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Via Electronic Submission

September 23, 2020

Seema Verma

Administrator Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attn: CMS-1736-P

Box 8013

Baltimore, MD 21244-1850

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems 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 (CMS-1736-P)

Dear Administrator Verma:

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the recent proposed rule for the Hospital Outpatient Prospective Payment System (OPPS) for calendar year 2021 published in the Federal Register on August 12, 2020.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We 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 2021 have the potential to undermine patient access to cancer care for Medicare beneficiaries.

- ASCO did not support the CMS policy in 2020 to establish a prior authorization (PA) process for certain outpatient department services. ASCO opposes the proposal to further expand this process in 2021.

- ASCO continues to object to CMS’s policy that sets a differential Medicare payment rate for separately covered outpatients drugs purchased under the 340B program. ASCO urges CMS to instead implement reforms to the 340B Drug Pricing Program which are needed to ensure the program meets its original intent to support high-quality care for the uninsured, underinsured, and low-income patients.
- ASCO supports policies that allow clinical judgement to determine critical medical decisions such as site of care. While ASCO sees potential value with the proposal to eliminate the Inpatient Only (IPO) List, we urge the agency to delay the implementation of this proposal until there is additional information available on how the proposed policy would be implemented and it can be more fully evaluated.

I. Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process (Section XVII, page 49027)

ASCO did not support the CMS policy in 2020 to establish a prior authorization (PA) process for certain OPD services. ASCO opposes the proposal to further expand this process in 2021.

In the CY 2020 OPPS final rule, CMS established a PA process for five cosmetic services identified as being potentially abused. The PA process was effective July 1, 2020. Under this process hospitals must submit a prior authorization request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for processing. The change applied to five categories of services that CMS believed were related to procedures that may be cosmetic in nature: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.

In this rule, CMS proposes to expand the PA process to include two new categories of services reimbursed under the OPPS that are unrelated to procedures that may be cosmetic in nature—cervical fusion with disc removal (described by CPT codes 22551 and 22552) and implanted spinal neurostimulators (described by CPT codes 63650, 63685, and 63688). Services in these two categories would be subject to prior authorization for dates of service on or after July 1, 2021.

ASCO is committed to supporting policies that reduce cost while preserving or increasing quality of cancer care, but we believe that utilization management tools such as PA should be implemented in a transparent and evidence-based manner and in a way that does not undermine patient access to medically necessary care. 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 and an increasing administrative burden for providers without any clear benefit.

If Medicare or other payers are going to establish PA processes, ASCO believes they must be designed in an evidence-based and transparent manner which does not compromise patient access to treatment or patient safety.

ASCO refers CMS to its [2017 policy statement](#) on utilization management in which we recommend an appropriate framework for the design of utilization management programs. We remain committed to the principles and recommendations conveyed in this document, and to working with stakeholder groups to develop and implement policies that benefit patients with cancer while reducing unnecessary or wasteful costs. We urge CMS to incorporate the principles of ASCO's statement as it works to develop streamlined, transparent, and evidence-based policies that support appropriate utilization of healthcare services. We set forth six critical principles that any utilization management policy must meet to ensure medically necessary care for patients with cancer is not jeopardized or unreasonably delayed:

- 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.

We believe that the PA process established by CMS fails to meet these principles. It lacks transparency, CMS has failed to provide information on how its policies are evidence-based, and significant concerns remain related to the administrative burden of the process and its impact on patient access to care. This is especially challenging as clinicians and their patients continue to weather the impact of an ongoing public health emergency.

- a. **ASCO believes it is inappropriate to expand the current PA process for certain OPD services until the current process has been evaluated.**

The PA process for certain OPD services was established in the 2020 OPPS Final Rule, but it was not implemented until July 1, 2020. Therefore, at the time of issuance of this proposed rule, the process had been operative for only a few weeks and the agency has not had an opportunity to collect data or to evaluate it. The agency must evaluate the benefits and risks of the 2020 process before it moves forward with any expansion in 2021.

Implementation of PA impacts patient access to treatment. Before the Agency commits resources to expanded implementation of this process, several critical elements should be evaluated:

- Patient access to care: What impact has the PA process for certain OPD services had on patient access to care? Are Medicare beneficiaries still able to access care in accordance with current clinical and scientific evidence?

