PREMIER TRANSFORMING HEALTHCARE TOGETHER®

September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
Submitted electronically to: http://www.regulations.gov

**Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (CMS–1772–P)**

Dear Administrator Brooks-LaSure:

On behalf of the Premier healthcare alliance serving approximately 4,400 hospitals and health systems and approximately 250,000 Continuum of Care and other providers, we appreciate the opportunity to submit comments on the calendar year (CY) 2023 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.

As discussed in greater detail below, Premier:

- Supports CMS taking swift action to reverse the harmful 340B cuts across all affected payment years. We strongly urge CMS to utilize notice-and-comment rulemaking to implement any remedies to the 2018-2022 payment cuts and lay out principles for CMS to consider, including reversing 340B cuts through a lump sum payment and holding all hospitals harmless from any payment clawbacks.
- Supports CMS' proposal to adopt a payment adjustment to inpatient and outpatient Medicare payments for domestically-produced N95s. We continue to urge CMS to expand this adjustment to other critical medical supplies and pharmaceuticals. CMS should also work with Congress to revise statute to allow for this policy to be implemented in a non-budget neutral manner under the OPPS.
- Continues to have significant concerns that the proposed hospital payment update is insufficient and does not adequately account for rising labor costs. We recommend that CMS reevaluate the data sources it uses to calculate labor costs and consider adopting new or supplemental data sources that more accurately reflect the cost of labor, such as more real time data from the hospital community.

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- Supports CMS' proposal to exempt rural sole community hospitals (SCHs) from its site-neutral clinic visit policy and urges CMS to extend the policy to other rural hospitals. We also continue to recommend that CMS discontinue its site-neutral policy for all hospitals.
- Supports CMS' ongoing health equity priorities and the principles it lays out for measuring disparities in quality. We provide additional feedback on the standardization and collection of social determinants of health (SDOH) data.
- Applauds CMS' proposal to permanently designate certain remote mental health services as covered and paid for under the OPPS.
- Urges CMS to not proceed with the JZ modifier as part of its proposal to determine the refund amount for single use vial drugs. We instead encourage CMS to determine appropriate incentives to encourage appropriate physician documentation with the existing JW modifier.
- Provides additional feedback on the design of the new Rural Emergency Hospital (REH) provider designation, including payment policies, quality measurement, and enrollment process.

## 340B DRUG DISCOUNT PROGRAM

Congress created the 340B Drug Pricing Program in 1992 to allow certain safety net hospitals and other healthcare entities (known as covered entities) to purchase outpatient drugs at a discount from drug manufacturers "to stretch scarce Federal resources" and to expand healthcare services to vulnerable populations. For nearly three decades, the 340B program has been critical in helping covered entities expand access to lifesaving prescription drugs and comprehensive healthcare services to low-income, underinsured and uninsured individuals in communities across the country.

The savings produced by the 340B program have become essential to covered entities in meeting 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 covered entities (e.g., those with a Medicare disproportionate share percentage of more than 11.75 percent) and other settings, enabling them 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.

In the 2018 OPPS rule, CMS adopted a policy to pay hospitals for 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. Consistent with statutory requirements, CMS applied a budget neutrality adjustment to all hospitals through an increase in the OPPS conversion factor which had the effect of increasing payments for all OPPS services paid through Ambulatory Payment Classifications (which excludes separately payable drugs).

This policy has been subject to ongoing litigation. Most recently, the Supreme Court ruled that the Secretary cannot vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs and remanded the case back to lower courts to effectuate a remedy.

Given the timing of the Supreme Court rule, CMS notes that it did not have time to modify its payment policy to reflect the ruling and therefore formally proposes to continue paying for drugs and biologicals acquired under the 340B program at ASP-22.5 percent. However, CMS fully anticipates adopting ASP+6

percent in the final rule for 2023. Additionally, CMS seeks input on the best way to craft potential remedies to address payments in 2018-2022.

**We applaud CMS for committing to reversing these harmful cuts.** As we have noted previously, paying for drugs and biologicals acquired under the 340B program at ASP-22.5 percent threatens access to care for the patients who benefit from the much-needed 340B program. Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals in their efforts to build healthy communities. Continuing the policy will harm vulnerable patients by cutting 340B drug savings that hospitals use to provide needed support for outpatient services in underserved areas.

The Biden Administration has made equity – including health equity – a centerpiece of its policies. The 340B program is a critical resource for safety net hospitals in providing care to the uninsured and low-income patients and should play a key role in the Administration's health equity agenda. 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, including but not limited to:

- Providing financial assistance to patients unable to afford their prescriptions;
- Providing clinical pharmacy services, such as disease management programs or medication therapy management;
- Funding other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- Establishing additional outpatient clinics to improve access;
- Creating new community outreach programs;
- Offering free vaccinations for vulnerable populations; and
- Funding community benefit programs to address social determinants of health, such as food and housing insecurity

Reversing the 340B payment cuts will require CMS to address the issue both retrospectively for payment years 2018-2022, as well as prospectively beginning in 2023.

***Retrospective Remedy for 2018-2022.*** While the Supreme Court case only applied to 2018 and 2019 payments, CMS has indicated that it plans to craft a remedy to reverse its policy retroactively for all effected payment years (2018-2022). **We support CMS taking swift action to reverse the harmful 340B cuts across all affected payment years (2018-2022). However, we strongly urge CMS to utilize notice-and-comment rulemaking if it chooses to implement a remedy on its own, absent a court ruling.** This will ensure that whatever remedy CMS adopts is done in a transparent manner that will allow for stakeholder input. While providing appropriate notice and comment may delay the implementation of a remedy by a few months, we believe it is critical to help to mitigate the likelihood of further litigation which would potentially delay a remedy by several additional years. Proper notice and comment would allow hospitals and CMS to move forward with this policy without the potential of having to reverse these remedies and payments in the future.

Furthermore, and most importantly, **we believe proper notice and comment is necessary to help flesh out ambiguity that exists in statutory language regarding whether retrospective remedies pursuant to a Supreme Court case are required to be implemented in a budget neutral manner**. It is imperative for CMS to clearly articulate their legal authority and rationale for potential remedies prior to finalizing.

In crafting its remedy, we urge CMS to consider the following guiding principles:

- **Remedy should be provided as a lump sum payment to hospitals.** CMS should provide 340B eligible hospitals with a lump sum payment equal to the difference in payment that these hospitals would have received if CMS had paid ASP+6 percent in 2018-2022. Since patient volume and types of services and drugs furnished by a hospital will vary over time, any attempt to fix these payments through a prospective claims adjustment will not accurately calculate the amounts that hospitals would have otherwise received if they had been paid at ASP+6 percent originally. As part of this, CMS should ensure all hospitals that received 340B payments between 2018-2022 are made whole, including hospitals that may have only received 340B payments for some of the years or that are no longer 340B eligible. Providing hospitals with a lump sum payment will ensure that 340B eligible hospitals are made whole expeditiously.
- **Hospitals should be held harmless in the development of a remedy.** In the development of a remedy, all hospitals, regardless of 340B status, should be held harmless and not punished for abiding by the rules put forth by CMS between 2018-2022. Specifically, no dollars should be clawed back from hospitals in the development of a remedy.
- **Pursue a remedy that minimizes burden on providers.** In 2020, CMS conducted a 340B hospital survey of drug acquisition costs. Hospitals were given two options for responding: (1) providing a detailed response of acquisition costs for each drug or biological or (2) providing a quick response where the hospital indicated that it preferred that CMS utilize the 340B ceiling price obtained from the Health Resources and Services Administration. Given the burden associated with the detailed survey, few hospitals (7 percent of respondents) chose to report detailed acquisition costs. Given the ongoing challenges that hospitals face due to staffing, we caution CMS from pursuing yet another survey of acquisition costs. To collect this information at the level of detail required to accurately calculate acquisition costs per the Supreme Court ruling would place significant burden on the hospital community. As we discuss in greater detail below, hospitals continue to face ongoing workforce challenges and rising costs due to inflation and labor. Any remedy that CMS pursues must take into account these ongoing challenges and look to minimize burden on 340B hospitals, allowing these hospitals to focus their time and resources on delivering care to our nation's most vulnerable patients.

