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September 13, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
Mailstop C-4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Calendar Year 2023 Proposed Rule (CMS-17720-P)

Dear Administrator Brooks-LaSure:

The Association of American Medical Colleges (AAMC or the Association) welcomes the opportunity to submit comments on the proposed rule entitled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs" 87 Fed. Reg. 44502 (July 26, 2022), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members comprise all 156 accredited U.S. medical schools; 14 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and nearly 80 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 191,000 full-time faculty members, 95,000 medical students, 149,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The following summary reflects the AAMC's comments on CMS proposals regarding hospital outpatient payments, quality proposals and requests for information.

<u>Payment Proposals</u>

- ***340B Drug Pricing Program***. Calculate the budget neutrality adjustment to ensure proper payments for CY 2023 and beyond. Ensure complete and proper repayment of underpayments to 340B hospitals.
- ***Payment update, outlier threshold***. Increase OPPS payment update to reflect higher growth in labor and supply costs. Consider using pre-COVID-19 inflation factor to calculate the outlier threshold.

- ***Remotely furnished behavioral health services***. Finalize proposal to create new OPPS category for furnishing behavioral health services using telecommunications. Ensure proper payment to hospital outpatient departments (HOPDs) by paying the full OPPS rate for these services.
- ***Organ acquisition***. Ensure proposals do not negatively impact access and equity.
- ***Prior authorization***. Do not finalize the proposal to add a new category – facet joint intervention – for prior authorization.
- ***Payment for NIOSH-approved N95 masks***. Finalize the proposal to include an OPPS payment adjustment for domestically produced NIOSH-approved N95 masks. Do not implement the OPPS proposal in a budget neutral manner.

Quality Proposals

- ***Changes to the Outpatient Quality Reporting (OQR) Program***. CMS should (1) return to voluntary reporting for OP-31 to reduce burden on hospitals, (2) align patient encounter quarters to the calendar year, and (3) re-evaluate potential future adoption of volume indicator and instead focus on developing outcome measures that are meaningful and comprehensible for patients.
- ***Measuring Disparities***: CMS should (1) focus on development of the Within Hospital Method to measure inequities, (2) prioritize process and access measures, (3) carefully evaluate the precise health-related social needs (HRSNs) and social risk factors to evaluate inequities, and (4) focus primarily on how to use inequities measurement to inform providers and interventions.
- ***Overall Hospital Quality Star Ratings***. CMS should (1) Add a filter to allow patients to choose to include Veterans Health Administration (VHA) hospitals in the ratings, (2) further clarify the data used for annual updates to the Ratings, and (3) provide transparency regarding impacts of the COVID-19 public health emergency (PHE) on the Ratings.

PAYMENT PROPOSALS

340B DRUG PRICING PROGRAM

Finalize Policy to Reimburse 340B-Acquired Drugs at Average Sales Price plus 6 Percent

On June 15, 2022, the U.S. Supreme Court struck down[1] CMS' policy to decrease the payment for drugs acquired under the 340B Drug Pricing Program (340B Program). The Court determined that because the Department of Health and Human Services (HHS) did not conduct a of survey of hospitals' acquisition costs for outpatient drugs, the HHS acted unlawfully by reducing reimbursement rates for 340B hospitals. In the proposed rule, CMS states that the Agency did not have sufficient time to formulate a response to the Supreme Court's decision. However, the proposed rule indicates that CMS "fully anticipates" finalizing a policy to reimburse for 340B-acquired drugs at average sales price plus 6 percent (ASP+6%). (p. 44648). In light of the Supreme Court ruling, the AAMC believes that CMS has no choice but to finalize this policy and reimburse 340B-acquired drugs at ASP+6%.

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[1] American Hospital Association et. al. v. Becerra. https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf

OPPS Payments Beginning January 1, 2023

Calculate the Budget Neutrality Adjustment for CY 2023 to Ensure Proper OPPS Payments for 2023 and Beyond

In the CY 2018 OPPS final rule[2], CMS described its methodology for determining the savings associated with its 340B policy of paying for separately payable drugs at ASP minus 22.5 percent. Based on these modeling assumptions and data from that time, CMS estimated that OPPS drug payments would be reduced by $1.6 billion, and a budget neutrality adjustment of +3.19 percent would be applied to all non-drug OPPS items and services to meet the statutory budget neutrality requirement of section 1833(t)(9)(B) of the Social Security Act (the Act). Given data limitations, CMS stated that it "may need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount within the OPPS."

This statement suggested that CMS would revisit its initial budget neutrality adjustment to determine whether it was correct. However, CMS has never changed any past year budget neutrality adjustments, including separately payable drugs. The availability of the JG[3] modifier would allow for more precision in its 340B budget neutrality adjustment. CMS routinely updates its annual calculation of the OPPS conversion factor to ensure budget neutrality for OPPS pass-through payments, the outlier adjustment the wage index adjustment, and any other applicable adjustments. Our review of the data show that the lack of an update to the 340B budget neutrality adjustment shows that CMS has taken out more money from 30B hospitals than it returned to hospitals for payments for non-drug services.

