October 5, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1736–P
Submitted electronically to: http://www.regulations.gov

Re: CMS–1736–P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

Dear Administrator Verma:

On behalf of the Premier healthcare alliance uniting an alliance of more than 4,100 U.S. hospitals and health systems and approximately 200,000 other providers and organizations, we appreciate the opportunity to submit comments on the CY 2021 Outpatient Prospective Payment System (OPPS) proposed rule. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Additionally, Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our member hospitals and health systems which, as service providers, have a vested interest in the effective operation of the OPPS. Below, the Premier healthcare alliance provides detailed comments with suggested modifications to the policies proposed by CMS.

340B DRUG DISCOUNT PROGRAM

Congress created the 340B Drug Pricing Program in 1992 to allow certain safety net hospitals (known as covered entities) to purchase outpatient drugs at a discount from drug manufacturers “to stretch scarce Federal resources” and expand healthcare services to vulnerable populations. For more than 25 years, the 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive healthcare services to low-income, underinsured and uninsured individuals in communities across the country. In the decades of the program’s existence, the savings produced by the 340B program have become essential to 340B hospitals as they struggle to meet the needs of the communities and patients they serve. Under the program, drug manufacturers are required to offer lower prices on covered outpatient drugs to eligible hospitals (e.g., those with a Medicare disproportionate share percentage of more than 11.75 percent) and other settings, enabling 340B hospitals to reinvest the difference between the discounted price and the amount paid by Medicare in healthcare services for underserved and uninsured patients. The ability to reinvest these savings is more critical than ever as our nation continues to face unprecedented healthcare challenges under the ongoing COVID-19 pandemic.

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In the 2018 OPPS rule, CMS adopted a policy to pay separately payable, non-pass-through drugs (other than vaccines and those furnished by rural sole community hospitals, inpatient prospective payment system (IPPS) exempt cancer hospitals, and children's hospitals) purchased through the 340B program at the average sales price (ASP)-22.5 percent, rather than ASP+6 percent. This policy has been subject to ongoing litigation. On December 27, 2018, United States District Court for the District of Columbia concluded the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP-22.5 percent for 2018 (see *American Hospital Association et al. v. Azar et al*). On May 6, 2019, the District Court ruled that the rate reduction for 2019 also exceeded his authority. The District Court remanded the issue to the Secretary to devise an appropriate remedy while also retaining jurisdiction. CMS subsequently appealed this ruling and on July 31, 2020 the U.S. Circuit Court for the District of Columbia entered an opinion reversing the earlier judgments.

As part of last year's rulemaking, CMS indicated its intention to conduct a survey of 340B acquisition costs, pending an appeal of the district court's decisions. Between April 24 and May 15, 2020, CMS surveyed more than 1,400 340B eligible hospitals. Hospitals were given the option of responding to a detailed survey, which provided acquisition costs for each individual drug or biological, or to a quick survey, whereby the hospital could indicate that it preferred CMS to utilize the 340B ceiling price obtained from the Health Resources and Services Administration. Only 7 percent of hospitals responded using the detailed survey and approximately 55 percent affirmatively responded using the quick survey response. For those hospitals that did not respond, CMS utilized the 340B ceiling pricing. As a result, CMS utilized the 340B ceiling price for 93 percent of hospitals. Based on this data, CMS estimates that the typical acquisition cost for 340B drugs for hospitals paid under the OPPS is ASP-34.7 percent.

CMS proposes a single uniform reduction using its authority under section 1833(t)(14)(A)(iii)(I) of the Act, which provides that the payment amount for a drug or biological "is equal to the average acquisition cost…determined by the Secretary taking into account the hospital acquisition cost survey data collected." Ceiling prices for individual drugs are protected from disclosure under section 1927(b)(3)(D) of the Act. As a result, CMS notes that proposing a single uniform reduction prevents any violation of this confidentiality requirement.