***Prospective Adjustment for 2023 and Beyond.*** In the proposed rule, CMS indicates that to maintain budget neutrality under its anticipated final policy of resuming ASP+6 percent, it will need to apply a budget neutrality adjustment of approximately -4.04 percent to all OPPS payments to offset the additional $1.96 billion in OPPS drug payments. CMS based this estimate on the separately paid line items in the 2021 claims with the "JG" modifier, which indicates when a 340B reduction was applied.

CMS adopted a +3.19 precent budget neutrality to all OPPS payments when initially adopting its 340B policy in 2018. By finalizing a -4.04 percent budget neutrality adjustment, the reduction in OPPS payments will exceed the initial increase in payments—resulting in a permanent decrease in OPPS payments.

CMS' budget neutrality adjustment of -4.04 percent would be appropriate had CMS updated the +3.19 percent adjustment in prior years for claims with the "JG" modifier. However, CMS has not changed or updated this budget neutrality adjustment despite public comments asking CMS to do so.[1] As the adjustment of -4.04 percent is now higher than the original +3.19 percent initially applied in 2018 according to CMS' estimates, it is clear that past year payments were too low as a result of CMS' not updating the budget neutrality adjustment for its 340B drug policy based on updated utilization.

[1] 85 FR 86054 and 86 FR 63648

Below Premier suggests an option for rectifying prior year underpayments as a result of not updating the budget neutrality adjustment for the 340B policy. More immediately, CMS should not compound the problem with a permanent reduction in OPPS payments. This permanent reduction in OPPS payments will be the difference between CMS' original 3.19 percent increase for budget neutrality and its proposed 4.05 percent reduction (-0.86 percentage points), a reduction of $410 million for 2023 based on CMS' data in the proposed rule compounding annually into the future.

CMS' failure to update the adjustment for its 340B policy is inconsistent with its practice for other policies like pass-through payment and outliers. For these policy adjustments, CMS removes the prior year budget neutrality adjustment before applying the payment year budget neutrality adjustment based on updated data.[2] CMS did not do this for the 340B budget neutrality adjustment. It applied a single +3.19 percent budget neutrality adjustment in 2018 despite having updated information on precise application of the adjustment beginning for payment years with 2020 using the "JG" modifier.

CMS cannot now rectify that inconsistency by removing 4.04 percent from the rates for the 340B policy as that would result in a permanent reduction in payment OPPS payments. **Premier strongly urges CMS to only apply a -3.19 percent adjustment for budget neutrality for reversal of its 340B policy in 2023.**

**We also ask CMS to consider an additional one-time increase in 2023 OPPS rates to compensate hospitals for past OPPS underpayments much as CMS did when reversing a budget neutrality adjustment of -0.2 percent for application of the 2-midnight rule under the inpatient prospective payment system (IPPS).[3]** In the FY 2017 IPPS, CMS increased IPPS rates by +0.6 percent - +0.2 percent for each of the three years the budget neutrality adjustment was in place and a permanent adjustment +0.2 percent to IPPS rates. If CMS did an analogous adjustment, it would apply an increase to OPPS rates for 2023 for the percentage underpayment that applied to OPPS payments for 2020-2022. The one-time adjustment would then be removed from OPPS rates for 2024 once hospitals are fully compensated for past year underpayments.

## PAYMENT ADJUSTMENT FOR DOMESTICALLY MANUFACTURED N95S

As part of the FY 2023 inpatient prospective payment system (IPPS) proposed rule, CMS had sought comment on a potential IPPS and OPPS payment adjustment for National Institute for Occupational Safety and Health (NIOSH)-approved N95 masks that are wholly domestically produced. This comes as CMS acknowledges the impact of overseas production shutdowns, export restrictions, and shipping delays during the pandemic on the availability of raw materials and components that are critical to public health supplies, such as personal protective equipment (PPE). In particular, CMS highlights the availability of surgical N95 respirators as being a critical type of PPE to protect healthcare workers and patients from future respiratory pandemics.

CMS further builds on this policy in the OPPS rule by proposing to adopt a payment adjustment under the OPPS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023.

From the beginning of the COVID-19 pandemic, Premier has been at the forefront of response efforts working around the clock to ensure hospitals, health systems and Continuum of Care providers across

[2] Medicare CY 2023 Outpatient Prospective Payment System (OPPS) Proposed Rule Claims Accounting, 2023-nprm-opps-claims-accounting.pdf (cms.gov), page 24
[3] 81 FR 57059

the country have access to the necessary PPE, medical supplies and pharmaceuticals to treat COVID-19 patients. This includes but is not limited to:

- Acquiring a minority stake in and making purchasing commitments to Prestige Ameritech, the nation's largest domestic producer of face masks located in Texas, to produce 8 million N95s and more than 45 million other PPE products annually.
- Collaborating with Honeywell to support the expansion of the U.S. production of nitrile exam gloves in Honeywell's Fort Worth, TX-based facility. Starting in Q3 of 2022, the collaboration will produce at least 750 million U.S.-made exam gloves in the first year alone.
- Creating a joint venture partnership with DeRoyal Industries Inc. that is expected to produce more than 40 million domestically manufactured gowns annually in Knoxville, TN. The gowns are now coming off the line and deliveries have begun.
- Acquiring a minority stake and committing to product purchasing in Exela Pharma Sciences to secure vital supply of 19 pharmaceutical products, including several generic injectables that frequently appear on the FDA's drug shortage list. Exela manufactures in Lenoir, NC.
- Using our global sourcing arm, S2S Global, to identify new sourcing of manufacturing capacity, ultimately contracting with seven different PPE factories across the globe to secure 36 million masks and respirators and 16 million gowns.
- Arranging cargo carriers and major airlines to expedite transportation of products so they could be onshore in hours, rather than months.
- Coordinating and allocating 2 million donated masks.
- Adding 40+ new manufacturers of COVID-19 related supplies, including new domestic entrants of N95 masks, to our national contracts using an expedited review process to rapidly increase options.
- Working with non-traditional and adjacent industries such as distilleries, textile manufacturers, and automobile manufacturers to fill supply gaps for essentials such as hand sanitizer, face shields, isolation gowns and surgical caps.
- Creating an online exchange for health systems, Resilinc, to trade PPE supplies among one another dynamically moving specific supplies to the neediest hot spots.
- Leveraging our existing drug shortage program, ProvideGx, to secure additional safety stock and dedicated supplies, thereby avoiding shortages for many critical products.

As part of these efforts, we have spent time reflecting on the experience of the healthcare industry during the COVID-19 response efforts. We agree with CMS' assessment that reliance on overseas manufacturing, along with export bans and manufacturing shutdowns globally were a contributing factor to the shortages our nation witnessed in critical medical supplies, such as N95 masks. The cost of acquiring domestically produced products is a challenge for hospitals and healthcare providers as domestically-sourced PPE in general is 20-30 percent more expensive than globally-sourced PPE.

**We strongly support CMS' proposal to adopt a payment adjustment to inpatient and outpatient Medicare payments for domestically produced N95s.** We continue to urge CMS expand this adjustment to include other critical medical supplies and pharmaceuticals. Below we provide additional feedback on this proposed policy.

**Definition of Domestic NIOSH-approved Surgical N95 Respirators**

CMS proposes to define "domestic NIOSH-approved surgical N95 respirators" as those where the respirator and all of its components are grown, reprocessed, reused or produced in the United States, which is based on the definition used for Department of Defense (DoD) contracting. Under this proposal, hospitals could rely on a written certification from the manufacturer or group purchasing organization (GPO) stating that the N95 respirator meets this definition.

