Via Electronic Submission

September 24, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children’s Hospitals -Within-Hospitals [CMS-1717-P]

Dear Administrator Verma:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology (ASCO) in response to the recent proposed rule for the Hospital Outpatient Prospective Payment System for calendar year 2020 published in the Federal Register on August 9, 2019.

ASCO is the national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries.

ASCO has significant concerns that the policies proposed by CMS for 2020 have the potential to undermine patient access to cancer care for Medicare beneficiaries.
In summary:

- CMS should not finalize its proposed policy implementing prior authorization for certain services paid for under the OPPS system.
- ASCO continues to object to CMS’s policy that sets Medicare payment for separately covered outpatient drugs purchased under the 340B program at ASP minus 22.5 percent.
- ASCO continues to object to CMS’s policy to set payment for certain separately payable drugs and biologicals at 103 percent of the drug or biological’s Wholesale Acquisition Cost (WAC).
- CMS should proceed cautiously with its efforts to require price transparency, particularly with its proposal to require hospitals to disclose charges for OPPS services.
- ASCO supports the proposal to loosen the physician supervision requirements for outpatient therapeutic services.
- ASCO opposes the proposed revisions to the laboratory DOS policy.

Specific comments are below.

I. ASCO’s specific comments with respect to CMS proposed Hospital Outpatient Prospective Payment System payment policies for CY 2020

1. CMS should not finalize its proposals to implement a prior authorization (PA) process for certain Medicare covered services provided in the OPPS setting. (Section XX., page 39603)

ASCO is concerned with the use and application of prior authorization requirements and the negative impacts that PA can have on patient access to care. ASCO remains committed to the principles and recommendations conveyed in its 2017 policy statement on utilization management, and to working with stakeholder groups to develop and implement policies that benefit patients with cancer. In this policy statement, ASCO outlined six basic tenets that any utilization management policy must meet in order to ensure that patient access to care is not jeopardized. These tenets are:

- Individuals with cancer should have full access to the anti-cancer therapy most appropriate for their disease when used in accordance with current clinical and scientific evidence.
- Cost should not be the primary driver of utilization management policies.
- Utilization management policies should be evidence-based and reflect the most current science and understanding of cancer treatment.
- Utilization management processes should result in timely and clear determinations that

are consistent with the health insurer's coverage and other policies.

- Payer cost containment strategies and decision-making processes should be transparent and without conflicts of interest.
- Payers should implement utilization management policies in a way that minimizes administrative burdens—specifically time and effort—on both providers and patients

a. **ASCO does not believe that CMS has the legal authority to implement a prior authorization process for OPPS services**

In the Proposed Rule, CMS takes the position that Social Security Act § 1833(t)(2)(F) allows the agency to implement a prior authorization program for five categories of services that the agency describes as “typically cosmetic” procedures and which have shown utilization growth inconsistent with CMS’s expectations. Section 1833(t)(2)(F) is broadly worded and gives CMS the authority to develop “a method for controlling unnecessary increases in the volume of covered [outpatient] services.” As outlined below, however, Congress did not intend for § 1833(t)(2)(F) to give CMS carte blanche to deviate from established outpatient payment methodologies.

The limitations inherent in CMS’s authority under § 1833(t)(2)(F) are most clearly evidenced by Congress’s response to the agency’s implementation of another payment policy – functional equivalence – that radically deviated from established outpatient payment principles. Specifically, in the CY 2003 OPPS Final Rule, CMS implemented a functional equivalence standard that would have allowed the agency to establish identical payment rates for distinct therapeutic products. At the time, CMS took the position that another broadly-worded provision codified in Social Security Act § 1833(t)(2) – § 1833(t)(2)(E), which allows CMS to make “other adjustments as determined to be necessary to ensure equitable payment” – authorized the agency to implement functional equivalence. In response, Congress enacted legislation that explicitly prohibited CMS from implementing functional equivalence. This sequence of events suggests that Congress did not intend to grant CMS broad exception-making authority under § 1833(t)(2)(F).