CMS states that it believes its decision to estimate average acquisition costs removes the need to also include an add-on of 6 percent, but the agency proposes an add-on to ensure parity with other Part B drugs outside the 340B program. As a result, CMS proposes to pay drugs acquired under the 340B program at ASP-28.7 percent, or ASP-34.7 percent plus the 6 percent add-on. This policy represents a 33 percent cut in payments from the statutory default methodology for hospitals participating in the 340B program. CMS also seeks comment on continuing its policy of paying at ASP-22.5 percent.

Premier continues to strongly object to these cuts as threatening access to care for the patients who benefit from the much needed 340B program. These cuts continue to punish hospitals for a policy that is designed to assist safety-net hospitals serving vulnerable patients, including those in rural areas. For the reasons cited below, we strongly urge CMS to drop these cuts.

CMS' 340B cuts harm our nation's most vulnerable patients

Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to build healthy communities. The proposed policies would harm vulnerable patients by cutting 340B drug savings that hospitals use to provide needed support for outpatient services in underserved areas. This will create devastating consequences for the patients and communities who rely

on this vital program. **We strongly urge CMS to withdraw its misguided 340B policy.** Our concerns are only heightened by the ongoing pandemic and effects that it will have on our nation's healthcare system. The savings achieved under this program will be even more critical for safety-net hospitals to provided needed services to vulnerable patients as they continue to navigate the challenges posed by COVID-19.

As noted above, the Congressional intent of the 340B program was to enable covered entities "to stretch scare federal resources as far as possible," allowing them to reach more eligible patients and provide more comprehensive services. 340B drug discounts help defray the costs that 340B hospitals and other covered entities incur in furnishing medicines to 340B eligible patients at low or no cost; the savings are also used to furnish other healthcare services to the poor, the uninsured and the underinsured.

Many safety-net hospitals are already operating on razor-thin or even negative margins and the ongoing pandemic will only serve to complicate finances for these hospitals. The 340B program is an essential resource for safety net hospitals in providing care to the uninsured and low-income patients. These resources are needed more than ever, as the ongoing pandemic has led to higher rates of unemployment and loss of health insurance, as highlighted by updated projections from CMS' Office of the Actuary (OACT) in the FY 2021 IPPS final rule to better account for the effects of the ongoing pandemic. CMS' OACT now estimates that nearly 10.2 percent of individuals will be without insurance in CY 2021.

Additionally, the ongoing pandemic continues to strain hospital operations and finances, resulting in significant lost revenue and increased expenses. The Medicare Payment Advisory Commission (MedPAC) estimates that hospitals lost between $20-30 billion in April alone. Others in the industry estimate that losses could be even higher, totaling as much as $50 billion in April. Continuing the 340B cuts will only serve to harm hospitals who are already severely strained by ongoing financial pressures from COVID-19.

Additionally, 340B hospitals use the savings they receive on the discounted drugs and reinvest them in programs that enhance patient services and access to care, as well as provide free or reduced priced prescription drugs to vulnerable patient populations. For example, hospitals operate a variety of programs and services that otherwise would not be financially viable:

- Provide financial assistance to patients unable to afford their prescriptions;
- Provide clinical pharmacy services, such as disease management programs or medication therapy management;
- Fund other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- Establish additional outpatient clinics to improve access;
- Create new community outreach programs; and
- Offer free vaccinations for vulnerable populations.

Safety-net hospitals are an essential part of the ongoing fight against COVID-19. It is unclear why the Administration would choose to continue to punitively target 340B safety-net hospitals serving vulnerable patients.

CMS' policy justifications are flawed

CMS has previously cited the fact that Medicare expenditures on drugs are rising due to higher drug prices as an impetus for its proposal. As we have stated before, this policy does not directly address this

issue and will have no effect on the price of pharmaceuticals. Instead the policy targets the assistance provided to 340B hospitals to protect patient access to healthcare.

CMS has also stated its belief that the policy will benefit beneficiaries by lowering coinsurance, contending that a reduction in the payments to 340B hospitals would also reduce beneficiaries' coinsurance as it is a percentage of payments. However, since this policy is applied in a budget neutral manner, the coinsurance obligation would simply shift to beneficiaries receiving other outpatient services as the payment for those services increases. Moreover, if hospitals drop out of the program, CMS only will succeed at reducing access to care or increasing the financial obligation for vulnerable populations.