**Premier supports CMS definition of domestically produced N95s and appreciates CMS recognizing the role that GPOs can play in validating product sourcing**. We appreciate CMS' efforts to align its definition of domestically manufactured with the DoD's definition, which is a familiar standard for the manufacturing industry. Leveraging the DoD definition is also essential to incentivize the domestic manufacturing of raw materials and other componentry for N95 masks. Furthermore, Premier's comprehensive supply chain data shows that there are sufficient domestic suppliers of N95 masks that meet the DoD definition and therefore the policy could be sustained.

**Payment Adjustment**

CMS proposes to base the payment adjustment on the Medicare share of the estimated difference in reasonable costs of a hospital to purchase domestically produced N95s compared to non-domestic N95s. These payments would be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. CMS plans to use existing cost report data, as well as a new N95 supplemental cost reporting form, where hospitals would report the total number of domestic and non-domestic N95s purchased by the hospital, including associated costs.

As we noted in our response to the IPPS comment solicitation, we continue to urge CMS to adopt a payment adjustment methodology that is least burdensome to the hospital community, including limiting frequency of reporting and seeking to utilize existing reporting processes. **We applaud CMS for utilizing the existing cost report process and available data, while minimizing new reporting to the extent possible.** We also continue to encourage CMS to work with the hospital and supply chain communities to automate reporting in the future. For example, to help alleviate provider burden, it is possible to build infrastructure that would allow purchases made from a GPO contract to be reported directly to CMS on behalf of providers.

**Budget Neutrality**

Under the exceptions and adjustments authority under IPPS, CMS can adjust payment without applying a budget neutrality adjustment. However, under the OPPS, CMS is statutorily required to apply the adjustment in a budget neutral manner. In the OPPS rule, CMS walks through its estimate of the budget neutrality adjustment it would apply to offset increased OPPS payments for domestically-produced N95s.

**We encourage CMS to work with Congress to revise statute to allow CMS to apply this policy in a non-budget neutral manner under the OPPS or find another authority for subsidizing hospitals for the purchase of domestic N95 masks that does not require a budget neutrality adjustment**. Applying a budget neutrality adjustment significantly reduces the effectiveness of this policy, especially as more hospitals acquire domestically-produced products. Such an adjustment would be counterproductive and would essentially remove the incentive that is being provided with the additional payment through a payment reduction elsewhere. Additionally, applying a budget neutral adjustment could have a detrimental effect on safety net or smaller hospitals, which may be less able to absorb the higher costs of acquiring domestically-produced medical supplies. Finally, applying a budget neutral adjustment would truncate the ability of the policy to be expanded to additional domestically-produced critical medical supplies and drugs, further disincentivizing domestic manufacturing and supply chain resilience.

**Leveraging Medicare Advantage (MA) to Strengthen the Domestic Supply Chain**

Nearly 18 million MA enrollees have access to an over-the-counter (OTC) benefit through their health plan. Typically, MA plans create a formulary or catalog of approved OTC products, which are available for enrollees to purchase using an allocated allowance. Many MA plans have elected to allow enrollees to

use their OTC benefits to purchase COVID-19 preparedness supplies, including at-home testing products and PPE, such as N95 masks. As noted above, Premier agrees that reliance on overseas manufacturing for medical supplies contributes to shortages, and we support CMS' efforts to stabilize the national supply chain by incentivizing the domestic production of PPE. **To advance this priority, CMS should require all MA plan sponsors participating in the MA Value-Based Insurance Design (VBID) model to cover domestically-manufactured N95 masks in any supplemental OTC benefits that the plan intends to offer.** Additionally, Premier urges CMS to reflect in the 2024 MA bid instructions that plans are strongly encouraged to cover domestically-manufactured N95 masks in any supplemental OTC benefit offerings.

**Future Policy**

CMS notes that it may revisit its proposed policy as it gains more experience with the adjustment, including expanding the policy to include other protective supplies, such as gowns and gloves. **We continue to urge CMS to expand this adjustment to other critical medical supplies and pharmaceuticals.** To help prioritize the products that should be added in the future, Premier encourages CMS to establish a Public-Private Advisory Council that includes representatives from the private sector such as manufacturers, GPOs, distributors, physicians, pharmacists, nurses, laboratorians, non-acute providers, patients, professional associations and others, as well as representatives from the public sector such as federal agencies (HHS, FEMA, ASPR, CDC, CMS, FDA, SAMHSA, the Veterans Health Administration, Indian Health Services, etc.), prisons, first responders, state and local representatives, and others. The advisory council will be critical to ensuring CMS is soliciting feedback from a broad range of entities to augment its policy through a data-driven approach that remains unbiased and supplier agnostic, supports a collaborative decision-making process and identifies innovative approaches.

In addition to creating incentives for healthcare providers to purchase domestically manufactured critical supplies, **we continue to urge the Administration and Congress to establish incentives for manufacturers to ensure that domestically manufactured, critical medical products are priced competitive with globally sourced products.** To that end, Premier is urging Congress to pass tax incentives to support domestically manufactured critical medical products and drugs, as well as the raw materials and other components for these products.

## PAYMENT UPDATE

CMS proposes a 2.7 percent increase in OPPS payments in CY 2023 relative to CY 2022. This proposed update is based on the proposed inpatient hospital market basket update of 3.1 percent less 0.4 percentage points for the productivity adjustment. Since publication of the OPPS proposed rule, CMS has released its IPPS final rule, which finalized a higher hospital market basket update of 4.1 percent and a lower productivity adjustment of -0.3 percent. As a result, we anticipate that the final OPPS payment update will be 3.8 percent (4.1 percent less 0.3 percent).

Even with the higher market basket update finalized in the IPPS final rule, **Premier continues to have significant concerns that the hospital payment updates do not reflect the rising cost of labor that hospitals continue to face.**

The hospital market basket is an input price index that measures the average percentage change in the price of goods and services hospitals purchase to provide inpatient 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. As a result, any changes in the mix of goods and services are not measured annually. CMS rebases the hospital market basket every four years. The current market

basket, which was rebased for FY 2022, reflects hospital costs from Medicare cost reports that began on or after October 1, 2017 and before October 1, 2018. CMS updates the market basket annually by forecasting costs using available historical data. The market basket update finalized in the IPPS rule reflects include historical data through second quarter of CY 2022.

A recent PINC AI™ analysis found that labor costs have increased by more than 16 percent since the start of FY 2021 and do not show signs of returning to a lower level. Labor costs have increased by more than 10 percent in FY 2022 alone. To determine changes in hospital labor costs, PINC AI™ 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 – all collected and validated by health system users daily. The data come directly from a hospital's general ledger.

Our analysis found that increased labor costs are significantly higher than what is reflected in the market basket update for 2023. Based on the latest data[4], CMS is currently estimating a 3.7 percent increase in compensation and benefits for FY2023. Labor costs for hospital workers make up approximately 53 percent of the 2018-based IPPS market basket.[5] CMS updates labor costs using data from the U.S. Bureau of Labor 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. This compares to the Premier data that comes directly from hospital payroll.

One critical difference between Premier's analysis and the ECI data is that the ECI survey of hospital employment costs only include employed hospital workers, not contracted ones.[6] Driving the growth in labor expenses has been an increased reliance on contract staff, especially contract nurses, who are integral members of the clinical team. 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 and the forecast for FY 2023 understates hospital increases in costs. Additionally, clinician resignations and retirements have increased significantly during the pandemic. A recent analysis finds that by 2025 it is expected that the United States may have a gap of between 200,000 to 450,000 nurses available for direct patient care, equating to a 10 to 20 percent gap. These factors have increased the use of contract labor and travel nurses, which have become a new reality in healthcare as well as increased competition for clinical staff that has driven up wages.

In the 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 3 percent of total compensation hours in 2020. As a result, the agency continues to believe that ECI data is "an appropriate measure to use in the IPPS market basket." However, the market basket 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. PINC AI™ 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.