- Provider burden: Has the process unduly increased provider burden? Are the steps and decision-making protocols transparent, understandable, consistent, timely and evidence-based?
- Program efficacy: Do the benefits of the process of reducing inappropriate or unnecessary care outweigh the costs of increased provider burden or any impact on patient access to care?

ASCO strongly urges CMS to evaluate the current OPD PA process prior to any expansion. We share the agency's concern that the Medicare program should be protected from inappropriate billing practices and that the Medicare program should only reimburse services that are medically necessary. However, there is no evidence that the current process is achieving these goals. It is incumbent on the agency to assess current program impact before larger scale implementation.

- b. **ASCO is concerned about the methodology proposed by CMS to select services to add to the PA process for certain OPD services. CMS has not provided a transparent or robust explanation of their methodology.**

ASCO has concerns with the methodology with which CMS selected these services and CMS's explanation has not been consistent. When the agency established the process in 2020, it indicated the services were selected because of potential abuse of cosmetic services. In the CY 2021 proposed rule CMS indicated services were selected based on increased utilization.

CMS indicated in the rule that the selected services had a higher growth rate percentage between 2007 and 2018 in comparison to the overall growth rate of OPPS services. CMS concluded based on some code specific analysis as well as a comparison to overall OPPS growth trends that the increases in volume for the selected procedures was unnecessary.

ASCO believes that as described, the methodology is too limited and does not appropriately capture all the relevant factors that may contribute to appropriate growth for these services. As CMS indicates, these services have experienced increases in utilization, but there may be appropriate clinical reasons for these increases.

We urge CMS to engage with the specialties that perform these services to help provide greater understanding of the clinical context around these services. For example, implanted neurostimulator services are provided to patients experiencing pain and are considered an alternative to opioids. A utilization growth in these services may be the result of providers trying to avoid prescribing opioids to their patients. As a country we continue to struggle with the opioid epidemic. The situation has become increasingly grave during the COVID-19 pandemic. Because opioid use affects respiratory health, those with opioid use disorders are more susceptible to COVID-19. At a time when we are struggling to reduce opioid use disorder rates, it is critical that Medicare beneficiaries have access to alternatives to opioids. CMS needs to ensure that this PA process will not prevent access to alternatives to opioids for the patients that need them.

While the agency did conduct a data analysis to select these new services, we believe this analysis does not provide context sufficient to understanding the factors that influence appropriate utilization changes for these services. ASCO urges CMS to engage with clinicians providing these services to gain a better understanding of the factors that may explain recent utilization trends.

- c. **It is inappropriate to expand the OPPS PA process at a time when providers are already struggling with financial burden and other challenges associated with COVID-19.**

The COVID-19 pandemic has wreaked havoc on all aspects of life in the United States and across the globe. Healthcare providers have played a critical role in meeting the challenges of providing care to COVID-19 patients and maintaining access to care for all other patients. The pandemic has also created historic financial pressures on large and small practices and health systems across the country. Beyond the financial pressure, providers have had to develop new ways of providing care to reduce exposure to the virus to patients and providers. With the increased combination of financial and administrative pressures, we were surprised to see that the agency was proposing to expand the PA process for certain OPD services at this time. In many other instances, in light of COVID-19, the agency has delayed implementing initiatives that would add participation requirements or increased burden on providers. We believe this is another area where CMS should delay further implementation.

Due to the burden of the COVID-19 pandemic, ASCO urges CMS to not finalize its proposal to expand the OPPS PA process.

II. CY 2021 OPPS Payment Methodology for 340B Purchased Drugs (Section V.6, page 48882)

ASCO continues to object to CMS's policy that sets a differential Medicare payment rate for separately covered outpatient drugs purchased under the 340B program. ASCO urges CMS to instead implement reforms to the 340B Drug Pricing Program which are needed to ensure the program meets its original intent to support high-quality care for uninsured, underinsured, and low-income patients.