CMS has not provided evidence that this policy, which was enacted three years ago, addresses the rising costs of pharmaceuticals nor protects beneficiaries.

Policy goes against Congressional intent

The goal of the 340B program is to enable 340B covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Report No. 102-384(II), at 12 (1992)). As noted above, 340B drug discounts from manufacturers allow 340B hospitals and other covered entities to furnish medicines to 340B eligible patients at low or no cost. In turn, these entities use savings achieved under the program to furnish other healthcare services to the poor, the uninsured and the underinsured.

That is what Congress intended when it enacted the 340B program; Congress has done nothing since 1992 to change those policy goals. In fact, under the Affordable Care Act (ACA), Congress specifically expanded the number of hospitals that could qualify as 340B covered entities and made other changes to ensure greater availability of the 340B drug discounts so that more individuals in vulnerable populations could get access to medicines and other healthcare services. It is also important to note that the ACA neither mandated any payment reductions in the payment amount for 340B drugs under any payment system under the jurisdiction of HHS, nor gave CMS any authorization to make such payment adjustments absent legislation.

As a result, any change to the fundamental policy goals of the 340B program can only be accomplished by Congress. As Premier has stated before, CMS' ongoing policy to pay differential rates for drug APCs based on 340B covered entity status is inconsistent with current law. **We urge CMS to discontinue its harmful 340B cuts to our nation's safety-net hospitals.**

IPO List and ASC Changes

The Medicare inpatient-only (IPO) list includes procedures that are only paid for under the IPPS, and thus are not paid by Medicare in other settings. Each year, CMS reviews the list to determine whether any procedures should be removed. Additionally, CMS maintains a list of procedures that CMS has deemed as appropriate for coverage and payment in the Ambulatory Surgical Center (ASC) setting. Over the last couple years, CMS has made notable changes to both the IPO List and ASC Covered Procedures List (CPL), including removing total knee arthroplasty (TKA) and total hip arthroplasty (THA) from the IPO List.

As part of this year's rulemaking, CMS proposes to eliminate the IPO List in its entirety over three years, starting with removal of nearly 300 musculoskeletal procedures in CY 2021. Additionally, CMS proposes two alternatives to how it approaches updates to its ASC CPL. Under both alternatives, CMS is proposing

to remove several criteria it uses when evaluating whether a procedure should be added to the ASC CPL, including whether the procedure does not lead to extensive blood loss nor is generally emergent/life-threatening in nature, among other criteria. This would have the effect of making it easier for CMS to add new procedures to the ASC CPL. Under the first alternative, CMS would seek input from external stakeholders, such as professional societies, and would then propose changes through its annual rulemaking processes, beginning with CY 2022. Under the second proposal, CMS would immediately implement the updated criteria for CY 2021, which would have the effect of adding nearly 270 new procedures to the ASC CPL in 2021.

We continue to urge caution as CMS looks to modify its IPO List and ASC CPL. Currently, we do not have enough information to understand whether these procedures would be clinically appropriate to be performed in an outpatient or ASC setting. Some private payers already allow for these procedures within the commercial population; however, the Medicare population can vary significantly from the commercial population, especially in terms of comorbidities and the risk for complications.