We are concerned the data that CMS uses to predict real inflation and cost of labor does not reflect reality and will result in a third consecutive year where the payment update is not reflective of the actual cost

[4] Office of the Actuary Market Basket Tables, Listserv delivery on September 2, 2022
[5] Wages and salaries and fringe benefits for civilian workers in hospitals account for 53 percent of the market basket. The remaining 14.6 percent of labor costs are accounted for by professional fees, administrative and facilities support, installation, maintenance and repair and all other labor costs.
[6] Per discussions with CMS Office of the Actuaries (OACT)

increases hospitals are experiencing now and into the future. This comes at a time when many acute care providers are struggling to stay afloat after years of COVID-related financial losses. At the same time, patient acuity and length of stay have increased when compared to earlier in the pandemic. Additionally, ongoing delays in non-emergent procedures and increased costs for supplies, medicine, testing and protective equipment has placed additional strain on hospital finances.

Finally, we do not believe these increased labor costs are transitory. Long 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.[7] Since that time, the pandemic has only exacerbated matters, with more than 500,0000 nurse retirements expected in 2022.[8] As talent shortages become more severe, providers are paying more to attract and retain scarce staff. These wage increases cannot be taken back and have set a new floor. However, the BLS' ECI does not appear to accurately reflect the increased labor costs resulting from these projected ongoing shortages.

**We recommend that CMS OACT reevaluate the data sources that it uses for calculating labor costs and consider adopting new or supplemental data sources in future rulemaking that more accurately reflect the cost of labor, such as more real time data from the hospital community.**

As noted above, the issue of an update being too low will be further compounded by CMS' budget neutrality adjustment for reversal of its 340B policy that Premier recommends be -3.19 percent instead of -4.04 percent that CMS proposes with consideration of a further adjustment for prior year underpayments. One additional adjustment that CMS must make to mitigate the impact of a lower update also relates to its 340B policy. Under current policy, separately payable drugs acquired through the 340B program are paid on pass-through payment at ASP+6 percent instead of ASP-22.5 percent. As a result of CMS' reversal of the 340B policy, all separately payable drugs will be paid at ASP+6 percent including those acquired under the 340B program without the need for pass-through payments. Pass-through payments will decline as they will no longer be needed to pay drugs acquired under the 340B program at ASP+6 percent in place of ASP-22.5 percent.

On page 44528 of the proposed rule, CMS says the difference between pass-through payments is 1.24 percent in 2022 and 0.9 percent in 2023 or a net adjustment of +0.34 percentage point to the update for budget neutrality. However, on page 44661 of the proposed rule, CMS says after taking into account the 340B policy that will be adopted in the final rule, pass-through payments will be nearly $593 million lower or 0.21 percent of OPPS payments. As pass-through payments will be 0.21 percent of OPPS payment, the net adjustment for pass-through will be the difference between 1.24 percent in 2022 and 0.21 percent in the final rule. The net adjustment should now increase to +1.03 percentage points. This larger budget neutrality adjustment for pass-through payments will also serve to mitigate a payment update that is otherwise too low. **Premier requests that CMS apply a net +1.03 percentage point adjustment for pass-through payments in the 2023 final rule.**

[7] 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
[8] American Nurses Association, "Nurses in the Workforce," https://www.nursingworld.org/practice-policy/workforce/

## SITE NEUTRAL CLINIC VISIT

Since 2019, CMS has paid a physician fee schedule (PFS) equivalent rate for clinic visits (HCPCS code G0463) provided in an off-campus provider-based department (PBD). The PFS equivalent rate was implemented over a two-year transition period at 70 percent of the full OPPS rate in 2019 and 40 percent of the full OPPS rate in 2020. CMS has previously sought comment on whether it should exempt rural or safety net providers from this policy, but ultimately felt that the two-year phase in of the policy helped mitigate financial concerns for these types of hospitals.

CMS is now proposing to exempt rural sole community hospitals (SCHs) from this policy and seeks comment on whether it should extend this policy to other rural hospitals. **We support CMS' proposal to exempt rural SCHs from the site-neutral clinic visit policy and urge CMS to extend the policy to other rural hospitals.** As CMS notes in the rule, many rural providers are often the only source of care in their communities, meaning beneficiaries and providers are not choosing between a higher or lower cost setting. Exempting these providers from the site neutral policy will help to maintain access to care in these rural communities.

Additionally, **Premier continues to recommend that CMS discontinue its site-neutral clinic visit policy**. As we have noted previously, the 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.

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 alternative payment models (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.

## CHANGES TO THE MEDICARE INPATIENT ONLY (IPO) LIST AND ASC COVERED PROCEDURES LIST (ASC CPL)

The Medicare inpatient-only (IPO) list includes procedures that are only paid under the IPPS, and thus are not paid by Medicare in other settings. Each year, CMS reviews the list against established criteria 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. The ASC payment is generally a percentage of the OPPS payment rate unless the service is "office-based." Payment for office-based services is capped based on the PFS non-facility payment.

In this year's rule, CMS proposes to remove 10 codes from the IPO list. CMS also proposes to permanently designate six CPT/HCPCS codes as office-based for beginning in 2023. These procedures

are performed more than 50 percent of the time in physicians' offices and CMS believes are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Codes on this list include 0101T, 0446T, 15275, 21198, 31574, and 40830. Additionally, CMS proposes to add one procedure to the ASC CPL (CPT code 38531).

There are many factors for physicians to consider in determining which patients are appropriate for the outpatient setting. CMS has not defined clinical criteria in the past, citing the need to preserve the role of the clinician in determining care. However, when CMS determines that a procedure can be safely performed in alternative settings, hospitals need defined criteria to ensure that they 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.**

As CMS continues to remove procedures from the IPO list and add procedures to the ASC CPL, as this rule proposes, we 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 CMS Innovation Center models before expanding nationally. APMs 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.

Finally, **we continue to urge CMS to proactively monitor changes in site-of-service to determine whether it needs to modify APMs,** such as Innovation Center models and the Medicare Shared Savings Program (MSSP). As was seen with the removal of total knee arthroplasty (TKA) from the IPO list, changes in site-of-service can have significant effects on whether participants can continue to succeed in models. 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 led CMS to modify the CJR model to better account for shifts in site-of-care, including expanding the definition of a CJR episode to include TKA and total hip arthroplasty (THA) when performed in the outpatient setting and introducing a new risk adjustment methodology to account for differences in patient case mix across settings.

To ensure participants' continued success in APMs, **Premier strongly recommends that CMS take proactive steps to mitigate the impact of site-of-service changes on benchmarks and target prices used in Innovation Center models and 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 changes in case and cost mix need to be recognized in the inpatient target prices and benchmarks set under these models and MSSP. CMS has historically been hesitant to change the composition of target prices or benchmarks due to fee-for-service (FFS) changes on the basis that risk should not be removed from models due to external changes. However, 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

[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)

policy changes. Providers participating in Innovation Center models and MSSP have made significant investments to lower cost while improving quality of care. As CMS makes changes to its fee-for-service (FFS), it must ensure its reforms do not hinder the movement to value. Instead, CMS should focus its policies on rewarding those who have adopted value-based care models.

## 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.

As part of CY 2020 OPPS rule, CMS finalized a policy to exempt procedures from certain medical review for compliance with two-midnight rule for the two years following removal from the IPO list. During this exemption 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. Along with its decision to eliminate the IPO list as part of the CY 2021 OPPS rulemaking, CMS finalized a policy to exempt procedures from site-of-service medical review until which time they were more commonly performed in an outpatient setting. In last year's rulemaking, CMS halted the elimination of the IPO List and reinstated its original policy for exempting procedures for two years following removal from the IPO List.

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. As noted above, clinical decision support can 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 beyond the two-year exemption.**

At a minimum, we recommend that CMS establish a list of procedures that would be exempt from two-midnight review permanently. 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 more than a set number of days or if a procedure is performed inpatient 70 percent of the time based on recent data, deference would always be provided to the physician.

## REMOTE DIRECT SUPERVISION OF CARDIAC AND PULMONARY REHABILITATION SERVICES.

Under the COVID-19 PHE, CMS has allowed for direct supervision of cardiac, intensive cardiac and pulmonary rehabilitation services furnished in the hospital to be met through a virtual presence. This policy will end with the conclusion of the PHE. Under this policy, a supervising professional can meet the direct supervision requirements by being immediately available through a virtual presence using real-time audio/video technology. CMS seeks input on whether it should extend this policy through the end of CY 2023, consistent with how the policy is currently applied under the PFS.

