August 31, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1786-P

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

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction [Docket Number: CMS-1786-P]

Dear Administrator Brooks-LaSure:

Premier Inc. appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year (CY) 2024 Outpatient Prospective Payment System (OPPS) proposed rule, which was published in the July 31, 2023 *Federal Register*.

In our detailed comments below, Premier urges CMS to:

- Adopt new or supplemental data sources to ensure labor costs are adequately reflected in the Medicare hospital payment update;
- Issue a formal Request for Information (RFI) to proactively engage with stakeholders on incorporating incentives and appropriate reimbursement models for artificial intelligent (AI) technology into Medicare payment systems;
- Finalize its proposal to leverage the new Medicare intensive outpatient benefit to increase access to treatment services for opioid use disorders;
- Partner with the Departments of Labor and Treasury to better align the various current price transparency requirements—with a focus on implementation of the Transparency in Coverage requirements—to minimize confusing or conflicting information for patients;
- Consider alternative non-budget neutral policy solutions to address drug shortages within its authority such as paying a differential reimbursement for domestically manufactured essential medications;
- Not finalize adoption of the Hospital Outpatient Volume Data on Selected Outpatient Procedures measure and instead work with stakeholders to identify measures that more appropriately evaluates the shift in procedures from inpatient to outpatient setting and related quality of care; and
- Continue to evaluate and revisit the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure and its utility for patients and facilities as part of next year's rulemaking. At a minimum, Premier urges CMS to revise the measure to only require annual reporting.

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I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters, and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. OPPS PAYMENT UPDATE AND IMPACT OF RISING LABOR COSTS

Background and Proposals

CMS bases the annual OPPS payment update off the inpatient hospital market basket, which is an input price index that measures the average percentage change in the price of goods and services hospitals purchase to provide care. As a fixed-weight index, the hospital market basket measures changes in prices over time of the same mix of goods and services purchased during a base period. CMS updates the market basket annually by forecasting costs using available historical data. The proposed market basket update utilizes the IHS Global Inc.'s (IGI's) fourth quarter 2022 forecast, which includes historical data through third quarter of CY 2022. Following past practice, Premier anticipates the final rule will be based on more recent data and include historical data through second quarter of CY 2023.

CMS proposes a 2.8 percent increase in OPPS payments in CY 2024 relative to CY 2023. This proposed update is based on the proposed inpatient hospital market basket update of 3.0 percent less 0.2 percentage points for the productivity adjustment. Since publication of the OPPS proposed rule, CMS has released its Inpatient Prospective Payment System (IPPS) final rule, which finalized a higher hospital market basket update of 3.3 percent and a productivity adjustment of -0.2 percentage points. As a result, Premier anticipates that the final OPPS payment update will be 3.1 percent once the final rule is published in November.

Recommendations

Premier continues to have significant concerns that the hospital payment update does not adequately reflect the rising costs that hospitals have faced over the last few years, especially as it relates to labor costs.

A Premier analysis found that labor costs have increased by more than 15 percent since the start of FY 2020 through the first half of FY 2023 and do not show signs of returning to a lower level. From FY 2021 to FY 2022 alone, labor costs increased by nearly 10 percent. To determine changes in hospital labor costs, Premier analyzed the data within its workforce optimization solutions, one of the nation's largest and most robust sources

for standardized geographically diverse payroll data and benchmarks. The data comes directly from a hospital's general ledger and is collected and validated by health system users daily.

The significant increases in labor expenses over the last couple years are largely driven by two factors:

- ***Increased utilization of contract staff****:* Over the past few years, many hospitals have relied on contract staff – especially contract nurses – to help alleviate workforce shortages. Based on Premier data, the use of contract labor (as a percentage of total staff hours) nearly doubled from the start of 2021 through 2022. With increased demand, we also saw a significant increase in compensation for contract labor. According to Premier data, the average salary for contracted nurses doubled between the start of FY 2020 and the first half of FY 2022, when salaries for contract labor peaked. Premier's data indicates that while salaries for contract nurses has decreased some from this peak in certain geographical areas, salaries remain 72 percent higher as of the first half of FY 2023 as compared to the start of FY 2020. In addition, the use of contract labor extends beyond nursing staff and also includes ancillary healthcare providers such as occupational therapists, pharmacists, respiratory therapists, and more.

While this increase in the use of contracted staff may be temporary, it does suggest a reason why the hospital market basket for FY 2021 and FY 2022 understated hospital increases in costs as CMS does not account for contract labor in the calculation of the market basket.