There are many factors for physicians to consider in determining which patients are appropriate for the outpatient setting. CMS has been reticent to define clinical criteria in the past, citing the need to preserve the role of the clinician in determining care. However, defined criteria are needed when CMS determines that a procedure can be safely performed in alternative settings to ensure that hospitals are able to follow clear clinical protocols and maintain compliance with setting of care guidelines. We encourage CMS to provide at least baseline criteria or guidance for providers to consider when determining which services would be appropriate in the outpatient or ASC setting. Establishing a baseline protocol does not limit clinical decision-making, as clinicians are still able to provide supporting clinical documentation to justify inpatient stays for patients that may otherwise be candidates for outpatient surgery. As discussed in greater detail below, **we urge CMS to exempt hospitals that utilize clinical decision support tools from patient status review for the two-midnight policy.**

CMS has recently removed several notable procedures from the IPO List and added procedures to the ASC CPL. We would urge CMS to continue to monitor the effects of these changes on patient care. Additionally, we encourage CMS to consider testing removal of codes in the context of Innovation Center models before expanding nationally. Alternative payment models offer the opportunity to test new payment approaches with minimal impact on beneficiaries as the accountable entities are responsible for the total cost of care and quality. This would afford CMS the opportunity to monitor outcomes of patients and develop clinical appropriateness criteria.

Additionally, CMS should consider adopting additional policies to safeguard patients. For example, ASCs are not subject to physician self-referral prohibitions. CMS should consider adopting a policy that would require physicians to inform beneficiaries of any ownership-interest in an ASC if the procedure meets certain criteria, such as involving extensive blood loss or could be life threatening. Additionally, while outpatient coinsurance is capped at the inpatient deductible, no similar cap is placed on beneficiary cost-sharing when the services are furnished in an ASC. CMS should adopt a policy that would require ASCs to inform patients of their cost-sharing obligations in instances where the coinsurance obligations would be higher at the ASC than if the procedure was furnished in an outpatient setting.

Proactively modify APMs to address changes to the IPO List.

CMS notes that it will continue to monitor changes in site-of-service to determine if changes need to be made to CMS Innovation Center Models. If these changes are finalized, **we strongly recommend that CMS take proactive steps to mitigate the effects of these changes.** Providers participating in Innovation Center models have made significant efforts to lower cost while improving quality of care. The

changes proposed in this rule may significantly impact the ability of participants to succeed in the model if additional steps are not taken.

As was seen with the removal of TKA from the IPO List, changes in site-of-service can have significant effects on whether participants can continue to succeed in models. In particular, when this procedure was initially removed in 2018, CMS had indicated that it did not expect the removal to have any significant impact on the Comprehensive Care for Joint Replacement (CJR) model[1]. However, CMS has since revised this conclusion, noting that that nearly 25 percent of TKA procedures in 2018 were performed in an outpatient setting.[2] This has lead CMS to propose changes to the CJR model to better account for shifts site-of-care, including expanding the definition of a CJR episode to include TKA and THA when performed in the outpatient setting.

CMS has historically been reticent to change the composition of target prices or benchmarks due to changes in policy set forth by the agency on the basis that risk should not be removed from models due to external changes. However, due to the significant likelihood of substantial financial impact on program participants as a result of eliminating the IPO list, **Premier recommends that CMS proactively adjusts MSSP and Innovation Center models to account for these effects, if the policy is finalized**.

To ensure participants continued success in the models, we recommend that CMS take into consideration the effect that these changes will have on have on the historical baselines used to set benchmarks and target prices for Innovation Center models and Medicare Shared Savings Program (MSSP). As lower acuity patients move to the outpatient setting, the risk profile of the remaining beneficiaries receiving inpatient care will be more complex. The change in case and cost mix would need to be recognized in the inpatient target prices and benchmarks set under these models and MSSP. These changes do not reflect changes in provider performance, but rather coverage determinations that place participating providers at financial risk. Without adjustment, it will be extremely difficult for participants to avoid being harmed financially by these policy changes.

MEDICAL REVIEW OF CERTAIN INPATIENT HOSPITAL ADMISSIONS

In the fiscal year (FY) 2014 IPPS final rule, CMS established the two-midnight rule (78 FR 50913-50954). Under the two-midnight rule, an inpatient admission is considered reasonable and necessary when the physician expects the patient to require hospital care that crosses at least two midnights. Since FY 2016, CMS has allowed for case-by-case exceptions to the two-midnight rule where the admitting physician does not expect the patient to require hospital care spanning two midnights but documentation in the medical record supports the physician's determination that the patient requires inpatient hospital care.