**Premier urges CMS to permanently adopt a policy to allow practitioners to meet direct supervision requirements through a virtual presence.** Allowing for direct supervision to be met through a virtual presence has been a critical flexibility during the PHE that has helped ensure continued access to care for the Medicare population. Coming out of the PHE, our nation's healthcare system continues to face workforce challenges, with many health systems facing significant labor shortages. Allowing for direct supervision to be met through a virtual presence would help improve the efficiency of care delivery and utilize available workforce to the fullest extent.

## HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM MEASURE CHANGES

**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536)**

CMS proposes to modify the reporting requirements for the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) (NQF #1536) measure from mandatory to voluntary beginning with the CY 2025 reporting period / CY 2027 payment determination. The measure is voluntary for the CY 2023 and 2024 reporting periods. Stakeholders have raised several concerns with the burden associated with this measure, which requires collection of visual function surveys from patients both preoperatively and postoperatively. Most notably stakeholders cite several challenges associated with the COVID-19 pandemic including fluctuations in patient case volume and staffing and supply shortages.

**Premier supports modifying the *Cataracts (NQF #1536)* measure from mandatory to voluntary reporting, beginning with the CY 2025 reporting period / CY 2027 payment determination.**
**Requests for Comment on Future Measure**

CMS seeks comment on the potential inclusion of a procedural volume measure in the Hospital OQR program either by (1) re-adopting the *Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26)* measure or (2) adopting another volume indicator. The OP-26 measure was removed from the OQR program during CY 2018 rulemaking because of lack of evidence linking better outcomes to the measure. CMS notes that given the notable shift in procedures from inpatient to outpatient settings, it believes tracking outpatient procedural volume will help inform patients about a given facility's experience with outpatient procedures.

We disagree with CMS' assessment that a volume indicator will be valuable to patients, as procedural volume may vary for a variety of reasons that have 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 inpatient. **We encourage 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.** As we noted when the OP-26 measure was first proposed for removal, we are concerned that the OP-26 measure is not related to patient outcomes and that the burden associated with the measure outweighs any potential value. We strongly urge CMS to pursue outcome-based measures that will provide patients and providers with meaningful information about quality of care, while minimizing reporting burden for providers.

**Measuring Healthcare Quality Disparities Across CMS Quality Programs**

Reducing disparities in care and achieving health equity across communities requires a holistic approach to care, shifting the incentives in our health system from sickness-based to wellness-based**. When providers are responsible for total cost of care for their patients and have flexibility to address social determinants of health (SDOH), providers will be proactive in addressing inequity and disparities.** Addressing the underlying social and economic inequities as well as systemic barriers and biases that drive disparities in care requires (1) data collection and monitoring of key outcomes and health equity measures and (2) shifting the payment system to account for a more comprehensive set of services that address disparities. We appreciate CMS' commitment to closing health equity gaps in the CMS quality programs and look forward to partnering with CMS in this area.

CMS seeks input on key principles the agency should consider when addressing disparities through quality measure development. These principles are stratified into five key categories.

**We recommend that all efforts to stratify measures by race, ethnicity and social factors begin with confidential reporting and appropriate risk adjustment to account for factors associated with outcomes that cannot be addressed by providers**. We must avoid a perverse cycle, wherein certain policies – such as public reporting of stratified quality data – discourages beneficiaries from visiting providers that care for patients in marginalized communities, subsequently leading to unequal care for those patients due to lack of equal resources to treat them. It is critical that information publicly shared on disparities in care is accurate and can be understood by consumers. Moreover, while stratification and comparing providers with similar populations helps identify opportunities for improvement, it does not provide hospitals with all the tools necessary to address any underlying factors contributing to health inequities. **These efforts must be combined with a broader set of supports to enable providers to respond to disparities in care**, such as learning networks and data on available community support services. Finally, we must recognize the challenges of stratifying measures that do not have adequate sample size. CMS must recognize the need for increased patient-level data and the associated burden to collect and report that information. **Overall, we support the principles outlined for stratifying measure results and offer additional perspectives on each principle below.**

*Goals and Approaches for Measuring Disparities using Stratification.* CMS discusses the within- and between- provider methodological approaches for comparing measures results. **We support using both approaches**, which has also been recommended by the Assistant Secretary for Planning and Evaluation.

*Selecting and Prioritizing Measures for Disparity Reporting.* CMS discusses measures that could be prioritized including existing measures; measures with identified disparities; measures with reliable and representative comparisons; and outcome, access, and appropriateness measures. We agree with these principles and encourage CMS to be transparent about why certain measures were selected for disparity reporting. CMS should use its existing processes (e.g., NQF endorsement, Measures Applications Partnership, and Notice of Proposed Rule Making) to seek stakeholder input before measures are stratified. Additionally, as we note above, CMS should first employ confidential reporting and seek additional feedback prior to public reporting.

*Social Risk Factors and Demographic Data Collection.* CMS notes that patient reported data is the gold standard and discusses other potential data sources, including billing and administrative data, area-based indicators of social risk and demographics, and imputed sources of social risk and patient demographics. Health systems are currently capturing sociodemographic data, but this information is not easily translatable for CMS purposes. For example, despite an available framework for mapping the more than 900 race ethnicity codes provided by the CDC to the OMB, race and ethnicity codes captured in the EHR cannot be consistently mapped. This is a result of lack of use of standard taxonomies—in part by the EHRs and in part by the providers to allow the category selections to align with how their populations would like to report information. Similarly, there are an abundance of tools to screen for SDOH with underlying definitions for certain social risk factors (e.g., food insecurity) significantly varying even when the same tool is used by different providers.

The Agency for Healthcare Research and Quality (AHRQ) has found that one of the biggest barriers most health systems face in improving quality and reducing disparities within their own walls is systematically identifying the populations they serve, addressing the needs of these populations, and monitoring improvements over time. AHRQ further found that the principal challenges in obtaining race, ethnicity, and language data for use in quality improvement assessments include a lack of standardization and understanding of why the data are being collected.

It is vital that CMS also invest in educating both patients and providers about the importance of collecting SDOH information, the evidence for how it affects care, and existing privacy requirements under HIPAA that safeguard information patients share with their providers. CMS should also consider advancing standards that clearly indicate the dates and times associated with data collection, as certain sociodemographic factors (e.g., homelessness) are subject to change.

**We ask that CMS make a concerted effort to advance standards for the collection of socio-demographic information, using existing tools such as the United States Core Data for Interoperability (USCDI), Z-codes, HL7 and Fast Healthcare Interoperability Resources (FHIR) standards.** As we note above, CMS needs a coordinated approach for using sociodemographic data for numerous purposes including payment and quality. This coordinated approach requires significant input from providers across the continuum, vendors, payers, and suppliers. **We recommend that CMS convene a dedicated Task Force or Expert Panel of stakeholders to support advancing standards and collection of socio-demographic factors.** The Task Force or Expert Panel should include, at a minimum, representation from acute and nonacute providers, vendors and suppliers, beneficiaries and plans.

**We do not support the use of indirect estimation techniques due to data inaccuracy.** Health systems are currently collecting self-reported sociodemographic data from their populations through a variety of methods. Inaccurate measure stratification can disrupt ongoing efforts to improve disparities in care. **Instead, we urge CMS to rapidly and meaningfully pursue efforts to improve access to directly collected race and ethnicity data from self-reported sources.**

Finally, **we support using area-based indicators of social risk as an initial step in providing hospitals confidential feedback**. As noted above, hospitals are currently working to identify disparities in their populations. Having measure rates using area indices will allow hospitals to compare their own stratified results to stratified results based on the area indices. This provides valuable information of how a hospitals population or performance may vary from the region.

*Identification of Meaningful Performance Differences.* CMS notes several approaches for detecting meaningful differences in stratified results. As we note above, we encourage CMS to approach

stratification of measures results similar to approaches used for collection and reporting of all measure results. CMS should convene a Technical Expert Panel.

