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October 5, 2020

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
ATTN: CMS-1736-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

***Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1736-P)***

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the proposed rule entitled “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs,” 85 *Fed. Reg.* 48772 (August 12, 2020), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a not-for-profit association dedicated to transforming health care through medical education, patient care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC appreciates CMS’ efforts to reduce regulatory burden on hospitals during the public health emergency (PHE) and the proposals included in this proposed rule that aim to make permanent some of the regulatory flexibilities offered during the PHE. These flexibilities have allowed AAMC member teaching hospitals and physicians to meet the needs of their communities during the PHE. We applaud CMS for acting so quickly during the initial phases of the pandemic to improve care delivery to patients. We believe that many of these flexibilities have led to improved access and opportunities for care delivery.

However, the AAMC has several serious concerns on the proposed rule. The AAMC continues to oppose reimbursement cuts for 340B-acquired drugs and believes that CMS does not have the legal authority to make these cuts. Further reductions to the reimbursement for 340B-acquired drugs will negatively impact safety net hospitals’ ability to serve their vulnerable communities, as was intended when the 340B Drug Pricing Program (340B Program) was established. Additionally, we

feel the proposals to eliminate the inpatient only (IPO) list and Ambulatory Surgical Center Covered Procedures List (ASC-CPL) inappropriately present quality, safety, and cost-sharing implications for beneficiaries as more complex procedures are performed in settings with limited or unknown quality and safety measures in place. We urge CMS not to eliminate the IPO list and to not remove ASC-CPL exclusion criteria.

The AAMC thanks CMS for this opportunity to comment on these proposals and has detailed its concerns on these issues in the sections that follow.

## **PAYMENT POLICIES**

- **340B Drug Pricing Program.** The 340B survey does not accurately reflect the hospitals that participate in the 340B Program and should not be used as the basis for further reimbursement cuts. We continue to believe that CMS does not have the legal authority to impose cuts on only a subset of hospitals participating in OPSS and we strongly oppose reimbursement cuts to hospitals for 340B-acquired drugs. These efforts by CMS subvert the congressional intent of the 340B Program that allows safety-net hospitals to invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients at no cost to taxpayers.
- **Inpatient Only List.** CMS should delay finalizing the elimination of the IPO List and solicit stakeholder feedback to evaluate which procedures are appropriate to be performed in the outpatient setting to ensure beneficiary safety and successful outcomes.
- **Ambulatory Surgical Center Covered Procedures List.** CMS should not remove the proposed exclusion criteria for the ASC-CPL in consideration of numerous oversight, quality, and safety concerns. Additionally, we support establishing a stakeholder nomination process to add procedures to the ASC-CPL through annual notice and comment rulemaking.
- **Prior Authorization.** CMS should not finalize prior authorization requirements for cervical fusion with disc removal and implanted spinal neurostimulators.
- **Site-Neutral Payment Policy.** We continue to believe that the non-budget neutral payment cut for clinic visits furnished by excepted off-campus provider-based departments (PBDs) is unlawful and causes undue harm to hospitals and the communities they serve. In addition, these actions are in direct contradiction to congressional actions on site neutral payment policies.
- **Wage Index.** CMS should continue to work with stakeholders to develop comprehensive wage index reform. CMS should not adopt proposed changes to the labor market delineations outlined in Office of Management and Budget (OMB) Bulletin No. 18-04.
- **COVID-19 Specimen Collection.** We support CMS' proposal to continue payment for COVID-19 specimen collection for calendar year (CY) 2021 using HCPCS code C9803 and Ambulatory Payment Classification (APC) 5371 with status indicator "Q1." CMS should also make payment for COVID-19 specimen collection permanent, even after the PHE ends to ensure hospitals are adequately compensated.

- ***Levels of Supervision Changes in Hospitals.*** AAMC supports permanently changing the minimal level of supervision to general supervision for non-surgical extended duration therapeutic services (NSEDTS). We also support permanently allowing hospitals and critical access hospitals (CAHs) to meet direct supervision requirements through interactive real-time audio/video communications technology for select rehabilitation services, and request CMS consider expanding this policy to standalone, non-hospital outpatient department (HOPD) providers in rural settings.
- ***Physician-Owned Hospitals.*** We urge CMS not to finalize the proposal to remove limitations for certain physician-owned hospitals that expand under the “whole-hospital” exception to the Physician Self-Referral (Stark) law. In addition, CMS should not remove the community input requirement as it provides transparency and accountability to stakeholders in the community.

### **OUTPATIENT QUALITY REPORTING PROGRAM / QUALITY STAR RATINGS**

- ***Develop an Alternative Approach to Overall Composite Star Ratings.*** The AAMC recommends CMS provide ratings on specific clinical conditions or areas that would be more meaningful and actionable for patients and consumers, and also for the hospital’s quality improvement efforts rather than using a single composite score rating.
- ***Improve Underlying Quality Measures.*** The AAMC urges CMS to improve existing measures in the hospital quality reporting and performance programs, including social and functional status-related risk adjustment, and to remove measures with serious flaws, such as the PSI-90 measure, from the Star Ratings.
- ***Scoring Measure Groups with an Explicit Approach.*** The AAMC at this time supports scoring measure groups based on an explicit simple-averages approach to replace the Latent Variable Modeling method in order to improve patient and hospital understanding of the methodology, increase transparency into rating calculations, and prevent significant or unexpected fluctuations in ratings that are explained by factors unrelated to changes in performance. We believe though that CMS should explore other methodologies that may more closely provide appropriate comparisons of quality of care such as the template matching.
- ***Stratifying the Readmission Measure Group.*** The AAMC supports aligning the scoring stratification of the Hospital Readmission Reduction Program with the scoring of the Readmission measure group and continues to urge CMS to invest in improving measure-level risk adjustment models to appropriately account for social risk factors.
- ***Peer Grouping.*** The AAMC as this time supports peer grouping ratings based upon the number of measure groups a hospital reports on and believes stratified comparisons are useful to hospital stakeholders for quality improvement activities and to provide patients a more nuanced overall comparison of hospitals that are more similar to one another.
- ***Assigning Ratings Based on Fixed Targets.*** The AAMC asks CMS to consider and model improvements to the k-means clustering method for assigning stars to create predictable, fixed targets.
- ***Future Methodology Improvements to Help Patients Differentiate High Quality Hospitals.*** The AAMC urges CMS to continue to explore improvements based on further reliability and

validity analysis, such as the template matching, which would give patients a more accurate picture of hospital quality through direct patient comparison groups, as well as ways to support patient values through the potential for user-customization approaches.

### **340B DRUG PRICING PROGRAM**

CMS is proposing to further reduce reimbursement for separately payable drugs paid under the OPPS and acquired through the 340B Program beginning January 1, 2021. CMS is basing this reduction on a Spring 2020 survey sent to 340B hospitals during the PHE for which the Agency received responses from slightly more than half of the hospitals surveyed. As we note below, this survey does not accurately reflect the hospitals that participate in the 340B Program nor the drugs acquired under the 340B Program and should not be the basis of further reimbursement cuts. Additionally, we call on CMS to be transparent about the methodology and data it uses to calculate the budget neutrality adjustment so stakeholders can replicate their proposals to ensure that they are correct. **Because of these concerns, it is the AAMC's belief and position in its ongoing litigation that CMS does not have the legal authority to impose cuts on only a subset of hospitals participating in OPPS, and we continue to strongly oppose reimbursement cuts to hospitals for 340B-acquired drugs.**

#### ***Survey Should Not Be the Basis for Imposing Cuts on 340B 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. Based on CMS' analysis of the results of this survey, CMS claims that the "typical acquisition cost for 340B drugs for hospitals paid under the OPPS is average sales price (ASP) minus 34.7 percent." (p. 48886). CMS is proposing an add-on payment of 6 percent of ASP for services associated with drug acquisition that are not separately paid for, such as handling, storage, and other overhead. Therefore, CMS is proposing a net reimbursement of ASP minus 28.7 percent for 340B-acquired drugs beginning January 1, 2021, an increased cut from the current ASP minus 22.5 percent.

**CMS should not base reimbursement on the results of the survey. The survey had a poor response rate as hospitals were focused on battling the PHE and, therefore, does not adequately reflect all 340B hospitals.** Furthermore, Congress did not design the 340B Program to pay hospitals at acquisition costs. Rather, the program allows eligible hospitals to purchase covered drugs at a discounted rate below the reimbursement rate – whether the payer be Medicare or in the case of non-Medicare beneficiaries, a commercial insurer – and use the difference to generate funds that will be used to reach vulnerable patients by making more services available to them. Consistent with the intent of the program safety-net hospitals invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients at no cost to taxpayers. Furthermore, we are concerned that CMS may have prejudged the results of the data survey since it stated in the OPPS CY 2020 final rule that “[w]e thus anticipate that the survey data

collected for CY 2018 and 2019 will confirm that the ASP minus 22.5 percent is a conservative measure that overcompensates 340B hospitals.”<sup>1</sup>

### ***CMS Needs to Be Transparent About the Data and Methodology Used to Determine Cuts to 340B Hospitals***

CMS continues to assume that all drugs purchased by 340B participating hospitals are acquired under the 340B Program; however, that is not the case. Not every patient that receives treatment at a 340B covered entity is eligible to receive 340B drugs.<sup>2</sup> Moreover, year to year changes in drug utilization, drug mix and drug prices should be reflected in the updated data. CMS acknowledged this in the CY 2018 OPPTS final rule by noting that “provider behavior” and “overall market changes...would likely lower the impact of the payment reduction.”<sup>3</sup> The AAMC is concerned that CMS is building on a faulty model and may be compounding errors that were made in the original calculations and assumptions. **The AAMC urges CMS to release the data and assumptions it uses in its methodology to calculate the 340B-acquired drug reimbursement reductions so stakeholders can confirm CMS’ calculations. Finally, the AAMC notes that the budget neutrality factor has not been updated since 2018.**

### **INPATIENT ONLY LIST**

CMS is proposing to eliminate the IPO list over three years beginning January 1, 2021. CMS states in the proposed rule “we no longer believe there is a need for the IPO list in order to identify services that require inpatient care.” (p. 48909). CMS goes on to say that it agrees that “the physician should use his or her clinical knowledge and judgment, together with the beneficiary’s specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient department or whether inpatient care is required.” (p. 48909). We agree that the decision of the appropriate setting for a service should rest with the treating physician in consultation with the beneficiary, accounting for many complex factors, including the condition of the beneficiary and the availability of adequate post-procedure care.

CMS does not provide the reasoning for eliminating the IPO list in the proposed rule. Moreover, the proposed 3-year timeline to eliminate the IPO list is inadequate to fully assess the impact of moving certain procedures to the outpatient setting. In the past, CMS has solicited stakeholder feedback for the removal of procedures from the IPO list. As technology changes to allow for more procedures to be performed in the outpatient setting, the IPO list has been modified to accommodate these changes. We believe this process should continue. **Therefore, we urge CMS to delay finalizing the elimination of the IPO list and solicit stakeholder feedback to comprehensively evaluate which procedures should remain in the inpatient setting given concerns about beneficiary safety and outcomes, and evolving standards of care.** These procedures should be reviewed and updated based on stakeholder feedback on an annual basis.

Many of the procedures listed in Table 31 (p. 48912 – 48934) are invasive and could require significant post-procedure monitoring. In other words, patients undergoing these procedures would

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<sup>1</sup> 84 *Fed. Reg.* 61322.

<sup>2</sup> 61 *Fed. Reg.* 55156 - 55158.