In previous years' comments, the AAMC has asked CMS to recalculate the 340B budget neutrality factor using the most recent data to ensure hospitals are properly reimbursed for non-drug services. In response, the Agency indicated that "while some of the [340B] claims may change based on drug payment and billing, as indicated by the 'JG' modifier, these drugs, including their utilization and expected payments, would be included as part of the broader budget neutrality adjustments, but collectively they would not have a separate budget neutrality adjustment specifically for the 340B drug payment policy."[4] But as the agency also noted, the OPPS budget neutrality is developed "on a prospective basis by isolating the effect of any changes in payment policy *or data* with all other factors held constant." (emphasis added). Therefore, the fact that the policy did not change does not obviate the need for CMS to fulfill its statutory obligation under section 1833(t)(9)(B) of the Act to apply a new prospective budget neutrality adjustment annually by taking into account any change in utilization data (in this case, based on 340B drug claims billed with the "JG" modifier) that affect the magnitude of payments being affected by the 340B adjustment.[5]

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[2] 82 FR 59482-59483
[3] CMS established the JG modifier in 2018. Hospitals apply this modifier on the claim when a drug is acquired under the 340B program and subject to the payment adjustment of ASP-22.5 percent. CMS established modifier TB to identify on the claim those drugs that are acquired under the 340B Program, but the payment adjustment does not as a result of being exempted by CMS through regulation.
[4] 85 FR 86054
[5] Cf. Cape Cod vs. Sebelius, 630 F.3d 203, 213 (D.C. Cir. 2011). "Having built the past into the cumulative methodology it chose for counteracting the budgetary impact of the rural floor, CMS may not now ignore past errors that have the effect of overly deflating current aggregate payments in violation of BBA section 4410(b)'s budget-neutrality mandate … Far from requiring CMS to carry over past adjustments that improperly deflate aggregate Medicare payments, BBA section 4410(b) seems to mandate precisely the opposite."

CMS now proposes to update the 340B budget neutrality adjustment that would impact the amount that is removed from the system even though CMS never updated the adjustment for each year to ensure the amount put back into the system was correct. The CMS proposes to remove 4.04 percent from OPPS rates beginning in CY 2023.

An adjustment of -4.04 percent is higher than the original 3.19 percent initially applied for CY 2018 and that has been maintained on the OPPS conversion factor. CMS indicates that this adjustment will reduce non-drug OPPS payments by $1.96 billion. Therefore, CMS is actually proposing a permanent reduction in OPPS payments of approximately $410 million. We strongly urge CMS to only apply a -3.19 percent budget neutrality adjustment to the CY 2023 OPPS conversion factor to restore the original adjustment CMS applied when it first implemented the policy.

Remedy for Underpayments in Calendar Years 2018 through 2022

In the proposed rule, CMS requests comments on a remedy to correct the underpayments for 340B-acquired drugs. We strongly encourage CMS to adopt as part of the CY 2023 OPPS final rule the remedy outlined below to ensure payments to hospitals are appropriately restored.

Ensure Complete and Prompt Repayment of Underpayments

In response to the Supreme Court's decision that payment reductions to 340B hospitals were unlawful, the Agency should promptly repay hospitals for 340B-acquired drugs the difference between ASP+6% and the amount actually paid to hospitals for 340B drugs (plus applicable interest) for all the years in which the Agency reduced payment to 340B hospitals.

Further, the Agency should not rely on the inadequate survey of 340B hospitals that it fielded in Spring 2020, at the height of a global health care pandemic and subsequently used to support its decision to reduce payments to hospitals. CMS sent hospitals participating in the 340B Program a voluntary survey during the initial weeks of the pandemic to gather information on acquisition cost data for drugs purchased under the 340B Program. As part of the survey CMS requested that hospitals provide either the 340B ceiling price, a 340B sub-ceiling price, or another amount, depending on the discounts the hospital received when it acquired a particular drug. Where the acquisition price for a particular drug was not available, not submitted, or if the hospital did not respond at all, CMS used the 340B ceiling price for that drug as a proxy for the hospital's acquisition costs. This survey did not accurately reflect the hospitals that participate in the 340B Program, nor the drugs purchased under the Program. The survey does not comport with the law and was never relied upon by the Agency as the basis to continue its unlawful policy. The survey is not fair, proper, or a legal basis for the Agency to delay or deny repayment.

Do Not Retrospectively Recoup Payments Which Would Be Unfair, Unlawful, and Unprecedented

In the past, CMS has raised the specter of invoking "budget neutrality" to retrospectively recoup funds from hospitals that receive them because of an unlawful policy. However, CMS should not penalize any hospitals for the policy that the Agency chose to implement. The AAMC urges CMS not to ask hospitals to return monies they received as a result of the implementation of the policy in a budget neutral manner. Moreover, nothing in federal law requires, or even permits, CMS to claw back funds to achieve budget neutrality. The law governing the OPPS makes it clear that budget neutrality applies prospectively, not retrospectively, as it addresses only future estimates and forward-looking periodic reviews. Finally, many of the funds that hospitals received were already spent during the COVID-19 PHE, an ongoing crisis that

continues to cause hospitals to struggle financially. Clawing back funds would further exacerbate these financial challenges that will continue to put patients and communities at risk.

PAYMENT UPDATE

Increase the OPPS Payment Update for CY 2023 to Reflect Higher Growth in Labor and Supply Costs

CMS is proposing a payment update of +2.7 percent for CY 2023. The proposed update is based on the IPPS proposed rule[6] market basket update of +3.1 percent and a total factor productivity adjustment of minus 0.4 percent. However, in the IPPS final rule[7], CMS finalized a market basket update of 4.1 percent less a total factor productivity adjustment of negative 0.3 percent which equaled a final update of 3.8 percent. We thank CMS for acknowledging AAMC's and other stakeholders' concerns that the proposed IPPS update did not adequately account for rising labor and supply chain costs due to the public health emergency. Therefore, we ask CMS to calculate the final OPPS payment update based upon the finalized IPPS update to be consistent with CMS' past practices for this calculation.