Furthermore, we note that when Congress has intended to give CMS the authority to implement a prior authorization requirement, it has done so explicitly. For example, CMS’s authority to impose a prior authorization requirement on durable medical equipment comes from a statutory provision (Social Security Act § 1834(a)(15)) that expressly requires Medicare contractors to “determine in advance of delivery of an item whether payment for the item may not be made.” Had Congress intended to give CMS the authority to subject other types of services to prior authorization, it likely would have done so expressly.
b. CMS must do a more compressive analysis of utilization and prescribing trends before implementing any policy that restricts access in order to determine if changes in the practice of medicine (e.g., new indications and/or uses) result in legitimate increased utilization.

While ASCO shares CMS’s concerns that the Medicare program be protected from abusive billing practices and that the program only reimburse services that are reasonable and necessary, we do not agree with this proposed prior authorization process to address perceived increases in utilization—particularly when those increases are explained by medically appropriate usages. While CMS describes its list of items subject to prior authorization as “an initial effort to focus our analysis ... on procedures that are likely to be cosmetic” the proposed rule does not state that prior authorization will stop with “cosmetic” services. In fact, the proposed regulations permit any “update” to the list of topics subject to prior authorization as long as updates occur through notice and comment rulemaking. Once this list is created, more and more items could require prior authorization whether they have any connection to “cosmetic” services.

We do not believe that CMS has provided sufficient information supporting the need for a broad-based prior authorization process. In the proposed rule, CMS states that the rate of growth in the number of unique claims within the five categories of services increased at rates that “far exceed the typical baseline rates or trends we identified.” This kind of broad statement fails to demonstrate how CMS reached the conclusion that the utilization growth for these groups of codes was reflective of inappropriate billing – as opposed to being reflective of growth and advancement in the practice of medicine.

If CMS suspects fraud and/or abusive billing is occurring, it should deploy its program integrity tools, including provider education, comparative billing reports, medical claims review and/or referral to law enforcement, on those specific providers who are improperly billing, rather than subjecting all providers in a specialty to an onerous process that will result in unnecessary payment restrictions.

The Medicare Program Integrity Manual provides a range of tools that CMS and the MACs can use when they determine that a program vulnerability exists. These tools range from provider educational outreach (e.g., comparative billing reports), post-payment medical review, pre-payment medical review and referral to law enforcement and include the recently developed Targeted Probe and Educate program. CMS and the MACs use these tools when data show a vulnerability either exists or is likely to exist. A sound data analysis plan contains the following elements:

- Identify those areas of potential errors (e.g., services which may be non-covered or not correctly coded) that pose the greatest risk;
- Establish baseline data to enable recognition of unusual trends, changes in utilization over time, or schemes to inappropriately maximize reimbursement;
- Identify where there is a need for an LCD;
• Identify where there is a need for targeted education efforts;
• Suggest claim review strategies that efficiently prevent or address potential errors (e.g., prepayment edit specifications or parameters);
• Produce innovative views of utilization or billing patterns that illuminate potential errors;
• Identify high volume or high cost services that are being widely over utilized. This is important because these services do not appear as an outlier and may be overlooked when, in fact, they pose the greatest financial risk;
• Identify program areas and specific providers for possible fraud investigations; and
• Determine if major findings identified by Recovery Auditors, CERT, and CMS represent significant problem areas in the MAC’s jurisdiction.

It does not appear that CMS followed this rubric when developing the prior authorization process it has proposed. CMS should not implement any utilization management tools without first having designed and completed a comprehensive data review that will not only identify vulnerabilities, but will also highlight whether such vulnerabilities are systemic—or are isolated to a handful of providers. By doing so, CMS can then target appropriate corrective actions in a way that does not impact access to care for all patients.

2. ASCO continues to oppose changes to the payment rate for separately payable Part B drugs acquired by hospital outpatient departments through the 340B program. Additional reforms to the 340B Drug Pricing Program are needed to ensure the program meets its original intent to support high-quality care for the uninsured, underinsured, and low-income patients. (Section B.2.b., page 39500)

ASCO opposed the reduction in 340B payment to ASP minus 22.5 percent for hospital outpatient departments in its response to the 2018 and 2019 OPPS proposed rules. We continue to oppose these reductions and any additional reductions in 340B payment levels. Instead of expanding potentially destabilizing reductions in payment, CMS should collaborate with the Health Resources and Services Administration (HRSA) to address widely recognized concerns with the program’s growth, administration, and oversight in a manner that is consistent with ASCO’s prior recommendations.