<sup>3</sup> 82 *Fed. Reg.* 52623.

best be served having inpatient care. We believe that if CMS chooses to finalize the elimination of the IPO list, CMS should continue to identify procedures that should only be performed in the inpatient setting, due to their complexity and need for significant post-procedure medical monitoring. **We feel physician deference on site of service should always be provided for these procedures and they should be exempt from medical reviews for site of service and the 2-midnight requirement for an inpatient admission as long as they are on the list of inpatient procedures.**

*Identify Procedures that Should Not be Subject to Medical and Site-of-Service Reviews*

Under current policy, Medicare Part A will pay for inpatient surgical procedures, diagnostic tests, and other treatments when the physician expects the patient to require an inpatient stay that crosses at least 2 midnights and admits the patient based on this expectation or the physician determines the patient requires inpatient care. (p. 48936-48937). Physician documentation in the medical record must support that the patient will require hospital care spanning at least 2 midnights, or the physician's determination that the patient requires inpatient care. Services on the IPO list are not subject to the 2-midnight policy and are paid under Medicare Part A regardless of the expected length of stay. CMS is proposing to exempt for two years site-of-service claims reviews for procedures removed from the IPO list. (p. 48939). The proposed rule also solicits comments on whether the 2-year exemption period for site-of-service claims denial is appropriate or whether a longer or shorter exemption period would be more appropriate. (p. 48939). As we note below, we understand that the record must document medical necessity but believe that the medical reviews for site of service should continue to defer to the physician's judgment when the procedure is one that is only appropriate to provide on an inpatient basis. Furthermore, the AAMC suggests that CMS identify procedures for which the physician is given automatic deference regarding the site of service and the 2-midnight requirement would not be applied. For example, it is hard to imagine that a coronary artery bypass graft (CABG) or a heart or liver transplant should ever be subject to the 2- midnight rule. CMS should work with stakeholders to identify a list of procedures that should never be subject to the 2-midnight rule and for which it makes sense to rely on physician judgement for site-of-service determinations. At a minimum, such procedures would be those that have an average length of stay of 2 days or more or are performed on an inpatient basis more than a threshold percentage of the time (e.g. 70 or more percent). If there is a time when they become routinely performed on an outpatient basis, consideration would then be given as to whether to remove them from the list.

CMS states in the proposed rule that it will encourage the Beneficiary and Family-Centered Care-Quality Improvement Organizations (BFCC-QIOs) to continue to review cases during the 2-year exemption period to "educate themselves and the provider community to appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis." (p. 48939). However, if these reviews continue to be performed during the 2-year exemption period, CMS should use the information to determine which procedures should only be performed in the inpatient setting and make the information publicly available to stakeholders to better inform patients and providers which surgical procedures are best performed only in the inpatient setting.

***Develop a Process to Identify Procedures that Should Not Be Performed in the Outpatient Setting Based on Considerations of Patient Safety and Quality of Care***

CMS acknowledges in the proposed rule “the seriousness of concerns regarding patient safety and quality of care” voiced by stakeholders if the IPO list is eliminated. (p. 48910). CMS believes that there currently are a variety of safeguards – state and local licensure requirements, accreditation requirements, Conditions of Participation – that serve to ensure patient safety even in the absence of the IPO list. (p. 48910). The AAMC agrees that these safeguards are important, but they are insufficient to assess patient safety and quality, which is why the Association recommends that CMS not eliminate the IPO list, as discussed above, to ensure patient safety and quality of care.

Procedures are performed in the inpatient setting due to factors including the complex nature of the procedure, the overall medical condition of the patient, and the need for significant clinical monitoring post procedure. The AAMC suggests that CMS continue evaluating which procedures and treatments are shown to be safely and successfully performed in the outpatient setting as medical technology advances to allow for a change in site-of-service. CMS should not finalize the proposal to eliminate the IPO list over the next 3 years but should work with stakeholders to identify a transparent process to identify procedures that should be performed in the inpatient setting and should not be subject to the 2-midnight rule.

***Ensure that Alternative Payment Models Are Not Negatively Impacted by Eliminating the IPO List***

We support CMS’ commitment to monitor whether the elimination of the IPO list may impact CMS Innovation Center models. (p. 48939). AAMC members are engaged in all the bundled payment models offered through the CMS Innovation Center. In addition to ensuring that patients are appropriately screened to have the procedure performed in the outpatient setting, the AAMC is concerned that eliminating the IPO list would create undue significant negative financial implications for hospitals participating in the Bundled Payments for Care Improvement (BPCI) Advanced, Comprehensive Care for Joint Replacement (CJR), and future bundled payment programs. CMS should ensure that changes to the IPO list do not unfairly penalize model participants.

***Elimination of the IPO List Could Impact Target Prices for BPCI Advanced and CJR***

The BPCI Advanced and CJR baseline periods include a subset of Medicare fee-for-service cases that could have been performed as outpatient procedures, if outpatient procedures had been allowed during that period. CMS’ proposal to permit procedures to be reimbursed under OPSS as well as IPPS may significantly alter the composition of BPCI Advanced and CJR participant hospitals’ patient populations, and thus unfairly hinder hospitals’ ability to generate savings under the models. CMS has noted in the past that younger, healthier patients and those with at-home assistance, are more likely to undergo outpatient procedures, meaning a higher proportion of patients receiving inpatient services would be higher-risk and more likely to require additional post-acute care support. As a result, this change in patient mix could increase the average episode payment of the remaining inpatient BPCI Advanced and CJR cases when compared to current payment levels. Because the episode payments for the remaining inpatient services are reconciled against the baseline target price calculated using both inpatient and outpatient eligible procedures, the remaining inpatient cases would appear artificially high relative to the target price. Consequently,

hospitals would be more likely to sustain losses in the BPCI Advanced and CJR models. In the absence of sufficient risk adjustment to modify target prices to reflect CMS' proposed change, some BPCI Advanced hospitals may voluntarily leave the program prior to its conclusion in order to mitigate financial losses. CMS should work to ensure that BPCI Advanced and CJR participants are not negatively impacted with the elimination of the IPO list.

## **AMBULATORY SURGICAL CENTER COVERED PROCEDURES LIST**

CMS proposes significant changes to the ASC-CPL that would modify both the current inclusion and exclusion criteria for any surgical procedures considered for the list, removing important guardrails that are already in place. The ASC-CPL identifies separately payable procedures that can be safely performed in an ASC and would typically not require active medical care or monitoring at midnight following the procedure. (p. 48957). The current criteria generally exclude surgical procedures from the list that are prolonged, high risk, or directly involve major blood vessels. While CMS has offered two alternative proposals to the current criteria, both proposals would eliminate several exclusion criteria. CMS would either continue the current process where it identifies procedures to be added to the ASC-CPL or use a public nomination process to identify which procedures are proposed to be added to the ASC-CPL. Under either process, annual rulemaking would continue to be used to determine which procedures are ultimately eligible for payment in the ASC. If the Agency continues with the current process, it proposes to add 267 procedures to the list for CY 2021. (p. 48957). If CMS adopts the public nomination process, only those procedures publicly nominated during 2021 as part of the annual CY 2022 rulemaking process would be added to the ASC-CPL beginning in CY 2022 (other than the 11 procedures CMS proposed to add to the ASC-CPL under current policy). As CMS considers allowing more procedures and treatments to be performed in ASCs, it must take into account that not all procedures are suitable to be furnished in the ASC setting. The AAMC prefers the proposed nomination process conducted through annual notice and comment rulemaking but, as described below, has significant concerns with details of the proposed changes. We urge CMS not to eliminate current exclusion criteria specified in both alternative proposals, regardless of the alternative finalized by the Agency in the interest of continued patient safety.

### ***HOPDs Are Better Equipped to Furnish Higher Complexity Services***

Patients seeking care at HOPDs, particularly those at teaching hospitals, tend to be sicker and have more chronic and complex conditions. These HOPDs are frequently the sole sources of care for low-income and otherwise underserved populations, and are also equipped and staffed to perform complex surgical procedures and furnish advanced treatments to a wide variety of patients. Furthermore, these HOPDs can also provide overnight post-procedure monitoring when needed. They are also subject to many regulatory requirements that do not apply to ASCs or physicians' offices. If patients require emergency care, highly trained medical response teams are readily available.

By contrast, ASCs are distinct entities that furnish ambulatory surgical services not requiring an overnight stay in a hospital. The most common ASC procedures are cataract removal with lens



insertion, upper gastrointestinal endoscopy, colonoscopy, and nerve procedures.<sup>4</sup> If a patient requires emergency care while undergoing care at an ASC, 9-1-1 must be activated and the patient transferred to a hospital emergency department, potentially delaying life-saving interventions.

The AAMC is concerned that eliminating the current exclusion criteria could result in complicated procedures being inappropriately performed in the ASC setting, negatively impacting patient safety and outcomes. CMS feels that even if current exclusion criteria are removed, the general criteria that remain in place will act as a limited safeguard to ensure procedures are not added to the CPL prematurely. (p. 48960). The AAMC does not agree. We are concerned that the general criteria will not provide sufficient safeguards to ensure patient safety and removing exclusion criteria could increase safety risks to patients. For example, for a procedure to be performed in an ASC, the patient would not require active medical monitoring at midnight on the day of the procedure. We feel that there are numerous procedures listed on Table 41, such as modified radical mastectomy,<sup>5</sup> that could be considered invasive and thereby may present safety risks to patients who are not suitable candidates to have certain procedures performed in the ASC. Additionally, some ASCs are not equipped to handle complex patients who could require significant post-procedure monitoring. For example, some ASCs require the patient to stay post procedure in a local hotel and the patient is seen again in the morning. These unusual situations do not provide appropriate post-procedure monitoring for patient safety. In reviewing this list, CMS must consider not only the ability to do the procedure but the additional need for post-operative monitoring based on the procedure and the patient's age and comorbidities. For these reasons, we urge CMS to not allow complicated procedures to be performed in the ASC until such time as clinical experts determine that these procedures can be performed safely in the ASC setting and that patients are able to be safely discharged to home after the procedure.

***Do Not Eliminate Current Exclusion Criteria and Adopt a Nomination Process for Additions to the ASC-CPL***

Both of CMS' alternative proposals would remove current ASC-CPL exclusion criteria that prohibit procedures which: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; and (5) commonly require systemic thrombolytic therapy.<sup>6</sup> Alternative Proposal One would remove these exclusion criteria and allow stakeholders to nominate procedures for inclusion on the ASC-CPL, while Alternative Proposal Two would remove the exclusion criteria and add the 267 procedures in Table 41 of the proposed rule for CY 2021. (p. 48958-48961, 48964). The AAMC does not support the removal of the exclusion criteria. If CMS chooses to finalize and adopt one of the alternatives as proposed, the AAMC would prefer that CMS adopt Alternative Proposal One's nomination process that would also leverage the notice and comment rulemaking process rather than simply shifting 267 procedures to the ASC-CPL in CY 2021 without stakeholder input. We feel that Alternative Proposal Two would create more significant issues related to patient

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<sup>4</sup> MedPAC, "A Data Book: Health care spending and the Medicare program," July 2020. Available at: [http://www.medpac.gov/docs/default-source/data-book/july2020\\_databook\\_sec7\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/data-book/july2020_databook_sec7_sec.pdf?sfvrsn=0).

<sup>5</sup> HCPCS Code 19307 (Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle).

<sup>6</sup> 42 C.F.R. § 416.166 (1)-(5).

safety, quality of care, and beneficiary coinsurance liability without sufficient time for the public to scrutinize the large number of procedures being added to the ASC-CPL.

### ***ASC Oversight is Severely Limited***

ASCs are also subject to considerably less stringent regulation and oversight. For example, ASCs are not subject to the Stark laws' prohibition on physician self-referrals; however, roughly 65 percent of ASCs are solely owned by physicians, and up to 90 percent are at least partially owned by physicians,<sup>7</sup> highlighting the need for more, rather than less, restrictive exclusion criteria to protect patients. In consideration of either proposal, CMS must consider the risk of patients being referred for procedures in a physician-owned ASC when a hospital outpatient or inpatient stay would be more appropriate for a patient's clinical circumstances.

Moreover, current quality and safety reporting required through the ASC Quality Reporting (ASCQR) Program is not comparable to Hospital Outpatient Quality Reporting (OQR) standards and measures. In fact, as CMS points out in the proposed rule, in the CY 2019 OPPTS/ASC final rule with comment<sup>8</sup> CMS suspended important quality reporting measures from the ASCQR – patient burn, patient fall, wrong site/side/patient/procedure/implant, and hospital transfer/admission<sup>9</sup> – until CY 2024. The suspended measures, however, are critical: they provide important data and transparency regarding clinical outcomes, patient safety, and quality at physician-owned ASCs. The AAMC believes these measures should remain as more procedures are performed at ASCs. (p. 48993). As we outline below, these measures are significant to ensure patient safety in the ASC setting, as they capture serious events and consequences to patients that are not otherwise meaningfully shared.

While CMS acknowledges the importance of these critical ASC measures and intends to reinstate them for CY 2024, the CY 2021 payment determinations currently in place for the ASCQR Program are woefully limited.<sup>10</sup> (p. 48994). Not requiring these measures means that CMS is not capturing potential patient harm at physician-owned ASCs, which is more concerning because over the next three years – while these measures remain suspended for ASCs – CMS proposes to eliminate the IPO list. As more than 1,700 procedures are removed from the IPO list and become eligible for inclusion in the ASC-CPL, CMS must reinstate the suspended measures to ensure patient safety, quality, and outcomes. At a minimum, if CMS finalizes the proposal to remove these procedures from the IPO list, the suspended measures must be reinstated through CY 2024 to capture important clinical information, until the measures are again required as part of the ASCQR payment determination.

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<sup>7</sup> Journal of Spine Surgery, "Ambulatory Surgical Center Ownership Models," Sep. 5, 2019. Accessed on Sep. 11, 2020 at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6790806/>.

<sup>8</sup> 83 *Fed. Reg.* 59117 through 59123 and 83 *Fed. Reg.* 59134 through 59135.

<sup>9</sup> ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission.

<sup>10</sup> ASC-9 Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; ASC-12 Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; ASC-13 Normothermia; ASC-14 Unplanned Anterior Vitrectomy.

Additionally, CMS should consider the impact of its decision to no longer require written transfer agreements and hospital physician admitting privileges. As we noted in previous comments,<sup>11</sup> without transfer agreements patients are transported to emergency departments with limited information about the reason for transfer instead of being directly admitted to the hospital. Further, not requiring admitting privileges for physicians performing surgery at ASCs bypasses hospitals' credentialing policies that are in place to ensure patient safety and access to high-quality care. If the Agency intends to add hundreds of procedures to the ASC-CPL this year, and more in coming years, it should reinstate these requirements.

**For these reasons, CMS should not eliminate the current exclusion criteria under either proposal. However, if CMS does elect to eliminate the exclusion criteria, the AAMC urges the Agency to reinstate critical quality and safety reporting requirements and establish additional ASC conditions for coverage and other safeguards to ensure patients are adequately informed and protected.** As further protection for patients CMS should require physicians to inform patients of the risks of having a procedure in the ASC rather than in an HOPD; in effect, this could become part of the informed consent process. For instance, the physician would need to discuss actions that would be taken in the case of an adverse event or the need for extended post-procedure monitoring which could not be performed in the ASC.

#### *Consider Impact on Beneficiary Coinsurance Liabilities for Procedures Performed in ASCs*

Finally, for both proposals the AAMC reiterates its previous comments<sup>12</sup> that CMS should consider the additional beneficiary cost-sharing in the ASC setting. While Medicare's overall costs may be lower in the ASC for some procedures, beneficiaries are not protected from cost-sharing liabilities in the ASC setting as they are in the HOPD. Currently, a beneficiary's cost-sharing liability is limited to the Part A deductible<sup>13</sup> for a service performed in the HOPD. There is no such protection in the ASC where beneficiary coinsurance for the procedure itself may be less, but beneficiaries pay coinsurance for each separate service. For example, beneficiaries who choose to have a total hip arthroplasty (THA) in an ASC would have higher cost-sharing than if that same procedure was performed in an HOPD. In HOPDs the beneficiary cost sharing for THA in CY 2021 would be \$1,408<sup>14</sup> for a single procedure due to the cap on beneficiary coinsurance. In contrast, beneficiaries receiving care in ASCs, on average, would pay at least \$1,784.79 for the same procedure, as well as additional coinsurance for separately paid ancillary services integral to the surgical procedure.<sup>15</sup> In adding procedures to the ASC list under either proposal CMS should carefully consider that beneficiaries are protected from additional cost sharing liability.

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<sup>11</sup> See "AAMC Comments on Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, CMS-3346-P," Nov. 19, 2018. Available at: <https://www.aamc.org/system/files/c/1/493598-aamccommentsonmedicareandmedicaidprogramsregulatoryprovisionsto.pdf>.

<sup>12</sup> See "AAMC Comments: CY 2020 OPSS Proposed Rule," Sep. 27, 2019. Available at: [https://www.aamc.org/system/files/2019-09/ocomm-org-FINALAAMCCY2020OPSSProposedRuleCommentLetter%209\\_26%20%282%29.pdf](https://www.aamc.org/system/files/2019-09/ocomm-org-FINALAAMCCY2020OPSSProposedRuleCommentLetter%209_26%20%282%29.pdf).

<sup>13</sup> Medicare.Gov, "Outpatient Hospital Services." Accessed on Sept. 11, 2020. Available at: <https://www.medicare.gov/coverage/outpatient-hospital-services>.

<sup>14</sup> 84 Fed. Reg. 61619, 61620.

<sup>15</sup> CY 2021 OPSS Proposed Rule, "Addendum AA: HCPCS Code 27130 Total hip arthroplasty," Jul. 24, 2020. Accessed on Sept. 15, 2020 at: <https://www.cms.gov/medicare/medicare-fee-service-payment/ascpaymentasc-regulations-and-notices/cms-1736-p>.

## **PRIOR AUTHORIZATION REQUIREMENTS FOR ADDITIONAL HOSPITAL OUTPATIENT DEPARTMENT SERVICES**

In the CY 2020 OPPTS/ASC final rule, CMS established the prior authorization process for certain HOPD services as a “method for controlling unnecessary increases in the volume of covered OPD services.”<sup>16</sup> (p. 49027). For CY 2021, CMS is proposing to expand the prior authorization requirements for certain HOPD services to include cervical fusion with disc removal and implanted spinal neurostimulators. (p. 49028). CMS asserts that review of the Integrated Data Repository (IDR) data has shown an increase in utilization of these procedures. The Agency believes prior authorization for these services is required because the increases in these services are not only unnecessary but also it believes there is no legitimate clinical or coding reasons for these changes. (p. 49029). If finalized, these procedures would be required to receive prior authorization in order to be eligible for coverage under the OPPTS beginning July 1, 2021. **We urge CMS not to finalize this proposal that could potentially limit beneficiaries’ access to needed medical care and increase burden on providers.** Furthermore, there will continue to be increases in outpatient services as more procedures are performed in the outpatient setting. As CMS expands prior authorization requirements based solely on increases in services, then it is possible that more services will be subject to prior authorization requirements, particularly in light of CMS’ proposal to eliminate the IPO list.

Prior authorization is a utilization management tool that payers often use to manage utilization of certain services. However, prior authorization often causes delays in patients’ ability to receive timely, medically necessary care and imposes additional administrative burden on providers by requiring providers to manually navigate time-consuming requirements. The American Medical Association surveyed 1,000 practicing physicians regarding their experience with prior authorization; 83 percent reported that prior authorization interferes with continuity of care including missed medications and interruptions in chronic treatment.<sup>17</sup> As we note below, these surgical procedures that would require prior authorization are often used to relieve chronic pain when other non-surgical options were unsuccessful, including as an alternative to prescription medicines such as opioids.

Furthermore, we believe that instituting prior authorization does not support the Agency’s goal of reducing provider burden, which CMS has acknowledged has been particularly challenging during this PHE when hospitals and outpatient departments struggle to meet the needs of their communities. The Agency should evaluate the process and clinical workflow factors contributing to the burden associated with prior authorization to see how these factors can be reduced.

### ***There Are Valid Reasons for the Increased Utilization of Certain HOPD Services***

More items and services are furnished in HOPDs due in part to advances in technology that allow more items and services to be safely performed there rather than in another setting. Depending on factors such as a beneficiary’s medical condition, and the need for post-procedure monitoring, an HOPD may be the optimal setting. To date, CMS has relied on an increase in volume as justification for a prior authorization requirement. However, there are many possible explanations to account for

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<sup>16</sup> 84 Fed. Reg. 61446 - 61465.

<sup>17</sup> American Medical Association. Measuring progress in improving prior authorization. Update 2019. <https://www.ama-assn.org/system/files/2020-06/prior-authorization-reform-progress-update-2019.pdf>.

the volume increase, including regulatory changes to Medicare requirements, such as the proposal to eliminate the IPO list, that influence the shift of services from the inpatient to the outpatient setting. In combination with the increase in the number of Medicare beneficiaries, it appears only natural that there would be an increase in the number of outpatient services. Rather than continue to rely on volume increases to determine which services require prior authorization, the AAMC urges CMS to develop a transparent process that will allow for the evaluation of all factors that contribute to increases in services to decide when to impose a prior authorization requirement. This will continue to ensure beneficiary access to needed medical services and will ensure that the administrative burden on physicians does not become overwhelming.

### ***Implanted Spinal Neurostimulators and Cervical Fusion with Disc Removal Treat Chronic Pain***

Chronic pain affects between 28 percent to 65 percent of U.S. adults. The World Health Organization estimates that 22 percent of the world's primary care patients have chronic debilitating pain making chronic pain a problem to be addressed by all physicians and health professionals.<sup>18</sup> Chronic pain is one of the most common reasons adults seek medical care. Prescription medications, such as opioids, have been used to manage chronic pain. However, the increase in the prescribing of opioid pain medications in recent decades has contributed to an increase in addiction to opioids and overdose deaths. Alternative therapies have been sought to limit dependence on opioids and other medications to treat chronic pain. In its efforts to fight the opioid epidemic, CMS recently approved Medicare coverage for acupuncture to treat low back pain for Medicare beneficiaries.<sup>19</sup>

Cervical fusion with disc removal and implanted spinal neurostimulator are used to treat chronic pain when non-surgical pain management treatments have been unsuccessful and to lessen dependence on medications, including opioids. We believe these procedures that provide alternatives to treat chronic pain in patients that have exhausted all other non-surgical options should not be limited by prior authorization requirements. The AAMC urges CMS to not finalize its proposal to introduce new prior authorization requirements that could limit beneficiaries' access to these procedures.

***Implanted Spinal Neurostimulators.*** A spinal cord stimulator is an implanted device that sends low levels of electricity directly into the spinal cord to treat chronic pain.<sup>20</sup> The implantable device offers a nonpharmacological approach to various pain conditions. Stimulators have been used for the treatment of both neuropathic and ischemic pain. Spinal cord stimulator implantation is used

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<sup>18</sup> Yawn, B., Wollan, P., Weingarten, T., Watson, J., Hooten, W. M., Melton, L. J. The prevalence of neuropathic pain: Clinical evaluation compared with screening tools in a community population. *Pain Med.* 2009 Apr; 10(3): 586-593. Available at: <https://academic.oup.com/painmedicine/article/10/3/586/1930948>.

<sup>19</sup> Centers for Medicare & Medicaid Services. CMS finalizes decision to cover acupuncture for chronic low back pain for Medicare beneficiaries. Jan. 1, 2020. Press release. Available at: <https://www.cms.gov/newsroom/press-releases/cms-finalizes-decision-cover-acupuncture-chronic-low-back-pain-medicare-beneficiaries>

<sup>20</sup> Johns Hopkins Medicine. Spinal Cord Stimulator. Available at: <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/treating-pain-with-spinal-cord-stimulators#:~:text=A%20spinal%20cord%20stimulator%20is,spinal%20cord%20to%20relieve%20pain.&text=Spinal%20cord%20stimulation%20is%20used,failed%20to%20provide%20sufficient%20relief.>

most often for patients who have failed various forms of conservative and pharmacologic treatment options.<sup>21</sup>

*Cervical Fusion with Disc Removal.* Cervical fusion with disc removal is performed for patients with herniated discs of the cervical spine. Patients with herniated discs experience neck pain and arm pain, and numbness and weakness in the shoulders, wrists and hands.<sup>22</sup> Non-surgical treatments include immobilization and non-steroidal anti-inflammatories (NSAIDs) and physical therapy.<sup>23</sup> However, some patients require surgical removal of the disc to relieve pain and numbness.

CMS states that research into the possible causes for the increase in volume of services did not explain why the volume of services increased for cervical fusion with disc removal. (p. 49029).

However, data analysis performed by Watson Policy Analysis (Figure 1) shows that increases in outpatient volume for cervical fusion is related to decreases in inpatient volume. This pattern of utilization is consistent with policy encouraged by CMS. CPT code 22551 was removed from the IPO list as of January 1, 2012.<sup>24</sup> Even though the base code (CPT code 22251) was payable on an

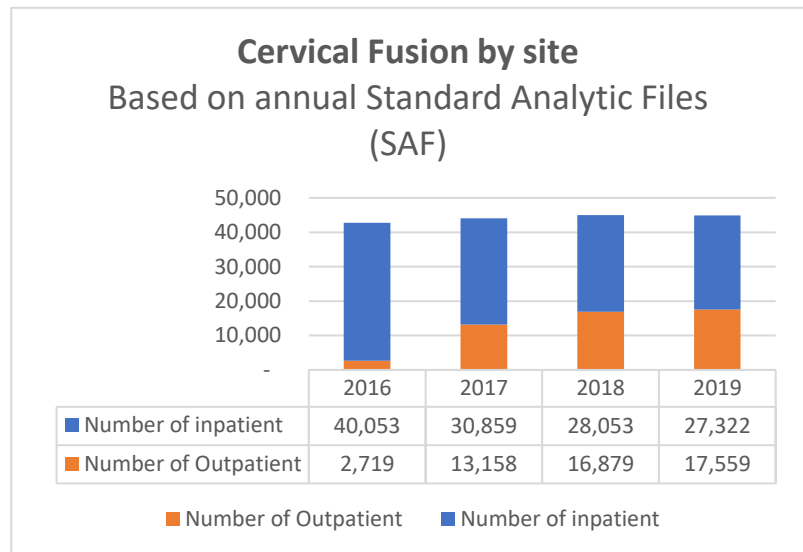


Figure 1. Watson Policy Analysis, Inc. 2020

outpatient basis, the add-on code (CPT code 22552) would be denied as an outpatient procedure because of its presence on the IPO list until 2016. The removal of these two procedures from the IPO list and the decline in inpatient utilization explains the outpatient utilization growth that CMS has found. CMS has not adequately demonstrated that the increase in these services are truly medically unnecessary. Further, it seems highly unfair for CMS to encourage outpatient utilization by removing a procedure from the IPO list and then discourage the very utilization CMS policy encouraged by subjecting the procedures to prior authorization. We feel that prior authorization will limit treatment with these necessary procedures more than “controlling unnecessary increases in the volume of these services” as CMS suggests. (p. 49029). Ultimately, providers strive to deliver quality health care in an efficient manner. However, the operational complexities required of

<sup>21</sup> Dydyk, A. M., Tadi, P. Spinal Cord Stimulator Implant. NCBI. July 8, 2020. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK555994/>.

<sup>22</sup> Johns Hopkins Medicine. Radiculopathy. Available at: <https://www.hopkinsmedicine.org/health/conditions-and-diseases/radiculopathy#:~:text=Radiculopathy%20is%20the%20pinching%20of, specialist%20for%20an%20accurate%20diagnosis.>

<sup>23</sup> Sharrak, S., Al Khalili, Y. Cervical Disc Herniation. NCBI. August 10, 2020. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK546618/>

<sup>24</sup> 76 Fed. Reg. 74355.

providers in order to obtain prior authorizations hinder efficient care. We urge CMS not to finalize prior authorization for either implanted spinal neurostimulators or cervical fusion with disc removal.

## **SITE-NEUTRAL PAYMENT POLICIES**

CMS proposes to continue its site-neutral payment policy for CY 2021 (p. 48900). As required by law, CMS introduced the site-neutral payment policy in CY 2017 for nonexcepted off-campus PBDs that were not billing under the OPSS prior to November 2, 2015. Payment to those off-campus PBDs that were billing prior to November 2, 2015 were grandfathered into OPSS. Under the policy, CMS pays the nonexcepted off-campus PBDs at 40 percent of the full OPSS rate. In the CY 2019 OPSS final rule, citing its authority under section 1833(t)(2)(F) of the Act, CMS finalized the expansion of that policy to off-campus PBDs specifically excepted from that reduction to address what it deems “an unnecessary shift of services from the physician office to the HOPD,” and implemented the policy in a non-budget neutral manner. Over CY 2019 and CY 2020, CMS phased in its policy to pay a physician fee schedule-equivalent rate for an outpatient clinic visit, HCPCS code G0463, justifying the policy by claiming that growth in outpatient services is caused by the difference in payment between sites of care.

The AAMC strongly opposed the reduction in payments in both CY 2019 and CY 2020, as the increase in the volume of items and services is caused by many appropriate factors, including but not limited to services transitioned from the inpatient to the outpatient setting, and therefore increases in items and services furnished in excepted off-campus PBDs should not be strictly considered “unnecessary” increases. The AAMC continues to believe that reducing reimbursement for items and services received in excepted off-campus PBDs in CY 2021 is detrimental to the important care provided by at these settings to vulnerable Medicare beneficiaries, which includes the right care in the right setting – for this reason, we reiterate our comments from previous years in opposition to this policy and urge CMS not to continue these reimbursement reductions.

### ***CMS Should Not Continue Site-Neutral Payment Reductions***

The AAMC maintains its assertion that the shift of services from physician offices to HOPDs is not “unnecessary” and can be explained by several factors unrelated to reimbursement rates. Appropriate factors that account for the shift in services include the growth of the Medicare population, increased referrals to HOPDs, and improved post-discharge care. Additionally, patients seen at HOPDs are substantially different and more medically complex than those treated in physicians’ offices. We also reiterate previous comments<sup>25</sup> on this policy taking issue with a host of CMS’ factual assumptions and legal conclusions, including that CMS lacked the statutory authority to implement the payment reduction, and that it was not required to implement the policy in a budget neutral manner. We commented that Congress has established a clear structure for CMS to make annual changes to payments for covered hospital outpatient services under Medicare,<sup>26</sup> and

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<sup>25</sup> See AAMC Comments on “CY 2019 OPSS Proposed Rule,” Sept. 24, 2018. Available at: <https://www.aamc.org/system/files/c/1/492444-aamccommentsontheycy2019oppsproposedrule.pdf>; See AAMC Comments on “CY 2020 OPSS Proposed Rule,” Sept. 27, 2019. Available at: [https://www.aamc.org/system/files/2019-09/ocomm-org-FINALAAMCCY2020OPSSProposedRuleCommentLetter%209\\_26%20%282%29.pdf](https://www.aamc.org/system/files/2019-09/ocomm-org-FINALAAMCCY2020OPSSProposedRuleCommentLetter%209_26%20%282%29.pdf).

<sup>26</sup> Social Security Act § 1833(t)(9)(A). Retrieved at: [https://www.ssa.gov/OP\\_Home/ssact/title18/1833.htm](https://www.ssa.gov/OP_Home/ssact/title18/1833.htm).

changes to payments that target only specific items or services must be budget neutral.<sup>27</sup> In addition, by subjecting excepted and nonexcepted PBDs to the exact same payment system and payment rate, the Agency inappropriately abolished the statutory distinction between those two entities.

To address these issues, the AAMC and others filed a lawsuit against the U.S. Department of Health and Human Services (HHS or Department) in January 2019 challenging CMS' authority to implement its CY 2019 site-neutral payment policy and received a favorable ruling in federal district court. However, the Department appealed the decision and in July 2020 the United States Court of Appeals for the District of Columbia Circuit ruled in favor of HHS, finding that its regulation "was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service." (p. 48900). The litigation is ongoing. Therefore, for CY 2021 the AAMC continues to object to and believe that the non-budget neutral payment cut for clinic visits furnished by excepted off-campus PBDs is unlawful and causes undue harm to hospitals and the communities they serve. For the reasons explained in these comments and in its lawsuit challenging the CY 2019 OPSS final rule CMS should not continue its site-neutral payment reductions in CY 2021.

## **MEDICARE WAGE INDEX**

For CY 2021, CMS proposes to adopt the finalized Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS) post-reclassified wage index as the wage index for the OPSS. As noted in the proposed rule, any adjustments finalized in the FY 2021 IPPS rule to the FY 2021 post-reclassified wage index would also be adopted for the CY 2021 OPSS wage index (p. 48803). In addition, the Agency would continue policies it finalized in the FY 2020 IPPS<sup>28</sup> that address disparities between high and low wage index hospitals present in the wage index system. This includes the Agency's policy to increase low wage index hospitals' wage indexes to provide an opportunity for these hospitals to increase employee compensation, as well as excluding reclassified urban-to-rural hospitals in its calculation of the rural floor. The main policy directly raises wage indexes of the lowest quartile wage index hospitals by half the difference between the 25th percentile wage index value and the hospital's individual wage index, which CMS will apply for a minimum of four years. Additionally, CMS would also continue to apply a 5 percent cap on changes to hospitals' wage indexes between CY 2020 and CY 2021 to limit the effect of significant OMB delineations it intends to adopt for CY 2021.

The AAMC submitted extensive comments on CMS' IPPS wage index policies<sup>29</sup> proposed and subsequently finalized in the FY 2021 IPPS rules, and on several previous occasions.<sup>30</sup> CMS

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<sup>27</sup> Social Security Act § 1833(t)(9)(B). Retrieved at: [https://www.ssa.gov/OP\\_Home/ssact/title18/1833.htm](https://www.ssa.gov/OP_Home/ssact/title18/1833.htm).

<sup>28</sup> FY 2021 IPPS Final Rule. <https://www.federalregister.gov/documents/2020/09/18/2020-19637/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

<sup>29</sup> See "AAMC Comment Letter on FY 2021 IPPS Proposed Rule," pp. 13-16. Jul. 10, 2020. Available at: <https://www.aamc.org/system/files/2020-07/ocomm-ogr-AAMC%20FY%202021%20IPPS%20Proposed%20Rule%20Comment%20Letter%207.10.2020%20FINAL.pdf>.

<sup>30</sup> See "AAMC Comment Letter on FY 2020 IPPS Proposed Rule," Jun. 24, 2020. Available at: <https://www.aamc.org/system/files/c/1/498220-aamccommentletteronfy2020ippsproposedrule.pdf>; "AAMC Comment Letter on CY 2020 OPSS Proposed Rule," Sep. 27, 2019. Available at: [https://www.aamc.org/system/files/2019-09/ocomm-org-FINALAAMCCY2020OPSSProposedRuleCommentLetter%209\\_26%20%282%29.pdf](https://www.aamc.org/system/files/2019-09/ocomm-org-FINALAAMCCY2020OPSSProposedRuleCommentLetter%209_26%20%282%29.pdf).



continues to believe that the IPPS wage index changes are appropriate for the OPSS, and proposes that the FY 2021 IPPS changes would be applied to the OPSS wage index for CY 2021. The AAMC is aware that CMS, in its responses to commenters in the FY 2021 IPPS final rule, did not find arguments for a delay in implementation or a longer transition period persuasive. The Agency believes that the need for a more accurate wage index requires immediate action, and that the extended transitional policies from 2015 were appropriate only to address more substantial changes than presented in CY 2021.<sup>31</sup> Nonetheless, the AAMC maintains that delaying adoption or providing a longer transitional policy would be appropriate measures for the OPSS wage index to address these significant changes and would enable hospitals to better prepare for potential payment reductions. The AAMC reiterates its comments and concerns with several aspects of these wage index proposals, as detailed below.

### ***Consider Impact of COVID-19 Public Health Emergency on Area Wage Indexes***

Across the U.S., the COVID-19 PHE has strained hospital resources and has severely impacted their ability to continue operations as prior to the PHE. AAMC members appreciate CMS' efforts to reduce regulatory burden during the PHE. However, due to the financial strain felt by hospitals as they face the demands of COVID-19, many made the difficult decision to temporarily or permanently reduce wages. As a direct result, depressed wages represented in the wage data during the PHE stand to lower the hospital wage index adjustment for certain areas once hospital wage index data from CY 2021 is used to determine area wage indexes. **For this reason, the AAMC recommends that CMS proactively address the COVID-19 PHE's impact on hospital wages and their wage indexes by excluding wage index data collected during the PHE from calculation of area wage indexes.**

### ***Work with Stakeholders to Develop Comprehensive Wage Index Reform***

Although AAMC supports CMS' goal to address difficulties faced by low wage index hospitals in recruiting and retaining staff, we continue to believe that a better solution is for CMS to reform the wage index in a more comprehensive manner. While the wage index has undergone numerous targeted legislative and regulatory changes since its inception, its disparities and issues persist. **At a point in the future when the PHE is over, the AAMC urges CMS to engage with stakeholders to develop more comprehensive wage index reform to address the disparities that exist within the current system.** Comprehensive reform will enable CMS to achieve its overarching goals of creating a wage index system that accurately represents the geographic differences in the cost of labor.

### ***Do Not Adopt OMB Bulletin No. 18-04 Delineations Until After the Decennial Census***

In CY 2020, CMS finalized a transitional one-year cap on reductions to a hospital's wage index between CY 2019 and CY 2020. The cap limited reductions to a hospital's wage index to no more than five percent between the two years in order to mitigate the impact of the finalized wage index policies and allow hospitals to prepare for payment reductions. CMS again proposes to implement the cap for changes to a hospital's wage index between CY 2020 and CY 2021. (p. 48803). CMS notes that its decision to continue applying the cap to all wage index changes is specifically

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<sup>31</sup> IPPS Final Rule Display Copy pp. 943, 966. <https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-19637.pdf>.

intended to mitigate effects of the revised core-based statistical area (CBSA) delineations and their corresponding impact on the wage index. (p. 48803)

In the FY 2021 IPPS final rule, CMS finalized its adoption of the labor market delineation updates described in the OMB Bulletin No. 18-04. In this final rule, CMS again acknowledges the significance of OMB Bulletin No. 18-04 as compared with other typical OMB delineations, but indicates that the overall impact of the changes is “more limited in scope than revisions that accompany the release of the decennial censuses.”<sup>32</sup> CMS reiterates in the OPSS proposed rule that the modifications to CBSAs in OMB bulletins issued between decennial censuses are typically minor. AAMC continues to be concerned that the new CBSA delineations outlined in OMB Bulletin No. 18-04 are more significant in comparison to other interim bulletins and that these changes will materially impact AAMC members and thus their ability to continue to provide comprehensive care. These changes include several new CBSAs, urban counties becoming rural, rural counties becoming urban, and some existing CBSAs would be split apart. Additionally, the changes are anticipated to have a cascading impact on hospitals with wage index reclassifications.

To address and mitigate the material changes that would be caused by adopting the OMB Bulletin No. 18-04, CMS proposes to implement a five-percent cap on changes to a hospital’s wage index between CY 2020 and CY 2021. The AAMC is concerned that the impact from the revised delineations may be more severe than CMS is indicating. In past rulemaking, CMS provided hospitals with more generous transitional policies when the Agency adopts more comprehensive OMB labor market delineations. For instance, as recently as FY 2015, CMS provided a three-year transition policy for hospitals negatively impacted by CMS’ adoption of OMB’s delineations based on the 2010 decennial census.<sup>33</sup> Hospitals in urban counties becoming rural were allowed to retain an urban wage index for three years while CMS implemented other changes through two-year transition period with wage indexes based on a 50 percent blend of the old and new delineations the first year.

**The AAMC urges CMS to delay adoption of the changes outlined in OMB Bulletin No. 18-04 under the OPSS.** The negative impacts on hospitals are material, and the 2020 decennial census will soon require more changes to OMB delineations. While CMS’ transitional cap would prevent reductions beyond 5 percent between CY 2020 and 2021, analyses show that some of our members may see up to a 15 percent decrease in their wage indexes as a result of the IPPS proposals.<sup>34</sup> This may well be the case for OPSS, too. As a result, in year 2, we anticipate a sharp decrease in the wage index for these hospitals. This decrease is on top of the significant revenue decreases hospitals are experiences due to COVID-19. CMS should not adopt updated OMB delineations until the 2020 decennial census data are available. **However, if CMS finalizes the adoption of delineations outlined in OMB Bulletin No. 18-04, the AAMC urges CMS to apply a two and three-year transitional policy to provide time for those hospitals that will experience a significant financial impact to adapt.**

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<sup>32</sup> FY 2021 IPPS Final Rule. 85 *Fed. Reg.* 58745.

<sup>33</sup> 79 *Fed. Reg.* 49957.

<sup>34</sup> AAMC analysis. Source: Table 2 – Proposed Case Mix Index and Wage Index Table by CCN of the FY 2021 IPPS Proposed Rule, with AAMC membership as of May 2020.

## PAYMENT FOR COVID-19 SPECIMEN COLLECTION

CMS created HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), and specimen source) and assigned the code to APC 5371 (Level 1 Minor Procedures) with status indicator “Q1” through the second interim final rule with comment period (IFC).<sup>35</sup> As noted in the proposed rule, the code was created “in response to the significant increase in specimen collection and testing for COVID-19 in Hospital Outpatient Departments” during the PHE in order to “meet the resource requirements for HOPDs to provide extensive testing.” (p. 48940). CMS intended to retire the code at the end of the PHE, which is currently scheduled to expire on October 23, 2020.

As CMS notes in the proposed rule, payment for specimen collection is necessary to support widespread testing at HOPDs. Widespread testing is integral for tracking and containing the spread of COVID-19, as well as for monitoring purposes to ensure that essential workers across numerous professional fields can safely provide critical services during the PHE. In response to the PHE, AAMC members increased testing capacity by standing up testing centers and/or staffing community testing centers in order to meet the needs of their communities. Through the IFC, CMS acknowledged the importance and cost of testing by providing payment to HOPDs for specimen collection during the PHE through HCPCS code C9803. As we move toward the flu season, experts believe that “quicker and more widely available testing is needed to distinguish between COVID-19 and influenza, which have similar symptoms, at least at first, but require different treatments”<sup>36</sup> will be necessary and the need for COVID-19 testing is nearly certain to remain well into 2021.

CMS proposes to continue assigning COVID-19 specimen collection at HOPDs to HCPCS code C9803 and APC 5371 with status indicator “Q1” for CY 2021 to account for the likelihood that the PHE will extend into the next calendar year. CMS is also soliciting comments on whether HCPCS code C9803 should remain active beyond the PHE, or whether payment under the OPSS for COVID-19 specimen collection should be made permanent. **The AAMC agrees that payment for specimen collection under the OPSS should continue for CY 2021 and urges CMS to make payment for this service under the OPSS permanent.**

## LEVELS OF SUPERVISION CHANGES IN HOSPITALS

In response to the ongoing PHE, CMS provided temporary regulatory flexibility to hospitals through the first IFC by making two changes to the level of supervision required for certain services.<sup>37</sup>

First, CMS used the IFC to temporarily modify the supervision level requirement for NSEDTS during the PHE. Ordinarily, for NSEDTS, CMS requires direct supervision during the initiation of

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<sup>35</sup> 85 Fed. Reg. 27550, 27604. May 8, 2020. Available at: <https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf>.

<sup>36</sup> Rita Rubin, MA, *What Happens When COVID-19 Collides With Flu Season?* JAMA. 2020;324(10):923-925. doi:10.1001/jama.2020.15260 Available at: <https://jamanetwork.com/journals/jama/fullarticle/2769835>

<sup>37</sup> 85 Fed. Reg. 19230, 19245 and 19266. April 6, 2020. Available at: <https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf>.

the service, and general supervision during provision of the service at the discretion of the supervising physician. General supervision requires only that “the procedure is furnished under the physician’s overall direction and control, but that the physician’s presence is not required during the performance of the procedure.” (p. 48936). In contrast, direct supervision requires that “the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure,” although physical presence is not required. (p. 48936). During the PHE, CMS temporarily established general supervision as the minimum required supervision level throughout the service, meaning general supervision would apply both at initiation and during the provision of the service. (p. 48935).

Second, CMS used the IFC to modify the direct supervision requirement for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services provided in hospitals and CAHs. Specifically, for the duration of the PHE, CMS permits hospitals to meet direct supervision by virtual presence of the supervising physician through audio/video real-time communications technology. However, the current requirement under the PHE to furnish assistance and direction during the service cannot be met through *availability* of audio/video real-time communications technology. Instead, the supervising physician would be required to be *present* using the technology throughout the performance of the procedure.

### ***Finalize Proposal to Make Interim Level of Supervision Changes for Hospitals Permanent***

In the proposed rule, CMS seeks to make permanent these two temporary changes to supervision requirements for NSEDTs and select rehabilitation services provided in hospitals beginning on or after January 1, 2021. As CMS notes, NSEDTs typically have low risk of complications and direct supervision can be challenging for hospitals to meet because of the extended monitoring component associated with these services. (p. 48935). CMS believes that requiring only a minimum general supervision level throughout the service would decrease burden on hospitals and may improve access where a supervising physician’s lack of availability under direct supervision requirements. Additionally, hospitals would still be able to provide direct supervision for NSEDTs when appropriate. **AAMC supports CMS’ proposal to permanently change the minimal level of supervision to general supervision for NSEDTs.**

Moreover, permanently allowing hospitals to meet direct supervision for the select rehabilitation services through interactive real-time audio/video communications technology would provide welcome relief to hospitals and provide continuity of care to patients. The PHE has ushered in an era of unprecedented use of telecommunication technology allowing hospitals and its teaching physicians the ability to expand their capacity to provide uninterrupted medical care to patients. Permitting hospitals to meet direct supervision for these select rehabilitation services through various technologies, CMS would provide hospitals with previously unseen opportunities to leverage existing telecommunications resources while improving beneficiary access and reducing burden beyond the PHE.

In previous comments on the first IFC, AAMC expressed support to make similar changes permanent where CMS allowed hospitals’ teaching physicians to meet direct supervision of resident services through interactive telecommunications technology.<sup>38</sup> Consistent with our comments on the

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<sup>38</sup> See “AAMC Comments on IFC-1,” p. 6, Jun. 1, 2020. Available at: <https://www.aamc.org/system/files/2020-06/ocomm-hca-AAMC%20Comment%20Letter%20First%20COVID%20IFC%206.1.2020.pdf>.

IFC, we believe that permanently allowing hospitals to meet direct supervision through interactive telecommunications technology achieves dual aims of reducing in-person interaction during the PHE while meeting the medical needs of patients and providing flexibility for providers beyond the PHE. The AAMC supports these policies and urges CMS to finalize its proposals.

In the IFC, CMS established that the direct supervision requirement can be met for cardiac, intensive cardiac and pulmonary rehabilitation services by the virtual presence of the supervising physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks to COVID-19 for the beneficiary or health care provider.<sup>39</sup> CMS believes the virtual presence of the physician could continue to improve access for patients and reduce burden for providers after the PHE. To that end, CMS is proposing to allow direct supervision for pulmonary, cardiac and intensive cardiac rehabilitation services using telecommunications technology when performed in the hospital or HOPD. The AAMC also supports CMS' proposal to allow hospitals and CAHs to meet direct supervision requirements through interactive real-time audio/video communications technology for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services. CMS should consider expanding this policy to standalone, non-HOPD providers in rural settings to better meeting the needs of beneficiaries receiving care in these facilities.

## **PHYSICIAN-OWNED HOSPITALS**

CMS is proposing several changes to the facility expansion exception under the Stark law. The Stark law prohibits physicians from making referrals to an entity with which the physician or the physician's immediate family has a financial relationship.<sup>40</sup> The "whole-hospital exception" to the Stark law permits physicians with ownership or investment interests in a hospital to make self-referrals so long as the physician meets several limited requirements listed at Section 1887(i)(1) of the Social Security Act.<sup>41</sup> Hospitals that qualify for the exception are generally prohibited from expanding the baseline number of operating rooms, procedure rooms, and beds beyond what they were licensed for in 2010<sup>42</sup> but, certain "high Medicaid facilities"<sup>43</sup> and other "applicable hospitals"<sup>44</sup> are permitted to request an exception from the prohibition on facility expansion (exception request process). (p. 49037). Hospitals seeking exception requests may only apply once every two years, cannot exceed 200 percent of their baseline number of rooms and beds, and are limited to expanding the main campus of the hospital, primarily defined as the "physical area immediately adjacent to the provider's main buildings."<sup>45</sup> (p. 49037). CMS seeks to modify several of the exception request limitations for high Medicaid facilities. **The AAMC urges CMS not to finalize these proposals, and instead maintain the current regulatory restrictions on expanding physician-owned hospitals for the reasons described below.**

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<sup>39</sup> 85 Fed. Reg. 19246.

<sup>40</sup> Social Security Act § 1877.

<sup>41</sup> Social Security Act § 1877(d)(2).

<sup>42</sup> Affordable Care Act § 6001(a)(3).

<sup>43</sup> Social Security Act § 1877 (i)(3)(E).

<sup>44</sup> Social Security Act § 1877 (i)(3)(F).

<sup>45</sup> 42 CFR § 413.65 (a)(2).

First, CMS proposes that high Medicaid facilities would be permitted to apply for an exception request at any time, so long as only one request is made at a time and would no longer be subject to either the 200 percent expansion cap or limited to expanding the main campus of the hospital. (p. 49038). In other words, as proposed, high Medicaid facilities would be able to expand the number of rooms and beds without limitation and may expand any part of the hospital. In comparison to nonphysician-owned hospitals, physician-owned hospitals have been shown to have increased overutilization of services, primarily treat patients with lower costs of care, and provide less uncompensated care than nonphysician-owned hospitals.<sup>46</sup> Additionally, the presence of physician-owned hospitals has been shown to have adverse impact on community hospitals, often siphoning profitable patients and leaving community providers to resort to difficult staff cuts and aggressive pricing strategies to compensate for lost revenue.<sup>47</sup> **Strict standards, including the Stark prohibition on facility expansion, have effectively regulated the operation of physician-owned hospitals and should not be modified.**

In comparison to physician-owned hospitals, AAMC member teaching hospitals provide care for complex patients and for patients who are unable to receive care elsewhere. For example, our members comprise only five percent of all acute care, general service hospitals but provide 32 percent of all hospital-based charity care, 22 percent of Medicare inpatient days, and 25 percent of all Medicaid hospitalizations.<sup>48</sup> Additionally, our members are well-established regional referral centers and centers for tertiary care that provide vital care to their communities and regions. Teaching hospitals also treat more complex patients. For example, Medicare transfer patients represented nearly 11 percent of inpatient cases at major teaching hospitals, compared with less than three percent at nonteaching hospitals, and both transfer and non-transfer patients were more complex than those at non-teaching hospitals.<sup>49</sup> In contrast, physician-owned hospitals, which take lower cost and complexity patients and do not offer expansive services, do not need fewer restrictions; these facilities are not primary medical providers in the communities they serve, and provide care to only select groups of patients. Such facilities are often not subject to state “Certificate of Need” (CON) laws, which aim to restrict duplicative services and determine whether new capital expenditures meet community need.<sup>50</sup> For these reasons, CMS should not finalize policies that further deregulate the expansion of physician-owned hospitals.

Finally, as part of the exception process, CMS is required to furnish an opportunity for community input when an applicable or high Medicaid hospital applies for an exception to the prohibition on expansion of facility capacity. (p. 49038). CMS is seeking comments on the importance of community input for the expansion of a high Medicaid facility. While applications for expansion

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<sup>46</sup> Medicare Payment Advisory Committee. “Report to the Congress: Physician-Owned Specialty Hospitals Revisited; 2006.” Aug. 2006. Available at: [http://67.59.137.244/documents/Aug06\\_specialtyhospital\\_mandated\\_report.pdf](http://67.59.137.244/documents/Aug06_specialtyhospital_mandated_report.pdf).

<sup>47</sup> *Id.*

<sup>48</sup> AAMC, “What We Do: Patient Care.” Accessed on Sept. 17, 2020 at: <https://www.aamc.org/what-we-do/mission-areas/patient-care>.

<sup>49</sup> AAMC, Fact Sheet, “Investment in Teaching Hospitals Benefits All: Transfer Cases,” Sept. 2019. Available at: <https://www.aamc.org/system/files/2019-09/Patient%20Care%20-%20Transfer%20Case%20Analyses%20One%20Pager%20-%2020190913.pdf>.

<sup>50</sup> Only 35 states have certificate of need laws, and there is considerable variation for the states that do – many provide exceptions to the requirement for physician-owned hospitals. See National Conference of State Legislatures, “CON-Certificate of Need State Laws,” Dec. 1, 2019. Available at: <https://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx>.

exceptions have been limited since introduced in 2013, the AAMC feels that community input remains a valuable part of the application process. Namely, community feedback from stakeholders serves as a critical feature of the exception process to validate that applicant-hospitals meet the expansion criteria to understand if hospital expansion is warranted, and to provide insight on the impact to surrounding providers. More importantly, the process serves to promote a level of transparency and accountability that this administration has made a core feature of its organizational aims. While community input is sometimes limited to a few comments, there have been instances where the process has been well-engaged.<sup>51</sup> In either scenario, removing the opportunity for community input only serves to reduce the level of transparency and accountability that protects the health of communities and beneficiaries. **For these reasons, CMS should not remove the community input requirement for high Medicaid hospitals.**

### **OUTPATIENT QUALITY REPORTING PROGRAM**

CMS proposes to update the Code of Federal Regulations text for the Hospital OQR Program to codify previously adopted policies, align deadlines for data submission and reconsideration applications for consistency with federal law, and expand the review and corrections policy for chart-abstracted measures to also apply to measures submitted via web-based tool. **The AAMC supports these proposals and appreciates the Agency's efforts to minimize changes to the OQR Program during the ongoing COVID-19 PHE.**

### **OVERALL HOSPITAL QUALITY STAR RATING**

The AAMC appreciates the efforts taken by CMS to improve the methodology for its Overall Hospital Quality Star Rating. Our comments evaluate these efforts and provide guidance for future improvement. In general, **we strongly support the initial efforts the Agency has taken in its proposals to address serious stakeholder concerns in regard to flaws with the current methodology but believe that more needs to be done. In particular, we are concerned that retaining an overall composite rating fails to provide patients and their communities with meaningful information about hospital quality.** The AAMC encourages CMS to continue to engage stakeholders to improve the Star Ratings in the future to ensure that the ratings are accurate and actionable for hospitals while providing patients and their families with information needed to make important healthcare decisions.

#### ***An Overall Composite Rating Adds to Confusion About Hospital Quality and CMS Should Develop an Alternative Approach***

The AAMC has long supported making quality data available in an easy to understand format for patients and the public. While we support efforts for greater transparency, we believe that this information must be accurate and displayed in a meaningful fashion. **A single composite rating**

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<sup>51</sup> CMS received 43 community input comments for one exception application. See "Medicare Program; Approval of Request for an Exception to the Prohibition on Expansion of Facility Capacity for Texas Health Presbyterian Hospital Rockwall," 81 Fed. Reg. 75090, 75091. Oct. 25, 2016. Available at: <https://www.govinfo.gov/content/pkg/FR-2016-10-28/pdf/2016-26119.pdf>.

**that combines disparate quality measures, particularly those that lack clinical nuance, such as hospital-wide measures, oversimplifies the complex factors that must be taken in account when assessing the quality of care.**

**Rather than using a methodology to compute a single composite score rating, the AAMC recommends the development of ratings for subsets of measures, which would ultimately be more meaningful and actionable for patients and consumers as well as also for the hospital's quality improvement efforts.** The current display does not illuminate the differences between hospitals compared or disclose the areas where a given hospital might not provide a given service or may lack a measure score. The composite score rating also does not give patients the ability to determine the hospital's quality performance on particular services that are relevant to them. For example, a patient who has cancer would be unable to determine from a single composite rating which hospital would be the best to select for cancer care. **Patients and consumers should have better access to quality information to inform those choices.** The AAMC continues to believe that distilling a large amount of information into one overall rating is not useful to consumers or hospitals.

***Inclusion of Critical Access Hospitals (§ 412.90(b)(3)) and Future Inclusion of Veterans Health Administration (VHA) Hospitals***

In addition to including all subsection (d) hospitals subject to the CMS portfolio of hospital quality and performance programs, CMS proposes to include CAHs that “wish to be voluntarily” included in the ratings so long as the CAH elects to submit quality measures included in CMS's hospital quality programs and publicly report its measure data on *Hospital Compare* or its successor website. In the preamble, CMS also discusses its intent to include VHA hospitals in the Star Ratings as early as 2023, pending future rulemaking.

The AAMC agrees that including CAHs in the Star Ratings is important since many CAHs are located in remote areas and are often one of few options for patients seeking care. Those patients should have equal access to publicly available quality information as other patients to inform their choices for seeking care. However, CAHs tend to be smaller facilities that provide more limited outpatient and inpatient hospital services than acute care hospitals. **For CAH ratings, the AAMC urges CMS to provide clear details on the services available in addition to the hospital's overall rating to ensure patients are able to best compare facilities providing the services they are seeking.**

CMS states that including VHA hospitals in the ratings calculations would influence national results without impacting payment under CMS programs (as VHA hospitals are not included in CMS's hospital quality performance programs). CMS intends to provide more information about the statistical impacts of adding VHA hospitals and procedural aspects of their inclusion in the ratings in future rulemaking. Currently, many of metrics used to calculate the Overall Hospital Quality Star Rating measure the quality of care for a subset of the Medicare patient population (typically only for those patients 65 years of age or older who have Original Medicare fee-for-service coverage, excluding patients with Medicare Part C coverage or Medicare patients with coverage due to end stage renal disease, etc.). Those similar claims-based measures for VHA hospitals expressly *exclude* the Medicare population, as Medicare does not pay for services at VHA hospitals except in very limited circumstances. The inclusion of VHA hospital performance on measures that are used



differently than how they were developed and endorsed must be analyzed thoroughly to ensure national performance comparison under the ratings is valid and reliable. **The AAMC believes veterans should have access to reliable quality comparisons, but we are unable to provide comment on the inclusion of VHA hospitals in the ratings without additional information, which we hope will soon be made available by CMS.**

***Frequency of Publication and Data Used (§ 412.90(c))***

CMS proposes to establish an annual update cycle for Star Ratings, using data publicly reported on Hospital Compare or its successor website from a quarter from the prior year. Many of the underlying quality measures used to determine the ratings are refreshed on an annual basis, making an annual update cycle reasonable. Additionally, the ratings have been *de facto* published on an annual cycle since CMS's December 2017 update. **The AAMC supports an annual publication cycle for the Star Ratings and appreciates the certainty for hospitals in codifying this policy in the regulations.**

***Measure Selection and Exclusion (§ 412.90(d)(1))***

An overall quality rating based upon individual quality measures can only ever be successful if the underlying measures themselves are reliable, valid, and incorporate appropriate and robust risk adjustment to accurately account for the differences in clinical and social risk of patients that a hospital serves. As currently designed, the Star Ratings include measures with methodological flaws, such as PSI-90. **The AAMC urges CMS to improve upon existing measures in its hospital quality reporting and performance programs in addition to its efforts to update and improve the Star Ratings methodology.**

***Remove PSI-90 from Star Ratings***

The AAMC has numerous concerns with the PSI-90 composite measure which previously have been shared with CMS.<sup>52, 53, 54</sup> Some of the components of the measure focus on surgical care, which unfairly disadvantages teaching institutions that tend to have a larger volume of surgical cases than do other hospitals. The PSI-90 tends to penalize hospitals that have large volumes of surgeries, even where the probability of an adverse event is the same as a low-volume hospital. Additionally, some components of the measure are susceptible to surveillance bias, making institutions more diligent about reporting those safety events more likely to be penalized.<sup>55, 56</sup> For example, teaching hospitals tend to have robust infection control programs, which focus on identifying and reporting patient safety events, with the result of potential increases in their reported

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<sup>52</sup> See "AAMC Comments on FY 2017 IPPS Proposed Rule." June 17, 2016. Retrieved from: <https://www.aamc.org/system/files/c/1/462432-aamccommentsonthefy2017ippsproposedrule.pdf>

<sup>53</sup> See "AAMC Comments on FY 2018 IPPS Proposed Rule." June 13, 2017. Retrieved from: <https://www.aamc.org/system/files/c/1/480592-aamccommentletterfy2018ippsproposedrule.pdf>

<sup>54</sup> See "AAMC Sends Introductory Letter to New CMS Administrator Seema Verma." March 14, 2017. Retrieved from: <https://www.aamc.org/system/files/c/1/477582-aamclettertocmspre-fy2018ippsproposedrule.pdf>

<sup>55</sup> Koenig, Lane et al. *Complication Rates, Hospital Size, and Bias in the CMS Hospital-Acquired Condition Reduction Program*. *American Journal of Medical Quality*. December 19, 2016. Retrieved from: <https://journals.sagepub.com/doi/abs/10.1177/1062860616681840>.

<sup>56</sup> Blay Jr., Eddie et al. *Evaluating the Impact of Venous Thromboembolism Outcome Measure on the PSI 90 Composite Quality Metric*. *The Joint Commission Journal on Quality and Patient Safety*. March 2019. Retrieve from: [https://www.jointcommissionjournal.com/article/S1553-7250\(18\)30220-4/pdf](https://www.jointcommissionjournal.com/article/S1553-7250(18)30220-4/pdf)

measure rate. Finally, the measure is based on administrative claims data rather than chart-abstracted data and therefore does not capture the full scope of patient-level risk factors.<sup>57, 58, 59</sup> While the modified composite may be an improvement over the previous version, many of the issues previously cited in comments to the Agency continue to apply, and because of this, **CMS should remove the PSI-90 measure from the Star Ratings methodology until CMS is able to provide auditing and benchmarking of measurement to address these concerns.**

*Incorporate Social Risk Factors (SRFs) into Measure-Level Risk Adjustment*

Approximately two-thirds of a hospital's Star Rating is based on its readmissions, mortality, and patient experience performance. There is significant peer-reviewed literature<sup>60</sup> demonstrating that hospital performance on many outcomes can be affected by factors outside the control of the hospital (e.g., housing, food insecurity, social support, and transportation). Furthermore, Congress recognized that hospitals that disproportionately care for vulnerable patient populations, who are at a higher risk of readmissions, are disadvantaged when these factors are not considered in the scoring methodology and mandated that CMS stratify hospital readmission penalties for the proportion of dually eligible patients under the Hospital Readmission Reduction Program. CMS has implemented this adjustment by stratifying penalties by the proportion of Medicare and Medicaid dual-eligible patients the hospital serves and proposes to mirror that approach for scoring the Readmission measure group in the Star Ratings methodology (our comments on that proposal are in further detail later in this letter). Stratification based solely on dual-eligibility, however, is only the first step toward appropriate risk adjustment for SRFs because dual-eligibility as a sole stratifying variable omits other important social and economic challenges<sup>61</sup>.

**To make accurate quality comparisons that eliminate inequities of outcomes and provides hospitals with actionable quality improvement data, CMS must also adjust the underlying measures.** The National Quality Forum (NQF) is leading efforts that can improve risk-adjustment in quality measurement. It recently announced the Best Practices for Developing and Testing Risk Adjustment Models project, which will oversee the development of technical guidance on social and functional status-related risk adjustment in quality measurement and identify best practices for risk adjustment models. Additionally, the NQF's Social Risk Trial, an initiative that runs through 2021, will have a role in assessing the risk adjustment model of measures submitted for

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<sup>57</sup> "MedPAC Comments on FY 2014 IPPS Proposed Rule." June 25, 2013. Retrieved from: <http://www.medpac.gov/documents/comment-letters/medpac's-comment-on-cms's-acute-and-long-term-care-hospitals-proposed-rule.pdf?sfvrsn=0>

<sup>58</sup> Rajaram, Ravi et al. *Concerns About Using the Patient Safety Indicator-90 Composite in Pay-for-Performance Programs*. *JAMA*. Vol 313, No. 9. March 3, 2015. Retrieved from: <http://jama.jamanetwork.com/article.aspx?articleid=2109967>

<sup>59</sup> *Medicare's Hospital-Acquired Condition Reduction Program*. *Health Affairs: Health Policy Briefs*. August 6, 2015. Retrieved from [http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\\_id=142](http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=142)

<sup>60</sup> See National Academies of Sciences, Engineering, and Medicine. 2016-2017. *Report Series: Accounting for Social Risk Factors in Medicare Payment*. Washington, DC: The National Academies Press. Details here: <http://www.nationalacademies.org/hmd/Activities/Quality/Accounting-SES-in-Medicare-Payment-Programs.aspx>

<sup>61</sup> Alberti, Philip and Matthew Baker, *Dual eligible patients are not the same: How social risk may impact quality measurement's ability to reduce inequities*. *Medicine*. Vol 99, No. 38. September 18, 2020. Retrieved from: [https://journals.lww.com/md-journal/Fulltext/2020/09180/Dual\\_eligible\\_patients\\_are\\_not\\_the\\_same\\_How.68.aspx](https://journals.lww.com/md-journal/Fulltext/2020/09180/Dual_eligible_patients_are_not_the_same_How.68.aspx)

endorsement review. **The AAMC urges CMS to work with measure developers to build on these efforts to improve the risk-adjustment models in quality measurement.**

***Grouping Measures (§ 412.90(d)(3))***

CMS proposes to re-group measures into five clinical measure groups: Mortality, Safety of Care, Readmission, Patient Experience, and Timely and Effective Care. The Timely and Effective Care measure group would represent the consolidation of three existing measure groups into a single group, in response to the Agency's recent efforts to cull measures from the hospital quality reporting and performance programs leaving those groups with fewer measures than when the Star Ratings program was initially designed. **The AAMC supports this proposal and its recognition of the significant removal of topped-out process measures included in the hospital quality and reporting programs.**

***Measure Group Scoring – Simple Average Method (§ 412.90(d)(4))***

CMS proposes to replace the latent variable model (LVM) method for scoring measure groups with a simple average approach. The LVM method is a complex statistical approach that seeks to reflect information about an underlying aspect or domain of hospital quality within each measures group. It is challenging to explain to both patients and hospitals. The LVM was chosen in part to reduce arbitrariness, but in return it introduces inherent uncertainty into the ratings because the measure loadings are unknown until data is refreshed and may change over time. This leads to little transparency or predictable advance notice for hospitals in how changes in individual measure scores may impact hospital Star Ratings. In addition, in the LVM approach, the higher a measure's "loading factor", the more it influences the performance in a particular measure group. In the past, the loading factors within the patient safety measures group fluctuated significantly despite very little change in performance on the safety measures. The PSI composite measure and hip/knee complications disproportionately impacted the Safety of Care group score even though there are other important patient safety measures in the group.

The AAMC agrees that an explicit simple averages approach is easier for hospitals and patients to understand and will introduce predictability and transparency to the ratings by allowing for a greater balance and consistency of measure weights. **We support the proposal at this time to score measure groups using a simple average method instead of the LVM method but ask CMS to continue to work to find a better methodology and improved subset ratings.**

***Stratifying Readmission Measure Group Scores (§ 412.90(d)(4)(v))***

CMS proposes to stratify hospitals into peer groups based on the proportion of patients dually eligible for Medicare and full-benefit Medicaid among a hospital's total Medicare discharges at each hospital, using peer groups annually designated by the HRRP to calculate the hospitals' Readmission measure group scores. This stratification by dual eligibility as a proxy for SRFs would apply only to scoring the Readmission measure group. This proposal is intended to respond to stakeholder concerns that hospitals may face unique challenges preventing readmissions among patients with complex SRFs and should at a minimum align with the HRRP payment adjustment policy addressing such risk factors.

The AAMC has previously commented<sup>62</sup> to CMS our belief that stratifying performance by the hospital's number of dual-eligible patients should only be a temporary solution for the HRRP. We have strongly recommended that CMS take steps to ensure that individual measures account for SRFs in the measure level risk adjustment model. The use of peer grouping involves making subjective choices about cut off points for particular groups. Under peer grouping, hospitals with very similar proportions of dual eligible patients could be placed into different groups depending on where the cut-off point is set. In addition, dual-eligible status is an imperfect proxy for social risk and is used in programs simply because it is the most complete SRF data that is readily available. It should be used only as a temporary measure of SRFs while better SRF data capture is incentivized and implemented into measure-level risk adjustment. To this end, **we support the proposal to align the scoring stratification of the HRRP with the scoring of the Readmission measure group and continue to urge CMS to invest in improving measure-level risk adjustment models to appropriately account for SRFs.**

***Minimum Reporting Thresholds for Receiving a Rating (§ 412.90(d)(5))***

CMS currently sets a minimum reporting threshold for hospitals in order to receive a rating and proposes to amend this threshold beginning with the forthcoming 2021 ratings. Similar to the current policy, CMS proposes that hospitals must report at least three quality measures for three measure groups to receive a rating. CMS then modifies the current policy by requiring that one of the measure groups be either the Mortality or the Safety of Care measure group (instead of any of the outcome measure groups). Once a hospital meets the threshold, all other measure scores groups would contribute to the hospital's overall summary score and, ultimately, its Star Rating. CMS proposes this modification to improve comparability of hospitals and in response to stakeholder feedback that mortality and patient safety are important aspects of quality to patients making healthcare decisions.

**We agree that a minimum threshold is necessary to ensure a baseline comparability of hospitals within the Overall Hospital Quality Star Rating program, and that Mortality and Safety of Care are critical measurement areas for patients and consumers. The AAMC supports this proposal.**

***Summary Score as a Weighted Average of Group Scores (§ 412.90(d)(6))***

CMS proposes to maintain the current methodology's measure group weights by maintaining the 22 percent weights for Mortality, Safety of Care, Readmission, and Patient Experience and combining the 4 percent weights for the three process measure groups into 12 percent for the single Timely and Effective Care measure group. CMS also proposes to continue to re-distribute the weights of missing measure groups evenly across remaining measure groups where a hospital does not report enough measures in one or more measure groups to receive a measure group score. Hospital summary scores would be calculated by multiplying the standardized measure group scores by the assigned measure group weights and then summing these amounts. As an alternative, CMS considered equally weighting the measure groups at 20 percent each but decided against this based

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<sup>62</sup> See "AAMC Submits Comment Letter on IPPS FY 2019 Proposed Rule," (June 2018). Retrieved from: <https://www.aamc.org/advocacy-policy/washington-highlights/aamc-submits-comment-letter-ippf-fy-2019-proposed-rule>

upon prior stakeholder feedback supporting higher weights for outcomes and patient experience measures.

The AAMC agrees that outcome and patient experience measures should be more highly weighted than process measures. Since these weights are critical to the determination of the Star Ratings, **the AAMC further recommends that higher weight be given to the Mortality measure group on the basis that it is an extremely important outcome measure area.** For example, CMS could weigh the Mortality measure group at 33 percent, Safety of Care, Readmission, and Patient Experience measure groups each at 19 percent and the Timely and Effective Care measure group at 10 percent. This would retain higher weights for outcomes and experience measure groups, while highlighting the importance of mortality for hospital comparisons.

### ***Peer Grouping Hospitals (§ 412.90(d)(7))***

CMS proposes to assign star ratings among peer groups based on the number of measure groups in which a hospital has at least three measure scores, in an effort to present the ratings results based on hospitals that “look like them.” Under this proposal, hospitals would be assigned to one of three peer groups, representing hospitals with sufficient reporting in three measure groups, four measure groups, or all five measure groups. CMS’s analysis finds that the majority of hospitals would be assigned to the five-measure group peer group, and that in order to have a sufficient number of hospitals in the three-measure group peer group it must include CAHs in the star rating program.

Currently, CMS compares all hospitals that meet the minimum threshold requirement regardless of differences in hospital characteristics, such as teaching or safety-net status, number of beds, or range of services provided. Teaching hospitals perform a wide array of complicated and common procedures, pioneer new treatments, and care for broader socio-demographic patient populations that may have limited access to care and may be sicker or have more co-morbidities than patients at other hospitals. Yet under the current Star Ratings program, they are compared directly to hospitals with homogenous patient populations and hospitals that do not perform enough procedures to be measured on a majority of the measures included in the methodology. This had led to observations that the ratings disadvantage large teaching hospitals and favor hospitals with fewer reported measures.<sup>63</sup> CMS’s analysis of hospital characteristic variables for peer grouping found that peer grouping based on measure groups reported led to predictability of hospital assignments to peer groups over time, in part because larger hospitals tend to submit the most measures and smaller hospitals submit the fewest and thus peer grouping by measure groups provides alignment with hospital size.

The AAMC has long urged CMS to adopt peer grouping as a way to stratify the ratings by hospital type or characteristic and has previously recommended that CMS explore measure performance within specific hospital peer cohorts so that hospitals with similar characteristics and risk profiles are compared to each other. As proposed, we believe it is an opportunity for CMS to better present differences between hospitals in the number of quality measures reported, which in turn increases patient understanding of differences in hospitals and aid their decision-making. **The AAMC at this**

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<sup>63</sup> See Maria Castellucci, “CMS star ratings disproportionately benefit specialty hospitals, data show.” Modern Healthcare (March 14, 2018) Retrieved from: <https://www.modernhealthcare.com/article/20180314/NEWS/180319952/cms-star-ratings-disproportionately-benefit-specialty-hospitals-data-show>

**time supports the peer grouping proposal and will continue to study the best method to stratify comparisons in order to be useful to hospital stakeholders for quality improvement activities and provide patients a more nuanced overall comparison.** As discussed previously, in addition to peer grouping, we encourage CMS to assess ways to improve the risk adjustment of the measures in the Star Ratings.

***Star Ratings Assignment (§ 412.90(d)(8))***

CMS proposes to assign star ratings using k-means clustering among hospitals within each peer group, relative only to hospitals in the same group, based on hospital's summary scores. Retaining k-means clustering aligns with the clustering algorithm used for the separate HCAHPS Star Rating. **The AAMC supports continued use of k-means clustering to assign stars and asks CMS to consider improvements to this method in order to create predictable, fixed targets.** The AAMC believes that a "line of sight" between a hospital's performance on the individual quality measures and its rating is critical to the future utility of the Overall Hospital Quality Star Ratings continuing to motivate quality improvement. Explicit predictable scoring targets are key drivers for hospitals to invest in meaningful improvement activities. CMS could, for example, each year set a performance threshold for each star rating within each of the peer groups in advance of the next performance cycle, based off the current year's clustering of ratings, similar to how the Agency sets performance thresholds in the Hospital Value-Based Purchasing Program.

***CMS Should Continue to Explore Future Methodology Changes to Improve the Star Ratings***

***The Potential of a Template Matching Model as an Alternative Methodologic Approach***

The current method of measuring hospital outcomes on *Hospital Compare* primarily focuses on an indirect standardization, where a hospital's own case mix is used for comparing performance. This approach broadly compares the performance of all hospitals and does not distinguish important differences in patient populations served (both in complexity and in social risk factors).

An alternative approach could combine the benefits of indirect standardization with the appropriateness of direct standardization, which seeks to compare hospitals relative to an external reference population. This may be more meaningful for patients in that such a method would be more reliable for defining how well the hospital has done with other patients who have the condition for which they are seeking care.<sup>64, 65</sup> A mixed approach, known as a "hospital-specific template matching method", recently developed by researchers, seeks "to better implement indirect standardization analyses for improving a hospital's quality of care specifically tailored to the index hospital's most relevant patients – the patients they see."<sup>66</sup> Under this approach, they have found that the method "combines the fairness of comparison from direct standardization with the specific institutional relevance of indirect standardization." Considering that the *Hospital Compare* Overall Quality Star Rating is meant to assist patients and consumers choose hospitals based upon quality information *and* help guide hospitals in their quality improvement activities, the template matching model may be a valid alternative worthy of full consideration. **The AAMC urges CMS to explore**

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<sup>64</sup> See Silber, JH et al. *A hospital-specific template for benchmarking its cost and quality*. *Health Services Research*. October 2014. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/25201167>.

<sup>65</sup> See also Silber JH et al., *Comparison of the Value of Nursing Work Environments in Hospitals Across Different Levels of Patient Risk*. *JAMA Surgery*. June 2016. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/26791112>.

<sup>66</sup> See Silber et al., *A hospital-specific template for benchmarking its cost and quality*, 1477

**and model the template matching model, or other approaches that directly compare patient groups, as a possible alternative model to use for rating hospitals in the future.**

### *User-Customized Star Rating*

Currently the Star Ratings are based upon fixed measure group weights, representing a generalized vision of aspects of quality that are important to measure, while allowing hospitals to be compared against each other under a common rubric. These group weights, however, may not capture priorities, preferences, or values of an individual patient or consumer. In February 2019, CMS sought feedback on whether to further explore the introduction of a user-customization tool to the Overall Hospital Quality Star Rating, and on how to build and implement such a tool. The AAMC would like to reiterate its comments in regard to the potential of user-customized ratings. We agree that a customizable ratings tool conceptually might create greater alignment with the consumer focus of the Ratings.

At that time, CMS described a measure group weight customization to generate Star Ratings, which appeared to follow the work by the RAND Corporation with its Personalized Hospital Performance Card.<sup>67</sup> Under RAND's concept, a user can see the difference among hospitals' Star Ratings under the prescribed measure group weightings. The user also can manipulate those group weightings to see changes in the ratings based on their own preferences. For example, a user who only cares about mortality would be able to re-weight mortality to 100% of the Rating and compare that result to CMS's Rating. This gives users the ability to see CMS's Rating, while also, if they should so choose, incorporating their own values and preferences. While this approach is simple enough, the AAMC raised in our comments that an issue arises in adjusting the customized Ratings where a hospital does not have a measure group score for a measure group a user wishes to prioritize. Would the user be able to see that the CMS Star Rating does not include that measure group and recalibrates to redistribute the weights to other measure groups, and thus in this case similarly redistribute the weights? Or would it result in a "not applicable" response to alert the user that the hospital is unable to be measured on that user's criteria? We believe that a user customized rating must provide patients and their families with the information they seek and make clear where that information is unavailable for a given hospital.

Another customization concept CMS could consider is one based upon clinical condition. This would be a significantly bigger project to implement, as CMS would need to assess which conditions could be "singled" out with a rating with sufficient measures, and whether the condition-specific ratings are valid and reliable. Given the complexities of implementing this type of customization, the AAMC puts it forth only as a potential area to explore for the future as this may be the most meaningful type of information for many patients and consumers.

**Generally, the AAMC remains supportive of exploring user-customization to the Overall Hospital Quality Star Ratings.** We continue to believe more investigation is needed to better understand patient and consumer interest in and understanding of the concept to ensure that any tool meets their needs and is not overly burdensome or complex. Additionally, customized ratings must be reliable and valid before a customization tool is released to the public.

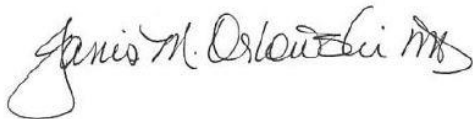
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<sup>67</sup> See RAND Corporation "Personalized Hospital Performance Card" available at: <https://www.rand.org/health-care/projects/personalized-hospital-performance-report-card.html> (Visited March 25, 2019).

## CONCLUSION

Thank you for the opportunity to comment on the CY 2021 OPPTS proposed rule. We also want to take this time to thank CMS for their flexibility, collaboration, and leadership during and continuing in the pandemic. In the first weeks of the pandemic CMS led the way in helping hospitals to prepare for countless of COVID cases by working with us and other hospital groups. 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 202.909.2084 or [mmullaney@aamc.org](mailto:mmullaney@aamc.org) or Andrew Amari at 202.828.0554 or [aamari@aamc.org](mailto:aamari@aamc.org) for questions on the payment policy proposals and Phoebe Ramsey at 202.448.6636 or [pramsey@aamc.org](mailto:pramsey@aamc.org) for questions on the quality proposals.

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orłowski M.D." with a stylized flourish at the end.

Janis M. Orłowski, M.D., M.A.C.P.  
Chief Health Care Officer

cc: Ivy Baer