Consider Using an Inflation Factor from Pre-COVID-19 Periods to Calculate the Outlier Threshold

CMS proposes to adopt an outpatient outlier threshold for CY 2023 of $8,350. This is a 35 percent increase from the CY 2022 amount. (p. 44533). CMS projects that the proposed outpatient outlier payments would be 1.0 percent of the estimated aggregate total payments under the OPPS for CY 2023. The proposed rule notes that to calculate the outpatient outlier threshold, CMS inflated the charges on the CY 2021 claims using the same proposed charge inflation factor that it used to estimate the IPPS fixed loss cost threshold for the FY 2023 IPPS proposed rule. However, in response to commenters' concerns that COVID-19 cases would have a significant impact on increasing the fixed-loss threshold, CMS finalized the IPPS proposal that will calculate two fixed-loss thresholds – one including COVID-19 cases and one excluding COVID-19 cases – and then averaging these two fixed-loss thresholds to determine the final fixed-loss threshold for FY 2023.[8]

We are concerned that the threshold for CY 2023 is also significantly impacted by COVID-19 cases, resulting in the dramatic increase over CY 2022. During the COVID-19 PHE, outpatient service mix and volume were severely and atypically affected, and these impacts may have continued into CY 2021. The application of the cost-to-charge inflation factor methodology across periods affected by the COVID-19 PHE may be overestimating the inflation factors from CY 2021 to CY 2023. In order to more accurately model the projected outlier payment amounts, we urge CMS to consider using a lower charge inflation factor to decrease the dramatic increase in the outlier threshold for CY 2023.

PAYMENT FOR REMOTELY FURNISHED BEHAVIORAL HEALTH SERVICES

CMS is proposing to designate certain services to diagnose, evaluate or treat a mental health disorder furnished via telecommunications as covered outpatient services and payable under the OPPS. Under this proposal, beneficiaries would not have to be in-person in the hospital outpatient department (HOPD) for these services to be covered. Rather, beneficiaries would be able to receive services while in their home.

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[6] 87 FR 28108
[7] 87 FR 48780
[8] 87 FR 48425-49426

CMS is also proposing that the treating clinical staff be physically located in the hospital when furnishing services remotely using telecommunications. Additionally, the proposed rule seeks feedback on whether it is necessary for the clinical staff to be physically located "in" the hospital when furnishing these telehealth services. The AAMC supports CMS' proposal to allow payment under the OPPS for mental health services provided by hospital clinic staff to beneficiaries in their home. It is important to allow utilization of all options to remotely furnish behavioral health services in light of the shortage of mental health providers and to meet the surging demands. Moreover, telehealth expands access to medically necessary care, especially for beneficiaries in rural and other underserved areas. Telehealth benefits patients who are unable to attend an in-person visit due to an inability to take time off from work, lack care for dependents, and do not have reliable transportation, for example. The Association supports efforts to expand telehealth to reach beneficiaries who may otherwise go without care. We refer CMS to more detailed AAMC comments on telehealth benefits in our comment letter to the proposed CY 2023 Medicare Physician Fee Schedule (PFS).[9]

Do Not Reimburse the PFS Facility Rate for Behavioral Health Services Furnished via Telehealth by HOPD Clinical Staff

As part of the COVID-19 waivers[10], hospitals can submit a claim for mental health services furnished via telehealth by clinical staff who ordinarily practice in a HOPD. This has allowed beneficiaries to remain at home and continue receiving health care services from HOPD clinical staff during the COVID-19 PHE. The ability for hospitals to receive reimbursement under the OPPS for these services will expire at the end of the COVID-19 PHE. This proposal would allow hospital clinical staff to furnish mental health services to beneficiaries in their homes and receive reimbursement under the OPPS without a waiver. The AAMC supports this proposal.

Under this proposal, hospitals would be able to bill for services that do not have an associated claim for professional services. (p. 44676). However, CMS is proposing to reimburse hospitals an amount equal to the facility fee under the Physician Fee Schedule for telehealth mental health services performed by hospital clinical staff, not the full OPPS facility fee. CMS contends that this is the appropriate payment because beneficiaries are in their homes and not physically present in the hospital so that hospitals are not accruing all the costs associated with an in-person visit and therefore the full OPPS rate may not accurately reflect these costs. (P. 44677). The AAMC disagrees.

HOPDs continue to incur fixed operating costs regardless of whether a patient is seen in-person or via telecommunications. HOPDs still need to employ nurses, medical assistants, and other staff to engage patients before, during, and after telehealth visits to coordinate care pre- and post-visit and ensure a seamless experience. Adequate staffing is necessary to ensure effective appointment scheduling, notifications, reminders for providers and staff, and learner supervision, as necessary. Protocols and infrastructure must be in place for managing patients' emergencies. Further, providers must establish a video platform that is HIPAA compliant, accessible, user-friendly, and compatible with patient-owned devices and that integrates with electronic medical records scheduling and enables multiple concurrent participants (e.g., learners, patients' family members). Sufficient internet access and bandwidth for providers and patients and appropriate devices – such as webcams, headsets, smartphones – for providers and in some instances patients is essential. Effective technology training is required for providers and staff, including real-time technical support for providers and patients, with contingency plans for

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[9] https://www.aamc.org/media/62416/download
[10] 85 FR 27562 - 27566

connectivity failures as well as private locations where others cannot hear or see the patient during the video visit.

For telehealth to successfully enable access to care for patients to receive timely and effective management of their health care needs, reimbursement for services must be commensurate with the costs of providing care through video visits. For many HOPDs, telehealth will no longer be sustainable if CMS pays the PFS facility rate. Limiting the availability of telehealth services could significantly impact patients' access to care. Therefore, we believe that the full OPPS rate is warranted, regardless of the location of the beneficiary. We urge CMS to finalize a policy that would pay the full OPPS rate to hospitals for these services.