For CY 2018, CMS implemented a sweeping and controversial change whereby Medicare pays for drugs covered and paid under the OPPS and purchased through the 340B Program at Average Sales Price (ASP) minus 22.5%, instead of the traditional ASP plus 6%. For CY 2019, CMS extended this policy by also paying ASP minus 22.5% for 340B drugs furnished by non-expected off-campus provider-based departments. CMS maintained the policy for CY 2020 despite ongoing litigation and court rulings that CMS exceeded its authority when it implemented these policy changes. However, on July 31, 2020, the US Court of Appeals for the District of Columbia Circuit held that CMS does have authority under the Social Security Act to reduce Medicare payment rates for 340B-eligible drugs reimbursed under the OPPS.

For CY 2021, CMS proposes to further revise current payment policy for 340B-eligible drugs. Specifically, CMS proposes to utilize data on drug acquisition costs in CYs 2018 and 2019 from

the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs to establish payment for CY 2021 and beyond.

ASCO opposed the reduction in 340B payment to ASP minus 22.5 percent for hospital outpatient departments in its response to the 2018-2020 proposed rules. We strongly oppose the additional reductions proposed for CY 2021. 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.

As an organization that represents oncology providers, ASCO is particularly concerned with policies that remove resources from the cancer care delivery system. 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. We fear this drastic policy could have a significant negative impact on cancer patients and other vulnerable patients who need these treatments to survive.

a. **ASCO believes the Hospital Acquisition Survey is inadequate to act as a source of data to base payment rates for the 340B Program.**

CMS is proposing further reductions to the 340B Program based on the Hospital Acquisition Survey. While CMS has released limited details on the results of this survey, based on available information we believe it is inadequate to serve as the basis for setting payment policy for the 340B program which will have a significant impact on patients' access to life saving treatments.

This survey was fielded in the midst of the COVID-19 pandemic when hospital resources were stretched thin and they may not have had the bandwidth to appropriately respond to the survey. Additionally, limited data has been provided on the analysis of the survey data conducted by CMS. The data response rate also seems to be lacking robustness to inform the setting of significantly important payment policy. CMS indicates that 7% responded to the detailed survey; 55% responded to the quick survey option; and more than a third (38%) did not respond.

In addition to the low response rate, ASCO has concerns about the agency's methodology for addressing missing data points and its impact on results. CMS indicated that in instances when the acquisition price is not available or was not submitted in a response to the survey, they used the 340B ceiling price as a proxy. We are concerned that CMS has imputed a value without evidence of its accuracy in reflecting actual acquisition costs. It is not clear what portion of the responses CMS imputed values in this way but the combination of the low response rate and the use of this method for imputed value does not make us confident in the accuracy of the survey results.

We strongly believe that the results lack the robustness required to determine payment policy for a program that is so critically important to vulnerable and low-income patients and the

facilities that care for them. We recommend that CMS does not use the results from the Hospital Acquisition Survey to set payment rates for the 340B Program.

- b. **ASCO urges CMS to consider other factors in its approach to reforming the 340B Program, including satisfaction of the original intent of the legislation, the presence or absence of appropriate safeguards for compliance and oversight, and the impact of changes on unique considerations related to cancer patients and other vulnerable patients.**

ASCO urges CMS to consider recommendations in our 2014 [statement](#) on the 340B Program. These recommendations include factors to consider when proposing policy changes. ASCO recommends the agency consider the following issues:

- Whether the program satisfies the original intent of the legislation.
- Whether the size of the program is appropriate.
- Whether adequate safeguards are in place to ensure appropriate compliance and oversight of the program.
- Whether unique considerations related to cancer care warrant special attention by policymakers.

The impacts of the 340B Drug Pricing Program are especially significant in the area of oncology, given the integral role that drug therapies play in the treatment of individuals with cancer. We are concerned that this proposal for continued reductions to the payment rates of 340B drugs fails to take these recommendations into account. As the agency considers the future of the 340B Program, we urge you to address the issues we have raised.

III. Proposed Changes to the Inpatient Only (IPO) List (Section IX.B, page 48908)

ASCO supports policies that allow clinical judgement to determine critical medical decisions such as site of care. While ASCO sees potential value with the proposal to eliminate the Inpatient Only (IPO) List, we urge the agency to delay the implementation of this proposal until it is more fully evaluated and additional information is available on how the proposed policy would be implemented.

The Inpatient Only (IPO) list was created to identify services that are required to be furnished in an inpatient setting due to the invasive nature of the procedure, the need for a 24 hour post-operative stay, or an underlying physical condition requiring the procedure be performed in an inpatient setting. These services would not be reimbursed by Medicare under the OPPTS. For CY 2020, there are 1,740 services on this list.

