



A Passionate Voice for Compassionate Care

October 5, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals Proposed Rule (Vol. 85, No. 156), August 12, 2020.

REF: CMS-1736-P

Dear Administrator Verma:

The Catholic Health Association of the United States (CHA) is pleased to submit these comments on the Centers for Medicare & Medicaid Services' (CMS) proposed calendar year (CY) 2021 Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) rule. This proposed rule includes provisions on payment for part B drugs acquired under the 340B program, physician supervision level, eliminating the inpatient only list, eliminating criteria that exclude surgical procedures from being paid in ASCs, site neutral payment, hospital quality star rating methodology and prior authorization, among other provisions.

We appreciate your staff's ongoing efforts to administer and improve the payment systems for outpatient hospital and ambulatory surgical services, especially considering the agency's many competing demands and limited resources. CHA offers the following comments on the proposed rule.

- **340B Payment Policies**

In the 2018 OPPS rule, CMS adopted a policy to pay separately payable Part B drugs in the hospital outpatient department acquired under the 340B program at average sales price (ASP)-

22.5 percent in place of ASP+6 percent. CHA objected to CMS' policy at that time on legal and policy grounds. In our public comments, CHA stated that CMS lacks authority to make this change, which has undermined the very purpose of the 340B program and caused harm to 340B hospitals, to the communities and patients those hospitals serve, and to Medicare beneficiaries. Despite objections from CHA and others, CMS decided to finalize its policy for 2018 and continued it in 2019 and 2020. For 2021, CMS proposes to further reduce reimbursement for 340B drugs from ASP-22.5 percent to ASP-28.7 percent.

The policy is the subject of ongoing litigation. The United States District Court for the District of Columbia in separate rulings concluded that the Secretary exceeded his statutory authority by adjusting Medicare payment rates for drugs acquired under the 340B Program to ASP-22.5 percent for 2018 and 2019. On July 31, 2020, just two business days before the 2021 OPPS rule was released, the United States Circuit Court for the District of Columbia released an opinion reversing the district court's judgment. The plaintiffs in that litigation are seeking review of the decision by the full Circuit Court. CHA remains optimistic that CMS' policy will be overturned and continues to urge CMS to avoid that result by returning to the prior policy of paying ASP+6 percent.

As a matter of policy, savings generated by the 340B program allow hospitals to provide many types of assistance to low-income patients and communities, including access to free or reduced priced drugs for those who cannot afford their prescriptions; clinical pharmacy services; funding for services such as obstetrics, psychiatry, diabetes education, and oncology; and establish outpatient services to increase access. Reducing 340B reimbursement harms vulnerable patients by cutting the savings hospitals use to provide needed services in underserved areas. Given the purpose of the 340B program is to "maximize scarce Federal resources as much as possible, reaching more eligible patients, and provide care that is more comprehensive," **CHA strongly urges CMS to return to paying for Part B drugs acquired under the 340B program at ASP+6 percent.**

For 2021, CMS is increasing the adjustment for drugs acquired under the 340B program from ASP-22.5 percent to ASP-28.7 percent based on a survey of 1,422 hospitals that participate in the 340B program. **CHA opposes this proposal.**

CMS did not survey hospitals that do not participate in the 340B program. Therefore, CMS is basing its payment for drugs and biologicals for 340B hospitals under one provision of the statute¹ that requires the payment be equal to the average acquisition cost based on a cost survey while basing its payment for drugs acquired by all other hospitals under another provision of statute² that defaults to ASP+6 percent. While the legality of selectively paying two different classes of hospitals for the same item under two different provisions of statute is unclear, CHA believes it is clearly an unwise policy. CMS should be using a single statutory authority and

¹ Section 1833(t)(14)(A)(iii)(I) of the Act

² Section 1833(t)(14)(A)(iii)(II) of the Act

policy to pay all hospitals for separately payable drugs. Either all hospitals should be surveyed and paid based on their acquisition costs or CMS should apply the default methodology when acquisition costs are unavailable and pay all hospitals for drugs at ASP+6 percent. **CHA supports paying all hospitals at ASP+6 percent.**