Hospital Clinic Staff Should Not Be Required to Be Physically Located "In" the Outpatient Setting

CMS is seeking comment on whether to require hospital clinical staff be physically located in the hospital when furnishing mental health services via telehealth. CMS is proposing to revise the regulatory text to remove the reference to the requirement that the practitioner be physically located in the HOPD. Specifically, CMS would remove the word "in" from the regulatory text. (p. 44676). We urge CMS to finalize this proposal and remove from the regulatory text the word "in." The AAMC does not believe that hospital clinical staff should be required to be physically present in an HOPD to successfully furnish telehealth services to beneficiaries. Providing flexibility for hospital clinical staff to furnish telehealth services from an offsite location could potentially expand the availability of these services particularly in light of the increasing demand for mental health services and the shortage of mental health care professionals.

In-Person Visits Should Not be a Requirement for Coverage of Mental Health Services Furnished via Telehealth

The proposed rule is proposing the requirement that payment for mental health services furnished remotely to beneficiaries in their homes would only be made if the "beneficiary receives an in-person service with the 6 months prior to the first time hospital clinical staff furnishes the remote mental health service." Further, an in-person mental health service within 12 months of each mental health service furnished via telehealth would also be required. The proposal would allow for limited exemptions to these requirements based on beneficiaries' needs. (p. 44678). The AAMC does not support this proposal. The AAMC believes mental health services furnished via telehealth should be permitted without requiring an in-person visit.

While we recognize that the statute[11] requires an initial in-person visit prior to the telehealth visit, we believe that an in-person requirement may act as a significant barrier to care for those who rely on mental health services. This barrier would disproportionally affect those in more vulnerable populations who, because of their job, lack assistance to care for their dependents, transportation issues and other limitations, would not be able to attend an in-person visit. Continuation of care is crucial for mental health services, and in-person visit requirement may result in a lapse of care and ultimately negative clinical outcomes for patients. If finalized, mental health services would be the only type of service provided by telehealth which would require an in-person visit at a specific interval, which is arbitrary and discriminatory against the patients who need this specific service.

[11] Section 123(a) of the Consolidated Appropriations Act, 2021.

Allow the Use of Audio-Only Telecommunications to Furnish Services to Some Beneficiaries

CMS acknowledges not all beneficiaries have access to two-way audio/video services to receive mental health services. Therefore, CMS is proposing that while hospital clinical staff must have the capability to furnish two-way, audio/video services, the use of audio-only services is permitted depending on an individual beneficiary's technological limitations, abilities, or preferences. (p. 44679). The AAMC strongly supports the use of audio-only communication to provide mental health services. During the PHE, coverage and payment for audio-only calls have been critical to ensure access to care for many patients. Providers have been able to provide a wide array of services efficiently, effectively, and safely to patients using audio-only technology. We urge CMS to finalize the ability to use audio-only services under the OPPS.

MEDICARE ORGAN ACQUISITION

CMS is proposing to change certain Medicare organ acquisition (OA) payments to transplant hospitals (THs) and organ procurement organizations (OPOs). We appreciate CMS not finalizing the significant changes to OA payments proposed in the FY 2022 IPPS proposed rule.[12] The AAMC continues to have serious concerns that changes to OA payment policy and the calculation of Medicare's share will have negative impacts that CMS has not fully considered. Instituting changes to OA payment may have cascading impacts on organ access and equity in organ distribution. We urge CMS not to finalize these proposals and to continue to work with all stakeholders – THs, OPOs, insurers, patient groups, and others – to conduct further study of the potential impact of changes to Medicare OA payments on organ access and equity, and to find alternative approaches to ensuring adequate payment for organ acquisition.

Ensure that Proposals Do Not Negatively Impact Access and Equity

CMS must consider the impact any changes on OA reimbursement may have on access and equity in organ transplant. Medicare has long played an important role in organ acquisition and the current system appears to work effectively. We urge CMS to ensure that any changes to Medicare's reimbursement for OA costs do not negatively impact access and equity. The smallest drop in available organs could exacerbate disparities in organ access equity. The AAMC wants to ensure that the procurement and allocation of available organs is not negatively impacted, to safeguard the equitable access to organs nationwide.

PRIOR AUTHORIZATION

Do Not Finalize Proposal to Add Prior Authorization Category – Facet Joint Intervention

CMS is proposing to add to the list of services that would require prior authorization to control "unnecessary increases" in volume of certain covered outpatient department services. This year, there is a proposal to add a new category – Facet Joint Interventions – to the list of services that would require prior authorization. If finalized, all outpatient services in the Facet Joint Intervention service group would require prior authorization beginning March 1, 2023. (p. 44802). The AAMC does not support additional services that require prior authorization. There will continue to be increases in all outpatient service

[12] 86 FR 25656

categories as advances in medical technology and research allows for more procedures to be safely and successfully performed in the outpatient setting. Additionally, the AAMC remains concerned that prior authorization requirements often cause delays in patients' ability to receive timely, medically necessary care and impose additional administrative burden on providers.

Osteoarthritis is the most common type of arthritis, commonly affecting the hips, knees, hands, lower back, and neck. Symptoms include pain, redness, swelling and stiffness of the joint.[13] The Centers for Disease Control and Prevention reports that osteoarthritis affects about 1 in 4 U.S. adults. This number is only expected to grow. It is anticipated that more than 78 million men and women will be diagnosed with arthritis by 2040. The CMS Chronic Conditions Data Warehouse indicates that the prevalence rate of arthritis, including osteoarthritis, among Medicare FFS beneficiaries has increased from 28.9 percent in 2009 to 34.7 percent in 2018.[14] Individuals with arthritis experience chronic pain, 25 percent of adults with arthritis report experiencing severe joint pain.[15]

Osteoarthritis is a common cause of facet joint pain and is prevalent in older adults.[16, 17] Patients with facet joint pain present with a variety of symptoms such as neck pain, back pain, and pain worsened with hyperextension, bending laterally, and rotation. Analysis of 2021 CMS claims data shows common diagnoses for patients receiving facet joint intervention include spondylosis (osteoarthritis), low back pain, or other chronic pain.[18] But facet joint pain is also a diagnosis of exclusion. Increases in the use of facet joint interventions is likely a result of the increased number of individuals experiencing chronic pain.