- ***Growth in employee salaries****:* Premier's data also indicates significant growth in salaries for employed workers over the last couple years; this growth does not show signs of slowing as employers leverage increased salary and benefits as a retention strategy to address workforce shortages. According to Premier data, salaries for employed staff have increased by 13.6 percent overall since the start of FY 2020, with employed nurses seeing a more than 17.5 percent increase in salaries on average overall.

Significant workforce shortages have driven the use of contract labor and overall increased labor costs. Before the pandemic, many clinical staff were in short supply and growing closer to retirement age. According to pre-pandemic research published in 2018, healthcare was projected to be short more than 1 million nurses by 2020 as a result of nurse retirements, an aging U.S. population and a stagnant talent pipeline.[1] Since that time, the pandemic has only exacerbated matters, prompting a significant increase in clinician resignations and retirements; for example, more than 500,0000 nurse retirements were expected in 2022.[2] A recent analysis estimates that by 2025, the United States will fall short of between 200,000 to 450,000 nurses available for direct patient care, equating to a 10 to 20 percent gap. This significant and growing deficit in the workforce supply indicates that it is unlikely these increased labor costs are transitory, but rather a new normal that reflects shifting market dynamics. As talent shortages become more severe, providers are paying more to attract and retain scarce staff, and Premier's analysis indicates it is likely that these wage increases have set a new floor.

Overall, the Premier analysis highlights that labor costs are significantly higher than what CMS has finalized over the last couple years and is currently estimating as part of its market basket update for 2024. The proposed market basket update of 3.0 percent for CY 2024 is based in part on its projection of a 3.9 percent increase in compensation and benefits for 2024.[3] CMS updates labor costs using data from the U.S. Bureau of Labor

[1] Zhang, Ziaoming, et al., "United States Registered Nurse Workforce Report Card and Shortage Forecast: A Revisit,"*Americna Journal of Medical Quality,* 2018, Vol. 33(3) 229–236, https://edsource.org/wp-content/uploads/2019/02/Zhang-Daniel-Pforsich-Lin-2017-United-States-Registered-Nurse-Workforce-Report-Card-and-Shortage-Forecast_-A-Revisit.pdf
[2] American Nurses Association, "Nurses in the Workforce," https://www.nursingworld.org/practice-policy/workforce/
[3] Approximately 67.6 percent of the market basket is related to labor costs, often referred to as the labor-related share. Wages and salaries and fringe benefits for civilian workers in hospitals – which is updated based on the BLS ECI data – account for 53 percent of the market basket. The remaining 14.6 percent of labor costs is accounted for by professional fees, administrative and facilities support, installation, maintenance and repair and all other labor costs.

Statistics' (BLS) Employment Cost Index (ECI). Specifically, CMS uses a four-quarter rolling average of change in compensation and benefits as measured through the ECI survey of hospital workers. As noted above, there is a lag in the data that CMS uses to update the market basket annually, and the proposed update is based on historical data through third quarter of CY 2022. (The 3.3 percent market basket update finalized in the FY 2024 IPPS rule in early August utilized data through second quarter of CY 2023.) This compares to the Premier data that comes directly from hospital payroll in real time.

Another critical difference between Premier's analysis and the ECI data is that the ECI survey of hospital employment costs only includes employed hospital staff, not contracted workers.[4] In the FY 2024 IPPS final rule, CMS acknowledged that the ECI measure only reflects price changes for employed staff but noted that Medicare cost report data shows that contract labor hours account for about 4 percent of total compensation hours in 2021. As a result, the agency continues to believe that ECI data is "accurately reflecting price changed associated with the labor used to provide hospital care."

The market basket, however, is intended to measure the increase in per unit costs for a fixed quantity of inputs. The substitution of contract labor for employed labor does not change the unit of measurement (labor) but does increase the per unit cost of that labor that is not recognized in the market basket. Premier data also indicates that the rise of contract labor has been more pronounced during 2021 and 2022. According to the data, use of contract labor (as a percentage of total staff hours) has nearly doubled since the start of 2021, further highlighting the challenges with using lagging data, such as that acquired from cost reports.