Procedures on the IPO list are appropriate for inpatient hospital admission regardless of the expected length of stay and are not subject to the two-midnight rule. However, the two-midnight rule is applicable once procedures have been removed from the IPO list. Procedures that are removed from the IPO list are also subject to initial medical reviews of claims for short-stay inpatient admissions conducted by Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs). BFCC-QIOs may also refer providers to the Recovery Audit Contractors (RACs) for further medical review due to exhibiting persistent noncompliance with the two-midnight rule.

[1] CY 2018 OPPS final rule (82 FR 59384)

[2] Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing (CMS-5529-P)

As part of FY 2020 OPPS rule, CMS finalized a policy to exempt procedures from certain medical review for compliance with the two-midnights for the two years following removal from the IPO list. During this time period, the procedures would not be eligible for referral to RACs for noncompliance. BFCC-QIOs would have the opportunity to review claims to educate practitioners and providers about compliance with the two-midnight rule, but claims identified as noncompliant would not be denied under Medicare Part A.

CMS proposes to retain the policy to exempt procedures for the two years following removal from the IPO list, regardless of whether it finalizes elimination of the IPO list. **Premier continues to support exempting procedures recently removed from the IPO list.**

Moreover, Premier believes the medical reviewers should give significant deference to the physician's judgment when evaluating the decision of where to treat the patient. Clinical decision support tools are useful in providing best practices content for enhanced patient safety. Additionally, these tools can leverage and pull data from evidence-based practice guidelines to provide patient-specific recommendations to ensure patients are receiving the most clinically appropriate care. If CMS finalizes its proposal to eliminate the IPO List, clinical decision support tools will be a critical tool for hospitals as they navigate the most appropriate setting for their patients. As a result, **we recommend that CMS exempt hospitals that utilize clinical decision support tools from two-midnight review of procedures that were once on the inpatient only list.**

At a minimum, we recommend that CMS establish a list of procedures that would be exempt from two-midnight review permanently. For example, solid organ transplants like heart and liver transplants have average length of stay of at least 8 days even for the healthiest of patients and are likely never to be performed outpatient absent significant improvements in technology. CMS could use similar criteria as it currently has established for the IPO List. For instance, if a given procedure performed inpatient has an average length of stay of over a set number of days, deference would always be provided to the physician. Alternatively, if a procedure is performed inpatient more than seventy percent of the time based on data from a recent year, deference would always be provided to the physician. Procedures on this list could be furnished in an outpatient setting but would not be subject to referral to a RAC for non-compliance if furnished inpatient.

SITE NEUTRAL CLINIC POLICY

In the CY 2019 OPPS rule, CMS adopted a policy to pay for clinic visits (HCPCS code G0463) provided in off-campus provider-based departments (PBDs) exempt from section 603 of the Bipartisan Budget Act (BBA) of 2015 at 70 percent of the full OPPS rate for 2019 and 40 percent of the full OPPS rate for 2020 and subsequent years. By paying at 40 percent of the full OPPS rate, CMS noted it would be paying these hospital outpatient departments at a "site neutral" physician fee schedule equivalent rate. CMS further decided not to subject this policy to budget neutrality, as it is required to do when making adjustments to payment rates for services paid under the OPPS.

This policy has been subject to ongoing litigation, with the American Hospital Association (AHA), the Association of American Medical Colleges (AAMC) and others are challenging CMS' policy in Federal District Court as being unlawful. In September 2019, the United States District Court for the District of Columbia ruled in favor of the plaintiffs and vacated applicable portions of the 2019 final rule[3]. While acknowledging the court ruling in its CY 2020 rulemaking and noting it would ensure 2019 claims were

[3] Amer. Hosp. Assoc. v. Azar (1:18-cv-02841) (Sept 17, 2019).

repaid consistent with the court order, CMS finalized its transition to paying outpatient clinic visits at a site neutral rate in 2020 and subsequent years. CMS subsequently appealed this ruling. As noted in the CY 2021 proposed rule, on July 17, 2020, the U.S. Court of Appeals for the D.C. circuit ruled in favor of the CMS. AHA and AAMC have requested a rehearing.