As first line treatment options are exhausted, coupled with patient and provider reluctance to use prescription pain medications, facet joint injections under image guidance have become a valuable tool in diagnosing and treating chronic pain.[19] Instituting prior authorization for this procedure could limit beneficiaries' access a valuable tool for diagnosing the origins of their chronic pain. Further, treatment of facet joint pain is a beneficial non-drug option. CMS 2021 claims data reveals facet joint interventions are used for patients with the diagnosis of drug therapy used to treat pain, including long term use of aspirin.[20] Nonsteroidal anti-inflammatory drugs such as ibuprofen and celecoxib are the most effective oral medications to treat osteoarthritis.[21] While most healthy individuals can safely take these pain relief medicines, long-term use of some drugs can have significant side effects. This minimally invasive procedure can provide patients with pain relief for months after injection.[22] The AAMC urges CMS not to finalize the proposal to require prior authorization for facet joint interventions. The option to use facet joint interventions as a safe and effective means to alleviate pain should be readily available to patients.

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[13] https://www.niams.nih.gov/health-topics/arthritis
[14] https://www.cms.gov/sites/default/files/2020-12/DataSnapshot-Arthritis-Nov2020.pdf
[15] https://www.cdc.gov/arthritis/pain/index.htm
[16] https://www.ncbi.nlm.nih.gov/books/NBK572125/
[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4012322/
[18] Source: Analysis by Watson Policy Analysis (WPA) using the Medicare Standard Analytic File from CY2015-2021. CPT codes and descriptions are copyrighted by the American Medical Association.
[19] https://www.ncbi.nlm.nih.gov/books/NBK572125/
[20] Source: Analysis by Watson Policy Analysis (WPA) using the Medicare Standard Analytic File from CY2015-2021. CPT codes and descriptions are copyrighted by the American Medical Association.
[21] https://www.arthritis.org/health-wellness/healthy-living/managing-pain/pain-relief-solutions/comparing-pain-meds-for-osteoarthritis
[22] Ibid.

PAYMENT ADJUSTMENTS FOR DOMESTICALLY MADE NIOSH-APPROVED SURGICAL N95 MASKS

Finalize the Proposal for an OPPS Payment Adjustment, Do Not Implement in a Budget Neutral Manner

The proposed rule includes a proposal for an OPPS payment adjustment for domestically made, NIOSH-approved surgical N95 masks which is based on comments received in response to the request for information (RFI) in the FY 2023 Inpatient Prospective Payment System (IPPS) proposed rule[23]. We refer the Agency to the Association's comprehensive IPPS proposed rule comments[24] on the initial proposal and the impact of supply chain challenges on teaching hospitals.

Under the proposal, beginning January 1, 2023, CMS would make biweekly interim lump-sum payments to hospitals that purchase domestically made, NIOSH-approved surgical N95 masks. Payment reconciliation would be made at cost report settlement. The AAMC supports the proposal to incentivize U.S.-based manufacturing; however, we continue to stress the need to strengthen current supply chains, specifically the need for more than one supply chain to ensure adequate product supply. Further, we urge the Agency not to apply this proposal under the OPPS in a budget neutral manner. Rather, we urge CMS to find an alternative authority for subsidizing the purchase of domestically made N95 surgical masks that does not require an offsetting reduction in OPPS payments. The AAMC supports the proposal for a hospital to rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 mask meets the proposed definition of domestically made. (p. 44691).

HOSPITAL QUALITY PROVISIONS

OUTPATIENT QUALITY REPORTING PROGRAM

CMS proposes to modify the OP-31 cataracts measure to return the measure to voluntary reporting status for the foreseeable future, an administrative change to align with the calendar year for chart-abstracted measurement, and a request for feedback on the readoption of OP-26 or a similar volume-based measure. The AAMC's comments are as follows.

CMS Should Return to Voluntary Reporting for OP-31 to Reduce Burden on Hospitals

In the CY 2022 rulemaking cycle, CMS finalized a policy to begin requiring hospitals to report OP-31: Visual Function Following Cataracts Surgery beginning with CY 2025 reporting, impacting CY 2027 payment. In this proposed rule, CMS proposes to retain the measure as voluntary effective with CY 2025 reporting, effectively pausing last year's policy. This proposal is in consideration of the reporting burden of the measure given the ongoing COVID-19 PHE. Specifically, CMS notes concerns raised by stakeholders regarding the burden of national staffing and medical supply shortages coupled with changes to patient case volumes. CMS notes that it intends to revisit mandatory reporting of this measure in the future. **The AAMC appreciates CMS's recognition of the COVID-19 PHE's impact on hospital operations and supports this proposal to retain this measure as voluntary to reduce burden.**

[23] 87 FR 28622 through 28625
[24] https://www.aamc.org/media/61361/download

CMS Should Align Patient Encounter Quarters to the Calendar Year

CMS proposes to align the patient encounter quarters with the calendar year for the OQR Program's chart-abstracted measures. Currently, CMS uses encounters occurring from Q2 of 2 years prior to the payment determination year through Q1 of 1 year prior to the payment determination year. Under the proposal, CMS would transition for CY 2025 payment determinations by utilizing only Q2 through Q4 of CY 2023. Then, beginning with CY 2026 payment determinations, CMS would use a full calendar year 2 years prior to the payment determination (which would be CY 2024). **The AAMC agrees that alignment with the calendar year is simpler, and we support this proposed transition.**