Given the significant delta between the increased cost of labor calculated by Premier versus what CMS is estimating, Premier has significant concerns that CMS' data source for estimating the cost of labor does not capture current market dynamics and woefully underestimates the true cost of healthcare labor across the country. This gross underestimate by CMS will result in a fourth consecutive year where the hospital payment update is not reflective of the actual cost increases hospitals are experiencing. This comes at a time when many providers are struggling to stay afloat after years of COVID-related financial losses, high inflation and increased labor expenditures. ***Premier continues to strongly recommend that CMS adopt new or supplemental data sources, such as Premier data inclusive of contract labor data, to ensure labor costs are adequately reflected in the payment update in the final rule.***

It is imperative that CMS diversify its data sources to ensure a more accurate, blended labor impact rate for 2024 and beyond. For example, Premier encourages CMS to utilize supplemental data sources to evaluate the accuracy of the ECI proxy and to modify methodologies, including adopting new or supplemental data, to calculate the payment update if its analysis determines that the ECI is not adequately capturing labor costs. Premier believes that the current market basket does not account for the higher costs of contract labor which have become more common in hospitals in an era of clinical labor shortages.

III. ENSURING APPROPRIATE PAYMENT FOR AI TECHNOLOGIES

As CMS considers future Medicare payment updates in light of ever-evolving costs and new technologies, ***Premier urges CMS to proactively address how to incorporate incentives and appropriate reimbursement models for AI technology into Medicare payment systems.*** While it has been thoroughly established that AI tools can provide life-saving insights to physicians, optimize workflow and reduce time spent on administrative tasks away from patients, these technologies have a prohibitively high up-front cost and current payment schemes do not adequately capture the value AI provides. ***Premier urges CMS to issue a formal Request for Information to learn from healthcare stakeholders how AI can be used to optimize the***

[4] Per discussions with CMS Office of the Actuaries (OACT)

delivery of healthcare for Medicare beneficiaries and how CMS can properly incentivize the adoption of new AI technology in future rulemaking.

IV. COVERAGE OF OPIOID USE DISORDER TREATMENT SERVICES

Background and Proposals

Section 4124(b) of the Consolidated Appropriations Act of 2023 created a new Medicare benefit category, effective Jan. 1, 2024, for intensive outpatient program (IOP) services. Per statute, IOP services may be furnished by hospital outpatient departments, community mental health centers (CMHCs), Federally-Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs). An IOP is similar to Medicare's existing partial hospitalization program benefit – it is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness and/or substance use disorder. However, IOP services are considered to be less intensive than a partial hospitalization program (PHP). In this rulemaking, CMS proposes to define intensive outpatient services in a manner largely consistent with the definition of PHP services, with two important distinctions: 1) IOP services are not required to be provided in lieu of inpatient hospitalization, as is the case with PHPs; and 2) IOP services are intended for patients who require at least nine hours per week of therapeutic services, compared to 20 hours per week for PHPs.

CMS notes that many opioid treatment programs (OTPs) already provide IOP services, and that IOP services can be effective in promoting greater treatment initiation and engagement, which may improve health outcomes. Thus, CMS proposes to establish payment under Medicare Part B for IOP services furnished by OTPs for the treatment of opioid use disorders (OUDs) beginning in 2024. CMS asserts that IOP services are intended to treat individuals with an acute mental illness and/or substance use disorder, and that IOP services are similar to the specific services enumerated in the existing Medicare benefit category for opioid use disorder treatment. Further, the agency has authority to add other items and services furnished by an OTP for the treatment of OUDs to this benefit category, as appropriate. To be covered, the services would have to: 1) be furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of OUD that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting;2) meet guidelines for reasonableness and necessity; and 3) be pursuant to a physician certification and plan of care.

Recommendations

Premier strongly supports CMS' proposal to leverage the new Medicare IOP benefit to increase access to treatment services for OUDs. Based on prevalence estimates from Premier's PINC AI data, the annual total cost of care for OUD-associated emergency department outpatient visits and inpatient admissions is estimated to be $95.4 billion nationally. The ongoing opioid epidemic continues to overwhelm hospitals with an estimated 66 million emergency department visits and 760,000 inpatient admissions each year. Earlier this year, Premier called on the Substance Abuse and Mental Health Services Administration (SAMHSA) to finalize its regulatory proposals to expand OTP services to include evidence-based care delivery models aligned with public health goals. CMS' proposal represents a meaningful step toward adequately funding critical behavioral health services.