Premier does not support continuation of this site neutral policy for the reasons articulated below. We continue to believe this policy will undermine high quality, cost-effective care.

Hospital Outpatient Departments and Physician Offices are not the Same

CMS' policy does not recognize the key differences between physician practices and off-campus PBDs that result in higher overhead expenses for off-campus PBDs. 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 CMS conditions of participation.

Congress Specifically Exempted Existing Off-Campus PBDs from Site Neutral Policies

Section 603 of BBA 2015 prohibits payment under the OPPS for new off-campus PBDs that began receiving Medicare payment on or after November 2, 2015. The statute authorized CMS to pay under another "applicable" payment system. Existing off-campus PBDs opened before November 2, 2015 were specifically exempted ("grandfathered") from section 603. Under section 603, CMS is paying for services at non-exempt off-campus PBDs at 40 percent of the full OPPS rate. By paying for clinic visits in exempt off-campus PBDs at 40 percent of the full OPPS rate, CMS is ignoring the explicit grandfathering provision for exempt off-campus PBDs.

Payment Change is an "Adjustment" Subject to Budget Neutrality

CMS argued in the 2019 proposed rule that its reduction in payment for a clinic visit is not subject to budget neutrality because it is not an "adjustment" and only adjustments are subject to budget neutrality. However, this rationale is flawed. A policy to cap payment rates for a particular code when furnished by a particular provider type is a payment adjustment for that service when furnished by that provider. An adjustment by any other name is still an adjustment. Further, the 40 percent payment is derived by multiplying the full OPPS payment by the PFS relativity adjuster. The result of multiplying one number by an adjuster, is an adjustment.

CMS should focus on methods to encourage providers to adopt risk-based alternative payment models.

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. A better approach would be to incent providers to manage total cost of care. Population health strategies seek to limit inpatient care when it is safe and medically appropriate. We are concerned that CMS' overreach is counterproductive and will have negative consequences for beneficiaries. In lieu of expansive site-neutral payment policies, **CMS should ensure providers are equipped to move to APMs and two-sided risk**. At a minimum, CMS should exempt providers participating in two-sided risk APMs from any future site neutral payment policies.

HOSPITAL STAR RATINGS

CMS proposes long-awaited changes to the Hospital Overall Star Rating to simplify the methodology, enhance measure predictability, and to improve comparability of ratings across hospitals. Most notably, CMS proposes to simplify its methodology by regrouping measures into five measure groups and by using a simple average to calculate measure group scores, moving away from its complicated latent variable model (LVM).

Premier applauds CMS for proposing to adopt a more transparent and replicable methodology. We have previously recommended that CMS move away from the LVM and adopt a more simplified methodology. The LVM is a complex statistical technique that calculates a numerical "loading factor" for each star rating measure. The higher a measure's loading factor, the more it drives performance within a particular measure group. The inability to predict the weight of a measure creates instability in the Hospital Star Rating program from year to year that is not related to measure performance improvement. Stability is critical as these measures are leveraged by providers who desire to use the star rating to drive quality improvement and for patients who make important healthcare choices based on these ratings. The simplified methodology will reduce volatility and improve hospital and patient understanding. We generally support adoption of the proposed methodology with a couple modifications as noted below.

Measure selection and timing

CMS proposes to maintain its current process of updating Overall Star Ratings once a year based on publicly available measures on *Hospital Compare* or its successor website. **Premier supports continuation of an annual refresh of the star ratings and recommends that CMS continue to utilize publicly available measures to ensure consistency across quality reporting programs and to reduce provider burden. We also encourage CMS to use the most recent data to reflect the most current facility performance.**

We also recommend that CMS assess the volatility of measures. Any measure with volatility year-to-year should be removed from the star rating due to lack of reliability. Moving forward, CMS should only include measures with NQF endorsement that are valid, reliable and aligned with other existing measures. Additionally, CMS should work to ensure that measure groupings and group weights are balanced and reflect areas of importance to patients.