Request for Feedback: Reimplementation of OP-26 or Adoption of Another Volume Indicator

CMS seeks feedback on the reimplementation of the OP-26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures or the adoption of another volume indicator. CMS notes that the measure was removed in the CY 2018 rulemaking cycle due to a lack of evidence specific to the measure and improved outcomes, though there is a history of using volume as a simple "proxy for quality rather than directly measuring outcomes."[25]

The AAMC urges CMS to be careful in its consideration of re-adopting OP-26 or some other volume indicator. We believe that going back to a measure that arguably serves as a proxy for quality has several pitfalls. Instead, the focus should be on developing measures that are meaningful to patients and clinicians and that are accessible and comprehensible.[26] In seeking to reintroduce a proxy measure, we believe CMS should consider the following questions to identify meaningful measures: (1) What is it that might make a volume indicator a more comprehensible measure for patients? (2) What do we lose if we return to volume as an indicator of quality without meaningful outcomes measures? **We suggest that CMS focus attention and resources on a two-pronged approach – better understanding what is meaningful and comprehensible for patients and developing measures that fit that bill.**

We appreciate that in making this request for feedback, CMS is looking at the concerns with the burden of reporting the previous OP-26 measure. It is notable that when CMS proposed to remove the measure from the OQR, there was widespread support for the measure's removal.[27] Reporting across several procedural categories[28] is burdensome for hospitals, and it is unclear how the information reported publicly was used to inform patients.[29] This suggests that there might be challenges for CMS in turning procedural volumes reported by hospitals into a coherent metric for public reporting. CMS must weigh the potential benefit of such an indicator with practicalities for measurement and balance those with the

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[25] 87 Fed. Reg. 44502 (July 26, 2022), at 44730.
[26] *See* Jha AK. "Back to the Future: Volume as a Quality Metric," JAMA Forum Archive (June 2015), concluding "[W]e still need to work to develop the measures that are meaningful to patients and clinicians and that are readily available in a way that is accessible and comprehensible."
[27] *See* "Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs", 82 Fed. Reg. 52356 (November 13, 2018), at 52569, stating "Many commenters supported the removal of OP–26 for the CY 2020 payment determination."
[28] *See* Centers for Medicare & Medicaid Services "Final 2012 Policy, Payment Changes for Hospital Outpatient Departments Fact Sheet," (November 2011) which details the HCPCS codes required for reporting under the measure.
[29]*See* CMS Archive April 2015 [hos_archive_05_2015.zip] "Hospital Compare Downloadable Database Data Dictionary," stating on page 56, "Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures **This measure is only found in the downloadable database, it is not displayed on Hospital Compare*." *emphasis added*

known burdens in reporting such information. CMS asks if focusing on specific procedures could reduce burden. As a start, the AAMC suggests that CMS consider testing a measure with a focus on a specific set of procedures to establish whether this approach reduces provider burden and yields information meaningful and useful to beneficiaries.

Finally, we appreciate that CMS has pre-emptively noted that the re-adoption of the OP-26 measure or any other volume indicator in the OQR would need to first go through the pre-rulemaking review process. **The AAMC strongly believes that measures in CMS's quality reporting and performance programs should be endorsed by the National Quality Forum (NQF) and supported by the Measure Applications Partnership (MAP) prior to proposed adoption.** Both the NQF endorsement process and MAP review help ensure that that the measure is valid and reliable and meaningful for adoption in a given CMS quality program.

RFI – Measuring Health care Quality Disparities Across CMS Quality Programs

CMS seeks feedback to inform future rulemaking to support the Agency's goal of addressing disparities, or inequities, in health care outcomes as part of the Agency's broader health equity goals. To do so, CMS presents key principles and approaches for consideration when addressing inequities through quality measurement and stratification. Comments to selected topics raised in the RFI are as follows.

Identifying Goals and Approaches for Measuring Health Care Inequities

The AAMC supports establishing express goals and approaches to measurement as a component of addressing health care inequities. We believe that a critical starting point is to clearly state the role of health care quality and measurement in promoting equity in health care delivered in an acute care setting versus those that are more appropriate to promote health equity and community health. We believe there is valuable overlap in these aims, but also that there are important distinctions that must be made when using quality measurement as a tool for improving equity. Health equity rightfully includes health care but must also evaluate and address broader community resources and needs. More and more evidence show that health care and genetics play a limited role in one's health compared to behavioral, social, and environmental risk factors.[30] Improving quality of care is one of myriad factors within the broader health equity aim. It is an important aspect for evaluating and driving equitable access to high quality care for all patient populations.

We appreciate that in creating a system for measuring health care inequities CMS sets out to establish alignment across CMS programs and provider settings. Consistency across CMS programs ensures that all health care providers can engage in health care equity work and collaborate on solutions. Alignment is also an important tool to reduce provider burden.

CMS currently employs two disparity methods as part of confidential reporting that hospitals receive: (1) Within Hospital and (2) Across Hospital. This reporting currently is based on patient dual-eligibility and statistically imputed race and ethnicity data. **CMS should prioritize expansion of inequity reporting based on the Within Hospital method.** The Within Hospital method is a useful metric for hospitals to understand the inequities within their own setting, so long as it is based on additional data points beyond dual eligibility. (We refer CMS to AAMC comments on the use of dual eligibility as a proxy for social

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[30] *See* National Quality Forum, Social Risk Trial Final Draft Report at 5 (April 19, 2021).

risk in further detail on principles for data selection and in response to the request for feedback to including disparities measurement in the Hospital Readmissions Reduction's performance measurement.) Given differences in case mix and community contexts, comparing inequities across hospitals is a potentially misleading picture and does not inform a hospital's understanding of its own performance as it does not incentivize local progress for health care equity.