*Reporting Disparity Results.* CMS discusses a goal of confidential reporting to providers for new programs and measures. **We agree with this approach and reiterate that CMS should seek stakeholder input prior to public reporting.**

## BEHAVIORAL HEALTH

**Remote Mental Health Services**

For the duration of the COVID-19 PHE, hospital and community mental health center (CMHC) staff may furnish certain outpatient therapy, counseling and educational services incident to a physician's services to beneficiaries in temporary expansion locations, including the beneficiary's home, as long as the location meets all conditions of participation to the extent not waived. Additionally, services may be furnished via telehealth if that beneficiary is registered as an outpatient. **Premier applauds CMS' proposal to permanently designate certain remote mental health services as covered and paid for under the OPPS**. However, we are concerned that CMS plans to allow flexibilities permitting remote provision of partial hospitalization program (PHP) services to abruptly end with the conclusion of the PHE.

Published research has found that the main differences between patients who participated in PHPs via telehealth and those who attended in-person were that those who participated via telehealth had greater lengths of stay and were more likely to stay in treatment until completed. CMS notes several requirements that apply to PHP in the proposed rule including the statutory requirement at section 1835(a)(2)(F) of the Act that PHP services are in lieu of inpatient hospitalization. The implication of the proposed rule is that PHP services are too intensive to be furnished in the patient's home absent the PHE. However, by abruptly terminating a policy that allows PHP services to be provided to patients in their homes, CMS risks overwhelming already strained inpatient hospital capacities or worse, causing beneficiaries to forgo medically necessary care. **Premier urges CMS to make permanent the PHE flexibilities that allow provision of certain PHP services via telehealth.** At the very least, CMS must temporarily extend coverage of these remote services beyond the PHE and work with provider and patient groups to create a glide path rather than a cliff when phasing them out.

## REPORTING DISCARDED AMOUNTS FOR SINGLE USE VIAL DRUGS

Beginning January 1, 2023, Part B drug manufacturers are required to refund discarded drug amounts exceeding 10 percent of total charges for the drug in a given calendar quarter. CMS proposes to use the JW modifier to determine the refund amount due for a discarded drug.

The JW modifier has been required on Medicare claims since CY 2017 to identify the amount of a drug that was discarded and eligible for payment. However, CMS expresses concern that this modifier is often omitted on claims. CMS believes this may be because there is currently a lack of incentive to bill accurately since CMS will pay up to the full amount of the labelled dose. To address this issue, CMS is proposing to establish a new modifier (JZ), which would be used to attest that the physician did not discard any drugs being billed from a single-use vial.

Under this proposed policy, a provider would bill Medicare for the amount of drug administered on one line of the claim and the amount discarded with the JW on another line of the claim. Units administered and units discarded would total to the labeled dose on the vial. Alternatively, the provider may administer

the full amount of the drug included in the single-use vial and bill one line with the JZ modifier attesting the entire vial was administered and no amount is being billed for discarded drugs.

Establishing the JZ modifier does not change the provider's incentive relative to current policy but it will increase provider burden. The provider will continue to be paid the same regardless of whether the entire vial is administered or a portion of the vial is administered and the remainder discarded as the refund provision applies to the *manufacturer*, not the provider. There is no reason to believe that requiring use of the JZ modifier will improve compliance for use of the JW modifier. **Premier urges CMS to not proceed with the JZ modifier and instead determine appropriate incentives to encourage appropriate physician documentation with the existing JW modifier. It is also essential for CMS to determine mechanisms for decreasing provider burden associated with documentation.** In speaking with our members, we learned that a primary reason providers are not currently using the JW modifier is because the potential rebate pales in comparison to the undue burden it creates in documentation. Implementing a new modifier, without addressing the misaligned incentives, only adds to provider burden in an environment where staffing shortages are dictating a need to reduce burden, not increase it.

## REQUESTS FOR INFORMATION: USE OF CMS DATA TO DRIVE COMPETITION IN HEALTHCARE

Last year, the Administration issued an Executive Order on Promoting Competition in the American Economy, which identifies hospital consolidation as a potential concern. In April, CMS released data on mergers, acquisitions, consolidations and changes of ownership from 2016-2022 for hospitals and nursing homes enrolled in Medicare. In this proposed rule, CMS solicits comments on what additional data would be helpful to identity the impact of M&A and other market transactions on the affordability and availability of medical care.

We believe it is important to note that the nature of healthcare competition is changing, transitioning from competition among providers seeking to generate volume of services to competition between integrated provider networks designed to deliver affordable, high-value outcomes. The old model is built on fee-for-service incentives that focus on sickness care and favors well-informed patients with excellent health coverage. A value-based system creates incentives that promote better health for both patients and populations and innovation to improve patient outcomes and reduce costs. **It is critical to distinguish between integration and consolidation in building high-value provider networks.** Some advocates are confusing integrated, high-value networks with provider consolidation. This confusion could set back a positive movement to more cost-effective, high-quality care.

One of the major causes of hospital mergers and physician employment is providers' need for scale under declining Medicare and Medicaid reimbursement. Hospitals are largely price takers, not price makers, and 60 percent or more of hospital payments are from public payers with administered pricing and no opportunity for price negotiations.[9] CMS can continue to support transparency in healthcare market trends by collecting, analyzing and publishing change in ownership information among both payers and providers. **Premier strongly encourages CMS to support analysis that moves beyond simply releasing Provider Enrollment, Chain and Ownership (PECOS) data and looks at how providers are impacting quality and affordability outcomes through high-value, integrated care.**

[9] American Hospital Association: Underpayment by Medicare and Medicaid Fact Sheet. https://www.aha.org/system/files/media/file/2022/02/medicare-medicaid-underpayment-fact-sheet-current.pdf

## RURAL EMERGENCY HOSPITALS (REHs)

Under the Consolidated Appropriations Act (CAA) of 2021, Congress established a new Medicare provider type – Rural Emergency Hospitals (REHs) – effective for CY 2023. Under this policy, Critical Access Hospitals (CAHs) and other small rural hospitals will have the opportunity to apply to become an REH, whereby they will furnish emergency department services, observation care and other outpatient services specified by CMS. Additionally, REHs will be required to meet other requirements, including maintaining a staffed emergency department 24 hours a day, 7 days a week and having an annual per patient average length of stay ALOS of 24 hours or less.

CMS is proposing to implement these policies through two separate rules: the CY 2023 OPPS proposed rule, as well as a standalone rule that covers the conditions of participation (CoPs) that REHs will need to meet. Our comments below are generally in reference to the proposals put forth in the OPPS proposed rule related to payment, quality reporting and the REH enrollment process. A copy of our comments on the REH CoP proposed rule are available for download here.

**Statutory Authority**

REHs are intended to protect access to essential healthcare services in rural communities by providing hospitals with an opportunity to discontinue inpatient care but still meet the needs of their communities for emergency and outpatient services. CAHs and rural hospitals that have 50 or fewer beds (as of enactment of the CAA of 2021) are eligible to convert to this new provider type. While REHs will be eligible for increased OPPS payment and a monthly facility fee, statutory restrictions may still make this new provider type financially untenable for many hospitals that could benefit or may result in the loss of other services to rural communities. As we note in more detail below, **we encourage CMS to work with Congress to modify relevant statute to address these challenges and ensure this new provider type is a viable option for rural hospitals and the communities they serve**.