Assignment and calculation of measure groups

CMS proposes to combine three process measure groups – Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging – into one group, Timely and Effective Care. CMS notes that the number of available measures has declined over the last couple years as result of efforts under its Meaningful Measures Initiative. Premier supports combining these measures groups, as it will help improve score reliability by ensuring enough measures are included in each group.

CMS proposes to discontinue use of LVM for calculating measure group scores and instead use a simple average of measure scores. As noted above, **Premier supports adoption of this new methodology, which will increase predictability and improve transparency around score calculations.**

CMS proposes that each measure within a group would be weighted the same. While we agree with CMS that applying equal weights is a simple method that will allow hospitals to anticipate how measures will be weighted, we would also encourage CMS to explore alternatives that ensure measures that are more

meaningful, or better reflective of the hospital's services, are given more weight in the star rating methodology. For example, CMS could weight each measure within the measure group based on the measure's denominator relative to the national average. This methodology would ensure that measures that are most relevant to a given hospital would be weighted higher relative to other measures in which the hospital may have a smaller and less relevant patient population. CMS might also consider a "harm-based" weighting, similar to the methods employed in the AHRQ PSI-90 component weighting. CMS should continue to work with stakeholders to finetune its methodology around measure weights.

CMS also proposes to stratify the readmissions measure group based on a hospital's proportion of dual eligible patients using the same quintiles as under the Hospital Readmissions Reduction Program (HRRP). It is important to understand the numerous and variable risks associated with socio-demographic factors that are outside of the control of the provider that can affect outcomes. **We generally support this policy as it will improve the comparability of scores across hospitals.** We are also supportive of CMS' proposal to align the quintiles with those used in HRRP, which will further simplify the methodology and ensure consistency across quality programs. While supportive of this proposed approach, **we urge CMS to continue to explore approaches that account for a broader set of social risk factors in the future and to utilize sociodemographic data when evaluating additional measure groups.**

Calculation of hospital summary scores and application of minimum thresholds

CMS proposes to weight the outcome and patient experience measure groups (Mortality, Safety of Care, Readmission, and Patient Experience) at 22 percent and the process measure group (Timely and Effective Care) at 12 percent. Additionally, CMS proposes to revise its minimum reporting thresholds. Under the revised policy, hospitals would need to report at least three measures for three groups, one of which must be either the Mortality or Safety of Care outcome group. We are generally supportive of these proposals.

Peer grouping hospitals and application of clustering algorithm

Before assigning an Overall Star Rating, CMS proposes to assign hospitals to one of three peer groups based on the number of measure groups for which the hospital reported at least three measures. **We generally support this policy as it will improve the comparability of scores across hospitals.** CMS' analysis found that similar types of hospitals tended to report the same number of measure groups. For example, larger urban hospitals with more diverse case mix and service mix tended to report more measures than smaller rural hospitals.

CMS proposes to continue use of the k-means clustering algorithm to establish cutoffs that group hospitals into the five-star rating categories. This methodology would be applied within the peer groups described above.

Premier has previously expressed concerns with the k-means clustering methodology primarily because of its lack of transparency and reproducibility. The lack of a clear relative placement within a cluster prevents a hospital from knowing if they are borderline to a better or worse performing grouping. Additionally, a single hospital would need to have all-hospitals' data to know their own cluster placement. This makes it difficult, if not impossible, for hospitals to measure themselves relative to the respective star rating thresholds throughout the evaluation period.

An effective quality measurement program enables hospitals to clearly understand where to focus and drive improvement. To this end, **Premier recommends that CMS establish star rating thresholds through annual rulemaking for the upcoming year.** Under this policy, CMS could utilize the k-means clustering methodology to establish cut-points for upcoming fiscal year based on the current year's performance. Such an approach would improve transparency and help inform hospitals quality improvement efforts.

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the CY 2021 OPPS proposed rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, vice president, policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
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Premier healthcare alliance