Additionally, to expand access to more intensive PHP services, Premier recommends that CMS leverage its Section 1135 authority to allow for expansion and relocation of off-campus hospital-based PHPs, as the agency has allowed during the COVID-19 public health emergency (PHE). Further, Premier recommends that even after all COVID-19 PHE-era flexibilities end, CMS continue waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 and the provider-based department requirements at 42 CFR §413.65 to allow provider-based PHP programs to establish and operate, as part of the hospital, any location meeting the conditions of participation that continue to apply. Additionally, Premier recommends that CMS continue to allow exempted, provider-based PHPs to relocate part of their exempted provider-based PHP

to a new off-campus location while maintaining the original location. An estimated 20.8 percent of adults in the U.S. with mental illness have experienced unmet need in the past year, and therefore Premier urges CMS to fully leverage its statutory authority to help close this gap in care.

V. UPDATES TO HOSPITAL PRICE TRANSPARENCY REQUIREMENTS

Background and Proposals

In the Hospital Price Transparency final rule published in November 2019, CMS adopted requirements for hospitals to make public their standard charges in two ways: 1) as a comprehensive machine-readable file (MRF); and 2) in a consumer-friendly format. In this proposed rule, CMS proposes to make a number of changes to the hospital price transparency requirements, including requiring hospitals to utilize specific templates and standards in their posted files.

Specifically, CMS proposes to require hospitals to use a "CMS template," which the agency defines as a CSV formal or JSON schema that CMS makes available for purposes of compliance. CMS also proposes to make conforming changes to relevant definitions in its regulations. Further, CMS proposes to require that each hospital comply with the following new requirements:

- Affirming in the MRF information is true, accurate and complete as of the date indicated on the file
- Updating the hospital's website with additional links and access points to the machine-readable file
- Certification by an authorized hospital official as to the accuracy and completeness of data
- Submission of an acknowledgement of receipt of an enforcement warning notice

CMS also seeks comment on additional considerations for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives.

Recommendations

Premier generally supports aligning requirements under a standardized template and format. CMS proposes a number of specific expectations for a standardized reporting format going forward, including encoding, as applicable, all data items in the MRF. Premier does have concerns with CMS' proposal to add a new field, "Consumer-friendly expected allowed amount," which is based on estimates rather than black-and-white contract language. The addition of this field would introduce subjectivity, leaving room for disagreement, and may actually create additional confusion.

Understanding the significant amount of work hours potentially required to update MRFs to account for the proposed changes in reporting requirements, Premier recommends that CMS finalize an implementation timeline that allows hospitals until Jan. 1, 2025 to come into compliance, if these policies are finalized as proposed.

Additionally, CMS notes the agency's interest in hearing from the public on how hospital price transparency requirements can best support and complement the consumer-friendly requirements that are being implemented through other regulatory vehicles, such as the Transparency in Coverage rule. ***Premier strongly urges CMS to work with partner agencies within the Departments of Labor and Treasury to align the various price transparency requirements that impact both provider workflows and information availability for consumers.***

Technological advances and recent federal and state policies have dramatically increased patients' access to information about healthcare costs. Patients may access pricing information directly from hospitals' and health systems' websites, or from state-based or private pricing tool websites, in addition to large, publicly-posted health

plan datasets with negotiated rates and out-of-network allowed amounts. Depending on the source, these estimates will vary widely. Premier and our members are concerned that as each additional healthcare "shopping" option introduced may add to patients' confusion over their out-of-pocket cost obligations – unless requirements are more carefully coordinated. ***Premier recommends that CMS, Labor and Treasury work collaboratively to better align the various current price transparency requirements to minimize confusing or conflicting information for patients.*** The most accurate source of out-of-pocket price information for consumers is their health plan, not their provider. Only the health plan will have the most up-to-date information about a patient's progress towards deductibles, annual out-of-pock maximums and other payment policies.

The first step in alignment is identifying the most appropriate price transparency resource for patients' needs, and then streamlining the constellation of federal and state price transparency policies to meet these needs. ***Ultimately the Advanced Explanation of Benefits (AEOB) will be the source of truth for patients looking for accurate cost liability, and Premier urges the Departments to reconsider whether continuing to require generic lists of charges, negotiated rates and allowable amounts will be at all helpful to consumers who are weighing decisions about their healthcare***.

VI. REQUEST FOR INFORMATION (RFI) ON ESTABLISHING AND MAINTAIN ACCESS TO ESSENTIAL MEDICINES

Background

The proposed rule indicates that over the last few years, shortages for critical medical products have persisted and continued to increase. CMS believes it is necessary to support practices that can curtail pharmaceutical shortages of essential medicines and promote resiliency in order to safeguard and improve the care hospitals are able to provide to beneficiaries.