CMS details in the rule myriad adjustments it made to the survey data to conclude that average acquisition cost for 340B drugs is ASP-34.7 percent and propose a 6 percent add-on for handling, storage and other overhead costs. CHA is concerned that this discussion suggests CMS may be making a future year adjustment to further reduce drug payments to 340B hospitals (e.g. including “penny pricing” in the estimate of acquisition costs). Again, CHA opposes both the reduction CMS proposes for 2021 and any further reductions in drug prices for 340B acquired drugs because these reductions are inconsistent with the purpose of the 340B program.

- **Physician Supervision of Outpatient Services**

For non-surgical extended duration services (observation services), the minimum default supervision level is direct supervision during the initiation of the service followed by general supervision during the monitoring period at the discretion of the supervising physician or the appropriate non-physician practitioner. CMS proposes to change the required level of supervision from direct to general for the entirety of the service. **CHA supports this proposal.**

For pulmonary, cardiac and intensive cardiac rehabilitation services, the Medicare statute describes a level of supervision required that is comparable to direct supervision. During the public health emergency, CMS is allowing a virtual presence in providing direct supervision for pulmonary, cardiac and intensive cardiac rehabilitation services using interactive telecommunications technology. CMS proposes to allow this virtual presence to meet the direct supervision requirement for pulmonary, cardiac and intensive cardiac rehabilitation services even after the public health emergency. **CHA supports this proposal.**

- **Inpatient Only List**

Services on the IPO list, which currently includes approximately 1,740 services, are not paid under the OPFS. Services on the IPO list require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient requiring surgery.

While CMS previously saw a need for the IPO list, it now believes physicians should use clinical judgment together with consideration of the beneficiary’s specific needs to select an inpatient or outpatient setting for care. As medical practice continues to develop, CMS believes the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. CMS further believes that the evolving nature of the practice of medicine, state and local licensure requirements, accreditation requirements, hospital

conditions of participation, medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list.

CMS is proposing to eliminate the IPO list over a transitional period beginning in 2021 and ending in 2024. For 2021, CMS is proposing to remove 266 musculoskeletal services from the IPO list. In addition, CMS notes that once procedures are removed from the IPO list they are exempt from the medical review for site of service selection (inpatient or outpatient) under the two-midnight rule for two years. CMS asks whether this two-year exemption period should be made longer or shorter.

Many services on the IPO list are surgical procedures that can be complex and require high levels of care and coordinated services. While we do believe physicians' clinical judgement should play a role in determining where patients receive care, we have concerns with the inconsistencies and barriers to care this proposal may create. **CHA urges caution as CMS considers eliminating the IPO list. If CMS moves forward, there are a number of concerns that must be addressed.**

Services on the IPO list require inpatient care because of the invasive nature of the procedures, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient requiring surgery. While many of the procedures may be safely performed in a hospital outpatient setting, that setting is not clinically appropriate for all procedures currently on the IPO list, such as invasive heart surgeries, organ transplants or amputations. Nor do all of the 266 musculoskeletal procedures proposed for removal in 2021 have adequate data to support their performance in an outpatient setting.

We are also concerned that the agency does not have the claims data necessary to appropriately determine how to place newly outpatient covered services into existing ambulatory payment codes (APCs) or create new APCs. While the proposed rule includes proposed APC assignments for 266 musculoskeletal-related services, CMS fails to provide any data or rationale for the proposed assignments. Further, given the breadth and timing of CMS' proposal to eliminate the IPO list over three years, determining appropriate payment for the volume of services would be a massive undertaking for the agency.

CHA believes that is premature to adopt a policy to eliminate the IPO list over three years. Instead, CMS should continue with its standard process for removing procedures. It should also consider setting general criteria for procedure selection based upon peer-reviewed evidence, patient factors including age, co-morbidities, social support, and other factors relevant to positive patient outcomes to facilitate the appropriate removal of procedures from the IPO list.

If CMS does move ahead with its proposal, it should reconsider the three-year timeframe, which is incredibly short. **CHA urges CMS not to finalize the IPO list removal policy as proposed.**

- **Medical Review of Certain Inpatient Hospital Admissions: the Two-Midnight Rule**

Under the two-midnight rule, an inpatient admission is considered reasonable and necessary when the physician expects the patient to require a stay that crosses at least two midnights. Since 2016, CMS has allowed for case-by-case exceptions to the two-midnight rule where the admitting physician does not expect the patient to require hospital care spanning two midnights but documentation in the medical record supports the physician's determination that the patient requires inpatient hospital care. Procedures on the IPO list are appropriate for inpatient hospital admission regardless of the expected length of stay. Once a procedure is removed from the IPO list, it is subject to medical review for compliance with the two-midnight rule by a Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs). BFCC-QIOs may refer cases for further review by the RAC if the hospital has high denial rates, consistently fails to adhere to the two-midnight rule or fails to improve after BFCC-QIO educational intervention.

CMS proposes that a procedure removed from the IPO list would not be subject to referral to Recovery Audit Contractors (RAC) for compliance with the two-midnight rule within the first two calendar years of their removal from the IPO list. **CHA strongly supports continuing to exempt from the two-midnight rule procedures recently removed from the IPO list.** CHA urges CMS to consider a longer exemption period if it finalizes the proposal to eliminate the IPO list and to identify procedures that should be permanently exempt.

- **ASC List**

Under the current regulations, surgical procedures are appropriate for inclusion on the ASC list if they would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC and if standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. In addition, surgical procedures are excluded from the ASC if they:

1. 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;
5. Commonly require systemic thrombolytic therapy;
6. Are on the IPO list;
7. Can only be reported using a CPT unlisted surgical procedure code; or
8. Are excluded from Medicare coverage (preventive exams, eye exams, custodial care, dental services, etc.).

Exclusion Criteria

As CMS is proposing to eliminate the IPO list, criterion 6 will no longer be relevant once the phase-out of the IPO list is complete in 2024. In addition, CMS is proposing to eliminate exclusion criteria one through five above. This would mean that a procedure could be added to the ASC list as long as it meets the inclusion criteria, is not described by an unlisted code and is not excluded from Medicare coverage, even if, for example, it is generally emergent or life threatening or results in extensive blood loss. Consistent with this proposal, CMS proposes to add 270 procedures to the ASC list effective in either 2021 or 2022 depending on the option selected for another proposal described below.

CHA opposes CMS' proposal to eliminate the ASC exclusion criteria, which are necessary to protect patients from having procedures performed in an ASC that are unsafe to perform in that setting. While CMS believes that the ASC conditions for coverage provide assurance that services furnished in the ASC setting are held to a high standard of safety, CHA remains concerned. For example, there could be a conflict of interest when the physician selecting the site of service owns or has a financial stake in the ASC. ASC services are not designated health services subject to the Stark self-referral provisions and CHA believes that CMS serves in an important quality oversight role by designating only those procedures that are safe to perform in an ASC. Once the above exclusion criteria are eliminated, patients could potentially have a procedure done in an ASC that is emergent or life threatening without any requirement to be informed that their life may be at risk when they are not in a hospital that will be better equipped to treat a patient in a life-threatening emergency situation.

Addition of 270 Procedures to the ASC List

We further note that ASCs are intended to be for scheduled, ambulatory surgical procedures. Among the 270 procedures that CMS proposes to add to the ASC list are many procedures that would never be scheduled in an ASC. For instance, there are several procedure codes for exploration of a penetrating wound (often billed when the patient has a gunshot or a stab wound). There are many other procedures related to trauma treatment that are not likely to be scheduled in ASCs and should not be eligible to be done in the ASC. Inclusion of these procedures on the ASC covered procedures list seems highly inappropriate and suggests that CMS has not fully thought through its proposal. Until such time as CMS can make a more reasoned proposal that only includes procedures that can be appropriately performed in an ASC, **CHA opposes CMS' proposal to add 270 procedures to the ASC list.**

Procedural Changes

CMS has proposed two alternative methods for determining whether to add a procedure to the ASC list. Under the first alternative CMS would add procedures to the ASC list using a public nomination process. Under the second alternative CMS would continue its current process for adding procedures to the ASC list. Under either alternative, CMS would eliminate exclusion

criteria one through five above. If CMS selected the public nomination process, it would not add the 270 procedures proposed for addition to the ASC list for 2021 as it would instead rely on public nominations for adding procedures to the ASC list. If CMS continued with the current process for adding procedures to the ASC list, it proposes to add 270 procedures to the ASC list effective for 2021.

As already noted, CHA opposes both the elimination of the exclusion criteria and the proposed addition of 270 procedures to the ASC list. However, should CMS go forward with changes to the ASC list, the public nomination process in the first alternative would be preferable. A nominations approach would result in procedures being added to the list based on the experience of medical professionals who have clinical experience to support which procedures can be safely added to the ASC list. Further, CMS would continue to use the rulemaking process to evaluate public nominations where the logic and rationale for a procedure being added to the ASC list would be fully explained. If, for example, CMS did not receive a public nomination to add a procedure from among the 270 that CMS proposes to add to the ASC list, the procedure would be ineligible to be added to the ASC list beginning in 2022.

- **Services Furnished in Off-Campus Provider-Based Departments**

Off-campus provider-based departments (PBDs) that opened after November 2, 2015 (non-excepted off-campus PBDs) are paid through the physician fee schedule (PFS) at a rate equal to 40 percent of the OPSS rate, pursuant to Section 603 of the Bipartisan Budget Act (BBA) of 2015 as implemented by CMS. In the BBA Congress specifically excepted from this new policy off-campus PBDs that existed prior to November 2, 2015 (excepted off-campus PBDs). However, in the CY 2019 OPSS final rule CMS adopted a policy to apply the PFS adjusted payment rate for clinic visits (HCPCS code G0463) in *excepted* off-campus PBDs and exempted this payment change from the required budget neutrality requirements that customarily apply to OPSS payment changes. CHA opposed these changes policy as being inconsistent with the statute.

On September 17, 2019, the United States District Court for the District of Columbia found “that the ‘method’ developed by CMS to cut costs is impermissible and violates its obligations under the statute. While the intention of CMS is clear, it would acquire unilateral authority to pick and choose what to pay for [hospital outpatient department] services, which clearly was not Congress’ intention. The Court [found] that the Final Rule is *ultra vires*.” While the United States Circuit Court for the District of Columbia has since taken an alternative view in this case, litigation remains ongoing.

As we noted in our comments last year, CHA hospitals provide services to low income and rural communities. Payment rates for non-excepted off-campus PBDs under section 603 are already affecting access to needed services by lessening the hospital’s ability to move into these communities when physicians are leaving their practices. Additional payment reductions to

hospitals' excepted PBDs that are neither required nor supported by the law negatively affect access to needed services in these vulnerable communities. CMS is not adequately taking into account the role off-campus PBDs play in the communities they serve as a crucial and often only point of access for health care services, nor does it acknowledge the key differences between physician practices and off-campus PBDs that result in higher overhead expenses for off-campus PBDs. **CHA continues to strongly oppose this policy and encourages CMS to restore payment for outpatient clinic visits in excepted off-campus PBDs to 100 percent of the OPPS rate. CMS should also make remedial payments to hospitals for underpayments in 2019 and 2020.**

- **Outpatient Hospital Quality Reporting (OQR) Program**

CHA supports the proposal to provide hospitals with the opportunity to review and correct measures submitted via a web-based tool, as is currently possible for chart-abstracted measures. Hospitals will submit data on three measures for the 2021 OQR program using a web-based tool: OP-22: ED Left without being seen, OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients, and OP-31: Improvement in Visual Function within 90 Days Following Cataract Surgery, which is a voluntary measure. Hospitals should have the opportunity to review and correct any data submitted on these measures and on any future measures reported using a web-based tool. **CHA also supports the proposed updates to the OQR Program regulatory text.**