The 340B Drug Pricing Program has a significant effect on the delivery of oncology services in the United States, especially given the critical role of drug therapies in the treatment of cancer. In 2014, ASCO prepared a detailed policy statement\(^2\) to provide guidance to policymakers on how to modify the 340B Drug Pricing Program to protect the interests of cancer patients and these recommendations remain relevant today.

In our July 2018 response to Secretary Azar’s “Request for Information: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” ASCO urged the Department of Health

and Human Service to consider reforms to the 340B Drug Pricing Program that would ensure that the program carries out its original intent of expanding patient access and ensuring high-quality care for underserved and vulnerable individuals.

Specifically, we suggested that policymakers should replace the Disproportionate Share Hospital (DSH) adjustment percentage as a program eligibility metric for hospitals with a metric that more appropriately reflects the original intent of the 340B program. Using the DSH adjustment as a measure of eligibility for the 340B program is flawed because it is based on inpatient data; the 340B program only provides discounts for drugs used in the outpatient setting. This creates a fundamental disconnect between how hospitals obtain 340B eligibility and the services that the increased 340B resources are intended to promote.

Further, we urged changes in the eligibility criteria for hospitals and for reforms that permit access to 340B pricing for standalone community oncology practices that care for low-income communities. Community-based oncology practices form the backbone of cancer care in many rural and underserved areas by serving as the sole point of access for oncology services. Community oncology practices are vital outlets for access to high-quality and cost-efficient oncology services for cancer patients from all walks of life. These practices regularly engage in the provision of care to indigent, underserved and uninsured individuals at a financial loss, yet do so without the benefit of 340B discounts enjoyed by oncology providers in other settings of care.

ASCO will continue to advocate for reforms to the 340B program that will ensure providers can continue to deliver critical cancer care to patients throughout the country.

3. **ASCO continues to object to CMS’s policy to set payment for certain separately payable drugs and biologicals at 103 percent of the drug or biological’s Wholesale Acquisition Cost (WAC).** (Section B.2.b., page 39500)

ASCO shares the Administration’s concerns regarding the rising cost of prescription drugs. For CY 2019 the Agency finalized its policy that reduced the add-on percentage for separately payable drugs paid according to WAC methodology from six percent to three percent.

As a part of its input to the CY 2019 OPPS proposed rule, ASCO commented—and continues to believe—that the reduction in payment will not meaningfully reduce drug costs, since most drugs are paid through the WAC-based methodology on a temporary basis while initial average sales price data is generated. The adverse impact of the proposed reduction is further exacerbated by the application of sequestration.

We once again urge CMS to forego efforts at incremental cuts unlikely to produce significant savings. Instead, the Agency should drive value-based cancer care by pursuing a comprehensive solution that addresses shortcomings in the current medical oncology reimbursement system.
4. **ASCO supports CMS’s efforts to increase price transparency through its proposal to require hospitals to disclose charges for OPPS services. However, CMS should proceed cautiously with its efforts. (Section XVI., page 39571)**

ASCO appreciates CMS’s efforts to examine pricing for healthcare services and to identify potential solutions to lower costs for patients. Patients with cancer are twice as likely to file bankruptcy as those without the disease. ASCO is concerned about the rising cost of healthcare—particularly prescription drugs—and stands ready to work with policymakers on real solutions that address the affordability of healthcare in general.

ASCO supports policies that increase price transparency. We strongly believe that price transparency allows payers and patients to make informed price comparisons and become better educated consumers of healthcare. However, transparency efforts must result in meaningful information being made available to patients in a way in which that information can be easily understood and used. Although CMS has proposed requiring that hospitals post payer-negotiated rates, this may or may not reflect the actual cost to an individual patient. Payers may offer a multiplicity of plans with different coverage, co-insurance, and prior authorization requirements. Insured patients (which comprise 90% of all patients) do not pay these rates *per se*, instead they pay the relevant deductibles, and copayments according to their insurance policy. Uninsured, self-insured or high deductible plan patients pay a rate that can range from a “cash discount” rate negotiated between the hospital and the patient to the full payer-specific negotiated charge. Medicare patients pay the appropriate Medicare coinsurance amounts. Instead, CMS should consider a policy alternative that would make available the range of charges and paid amounts for the procedure instead of each individual charge.

As we have previously commented, ASCO strongly supports real-time benefit tools that allow patients to make informed decisions based on their individual circumstances.