First, REHs would not qualify under the statutory definition of eligible entities for the 340B Drug Discount Program. For nearly three decades, the 340B program has been critical in helping covered entities expand access to lifesaving prescription drugs and comprehensive healthcare services to low-income, underinsured and uninsured individuals in communities across the country, including rural areas. Many CAHs and small rural hospitals have greatly benefited from the 340B program and would lose much needed funding with the conversion to a REH. **We strongly urge CMS to work with Congress to modify statute to ensure that REHs are eligible for 340B Drug Discount Programs.**

Second, statute restricts REHs from furnishing any inpatient services, except skilling nursing services that are furnished in a separate and distinct unit of the REH. This would exclude REHs from maintaining inpatient psychiatric or rehabilitative services, even if furnished in a separate and distinct unit. Rural patients often face limited access to both psychiatric care and rehabilitation services and rely on rural hospitals to furnish these services. **We encourage CMS to work with Congress to expand the statute to allow REHs to furnish inpatient psychiatric and inpatient rehabilitative services if furnished in a separate and distinct unit.** This would allow communities to expand care, potentially utilizing space that might be available as the CAH or small rural hospital converts out of inpatient care into emergency services.

Additionally, we encourage CMS to consider the impacts of the REH designation on access to maternal care in underserved rural areas and to ensure the policies it adopts do not hinder efforts to address the maternity health crisis in the United States. Premier recognizes that REHs are able to provide additional medical and health outpatient services that are commonly furnished in a physician's office or at another entry point into the health care delivery system, including maternal health services. However, that doesn't

go far enough since emergent deliveries would require transportation to other entities for a patient's recovery, creating the possibility of unforeseen complications. **We encourage CMS to work with stakeholders to ensure implementation of the REH designation does not create unintended access issues for maternity care,** including identifying what changes to statute may be necessary to allow REHs to continue to furnish safe and high-quality maternal and perinatal health care in rural communities.

Third, statute restricts CAHs and rural hospitals with 50 or fewer beds that may have closed on or before Dec. 27, 2020 (date of enactment of the CAA of 2021) from converting to REH status. Since 2010, nearly 140 hospitals have closed,[10] leaving many rural communities without access to critical medical services and resulting in widening disparities in healthcare. For some of these communities, the opening of an REH could help to narrow these gaps in care and improve access. **We urge CMS to work with Congress to broaden eligibility to include communities where hospitals may have closed prior to the passage of the CAA of 2021.** Additionally, statue does *not* preclude hospitals that may have closed after Dec. 27, 2020 from REH conversion. We recommend that CMS clarify in regulation that these hospitals are eligible for conversion and the process for reenrolling in Medicare as an REH.

Finally, we encourage CMS to monitor and assess uptake of the REH provider type and evaluate if there are barriers or disincentives associated with the policy that may be prevent rural hospitals or CAHs who could benefit from the policy from converting. Based on these learnings, CMS should look to modify its policies or work with Congress to adapt statute as needed. The challenges that rural communities face can be regional in nature. As a result, CMS must avoid adopting a one-size-fits-all approach to addressing the healthcare needs of rural communities.

**Payment Policies**

The CAA of 2021 sets REH payment equal to the applicable OPPS payment plus an additional 5 percent. REHs are also eligible to receive a monthly facility payment. Statute sets the monthly facility payment equal to the difference in total CAH payments in 2019 and the amount that would have been paid to CAHs under IPPS, OPPS and Skilled Nursing Facility (SNF) PPS in 2019 (divided by the number of CAHs in 2019 divided by 12 months).

In the CY 2023 OPPS rule, CMS proposes to implement REH payments equal to the applicable OPPS payment amount plus an additional 5 percent and notes it will update the OPPS claims processing logic to include an REH-specific payment. Beneficiary coinsurance will remain at 20 percent of the OPPS payment amount (without the additional 5 percent). Since CMS is defining REH services as all covered outpatient department services paid under the OPPS, any outpatient service not paid under OPPS – such as laboratory services and outpatient rehabilitation therapy services – would be paid under its applicable payment system or fee schedule.

In the rule, CMS walks through its calculation of the monthly facility payment, including data sources and assumptions. CMS proposes that REHs would be eligible for a monthly facility payment of $268,294 in 2023. CMS will update this amount annually using the hospital market basket update. Statute requires REHs to maintain detailed information on how the REHs utilized facility payments and to make the information available to CMS upon request. CMS believes that this requirement can be met through the existing cost report requirements and therefore does not propose any additional reporting or data collection requirements.

We support CMS' decision to not introduce any additional reporting requirements for REHs. We also applaud CMS for not specifying how the facility payments must be used. This will allow REHs maximum

[10] University of North Carolina, Sheps Center, Rural Hospital Closures, https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/

flexibility in utilizing funds to best meet the needs of their communities, such as by providing additional medical or social support services. In addition to emergency department services and observation care, CMS proposes to allow REHs to provide any other outpatient services provided in hospital outpatient departments. Premier supports CMS' proposal.

We also urge CMS to continue to evaluate whether the OPPS payment rate plus 5 percent is sufficient for covering costs for REHs. Many REHs will have previously been CAHs and would have therefore been previously paid at 101 percent of reasonable cost. Some facilities moving to OPPS plus 5 percent may find this payment insufficient to stabilize its finances. As a result, CMS should continue to evaluate the impact of REH payments on the financial stability of facilities and access to care in rural communities and work with Congress to make necessary adjustments to statute.

**Enrollment Process**

CMS proposes several policies that are aimed at streamlining the enrollment process for REHs as much as possible. First, CMS proposes that REHs would not need to submit an initial enrollment application and instead only require them to submit a change of enrollment form, which is shorter than the initial application and does not require an application fee. Second, CMS proposes to categorize REHs at a limited level of risk, meaning they would not be subject to additional screening.

Premier applauds CMS for streamlining the REH enrollment process as much as possible, including reducing the burden and costs associated. As noted above, **we recommend that CMS clarify the process by which hospitals that closed after Dec. 27, 2020 can apply to become an REH.**

**Quality Reporting**

Statute requires CMS to establish a quality reporting program for REHs, including a process for publicly reporting results. In the proposed rule, CMS shares the key considerations it will use for measure selection and seeks additional input on specific measures as well as topics, such as telehealth, maternal health, mental health and health equity.

We continue to urge CMS to work **with the NQF Rural Health Workgroup to develop a set of measures that capture the unique health needs of rural communities**. As part of this, CMS should:

- Pursue a narrow set of rural-relevant measures that advance quality of care in rural communities while minimizing burden on REHs;
- Seek alignment across Medicare, Medicaid and other payers to reduce burden on rural facilities;
- Work with stakeholders and technical experts to address challenges related to reporting and measurement, such as low patient volume; and
- Provide technical assistance to support rural providers in establishing systems to monitor and report quality performance

**Incentivizing movement to value-based care**

CMS should continue to explore ways to include REHs in value-based care initiatives. As we've noted in the past, there are several barriers that discourage or prevent rural providers from participating in APMs, including inability to absorb high discount rates commonly applied under APMs. **CMS should continue to work with stakeholders to adapt existing APMs to be more inclusive of rural providers, including REHs, and to ensure rural providers have the necessary flexibilities and tools to succeed in value-based care.**

## CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the CY 2023 OPPS proposed rule. If you have any questions regarding our comments or need more information, please contact Melissa Medeiros, Senior Director of Policy, at melissa_medeiros@premierinc.com or (202) 879-4107.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President, Government Affairs
Premier healthcare alliance

**Appendix: PINC AI™ Data: CMS Data Underestimates Hospital Labor Spending**

April 12, 2022

# PINC AI™ Data: CMS Data Underestimates Hospital Labor Spending

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**Key takeaways:**

- CMS updates hospital rates based on a wage inflation index that represents historical data. For FY 2022, this resulted in hospitals receiving only a 2.7 percent rate increase, compared to a 6.5 percent increase in hospital labor rates, according to PINC AI™ data. Labor costs account for nearly 68 percent of hospital costs in calculating the IPPS payment update.
- For FY 2022, CMS's estimates of hospital spending growth using historic data represented less than the actual growth in the prices paid by hospitals for labor, supplies and services.

- The data CMS uses to account for real inflation in the cost of labor and other expenses is unlikely to reflect reality and produce an accurate payment update for the FY 2023 IPPS rule, due this spring.

**For more on this topic:**

- Read the hospital group letter signed by Premier, recommending sequestration relief for providers.
- Read a second hospital group letter signed by Premier, recommending additional provider relief funds be allocated to hospitals and health systems.

