-charts>

³¹ <https://innovation.cms.gov/Files/reports/nextgenaco-firstannrpt.pdf>

³² 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>

³³ 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>

Limited EHR Functionality

Providers need robust, scalable, and interoperable health IT systems and 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.³⁴ 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.^{35 36}

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

³⁴ [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)

³⁵ <https://assets.sourcemediacom/a4/a3/98a6529b44e9ab724f84f89b4d2b/piliphs-wellcentive-realizing-the-value-in-value-based-care-wp-final.2.pdf>

³⁶ <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 ³⁷ ³⁸ and should be able to get credit for their use of health information technologies and applications beyond certified EHRs.

³⁷ 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/>

³⁸ 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 IT; 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.³⁹

³⁹ 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 APMs 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 health IT 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 APMs. 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 VBC transition across the care continuum. The 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.**

PRICE TRANSPARENCY: IMPROVING BENEFICIARY ACCESS TO PROVIDER AND SUPPLIER CHARGE INFORMATION

The Affordable Care Act established the Public Health Service Act, which requires each hospital operating within the United States to make public a list of its standard charges for items and services including for diagnosis-related groups according to guidelines established by the Secretary. In the FY 2018 IPPS rule, CMS required hospitals to make available a list of their

current standard charges via the internet in a machine-readable format and to update this information at least annually. CMS discussed continued challenges for patients due to insufficient price transparency, including that surprise billing and chargemaster data is not helpful for patients, and seeks comment on improving price information for consumers.

Premier supports price transparency and believes that CMS should work to help consumers understand price information; however, providing standard charges will not address CMS' concerns with price transparency. Gross level costs are not useful to patients in that it does not consider contractual allowances, plan coinsurance structures, charity care policies and mission driven expenses such as teaching programs, etc. Moreover, it is difficult to identify the actual costs associated of care because the components such as staffing, overhead, and materials costs are accounted for inconsistently across the healthcare system. Moreover, there is a lack of price transparency for underlying materials costs. Better price transparency on underlying material costs could be a first step in providing more consistent information. In order to make progress in being able to better identify costs, which would assist in estimating expected payment by the uninsured, under-insured and those patients with health savings accounts, Premier recommends chargemaster reform.

The current Medicare cost reporting system precludes providers from fundamentally overhauling charge masters. **CMMI should establish a multi-payer voluntary demonstration that allows providers to rebase and reset relative costs within their charge masters.** Private payers would need to develop a hold harmless to ensure provider payments do not drop significantly by reducing charges. CMS would need to waive cost reporting rules and make adjustments to the payment systems that rely on cost to charge ratios for rate setting. Recognizing this would require significant effort, CMS should provide technical assistance as well as funds to providers during a transition period when participants would need to submit cost reports under the old system and a new system. Demonstration participants would provide ongoing feedback to CMS regarding the initiative.

Ms. Seema Verma
September 24, 2018
Page 32 of 32

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the CY 2018 outpatient PPS proposed rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, senior director, 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 the first name "Blair" being more prominent than the last name "Childs".

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance