



September 27, 2019

VIA ELECTRONIC MAIL
regulations.gov

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Re: CMS-1717-P, CY 2020 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center (ASC) Payment System Notice of Proposed Rulemaking

Dear Ms. Verma:

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Calendar Year (CY) 2020 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule. Our organization is the policy voice of five Seventh-day Adventist affiliated health systems that include 89 hospitals and more than 300 other health facilities in 15 states.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. Due to the difference among our hospitals and their geographic locations, our comments provide an objective and sound policy voice that work for health care as a whole.

We have read the proposed OPPS/ASC rule for acute care hospitals and appreciate the opportunity to provide comments. Below, please find AHPA's comments and recommendations on CMS' proposed policies. Specifically, we comment on the following 12 issue areas:

- Price Transparency
- Reimbursement for 340B Drugs
- Site-Neutral Payment Cut for Outpatient Clinic Visits
- Changes to the Inpatient Only List
- Ambulatory Surgical Center List
- Ambulatory Surgical Center Quality Reporting

- Outpatient Quality Reporting Program
- Drugs, Biologicals, Radiopharmaceuticals
- Prior Authorization
- Flexible Supervisory Requirements
- Children's Hospitals-Within-Hospitals
- Organ Procurement and Transplant

Price Transparency

Starting in CY 2020, CMS is proposing that hospitals make public a list of standard charges, including payer-specific negotiated rates, for 300 “shoppable” services. This proposal is in response to an Executive Order issued by President Trump in June, which instructed the Department of Health and Human Services (HHS) to publish a proposed rule requiring the publication of hospitals’ negotiated rates.¹

AHPA supports CMS’ goal to empower consumers by increasing their access to information about the cost of health care. We do believe that as health providers we have a responsibility to facilitate access to such information. However, we must ensure that the price information shared is actually meaningful to patients and not a “check the box” requirement. To ensure this, we ask that CMS revise its proposals to focus on the key policy principles we note below:

- **Focus on the cost to the consumer.** Meaningful price information will help patients understand the amount of money they are responsible for and enable them to better shop for services. This includes co-payments, out of pocket costs, deductibles, etc.
- **Couple price information with quality information.** Price information also needs to be paired with objective and understandable quality information for consumers to make an educated decision about where to obtain high value health care services.
- **Focus on Consistency.** Concentrate on consistent price and quality information across providers, allowing consumers to compare and contrast their options. For example, allowing hospitals to identify their own shoppable services may result in significant variation and fail to facilitate price comparisons.

¹ Executive Orders. [Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First.](#)

- **Partner with multiple stakeholders.** To advance CMS' goal of empowering consumers, we recommend that the Agency work collaboratively with patient groups, insurers (including Medicare Advantage and Managed Care Plans), and hospitals, to determine what information would be most helpful for patients and the most consumer-friendly way to access such information. This could be accomplished through different vehicles, such as patient focus groups and round tables.

Hospitals across the nation, such as our member system AdventHealth, have already developed strategies to share price information with patients. For example, AdventHealth has utilized the tool Simplee, which enables patients to identify their out of pocket costs for a variety of shoppable services. We welcome the opportunity to work with CMS in identifying best practices in sharing price information and collaborating with other industry leaders to identify potential solutions.

The comments below focus on specific responses to CMS' price transparency proposals and share the operational challenges of complying with the proposals as they stand. We urge the Agency to consider these operational challenges, along with the principles outlined above, before instituting any price transparency requirements.

Payer-Specific Negotiated Rates

CMS intends to further price transparency in health care by mandating that hospitals release their payer-specific negotiated rates. CMS proposes to define these rates as "all charges that the hospital has negotiated with third party payers for an item or service."

AHPA believes that payer-specific negotiated rates and gross charges are not meaningful to patients. A patient's copay, deductible and total out-of-pocket costs are more meaningful to patients when making health care decisions. Patients' financial obligations are typically not a hospital's negotiated rate with insurers. Furthermore, patients will not be able to deduce the amount they are financially responsible for from negotiated rates, which makes it difficult to shop for services. For example, medical supplies such as drugs and implantable devices have variable, interactive pricing based on the actual cost of the item to a hospital. The charge for a particular drug may also vary depending on the weight of the patient and the dosage needed. Therefore, displaying the charge for a drug on a website would not allow any person to appropriately estimate the drug's price. Other variables, such as a patient's

deductible and whether a health provider is in-network, also affect a patient's out-of-pocket costs. This information is held by insurers and is not always communicated to hospitals, which highlights the need for insurers to also be part of these transparency efforts. In addition to these issues, allowing hospitals to choose their own 230 shoppable services may make it more difficult for individuals to shop for health care services as not all hospitals would display the same information.

We also ask that CMS consider the potential unintended consequences of requiring the disclosure of negotiated rates. In 2015, the Federal Trade Commission (FTC) issued a memo in response to proposed amendments in the Minnesota Government Data Practices Act (MGDPA), which sought to classify provider contracts as public data. The FTC stated in their memo that sharing this sensitive information among competitors could, “facilitate their [competitors’] ability to coordinate or collude to fix prices, allocate markets, or engage in other conduct that harms competition.”² CMS notes that it is unsure of the impact of the proposal on the health care industry. Additionally, CMS acknowledges that the proposal may raise health care costs or encourage anticompetitive behavior, or both. We agree that making proprietary information on negotiated rates publicly available has the potential to undermine competition, which may lead to higher prices for healthcare services. This will not help beneficiaries, and it will not achieve the goals the agency seeks to advance. **Due to the lack of understanding of the potential impact, we believe that CMS should focus efforts on the primary intent of the proposal—to help provide patients with meaningful information that will assist them in health care decision making.**

Requiring hospitals to post their negotiated rates is a complex exercise that would impose a significant administrative burden. While CMS states that the chargemaster “contains all billable procedure codes performed at the hospital” and that “the hospital’s billing and accounting systems maintain the negotiated charges for service packages, which are commonly identified in the hospital’s billing system by recognized industry standard codes,” this is not the case. Each hospital maintains a single chargemaster, which contains a *portion* of the information that is completed on the hospital bill. This billing format, specifically the UB-04, is created by CMS and utilized as the industry standard for all payers. This bill is complex as it attempts to communicate and summarize the care provided to a patient

² Federal Trade Commission. [Amendments to the Minnesota Government Data Practices Act Regarding Health Care Contract Data.](#)

utilizing different types of codes, including the charges. Payments are calculated through codes on the patient claim that are assigned by Health Information Management (HIM) professionals based on the patient's medical record. Both hospitals and payers use software that review the charging and numerous codes of a hospital bill to determine the appropriate reimbursement.

Therefore, the requirement to post negotiated rates is not a straight-forward identification of the payer negotiated rates on the chargemaster. Rather, it would require compiling multiple sources of information for each of the 300 services. Additionally, payer-specific negotiated charges do not exist for all of the proposed 70 shoppable services identified by CMS. If the proposed policy is finalized, hospitals would have to potentially create multiple payer-specific negotiated charge amounts under a single third-party payer agreement. This is not simple and creates a hardship for hospitals because the information is not currently maintained.

AHPA is also concerned that significant resources will have to be deployed to create and display the payer-specific negotiated rates for physician groups affiliated with hospitals. That is because each specialty within a physician group may have different payer-specific negotiated charges. This information is not currently available and would create a significant hardship especially for large multi-specialty group practices.

Requirement to Display Price Information

CMS proposes that hospitals' standard charges be displayed in a consumer-friendly way that is derived from a comprehensive, machine-readable file. Below are the data elements that CMS proposes for hospitals to include when displaying the list of standard charges. CMS estimates that the total annual burden for hospitals to review and post their standard charges would be 12 hours per hospital and cost \$1,017.24 per hospital.

- Description of each item or service (both individual items and packaged services)
- Corresponding gross charge that applies to each individual item or service
- Payer-specific negotiated charge to each item or service (individual or packages) with corresponding third-party payer
- Any code used for accounting or billing, including CPT code, HCPCS code, DRG code, or NDC code

- Revenue code, as applicable
- Location at which each service is provided
- Associated ancillary items and services

AHPA believes that CMS' estimate does not accurately capture the amount of time and resources that hospitals would need to invest to implement the proposed policy. Displaying the proposed data elements, along with the hospital's standard charges, will be a significant undertaking. States that require hospitals to post their charges only require them to post for 25-50 services with none to the level of detail that CMS proposes. For example, a typical chargemaster does not indicate the "associated ancillary items and services" to a specific service. To comply with CMS' requirement, hospitals would need to identify these ancillary items and services through a review of historical data for similar shoppable services. This would not only be administratively burdensome but also of minimal value to individuals shopping for health care services. Since these ancillary items and services are not listed in hospitals' chargemasters, each hospital may list them differently, making it difficult for consumers to make meaningful price comparisons.

Additionally, CMS proposes including within the definition of all "items and services," the professional fees or charges for employed physicians and non-physician practitioners. This information would also be significantly difficult to provide because physician charges are separate and distinct from the hospital chargemaster and billing system. While it is possible to bill for both professional and hospital services on a UB-04 claim, most commercial insurers that receive a single bill for hospital and professional services do not reimburse separately for the professional component. To comply with CMS' policy, hospitals would need to combine the hospital and physician billing systems, which would require additional financial resources.

Due to these challenges, AHPA recommends that CMS implement the transparency requirements gradually, starting with a smaller amount of mandated shoppable services identified by the Agency in collaboration with providers. As mentioned earlier, allowing hospitals to identify their own 230 shoppable services may result in significant variation and fail to facilitate price comparisons.

Additionally, extending the implementation date may be needed to allow hospitals sufficient time to comply with the proposed policies. The OPPTS proposed rule is set to be finalized in November, which would give hospitals only two months to comply with the new requirements. Complying within this short timeframe will not be feasible, particularly for hospitals with limited resources such as safety-net

hospitals and Critical Access Hospitals. The transparency requirements should reflect what all hospitals can reasonably achieve.

Displaying Quality Information

The main goal of price transparency should be to empower patients to make educated health care decisions. While price information is a critical piece of the puzzle, it alone does not achieve this goal. Rather, it must be considered in light of other contextual information such as quality. For example, a minimally invasive robotic surgery may be costlier than a standard surgery, but a patient will encounter less blood loss and have a faster recovery. On the other hand, the most expensive care does not necessarily translate into the best care. Without objective and understandable quality information, individuals are most likely to assume that higher prices mean better care, when cost does not equate to value.³ Services provided in one hospital may be costlier than another, however the costlier hospital may have higher readmission and mortality rates. Another factor to consider would be the volume of patients that a provider sees. Physicians who have done 1,000 surgeries have more experience and practice than a physician who has only done 100. **Therefore, we recommend that CMS use both price and quality information to help consumers choose the best care.**

AHPA also recommends that quality information be risk adjusted so that hospitals serving more vulnerable populations are not penalized. As recognized by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), providers that disproportionately serve beneficiaries with social risk factors tend to have worse performance on quality measures, even after accounting for their beneficiary mix. These providers are more likely to face financial penalties across all five Medicare value-based purchasing programs in which penalties are assessed.⁴ Without appropriate risk-adjustment for socio-economic factors, consumers will be unable to get an accurate picture of a hospital's quality.

Initiatives to provide price estimates should also be tied to quality metrics. As explained earlier, having quality metrics readily available beside price information would empower patients to make meaningful comparisons between services. Currently, there are many different sources of quality information,

³ Associated Press-NORC Center for Public Affairs Research. [Finding Quality Doctors: How Americans Evaluate Provider Quality in the United States.](#)

⁴ Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.

including Leapfrog, the Joint Commission and the Hospital Overall Star Ratings. We believe that health providers, payers and patients should work together to determine what quality information consumers would need the most to make informed decisions. Moreover, the quality metrics included need to capture the socio-economic factors of the populations served by a hospital. Otherwise, a hospital serving a high population of dual-eligible beneficiaries or underserved communities may appear as being a low-quality provider.

Provide Education on Health Literacy

AHPA recommends that CMS launch outreach efforts, in collaboration with other health care stakeholders, on health literacy. Patients frequently ask hospitals for an explanation of cost information. Without appropriate health literacy, this information can often be very difficult to understand. We find that patients lack knowledge surrounding their own health plans and what contributes to their out-of-pocket costs. Hospitals see this as an opportunity to educate patients, but more must be done to provide the average American with basic health care literacy. To promote health literacy, AHPA recommends that CMS create standard health care definitions and patient-friendly vocabulary that could be used across the nation to help share price information.

As we all seek to provide more meaningful transparency in health care it is critical that we focus on the intent of the policy proposals. If CMS' goal is to help arm consumers with meaningful information to effectively shop for the highest-value service needed, then the proposed policy will not help achieve this goal. Our comments above provide a realistic representation of what it will take for hospitals to meet the requirements proposed by CMS. **This will prove to be a complex and time-intensive process that will not result in meaningful information to consumers.**

Request for Information

As part of the long-term price transparency initiative, CMS requests information to improve policies on how health care providers and suppliers can best support patients in using quality and cost information. **In developing these policies, AHPA urges CMS to create guidance for providers on how to best assist patients in assessing this information while avoiding exposure to violations of the Physician Self-Referral ("Stark") Law.** For example, as a patient is comparing information about a specific procedure, such as a joint replacement, and its cost and quality variations across providers, questions on the value of

care may be raised by the patient. If those questions are posed to a health care provider, Stark provisions may limit the ability of the health care provider to offer meaningful guidance. If CMS intends to measure health care providers on assisting patients understand cost and quality information in the future, CMS must ensure providers have clear guidance on what HHS, DOJ and CMS would consider lawful.

Reimbursement for 340B Drugs

For CY 2020, CMS proposes to continue the reduced payment of Average Sale Price (ASP) minus 22.5 percent for drugs acquired through the 340B program. Additionally, CMS seeks comments on a potential remedy should the Agency lose the pending appeal of *American Hospital Association et al. v. Azar et al.* On this ruling, the United States District Court for the District of Columbia found that HHS exceeded its statutory authority when reducing the payment rates for drugs purchased through the 340B Program in both 2018 and 2019. Despite this ruling, CMS seeks to continue the ASP minus 22.5 percent rate and proposes to adopt a prospective remedy of ASP plus 3 percent should the District Court's ruling be affirmed on appeal.

340B Drug Reimbursement Rate

AHPA strongly opposes the continuation of the ASP minus 22.5 percent reimbursement rate for 340B acquired drugs. As mentioned in previous comments, the 340B program is of significant value to hospitals, as it allows us to reinvest in programs designed to increase access to prescription medicines and other critical health services for low-income patients. Losing these 340B savings may affect the long-term viability of those programs and exponentially increase costs in other areas.

For example, Adventist GlenOaks Hospital is a rural hospital located in Glendale, Illinois. This 340B covered entity uses the savings from the program to provide medication reconciliation and bedside medication delivery. The hospital devotes one full-time pharmacist to managing both admission and discharge medication reconciliation. Much of the cost of those services is covered by 340B savings. Because of this program, GlenOaks can deliver medications to the hospital bedside of approximately 50 percent of its patients for at-home use and have a pharmacist provide medication and disease state counseling. The pharmacists at GlenOaks also utilize 340B pricing on critical medications, such as insulin, to provide affordable or free medication to uninsured or underinsured patients at the time of discharge.

Proposed Remedy Pending Appeal

The U.S. Court of Appeals for the D.C. Circuit is now considering a consolidated appeal challenging the District Court's ruling against the 2018 and 2019 340B reimbursement rate of ASP minus 22.5 percent. In anticipation of potentially losing the appeal, CMS seeks comment on potential remedies. The Agency specifically requests comments on adjusting the payment for 2018-2020 from ASP minus 22.5 percent to ASP plus 3 percent. CMS would apply this payment adjustment prospectively to all claims submitted by 340B hospitals.

AHPA believes that there is no legitimate basis for paying hospitals less than the statutory rate of ASP plus 6 percent. The ASP plus 6 percent default reimbursement rate was the methodology used from 2013 to 2017. When Congress enacted the 340B Program, the purpose was to help hospitals "stretch scarce federal resources." Read *in pari materia*, Section 340B of the Public Health Service Act and Section 1842(o) of the Social Security Act support a reimbursement rate of ASP plus 6 percent for drugs acquired at 340B prices.

The rate setting methodology defined by statute provides limited circumstances under which CMS may deviate from the statutory ASP plus 6 percent. Deviating from this rate on CMS' stated basis that it sought "to apply a downward adjustment that is necessary to better reflect acquisition costs of 340B drugs" contravenes Congress' intent for the 340B program and introduces the very harm that it was intended to mitigate. Given the legal boundaries, we cannot support any remedial reimbursement reduction that would weaken hospitals' ability to better serve patients and offer access to 340B drugs.

Administration of a Remedy

We urge the Agency to refund payments to each affected 340B hospital for all claims using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018 and 2019 hospital OPPTS rules. Specifically, the Agency can recalculate the payments due to 340B hospitals based on the statutory rate of ASP plus 6 percent provided by the 2017 OPPTS rule. Hospitals that have already received partial payment should receive a supplemental payment that equals the difference between the amount they received and ASP plus 6 percent.

In conclusion, the 340B program is a vital lifeline for safety-net providers and supports critical health services in our communities. The program is narrowly tailored to reach only hospitals that provide a high

level of services to low-income individuals or that serve isolated rural communities. Savings from the 340B program help hospitals meet the health care needs of underserved patients across the country. Due to these reasons, we do not support any further payment reductions to the program.

Site-Neutral Payment Cut for Outpatient Clinic Visits

For CY 2020, CMS proposes to complete the previously finalized two-year phase-in of site-neutral payments for clinic visits (HCPCS code G0463) furnished in grandfathered, off-campus Provider Based Departments (PBDs). These are the PBDs that were originally exempted from site-neutral payment reductions in the Balanced Budget Act of 2015. Specifically, CMS proposes to reimburse hospital outpatient clinic visits offered in grandfathered PBDs at the Physician Fee Schedule (PFS) payment rate, which is 40 percent of the OPPTS payment amount. As it did in CY 2019, the agency proposes to implement this proposal in a non-budget neutral manner, reducing hospital payments under the OPPTS by an estimated \$810 million in CY 2020.

As mentioned in previous comments, AHPA strongly opposes the implementation of this payment reduction as we believe it runs counter to Congress' intent under the Balanced Budget Act of 2015. Section 603 of the Act adopted an exemption for off-campus PBDs billing Medicare prior to the law's enactment. Specifically, the exception states:

EXCEPTION.—For purposes of paragraph (1)(B)(v) and this paragraph, the term ‘off-campus outpatient department of a provider’ shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph.

This exception makes it clear that Congress intended for the site-neutral payment reductions to apply only to those off-campus PBDs that were *not* billing under OPPTS for items and services furnished prior to November 2, 2015, when the law was enacted. OPPTS eligibility would be determined on a facility-by-facility basis rather than by specific services. Recognizing the financial investments made by hospitals, Congress also created a mid-build exception for off-campus PBDs that were under construction prior to November 2, 2015. Therefore, CMS' proposed payment reduction for clinic visits provided in exempted PBDs runs contrary to Congress' intent and should not be implemented.

While we understand CMS' efforts to reduce health care costs and wish to be a partner in those efforts (e.g. bundled payments and other models), we believe the Agency should proceed cautiously

with site-neutral payments to avoid hampering access to care. PBDs are more likely to serve higher acuity patients that have higher prior utilization of hospitals and emergency departments than patients seen in physician offices.⁵ Due to the increased complexity of these patients, PBDs tend to incur increased costs compared to physician offices. Limiting reimbursement may pressure hospitals to move physicians away from the community-based off-campus PBDs and onto centralized hospital campuses. This would make it increasingly difficult for beneficiaries to access health care services in locations near their communities.

Services provided at a PBD and a physician office should also be reimbursed differently because the cost associated with providing such services is different. To be eligible for provider-based status, PBDs must comply with a variety of regulations that are not required for physician offices. These include having quality assurance and infection control programs as well as disaster preparedness and response plans; meeting Joint Commission accreditation; complying with the Medicare Hospital Conditions of Participation; and following stringent building codes such as specific hallway widths, ceiling heights, ventilation systems. The labor and administrative costs associated with complying with these distinct regulations increase the cost of care. Unless CMS aligns the regulatory requirements between outpatient facilities and physician offices, we believe it is inadequate to pay PBDs at the same rate as physician offices. In other words, if the regulatory requirements are not the same, the payment rate should not be the same. AHPA believes that any site-neutral payment policy must be preceded by a policy to equalize the regulations between the settings. Without such a policy, PBDs would no longer become financially viable.

Changes to the Inpatient Only List

CMS proposes removing Total Hip Arthroplasty (THA) from the Inpatient Only List (IPO), thus allowing the procedure to be performed in both the inpatient and outpatient settings. According to CMS, this procedure can be performed safely in the outpatient setting and is related to codes that the Agency has already removed from the IPO list, such as Total Knee Arthroplasty (TKA).

AHPA commends CMS for creating opportunities for Medicare patients to receive care at lower costs by expanding surgical sites to less resource-intensive settings. However, we are concerned that allowing

⁵ [Comparison of Care in Hospital Outpatient Departments and Physician Offices](#), prepared for the American Hospital Association by KNG Health Consulting, LLC.

THA to be performed in the outpatient setting could pose safety risks for the Medicare population. According to the American Association of Hip and Knee Surgeons, while several case studies demonstrate the benefits of conducting THA in the outpatient setting, it remains uncertain whether this experience can be generalized to a broader population of patients and providers.⁶ The Medicare population tends to have more comorbidities than the general population and is therefore at greater risk of experiencing complications in the outpatient setting.

To ensure patient safety, AHPA recommends that CMS develop clear, standardized, evidenced-based criteria for determining appropriate candidates for outpatient THA. These criteria should be in place prior to the policy's implementation and developed in collaboration with the American Association of Hip and Knee Surgeons. Medical comorbidities for patients eligible for outpatient THA should be minimal, and patients should generally be healthy, active and at low risk for medical or surgical complications.⁷

If CMS finalizes this proposal, we recommend that CMS monitor the impact of the change by doing a comparison analysis of patient outcomes for both inpatient and outpatient THAs (e.g. patient complications and readmissions). We also encourage CMS to assess the impact that this policy will have on beneficiary access to post-acute care services. Currently, Medicare's three-day Skilled Nursing Facility (SNF) rule requires Medicare beneficiaries to have an inpatient admission of three days for Medicare to cover SNF services. Allowing THA to be performed in the outpatient setting among will negatively impact patient access to SNF services. Patient experience should also be considered when evaluating the impact of the proposed policy. Many lower joint replacement candidates need bilateral interventions. If patients have one hip or knee replaced on the inpatient setting, confusion may arise if the patient is later informed that the subsequent joint procedure must be performed in the outpatient setting. Additionally, patients may experience significant and unexpected costs that arise from the 20 percent coinsurance on outpatient surgeries.

Effect on Bundled Payments

⁶ American Association of Hip and Knee Surgeons, Position Statement on Outpatient Joint Replacement (2018).

⁷ Gronbeck, C.J., et al., Predicting Inpatient Status After Total Hip Arthroplasty in Medicare-Aged Patients, *The Journal of Arthroplasty* (2018).

Changes to the IPO list not only affect patients but also provider participation in value-based payment models. **Accordingly, AHPA strongly recommends that CMS consider the impact of removing THA from the IPO list on models such as the Bundled Payments for Care Improvement Initiative (BPCI) and the Comprehensive Joint Replacement (CJR) model.** Under these models, a hospital's expenditures are reconciled against a target price for an episode of care. That target price is calibrated based on multiple years of data that captures the price of care for healthier, low-cost patients along with more complex, higher-cost patients. If a hospital's cost of care is less than the target price, the hospital receives a reconciliation payment from CMS. If the actual cost of care is more than the target price, the hospital is required to pay the difference to CMS. The episode target prices are currently based on a blend of hospital-specific data and regional historical data. Because THA has always been under the IPO list, there is no claims history for beneficiaries receiving these services on the outpatient setting.

If CMS were to remove THA from the IPO list, the current target prices would no longer be an accurate predictor of episode spending. As healthier patients shift to the outpatient setting, providers participating in inpatient-only episodes would be left with only the more complex patients. These patients are more expensive to treat due to the increased risk of complications, thereby making it more difficult for providers to meet the originally set target prices. **To address this issue, we recommend that CMS adjust the target prices of both the CJR and BPCI models should the proposal be finalized.** Implementing the proposed policy would impact a hospital's ability to maintain costs within the target price. This could consequently compromise the validity of both the CJR and the BPCI models.

Changes to the patient case mix of CJR and BPCI could also undermine CMS' efforts to engage more hospitals in these models. In the 2019 OPPTS/ASC final rule, CMS removed TKA from the IPO list. Though data from this change is scarce, preliminary analyses have shown that outpatient TKA could result in the attrition of savings formerly realized under the BPCI model. One study indicated that hospitals could see a \$1,100 reduction in savings—largely due to higher utilization of skilled nursing and home health by the remaining inpatient populations—which may disincentivize participation in BPCI.⁸ While data may currently be limited, assessing the impact of outpatient TKAs could serve as a predictor of the proposed policy's success. Therefore, AHPA recommends that CMS evaluate such impact before

⁸ Curtin, B. & Odum, S. Unintended Bundled Payments for Care Improvement Consequences After Removal of Total Knee Arthroplasty From Inpatient-Only List, *Journal of Arthroplasty* (2019).

proceeding with the removal of THA from the IPO list. If the episode bundles are consistently placed at risk of dramatic changes to the patient case mix, hospitals will not be able to build reliable cost containment and quality improvement strategies around these models.

Recovery Audit Contractor (RAC) Review Exemptions

For the initial year following the removal of a procedure from the IPO list, CMS proposes to exempt procedures from RAC review referral by Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC QIO). CMS also proposes a one-year RAC review exemption for the two-midnight rule.

As an area fraught with confusion and administrative burden, AHPA commends CMS for seeking to facilitate the transition of procedures off the IPO list with RAC review exemptions. AHPA supports the one-year RAC review exemption, as we believe this allows a reasonable window for providers to adjust to the changes and develop any needed training.

AHPA urges CMS to make one year the *floor* for the two-midnight rule exemption, extending it as needed on a per procedure basis until enough data is available to understand the impact on patient outcomes and bundled payments. Because procedures removed from the IPO list have never been reimbursable in the outpatient setting for Medicare patients, we believe it is essential for CMS to evaluate patient outcomes before lifting the two-midnight rule exemption. In our opinion, one year of data may not be sufficient to successfully assess such impact. The two-midnight rule could exacerbate any potential adverse consequences by pressuring providers to perform a surgery in the outpatient setting despite medical judgement suggesting otherwise.

Changes to Ambulatory Surgical Center (ASC) List

As another strategy to lower costs, CMS proposes the addition of TKA to the list of procedures that can be conducted in an ASC. The addition of TKA to the ASC list adds another outpatient option for Medicare beneficiaries undergoing this procedure.

AHPA recommends delaying the addition of TKA to the ASC list until more data can be collected on the impact of performing TKA as an outpatient procedure. Just as removing TKA and THA from the IPO list can impact providers' ability to meet target prices in both the CJR and BPCI models,

transitioning it to the ASC list may further compound the issue. Moreover, continuously adding new sites of surgery can disincentive hospital participation in bundled payment models by disrupting the patient case mix that is essential to risk pooling and optimizing aggregate clinical outcomes. Delaying the proposed policy would allow providers and CMS to better predict the long-term effects on quality and safety. It would also allow for the adjustment of current payment models if needed. If CMS were to finalize this proposal, we encourage the development of standardized, evidenced-based criteria for determining appropriate candidates for having TKA in an ASC.

Ambulatory Surgical Center Quality Reporting

CMS proposes to adopt the quality measure “ASC-19 Facility-Level 7-Day Hospital Visits After General Surgery Procedures performed at ASCs” in the ASC Quality Reporting Program (ASCQR). This measure captures all-cause, unplanned hospital visits within seven days of any general surgery procedure performed at ASCs. No measure is formally in place that captures this data at this time.

As the Agency notes, ASCs are largely unaware of readmissions once a patient is discharged, since the readmission is typically to an unaffiliated facility. Therefore, adopting this quality reporting metric can assist CMS in comparing relative readmission risks between sites of surgery to better inform changes to the IPO and ASC lists. Because CMS currently collects this data from hospital claims, there is no additional administrative burden for ASCs or hospitals if the measure is adopted. **To provide further clarity, we do recommend that CMS rename the metric. The current name suggests that it assesses hospital visits that are seven days in duration, rather than visits within a seven-day window after discharge from an ASC.**

Outpatient Quality Reporting Program

Measure Removals

CMS proposes to remove OP-33: External Beam Radiotherapy for Bone Metastases measure from the Hospital Outpatient Quality Reporting (OQR) Program. The removal would be effective beginning with the CY 2022 payment determination.

AHPA supports the removal of this measure from the OQR program. Because treatments delivered to different anatomical locations on the same patient are counted separately and many software

applications do not aggregate the total dose provided, the OP-33 measure often requires manual review and dose calculation. This process is labor intensive for clinicians, increasing administrative burden.

Future Measure Adoptions

CMS requests comments on the potential future adoption of the following four patient safety measures, previously included in the ASCQR program:

- ASC-1: Patient Burn
- ASC-2: Patient Fall
- ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant
- ASC-4: All Cause Hospital

The National Quality Forum (NQF) endorsement of these measures was allowed to lapse by the measure steward. Subsequently, data collection for these measures was suspended in the CY 2019 OPPTS/ASC final rule due to data collection concerns. If adopted, these measures would be specified for the hospital outpatient setting.

AHPA commends the Agency for seeking to protect patient safety and urges it to reobtain NQF endorsement prior to measure adoption. The NQF evaluation and endorsement process provides a valuable examination of the validity, reliability and feasibility of measures. While we support the goal of monitoring events detrimental to patient safety, we believe that this endorsement is critical to protect the integrity of measures used across quality programs.

Drugs, Biologicals and Radiopharmaceuticals

CMS proposes the addition and removal of several drugs and biologicals from the pass-through status list. These proposals are consistent with the three-year statutory limit for pass-through status and are reflective of the progression of the listed drugs and biologicals through the transitional window. Under this same policy, CMS also proposes a \$130 per diem threshold for packaged drugs. Items above this threshold would be separately payable unless otherwise policy-packaged.

AHPA recommends that for the per diem threshold, CMS consider creating an exception when drug shortages create the need to use a higher cost substitute for one or more drugs that are

otherwise packaged. In these exceptional cases, AHPA would recommend that CMS pay for the higher cost substitute at a separately payable rate of ASP plus 6 percent.

Prior Authorization

CMS proposes the addition of five procedures to the Prior Authorization (PA) list which have shown a significant increase in utilization. Though these procedures have therapeutic indications, they are also often prescribed for cosmetic purposes and do not generally require prior authorization. CMS seeks to reduce the medically unnecessary use of these procedures, while still allowing physicians who demonstrate a provisional authorization threshold of 90 percent on a semiannual basis to be exempt from prior authorization.

AHPA supports CMS' proposal to require prior authorization for these procedures, as well as the effort to consider physician burden reduction with the establishment of the authorization threshold.

AHPA believes this proposal adequately accounts for physician and patient needs, while reducing overutilization that contributes to rising costs of care. However, if the provisional authorization threshold is finalized, we urge CMS to remain open to revising such threshold in future rulemaking if it proves to be administratively burdensome or difficult to attain.

Additionally, AHPA recommends that CMS provide clarity around the specific timeframe to perform a procedure once authorization is granted. For example, if CMS authorizes that rhinoplasty is medically necessary for a patient, providers should be informed whether that authorization will expire and, if so, when. This will better position providers to discuss medical options and the course of patient care.

Flexible Supervisory Requirements

CMS proposes to change the generally applicable, minimum required level of physician supervision for outpatient services from "direct supervision" to "general supervision" for services delivered in hospitals, including Critical Access Hospitals. Currently, "direct supervision" is the generally applicable, minimum required level of physician supervision. Under this proposal, physicians would still be required to direct and control all outpatient therapeutic services; however, they would not have to be physically present during the procedure's performance.

AHPA supports allowing hospital outpatient therapeutic services to be delivered under general physician supervision. We also support allowing physicians to opt for a higher level of supervision on a case-by-case basis, according to each patient’s individual clinical needs. AHPA believes that permitting this flexibility will streamline the supervisory standards and help small, rural hospitals to share specialty physicians when appropriate.

Children’s Hospitals-Within-Hospitals

A Hospital-within-a-Hospital (HwH) is defined as a hospital occupying the same building as another hospital, or in one or more entire buildings located on the same campus as the other hospital. Grandfathered children’s HwHs can preserve their exempted status as long as they operate under the same terms and conditions—including the number of beds. CMS proposes to allow these hospitals increase their number of beds without losing their grandfathered status.

AHPA commends the Agency for this change and supports allowing children’s hospitals to expand their number of beds. We agree that there appears to be no payment policy rationale within Medicare for this prohibition and that it would not give these hospitals an economic advantage over their freestanding peers. The flexibility granted by this proposed change will permit children’s hospitals to expand their graduate medical education residences and increase access to care for the children they serve.

Organ Procurement and Transplant

Revised Definition of “Expected Donation Rate”

Organ Procurement Organizations (OPOs) are evaluated on outcome measures that use, among other factors, the expected donation rate for an OPO. Currently, CMS defines this rate as the “donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and Donation Service Areas (DSAs).” CMS proposes to redefine the expected donation rate as follows:

“The expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. *This rate would be adjusted for the distributions of age, sex, race and cause of death among eligible deaths* (emphasis added).”

AHPA supports the proposed update to the expected donation rate definition. We believe that this change will strengthen measure integrity and ensure that OPOs are being evaluated against a relevant

metric. In addition, the updated definition is in alignment with the Scientific Registry of Transplant Recipients' definition, which adjusts for age, sex, race and cause of death. Harmonizing these two definitions will reduce burden for OPO administrators and reduce potential provider confusion.

Potential Changes to OPO and Transplant Center Regulations

CMS seeks comment on modifications to current Conditions for Coverage (CfCs) for OPOs and Conditions of Participation (CoPs) for transplant centers. Specifically, the Agency requests information on revisions that can more accurately capture performance data and assist in quality improvement.

AHPA requests that CMS reevaluate transplant center CoP metrics and remove those that disincentivize accepting less-than-perfect, but safe donor organs. Fear of being flagged for low performance can unintentionally limit access for transplant patients, particularly the elderly. While a kidney from a 60-year-old donor has a shorter forecasted longevity, it may meet the need of an elderly transplant recipient. Unfortunately, more than half of all kidneys with a Kidney Donor Profile Index (KDPI) greater than 85% are discarded each year, despite the survival benefit of receiving a high-KDPI transplant over remaining on a waitlist.⁹ As transplant centers become more risk-averse, a conflict of interest emerges for centers that want to provide life-saving procedures but are afraid of jeopardizing their status and incurring penalties from CMS. Utilization of organs from older donors is depressed, as their donor profile index is often lower.

AHPA also requests that CMS create a path similar to the Systems Improvement Agreement (SIA) to assist underperforming OPOs with performance improvement. We see great value in the current SIA process for underperforming transplant centers. Since 2007, transplant centers that fail to meet outcome benchmarks are given the opportunity to enter an SIA with CMS to correct deficiencies. Currently, no such path to performance improvement exists for OPOs that fail to meet outcome measure requirements.

Future Measure Adoptions

CMS solicits comment on whether the following two OPO outcome measures would be valid and reliable for future inclusion:

⁹ Jay, C., & Schold, J. D., [Measuring Transplant Center Performance](#). Current Transplantation Reports (2018).

- Actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation,
- Actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation.

AHPA supports the inclusion of these two metrics into OPO performance measurement. We believe that these measures accurately reward well-performing OPOs for organ procurement and placement.

Conclusion

AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact me at Carlyle.Walton@AdventistHealthPolicy.org or Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AdventHealth.com.

Sincerely,



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