- **Overall Hospital Quality Star Rating**

CMS proposes major changes to the methodology used to calculate the Overall Star Rating on the *Hospital Compare* portion of Medicare's new *Care Compare* web page. CHA appreciates CMS' attention to address concerns raised by hospitals about the difficulty in replicating and explaining the Overall Star Rating methodology. In particular, we support changes that will make the Overall Star Rating calculations easier for hospitals to predict and replicate based on their performance on the underlying quality measures. **CHA supports the proposed replacement of the Latent Variable Model (LVM) with a simple average when calculating scores for the five measure groups will avoid annual and unpredictable changes in the weighting of the underlying measures.**

Regarding the proposal to stratify the readmission measure group scores by hospitals' proportion of dual eligible patients, **CHA agrees that there should be alignment between the Overall Star Rating and the Hospital Readmission Reduction Program (HRRP).** We understand that the same peer group definitions would be used, and hospitals that do not participate in the HRRP would be assigned an HRRP-designated peer group for purposes of the star ratings calculation. In a May 2020 report, the Assistant Secretary for Planning and Evaluation recommends that the existing stratification eventually be eliminated, and that *Care Compare* should separately display performance on these measures for dual eligibles and other Medicare beneficiaries. Accounting for differences in the socioeconomic status of hospital patient populations is critical to

understanding quality performance. CMS should not make any changes in the treatment of dual eligible status without taking the time to consult with stakeholders before proceeding through notice and comment rulemaking. **More broadly, CMS should continue to work toward greater accounting of socioeconomic status in the quality measures that compose the Overall Star Rating.**

- **Prior Authorization**

Effective for dates of services on or after July 1, 2021, CMS proposes to add the following two services categories to the prior authorization list: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. CMS proposes to add these services to the list of services subject to prior authorization because it believes the services have high rates of utilization growth. Without having done any medical review on these procedures, CMS concludes that a high rate of utilization growth equates to unnecessary utilization. **CHA disagrees and opposes adding these two sets of codes to the list of those subject to the prior authorization.**

With respect to cervical fusion, the increase in outpatient utilization growth for the two cited codes followed and can be attributed to their removal from the IPO list. Transition of procedures to outpatient settings consistent with CMS policy inevitably increases outpatient volumes over time. CMS should take a broader view of total service utilization before recommending the application of prior authorization. **CHA requests CMS not make the surgical fusion codes subject to prior authorization.**

CMS says that the average annual increase in volume was 17 percent for implanted spinal neurostimulators between 2016 and 2018. However, the Standard Analytic File also shows utilization increasing 6 percent in 2013, 2 percent in 2014, decreasing 4 percent in 2015 and decreasing 7 percent in 2019. Clearly, the 2016 to 2018 utilization growth is atypical and lower utilization growth or declines in utilization do not suggest that prior authorization is warranted even under CMS' assumption that growth higher than the national average means the procedure is being provided unnecessarily.

We further note that implantable neurostimulators are used as an alternative to opioids in treating chronic intractable pain. Subjecting this procedure to prior authorization could lead physicians to prescribe opioids for their patients. CHA believes that CMS should be encouraging rather than discouraging non-opioid treatment alternatives given the epidemic of opioid addiction in the United States. CHA urges CMS not to subject implantable spinal neurostimulators to prior authorization.

In closing, thank you for the opportunity to share these comments on the proposed 2020 OPSS proposed rule. We look forward to working with you on these and other issues that continue to

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challenge and strengthen the nation's hospitals. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director, Public Policy, at 202-721-6300.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa A. Smith". The signature is fluid and cursive, with the first name "Lisa" being the most prominent part.

Lisa A. Smith
Vice President
Public Policy and Advocacy