CMS is seeking comment on separate payment under the IPPS for establishing and maintaining access, including through contractual arrangement, to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. This separate payment would not be budget neutral. An adjustment under the OPPS could be considered for future years. Based on the public comments, CMS would consider adopting a policy that would be effective as soon as cost reporting periods beginning on or after January 1, 2024.

Recommendations

While Premier applauds CMS for thinking creatively about how it can leverage its authority to address drug shortages, Premier has serious concerns that the approach outlined by CMS will actually exacerbate drug shortages, and therefore Premier urges CMS to not move forward with its proposal. As proposed, hospitals would be reimbursed the costs associated with establishing and maintaining a 90-day stockpile of essential medications as defined by the Administration for Strategic Preparedness and Response (ASPR). Premier is concerned that incentivizing individual stockpiling at the hospital level will create 6,000+ disparate stockpiles throughout the country that will all compete with one another for inventory, further creating silos and fragmentation in our nation's emergency preparedness infrastructure. One major lesson learned during the COVID-19 pandemic is the need for cohesive, holistic and national strategies for preparedness, not strategies that create further fragmentation. In addition, if the policy were to go into effect on Jan. 1, 2024, all 6,000+ hospitals in the country could conceivably begin ordering 90-day supplies of the essential medications which would guarantee result in widespread national shortages of these essential medications due to how the policy would skew the supply vs demand curve for these medications.

In addition, the policy as proposed would essentially create winners and losers amongst hospitals and further fragment rural, community, safety net and other smaller hospitals. While the policy covers the costs of maintaining a stockpile, it does not cover the costs associated with acquiring the initial 90-day supply of the medications. Therefore, while larger hospitals and health systems may have the necessary capital to build a stockpile and take advantage of the proposed policy, it is unlikely that smaller hospitals and those struggling financially will have the same opportunity thereby further disadvantaging providers who have the greatest resource limitations during shortages.

Instead, Premier urges CMS to consider alternative non-budget neutral policy solutions to address drug shortages within its authority such as paying a differential reimbursement for domestically manufactured essential medications, similar to CMS' recent policy of paying a differential reimbursement for domestically manufactured NIOSH-approved N95 surgical masks. In the FY 2023 IPPS and CY 2023 OPPS final rules, CMS finalized a policy for differential reimbursement where payments can occur as frequently as biweekly interim lump-sum payments reconciled as part of the cost reports. In order for the domestic NIOSH-approved surgical N95 respirators purchased during a cost reporting period to be reimbursable by Medicare, they must be wholly made in the U.S. based on the Berry Amendment (10 U.S.C. §4862), and the respirator and all of its components must be grown, reprocessed, reused or produced in the U.S. This policy is fully implemented now and several hospitals throughout the country are taking advantage of it to help offset the higher costs associated with purchasing domestic N95 masks versus globally sourced masks. The policy is also supporting domestic manufacturing, supply chain resiliency and preparedness for the next public health crisis.

Given the success of CMS' policy for differential reimbursement associated with N95 masks, Premier urges CMS to repurpose the funds set aside for the stockpiling proposal and leverage them to institute a similar policy for differentially reimbursing domestically manufactured essential medications. A policy of this nature would permit hospitals to support domestic manufacturing and supply chain resiliency while also helping to avert drug shortages by investing in locally made, high-quality products. However, given the differences between drugs and masks, Premier notes that few drugs would qualify as domestically manufactured under the Berry Amendment definition. Therefore, Premier urges CMS to adopt the Buy American Act of 1933 (41 U.S.C. §§8301–8303) definition of domestically manufactured, which requires that at least 60% of the costs of its components must be manufactured in the United States.

Finally, in lieu of utilizing ASPR's list of essential medications, Premier urges CMS to leverage the Food and Drug Administration's (FDA) List of Essential Medicines, Medical Countermeasures, and Critical Inputs that are medically necessary to have available to serve patient needs as required by Executive Order 13944. The FDA's list of essential medications is the most recognized list amongst healthcare providers and therefore should serve as the source of truth for CMS.

VII. HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAMS

Background

The Hospital Outpatient Quality Reporting (OQR) Program is a pay-for-reporting quality program. Hospitals that do not submit specified quality data or fail to meet all program requirements are subject to a 2.0 percentage point reduction in their annual payment update.