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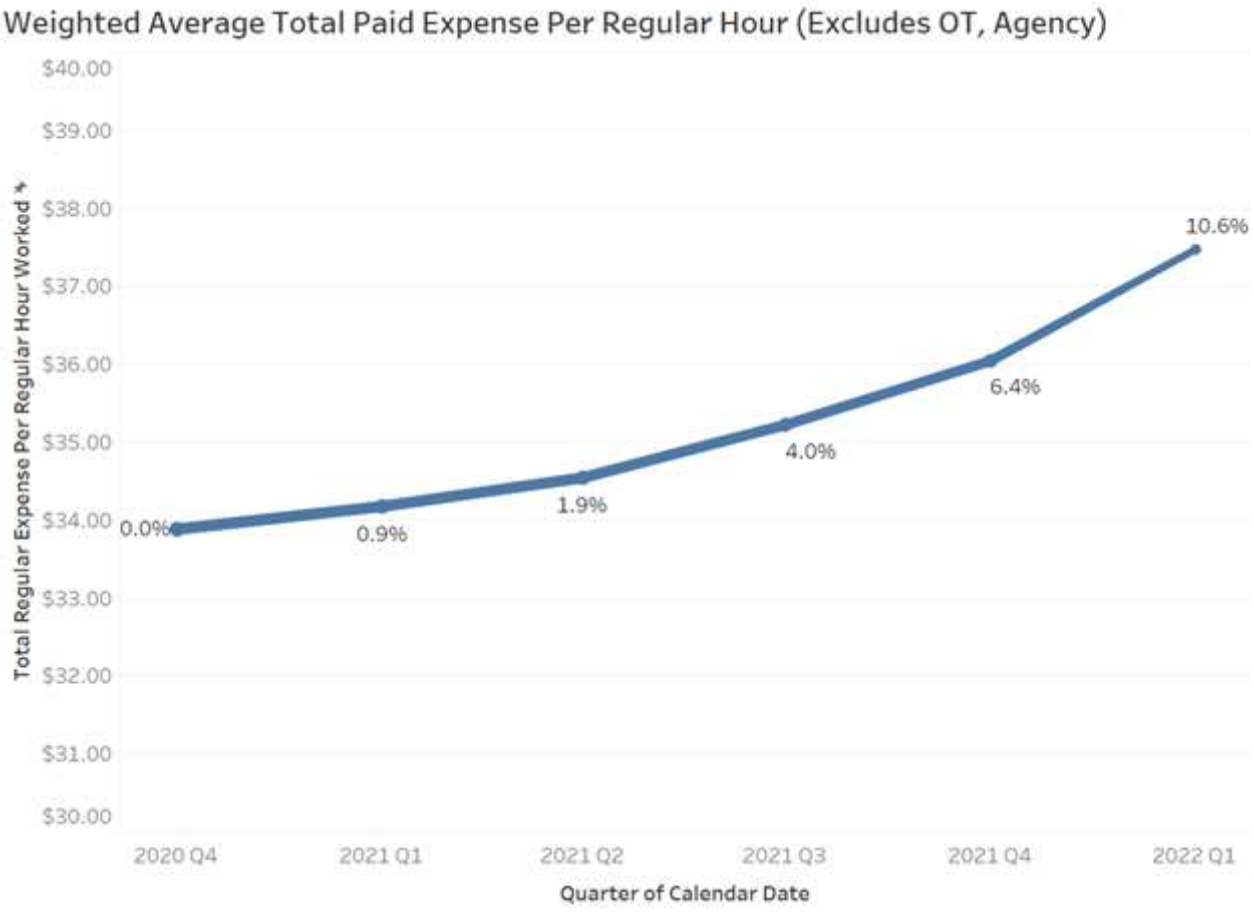
Later this spring, the Centers for Medicare & Medicaid Services (CMS) is expected to release proposed rules for the Inpatient Prospective Payment System (IPPS). For the FY 2021 and FY 2022 rules, CMS applied upward payment adjustments of 2.4 and 2.7 percent, respectively.

However, a recent PINC AI™ analysis finds that CMS's payment adjustments did not adequately address hospitals' increased costs. According to new data, hospitals' labor rates alone jumped 16.6 percent on a per-paid-hour basis since Q4 2020 (start of government FY 2021) and do not show signs of slowing. Labor makes up about 67.6 percent of the CMS market basket calculation used to adjust hospital payments. A very high payment update in FY 2023 will be needed to match the rates most acute care providers are now paying their staff.

Importantly, these costs do not appear to be exclusively COVID-19 pandemic-related or transitory. Long 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. Since that time, the pandemic has only exacerbated matters, with more than 500,0000 nurse retirements expected in 2022. In fact, latest research from JOLTS/BLS indicates that there are 2.7 open positions for every one position filled. As talent shortages become more severe, providers are paying more to attract and retain scarce staff, a reality that is not expected to slow down as the pandemic subsides.

In fact, even removing use of temporary agency labor and overtime expenses that may have been more readily used to manage pandemic surge, inflation for labor expenses is still up 10.6 percent since Q4 2020.




Moving into the third year of the pandemic, our nation's hospital and health system workers have cared for more than 4 million COVID-19 patients. At the same time, patient acuity and length of stay have increased when compared to earlier in the pandemic. These challenges are compounded by ongoing delays in non-emergent procedures and increased costs for supplies, medicine, testing and protective equipment.

Exacerbating the problem is the fact that relief from the 2 percent sequestration cuts has also expired, replaced by 1 percent cuts from April to the end of June, followed by a full resumption of the cuts by July 1. The net effect would be to add insult to injury – holding payment to below the actual increases in

costs when many acute care providers are struggling to stay afloat after years of COVID-related financial losses.

As a result, it is imperative that CMS and Congress take action to ensure hospitals are adequately compensated. CMS should account for these expenses appropriately as part of its proposed IPPS rule update, due sometime this spring. Congress should also place a moratorium on the sequester, make additional provider relief funds available and provide additional time to spend provider relief funds previously distributed.

**Methodology**: To determine changes in hospital labor expense rates, PINC AI™ analyzed the data within its workforce optimization solutions, one of the nation's largest and most robust sources for geographically diverse productivity data and benchmarks – all collected and validated by health system users daily. Paid Expense (Excluding Bonus) and Paid Hours figures are provided to PINC AI™ by its client health systems. The database of more than 1,400 hospitals was filtered to include only hospitals that provided both of these figures accurately for the same quarter, resulting in a representative sample of 580 hospitals across 110 health systems. For each quarter, the sum of Paid Expense (Excluding Bonus) was divided by the sum of Paid Hours, resulting in the Weighted Average Paid Expense Per Paid Hour figure shown in the chart. The value of this figure for each quarter was compared to the value for the initial quarter (Q4 2020) to calculate a percentage increase.

Paid Expense (Excluding Bonus) includes the wages for all salaried and hourly employees, including overtime but excluding bonus and other incentive payments. Expenses paid for contracted employees are included if provided by the health system. Paid Hours includes all worked, vacation, sick and other PTO hours for which the worker was paid. These two figures, and the resulting Weighted Average Paid Expense Per Paid Hour figure, provide the most direct comparison to the Employment Cost Index (ECI) used by CMS when determining the percentage change in hospital per-unit labor costs for the annual IPPS payment update. For FY 2023 IPPS proposed rule, the ECI data will include historical data through Q4 2021 and forecasted data for Q1 2022. The final rule will use updated data that includes historical data through Q1 2022 and forecasted data for Q2 2022.

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## Blair Childs

Senior Vice President of Public Affairs

Blair is the primary spokesperson and communications strategist for the organization on key issues impacting healthcare costs and quality. He serves as liaison to the U.S. Congress, White House, healthcare policymakers and other major bodies involved in healthcare policy and regulation. Based in Washington, D.C., Blair leads Premier's advocacy and thought leadership units, and is a member of Premier's Executive Team.

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Aisha leads Premier's advocacy efforts on provider reimbursement, including quality measurement and alternative payment models.

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