As you consider ways to incentivize and encourage price transparency, it is critical that any requirements placed on providers not impede access for patients, particularly those with cancer.

5. **ASCO supports CMS’s proposal to loosen the physician supervision requirements for outpatient therapeutic services. (Section X.A., page 39525)**

In the proposed rule, CMS signals their intention to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs. CMS states its belief that Medicare providers will provide a similar quality of hospital outpatient therapeutic services, regardless of whether the minimum level of supervision required under the Medicare program is direct or general.

We believe that this proposal may have many positive effects on physician workload and could allow physicians to devote more time to clinical work and allow more flexibility on the part of
cancer clinics to provide more timely care.

ASCO remains committed to ensuring that cancer patients have access to high quality and safe care. While we support CMS’s proposal, we urge CMS to carefully monitor its implementation to ensure that it does not unintentionally place some patients at elevated risk for medical errors.

6. ASCO opposes CMS’s proposed revisions to the laboratory date of service (DOS) policy

ASCO opposes the proposed revisions to the laboratory DOS policy. These proposed revisions have the potential to limit or delay beneficiary access to precision diagnostic testing which in turn could have a devastating effect on the ability of cancer patients to access the care they need in a timely manner.

The current date of service policy has improved access to precision tests and targeted treatment by removing barriers that once led to delayed and canceled orders. Before the current policy was established in 2018, hospitals would delay the ordering of tests because of billing complexity and confusion, sometimes waiting until at least 14 days after the patient was discharged from the hospital outpatient department, and in other cases canceling orders. Both delays and cancellations of orders restricted patient access to timely test results and targeted treatment for Medicare Part B beneficiaries suffering from cancer.

The current policy allows the performing laboratory to bill Medicare for outpatient molecular pathology tests and “Criterion A” Advanced Diagnostic Laboratory Tests (ADLTs). By doing so, CMS has limited delays in ordering precision diagnostic tests and removed administrative burdens in ordering these tests for patients seeking care during a hospital outpatient encounter. This, in turn, has afforded physicians more consistent and timely access to precision diagnostic information to guide clinical decision-making.

Furthermore, the proposed policy sets unrealistic expectations on physicians ordering testing. The proposed policy would require the physician to determine whether the test results are intended to guide treatment during either the current or some future yet-to-occur hospital outpatient encounter. The proposed policy does not reflect the reality of clinical practice, is administratively unworkable, and places physicians in an untenable decision-making position.

Ordering physicians cannot be expected to reasonably predict whether the results of a given test will be used in a subsequent outpatient encounter for two clear reasons. First, the very reason they are ordering the testing is to determine the next clinical interventional step(s) to take for the patient. If the physician knew how and where they would be treating the patient at the time they ordered the test, they would not be ordering the test to begin with. Second, the physician ordering the testing may not be the same physician who treats the patient based on the results. Thus the ability of the ordering physician to make a prediction about use of test results will vary widely based on the type of physician, the type of test, the treatment options available to the patient, and other factors.
For this reason, we believe that CMS should not finalize the first two proposed revisions in the Proposed Rule, which involve (1) requiring physicians to predict whether test results will inform treatment during a future outpatient encounter and/or (2) limiting the DOS policy to “Criterion A” ADLTs. Both of these options would significantly curtail beneficiary access to precision diagnostics and would be highly burdensome to implement just two years after establishing new billing rules.

II. **ASCO’s response to CMS’s request for public comment on how to structure a remedy in response to the district court ruling in the case of American Hospital Association et.al. v Azar et.al. (Section V.B.6, page 39504)**

On May 6, 2019, after briefing on remedy, the district court issued an opinion that reiterated the 2018 rate reduction exceeded the Secretary’s authority, declaring that the rate reduction for 2019 (which had been finalized since the Court’s initial order was entered) also exceeded his authority.

CMS rightly acknowledges the complexities inherent in effectuating a remedy in response to the court decision. We agree that CMS should attempt to minimize any economic impact that any remedy may have on providers as well as any impact on beneficiary cost sharing.

ASCO believes that any remedy, whether it be prospectively or retrospectively applied, should hold beneficiaries harmless from any additional financial liabilities.

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Thank you for the opportunity to provide comment on the CY2019 Hospital Outpatient Prospective Payment System proposed rule. Please contact Karen Hagerty at karen.hagerty@asco.org with any questions.

Sincerely,

[Signature]

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