Proposals and Recommendations - Measures Proposed for Adoption

CMS proposes to adopt three measures into the OQR Program:

1. Hospital Outpatient Volume Data on Selected Outpatient Procedures (HOPD Procedure Volume) measure.

   CMS is proposing to readopt the Hospital Outpatient Volume Data on Selected Outpatient Procedures (HOPD Procedure Volume) measure into the OQR program, beginning with the 2026 reporting period/2028 payment determination, in recognition of the growing volume of services performed in hospital outpatient departments. The structural measure, which collects surgical procedure volume data on specified categories of procedures, was removed from the OQR program as part of CY 2018 rulemaking because CMS believed there was a lack of evidence to support its link to a facility's overall performance or quality improvement.

   Given the notable shift in procedures from inpatient to outpatient settings, CMS believes tracking outpatient procedural volume will help inform patients about a given facility's experience with outpatient procedures. In its proposal, CMS modifies the original measure to only track data for the top five most frequently performed procedures among hospital outpatient departments in each of the following categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory and Skin. Data on the top five procedures in each category would be submitted through the Hospital Quality Reporting (HQR) system and publicly displayed on Care Compare. CMS would update the top five for each category annually.

   Premier strongly opposes readoption of this measure as the burden associated with reporting the measure outweighs any potential value. Premier disagrees with CMS' assessment that a volume indicator will be valuable to patients, as procedural volume may vary for a variety of reasons that has nothing to do with a facility's experience or quality of care it delivers. For example, some facilities may have a higher proportion of complex patients which requires care to continue being furnished in the inpatient setting. Premier encourages CMS to work with stakeholders to identify measures that would be appropriate and useful in evaluating the shift in procedures from inpatient to outpatient setting and related quality of care.

2. Risk-Standardized Patient-Reported Outcome-Based (PRO) Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO-PM) measure.

   The Risk-Standardized Patient-Reported Outcome-Based (PRO) Performance Measure Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty in the HOPD Setting (THA/TKA PRO–PM) assess patient-perceived pain and function following an elective primary THA/TKA in the outpatient setting using a standardized, validated survey instruments completed within three months pre- and at about one-year post-operatively. CMS adopted a similar measure into the Hospital Inpatient Quality Reporting (IQR) Program evaluating elective THA/TKA furnished in an inpatient setting as part of the FY 2023 rulemaking. Given the volume of THAs and TKAs furnished in the outpatient setting has increased significantly since the procedures were removed from the inpatient-only list in recent years, CMS is proposing to adopt this measure into the OQR program. Under the proposal, there would be two voluntary reporting periods (2025 and 2026) followed by mandatory reporting starting in 2027 for payment determination year 2030.

   Premier generally supports the addition of PRO measures to CMS quality programs related to clinical scenarios for which reliable outcome tools are available for patient completion. However, Premier is concerned about the level of burden associated with data collection for this measure. Hospitals participating in the Comprehensive Care for Joint Replacement (CJR) payment model have had the option of reporting an inpatient version of this measure since the model began in 2016 in exchange for bonus points under the model's quality reporting program. Many model participants have found that the

burden of data collection for this measure outweighed any potential for bonus points for successful measure reporting.

As part of last year's rulemaking cycle, CMS added the inpatient measure to the Hospital IQR Program. As part of that, CMS indicated that it incorporated lessons learned from the CJR model, including requiring fewer variables and setting a lower reporting threshold. ***If CMS wishes to move forward with the measure in the Hospital OQR program, Premier strongly encourages CMS to maintain the measure as voluntary until CMS has sufficient information to similarly evaluate implementation in the IQR Program***.

From a methodological perspective, Premier is also concerned that because the post-operative assessment occurs anywhere from 300 to 425 days following surgery, this may introduce biases from events that happen outside the control of the provider. Premier also encourages CMS to explore data collection through orthopedic practices, rather than assigning the responsibility of data collection to a hospital. Any ongoing follow-up with the patient is likely to occur through the orthopedic practice. As a result, CMS may want to consider adoption of the measure into the Quality Payment Program (QPP) as part of its specialty care-focused Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs).

3. Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) eCQM (Excessive Radiation eCQM).