Guiding Principles for Selecting and Prioritizing Measures for Inequity Reporting

The AAMC believes that measures should be prioritized for inequity reporting that satisfy the following conditions: (1) existing, validated, reliable clinical quality measures that can be feasibly stratified for disparity measurement; (2) evidence supporting inequities exist when measuring for a specific social risk factor, demographic factor, or community-level characteristic for the clinical quality measure; and (3) valid and reliable data to measure such inequities (i.e., there is sufficient data to stratify measure performance to that social risk factor, demographic factor, or community-level characteristic). Regarding the first criterion, we believe that there should be a prioritization of measures for stratification, focusing first on measures of equitable access to care and equitable health care policies. Then, as the measurement program develops CMS should commit to thoughtfully building a strong foundation to support this work for the long term. In that way health care providers can begin to invest in the necessary infrastructure to understand and respond to inequities measurement, including data collection and reporting.

Principles for Social Risk Factor and Demographic Data Selection and Use

The AAMC believes that measurement of inequities must measure and shine light on the broad mix of factors at play in order to find appropriate solutions. Quality measurement of health care must measure factors which are in the control of providers and help shed light onto the social factors that are outside the realm of health care delivery.[31] The role of improved risk adjustment that addresses clinical, social, and functional status risk factors is crucial for ensuring accurate and fair assessment so that safety net providers are not penalized by losing the very resources they need.[32] We agree with the National Academies, that when measurement is paired with stratification,[33] we can and should ensure that adjustment does not mask inequities, but rather highlights them in a way that points to appropriate intervention and guides investments needed to drive improvement.

We are supportive of CMS proposals to use quality measurement as an incentive for provider screening of health-related social needs (HRSNs). We believe this has the potential to improve data collection of individual-level social risk factors that contribute to inequities and highlight potential intervention points. **We must start by identifying precisely which HRSNs are key and can inform improvement.** However, as we note in our comments to both the request for information on incorporating Z codes into DRG payment and the adoption of new quality measures for the Inpatient Quality Reporting (IQR) Program, CMS should look to align approaches to data collection and use of HRSNs to mitigate burden on providers, including costs associated with data collection.

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[31] *See* National Quality Forum Issues Quality Roadmap for Reducing Healthcare Disparities
[32] *See* the National Quality Forum's framework to develop risk adjustment guidance for CMS, a second report is forthcoming in 2022.
[33] See National Academies of Sciences, Engineering, and Medicine, Accounting for Social Risk Factors in Medicare Payment (2016) at 71, finding a conceptual framework "that social risk factors may influence health care process as well as outcomes of care among Medicare beneficiaries in many interrelated way….At the same time, there are mechanisms through which the health care system can itself ameliorate the impact of social risk factors on quality, outcomes, and cost."

Patient self-reported demographic information is noted as the gold standard, and only such demographic data should be used for measuring inequities. CMS should also be clear that demographics themselves are not actionable risk factors. Furthermore, disparities surveillance does not tap into patient populations' perception[34] of (or the reality of) equitable opportunity for optimal care. Stratified quality measurement's ability to reduce inequities is only as good as the stratification factors used. For example, using dual eligibility and race and ethnicity as proxies for actual social risk factors likely reduces the intended impact because there is no intervention for "Dually Eligible" or "Asian-American". Finally, we support the use of community-level factors such as the area deprivation index, to ensure that we measure inequities for whole communities, in addition to individual social risks. Addressing health care equity through measuring inequities must give us insight into both individual and community-level factors, but hospitals must only be held accountable for those factors which are hospital specific and that hospitals can address, while still being supportive of community activities that address the broader health-related needs.

Identifying Meaningful Performance Differences

The AAMC believes that we must first focus on building the measurement basics for informing intervention. CMS should prioritize valid and reliable measurement that can support hospital improvement at the outset. Understanding meaningful performance differences is a critical component to measurement. With time, and maturity, national or state benchmarking could become a key tool for helping providers understand and contextualize their own performance in relation to that of their peers. Then, even further down the line, CMS could consider additional approaches, such as ranked ordering and percentiles, or defined thresholds, if there is evidence that such approaches can further support improvement and expand our understanding of measure performance.

Guiding Principles for Reporting Inequity Measures

The goal of inequity measurement is to both inform providers of areas where inequities exist and must be addressed and to eventually shine light on provider performance for patients and communities. Confidential reporting should be prioritized as inequity reporting is expanded to meet that first goal of informing providers. Providers and policymakers must agree that they have the data necessary to measure inequities and how measurement informs improvement. Public reporting should not be considered until such agreement is widely accepted. Furthermore, providers should have at least one year of data to understand performance on a given inequity measure before any consideration of public reporting.

The AAMC believes that any public reporting of disparity measure performance is premature at this stage. When implemented in the future it must be meaningful and well understood. Patients and communities must trust the information that is presented to them. CMS should thoughtfully examine the potential unintended consequences of public reporting, including understanding how patients and communities interpret inequity measurement. Public reporting should not place a burden on patients and

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[34] For example, refer to the Minnesota Department of Health's Guild, "HEDA: Conducting a Health Equity Data Analysis," Version 2 (February 2018), which recommends that health equity data analysis (HEDA) requires engaging populations that experience health inequities in the assessment process, including a principle for community engagement that stakeholders must learn about the community's perceptions of those initiating the engagement activities. Additionally, the AAMC Center for Health Justice's "Principles of Trustworthiness" project builds on foundational principle that trust is crucial for equitable community partnerships.

communities to "do their homework" to parse through stratified and non-stratified results to gain a comprehensive understanding of their health care providers.