For CY 2021, CMS proposes to eliminate the IPO list over a three-year transition period, with completion by January 1, 2024. In its discussion of the proposed change, CMS noted several safeguards to ensure beneficiary safety in the absence of the IPO list, including: state and local requirements, accreditation requirements, hospital conditions of participation, medical malpractice laws, and other quality and monitoring initiatives.

This is a significant proposal that will impact many services across a range of medical specialties. It entails clinical issues related to determining medical necessity for the appropriate site of care as well as complex administrative policies that set payment rates for outpatient services. ASCO appreciates the agency's attempt to design a system that allows clinical judgement to ensure patients are receiving care in the most appropriate setting. However, we are concerned this proposal could have unintended negative impact on access to care and patient safety. Currently, the IPO List ensures coverage for certain medically necessary services provided they are performed in an inpatient setting. With this proposal, it is unclear how the agency will determine if the appropriate site of care is selected. Specifically, ASCO is concerned that without specific rules and regulations, the proposed policy could become a de facto prior authorization program. A situation could evolve where facilities feel as if they are under additional scrutiny by the agency, and in turn could pass this pressure onto physicians, making the outpatient department the default site of service and creating barriers for physicians to provide this service in the inpatient department. These uncertainties could have a negative impact on patient access to care and safety.

ASCO is also concerned about how the agency will set payment rates for services that have historically been performed in the inpatient setting. The agency has provided APC crosswalks for many of the codes they are proposing to remove from the IPO list in 2021 (Table 31). Unfortunately, few details have been provided on how these proposed crosswalks were determined. There are many services on the IPO List. Even if this proposal is phased-in over a multi-year period, the cross-walking of these codes represents a significant effort for CMS in an area where the agency likely lacks robust data. Since these services are not currently covered in the outpatient setting, any data that is available may be inappropriate and/or non-representative. Until there is a clear process to establish new rates for this large number of codes--especially in light of data limitations—we do not believe the Agency should finalize this proposal for CY 2021.

Until now, when a stakeholder believed it was appropriate to remove a code from the IPO List, there was a process in place to submit a request to CMS and present evidence as to why the code should be removed from the List. We believe that this process has worked well for the agency, hospitals and physicians, and patients. We urge CMS to continue the current process and not finalize the proposal as described in the proposed rule.

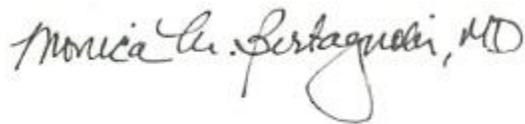
Another unintended consequence of this proposal is an increased administrative burden on hospitals and physicians. This could be especially true if there is not clear guidance and rules around the intent and implementation of this proposal. Especially during the COVID-19 pandemic, CMS should critically evaluate how each policy adds additional burdens to the frontline providers who are care for the most vulnerable and severely ill patients.

ASCO supports policy changes that increase flexibility for physicians and their patients and believe that this policy has the potential to do so; however, ASCO urges CMS to delay the elimination of the IPO List to in order for the agency to appropriately evaluate how this proposal would impact patient access to care and safety, physician clinical decision making and

administrative burden. We believe a proposal of such magnitude requires a more robust plan that addresses the overall impact of this proposed policy, as well as more details on how the agency plans to implement the proposal. Additionally, we urge the agency to incorporate feedback from stakeholders in the design and implementation of this proposal. We do not believe all of this can be accomplished during this rule-making cycle, especially given CMS' stated intent to release the final rule by December 1st, a full month later than the usual November 1st. This will not provide sufficient time for hospitals to prepare for a change of this size.

Thank you for the opportunity to provide comment on the CY2021 Hospital Outpatient Prospective Payment System Proposed Rule. Please contact Gina Baxter at gina.baxter@asco.org or Karen Hargerty at karen.hargerty@asco.org with any questions.

Sincerely,

A handwritten signature in black ink that reads "Monica Bertagnolli, MD". The signature is written in a cursive style with a large, looped "M" and "B".

Monica Bertagnolli, MD, FACS, FASCO

Chair of the Board

Association for Clinical Oncology