The Excessive Radiation eCQM provides a standardized method for monitoring the performance of diagnostic computed tomography (CT) scans to discourage unnecessarily high radiation doses while preserving image quality. The measure captures the percentage of eligible CT scans that are out-of-range on either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam. CMS is proposing adoption of the ecQM into the OQR program, beginning with voluntary reporting in 2025 and followed by mandatory reporting beginning with the 2026 reporting period/2028 payment determination. As part of the FY 2024 IPPS rulemaking, CMS finalized adoption of a similar inpatient-specified measure as an option for hospitals to report in meeting their eCQM reporting requirements under the Hospital IQR and Promoting Interoperability programs.

While Premier was supportive of the eCQM as an option that hospitals could select from to meet the Hospital IQR eCQM reporting requirements, we are concerned that CMS is proposing to mandate the eCQM in the OQR program beginning with 2027 reporting period. ***Premier strongly discourages CMS from considering this measure as a mandatory measure at this time.*** While this is an important patient safety measure, hospitals will need to work through several operational challenges to implement this measure. This includes building new templates and implementing modifications to their electronic medical records (EMRs) to operationalize the measure, which takes both time and resources. For example, the data necessary to report this measure is generally not captured in the outpatient department EMR system, but instead would be captured by the imaging software program. Hospitals will need to develop systems to extract this information.

As a result, Premier encourages CMS to maintain the measure as voluntary to allow hospitals time to develop the necessary systems to operationalize the measure and until which time reporting becomes more common. Premier also encourages CMS to explore streamlining and allowing hospitals to report one set of data for both the Hospital IQR and OQR programs, similar to how it approaches reporting for the influenza vaccine measures.

Proposals and Recommendations - Measures Proposed for Refinement

CMS proposes to refine three OQR Measures

1. COVID-19 Vaccination Coverage among Healthcare Personnel (HCP).

   As part of FY 2022 rulemaking, CMS adopted the COVID-19 Vaccination Coverage among HCP measure across multiple quality reporting programs, including the Hospital OQR Program. This process measure requires hospitals to submit on a quarterly basis data on the percentage of HCP who have received a complete vaccination course against COVID-19. The measure is reported via the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). Since adoption of the measure, CDC's guidelines regarding whether an individual is considered up to date on their COVID-19 vaccinations have evolved with the development of booster vaccines. As a result, CMS proposes to modify the measure to match current CDC guidance, beginning with the 2024 reporting period/2026 payment determination for the OQR Program.

   Under this proposal, CMS would modify the measure to replace the term "complete vaccination course" with the term "up to date." Hospitals would be required to refer to the CDC definition of "up to date" as of the first day of the reporting quarter.

   Premier is generally supportive of aligning with the CDC's definition of "up to date," however we are concerned this change will impose significant burden on facilities and that publicly reporting this data may have limited value to the public given the one-year lag in reporting and the end of the COVID-19 PHE.

   In the OPPS proposed rule, CMS notes that it does not believe updating the measure specifications will impose any additional burden on facilities as the modifications do not change the amount of data that hospitals must submit to CMS nor the frequency in which data hospitals must submit data. ***Premier continues to disagree with CMS' assertion that the measure changes will not impose new burden on facilities.*** In response to comments received as part of the FY 2024 IPPS, CMS noted that facilities have been reporting the measures since October 2021 and have had sufficient time "to allocate the necessary resources required to report the measure." Additionally, they note that for purposes of NHSN surveillance, the CDC already began using the same definition of "up to date" reflected in the revised measure specifications with Q3 2023 surveillance period.

   While the changes to measure specifications do not change the frequency nor amount of data that hospitals must submit, the updates to the measure will require facilities to track CDC guidance on a quarterly basis and will also require facilities to change their processes to track whether HCP have received multiple doses. If CDC were to update its guidance and require additional boosters, facilities would then need to validate whether all HCP within the facility met the new requirements. Facilities would also need to revise their exceptions process to ensure it is still consistent with any updated guidelines and that exceptions are still applicable for HCP who may have previously received exceptions.

   Premier also continues to urge CMS to expand the criteria of HCP that are exempted beyond those with contraindications as defined by the CDC. There are numerous reasons beyond health contraindications that HCP may decide whether to be up to date with CDC recommendations. Over the course of the PHE, there have been many changes in COVID-19 vaccine availability and evolving CDC recommendations, contributing to wide variation in rates of vaccination among HCP. Further, rates of vaccination among HCP are largely dependent on factors outside a hospital's control, such as where the facility is located and personal preference of the hospital's staff. Additionally, state, local and even individual health system policies governing COVID-19 vaccinations also vary. Some hospitals are

requiring that all staff receive the vaccine and subsequent boosters, while some hospitals are located in states or localities where political pressure prevents them from setting a mandatory vaccine or booster policy.