OVERALL HOSPITAL QUALITY STAR RATING

CMS Should Add a Filter to Allow Patients to Choose to Include Veterans Health Administration (VHA) Hospitals in the Overall Hospital Quality Star Ratings

When CMS codified the Star Ratings program through the formal rulemaking process in the CY2021 OPPS, CMS noted its intention to begin including VHA hospitals in the ratings beginning with the CY 2023 annual update. In this rule, CMS provides an update on projected impacts of inclusion of VHA hospitals in the Overall Quality Star Ratings. Specifically, CMS notes that using the April 2021 update to the Star Ratings for analysis, 119 VHA hospitals would meet the requirements to receive a rating. With the inclusion of VHA hospitals, 213 non-VHA hospitals would have lost a star in that update. Looking at the 5 Measure Group peer group, CMS found that VHA hospitals in that peer group reported a lower median number of Safety and Readmission measures than non-VHA hospitals in the peer group. Finally, CMS found that for several measures, VHA hospitals reported different measure periods than non-VHA hospitals.

The AAMC supports veterans having greater access to quality data and comparisons with non-VHA hospitals to make treatment decisions. However, we are concerned with comparing VHA hospitals with non-VHA hospitals on measures without comparable data and the overall impact on ratings for non-VHA hospitals. The inclusion of VHA hospitals appears to reintroduce bias towards hospitals reporting fewer measures, which is one of the reasons CMS adopted the measure group peer group approach. That the reduced measure reporting bias is focused on the critical Safety and Readmission outcomes measure groups is particularly concerning. The inclusion of VHA hospitals might distort perception of care for non-VHA hospitals as it suggests that the absence of Safety and Readmissions measure scores can be presumed to indicate better quality. We urge CMS to instead consider including VHA hospitals in the Star Ratings as an *option* on the Compare website. This would allow veterans the opportunity to compare VHA hospitals and non-VHA hospitals, while broadly allowing patients without access to VHA hospitals the default option to see ratings without VHA hospitals.

CMS Should Further Clarify the Data Used for Annual Updates to the Ratings

Regarding the frequency of publication and data used in the Star Ratings, CMS proposes to amend § 412.190(c) to replace "from a *quarter in the prior year*" with "from a *quarter within the previous 12 months* [emphasis added]."[35] CMS believes this clarifies their intention that the data used be from any time within the prior 12 months, and not to a Care Compare refresh from the prior calendar year.

The AAMC appreciates CMS's intention to clarify. However, we believe the proposed change and discussion within the rule may create *further* confusion. CMS provides the following example "for the Overall Quality Star Ratings in July 2023, we would use any Care Compare refreshes from the previous 12 months: July 2023, April 2023, January 2022, October 2022, or July 2022."[36] We believe that the example's reference to five quarterly refreshes in a 12-month period is not intuitive as one generally

[35] 87 Fed. Reg. at 44808.
[36] *Ibid.*

assumes there are four, not five, quarters in a given time period. Of greater concern is that CMS noted that its intention to use data from a prior Care Compare refresh was to ensure hospitals had more time with the underlying measure results in the CY 2020 proposal of the original "prior year" policy.[37] The example in this year's rulemaking suggests that CMS no longer holds that intention, as it includes the simultaneous refresh of new measure results as a potential underlying data set for the annual update to the Overall Star Rating. We ask CMS to provide greater discussion on this change in policy. If CMS does indeed wish to include measure results from the concurrent Care Compare refresh as possible data used for the annual update, it should consider further clarification to the regulatory text to this point.

CMS Should Provide Transparency Regarding Impacts of the COVID-19 PHE on Ratings

CMS reiterates the suppression policy it adopted in the CY 2021 rulemaking cycle, including the potential suppression of the ratings in a year where a Public Health Emergency substantially affects the underlying measure data. CMS notes that although the agency intends to publish the ratings in CY 2023, it may exercise the option to suppress the ratings should the COVID-19 PHE substantially affect the underlying measure data available for update. The AAMC appreciates CMS's review of the suppression policy and its commitment to best understand the impacts of the COVID-19 PHE on underlying measure data before deciding to update the ratings again in CY 2023. If CMS does publish an update to the Star Ratings next year, we ask CMS to be transparent regarding any impacts on the ratings (i.e., reduced number of hospitals meeting requirements to receive a rating or reduced measures/measurement periods available for scoring in certain measure groups, etc.) due to the effects of the COVID-19 PHE on the underlying measure data. CMS should test ratings and any associated disclaimer explanation on their beneficiary user groups to better understand how patients interpret the pandemic's impact on quality information.

CONCLUSION

Thank you for the opportunity to comment on the CY 2023 OPPS proposed rule. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic medical community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at mmullaney@aamc.org for questions on the payment policy proposals and Phoebe Ramsey at pramsey@aamc.org for questions on the quality proposals.

Sincerely,

Rosha C. McCoy MD

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Acting Chief Health Care Officer

cc: David J. Skorton, M.D., AAMC CEO and President
Ivy Baer, JD, MPH, Senior Director and Regulatory Counsel

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[37] *See* 85 Fed. Reg. 48772 (August 12, 2020) at 49026, stating "This proposal [for a 30-day preview period] as well as the proposal to report Overall Star Rating annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year would allow hospitals more time to review and understand the methodology and their results, as well as reach out with questions."