With the end of the PHE on May 11, 2023, CMS has rolled back numerous requirements that were in place to tackle the COVID-19 pandemic, including a federal mandate requiring the vaccination of healthcare personnel.[5] In the IPPS final rule, CMS notes that the measure continues to align with its goals to promote wellness and disease prevention and fits with its quality priorities of immunization and public health. Premier is comfortable with continuing reporting on this measure for 2024 as the Administration and the broader healthcare ecosystem continue to assess what COVID-19 looks like moving forward and the need for ongoing vaccinations and boosters. However, Premier encourages CMS to continue to evaluate and revisit the measure requirements and the utility of this measure for patients and facilities as part of next year's rulemaking. ***At a minimum, Premier urges CMS to revise the measure to only require annual reporting, which would align with reporting requirements for the influenza measure.***

2. Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure.

   The Cataracts Visual Function measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the surgery via the administration of pre-operative and post-operative survey instruments. The measure, which was first adopted into the OQR program with the 2014 reporting period/2016 payment determination, is available for voluntary reporting. Currently, facilities can select a survey instrument method of their choice.

   CMS is proposing to modify the measure to standardize the survey instrument that facilities must use to one of three available surveys: the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25), the Visual Functioning Patient Questionnaire (VF-14) and the Visual Functioning Index Patient Questionnaire (VF-8R). CMS believes that standardizing the survey instrument will improve measure reliability and minimize collection and reporting burden.

   Premier does not have concerns with CMS' proposal to modify the measure to require use of a standardized tool. However, Premier strongly urges CMS to maintain the measure as voluntary in the OQR program. Additionally, since patients will likely receive ongoing follow-up care from an ophthalmologist following cataract surgery (and not the hospital outpatient department), Premier encourages CMS to explore whether it would be more appropriate to include this measure in the QPP, especially as CMS continues to develop specialty-focused MVPs.

3. Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure

   The Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (Colonoscopy Follow-Up Interval) measure assesses the percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. In May 2021, the United States Preventive Services Task Force (USPSTF) issued revised guidance recommending that adults who do not have signs or symptoms of colorectal cancer and who are at average risk begin screening at age 45 instead of the previous recommendation of age 50.

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[5] https://public-inspection.federalregister.gov/2023-11449.pdf

As a result, CMS is proposing to modify the denominator for the Colonoscopy Follow-up Interval measure to align with the updated USPSTF guidance. Under the proposed change, the measure would include all patients aged 45 to 75 years.

Premier is generally supportive of CMS' proposal to align the measure specifications with the updated USPSTF guidance. The revised denominator will increase the patient population that is eligible for the measure. Premier urges CMS to maintain the current sample size for the measure to prevent increased reporting burden to facilities from chart abstraction.

Proposals and Recommendations - Measures Proposed for Removal

CMS proposes to remove one OQR measure:

1. Left Without Being Seen (LWBS) measure.

   The Left Without Being Seen (LWBS) measure is a process measure that assesses the percent of patients who leave the emergency department (ED) without being evaluated by a physician, advanced practice nurse or physician assistant. The measure, which was originally adopted as an indicator of ED overcrowding, had its consensus-based entity (CBE) endorsement removed in 2012.

   CMS proposes to remove the measure from the OQR program, beginning with the 2024 reporting period/2026 payment determination under its Removal Factor 2 – performance or improvement on the measure does not result in better patient outcomes. CMS notes that it does not believe there is evidence to indicate that the measure promotes quality of care and improved patient outcomes and that the measure does not provide actionable data that will help hospitals understand opportunities for quality improvement. Finally, CMS notes that there are other measures in the program, such as the Median Time for Discharged ED Patients measure, which provide more granular data on length of time in the ED and are more meaningful for improvement efforts.

   Premier agrees with CMS' assertion that there are more meaningful measures in the OQR program that assists hospitals in identifying opportunities for quality improvement and supports CMS' proposal to remove this measure.

VIII. CONCLUSION

In closing, Premier appreciates the opportunity to submit comments on the CY 2024 OPPS proposed rule. If you have any questions regarding our comments or need more information, please contact Mason Ingram, Director of Payer Policy, at mason_ingram@premierinc.com.

Sincerely,

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