September 13, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

Submitted Electronically at www.regulations.gov

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (CMS-1772-P)

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the fiscal year 2023 Hospital Outpatient Prospective Payment System (OPPS) proposed rule published in the Federal Register on July 15, 2022.

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.

We are pleased to offer our comments in response to select proposals and requests for information (RFIs) below:

• Proposed Changes to the Inpatient Only (IPO) List
• Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services and Proposal to Exempt Rural Sole Community Hospitals from the Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments
• Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status (340B)
• Proposed Payment Adjustments for NIOSH-Approved Domestic Surgical N95 Respirators
Proposed Changes to the Inpatient Only (IPO) List (Section IX, page 44669)

The Centers for Medicare and Medicaid Services (CMS) is proposing to remove 10 codes from the Inpatient Only (IPO) list beginning in calendar year (CY) 2023 based on its determination that they meet the five longstanding criteria for removal. Additionally, upon clinical review, CMS proposes to add eight codes, newly created by the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel, to the IPO list for CY 2023.

ASCO supports policies that allow clinical judgement to determine critical medical decisions such as site of care, and we believe this policy has the potential to do so. We urge CMS to consider input from providers who perform these services and other stakeholders as you determine your final policy for these services.

Section 1833(t)(1)(B)(i) of the Act allows the CMS to define the services for which payment under the OPPS is appropriate. Established over 20 years ago, the IPO list has been used by CMS to determine whether a procedure should be performed in an inpatient setting. Services designated as “inpatient only” are not considered appropriate for delivery in a hospital outpatient department.

ASCO applauds CMS for proposing removals to the IPO list based on evidence, clinical review, and the five longstanding criteria for removal. Historically, the agency has used the rulemaking process to solicit input from providers of the service and other stakeholders in determining its policy for individual codes. We believe that this process has worked well for the agency, hospitals, physicians, and patients. We urge CMS to continue the current process of adding and removing services from the IPO list. Gradual additions and removals allow time for the agency to appropriately evaluate how additions and removals to the IPO list might affect patient access to care and safety, physician clinical decision making, and administrative burden.

ASCO supports policies that provide flexibility for physicians and their patients to choose appropriate care in the right place at the right time. We believe the current review process for the IPO list allows for this.
Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services (Section VII, page 44661) and Proposal To Exempt Rural Sole Community Hospitals From the Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs) (Section X, page 44696)

Beginning in 2019, CMS implemented a policy that reduced OPPS payments for clinic visits described by HCPCS code G0463 and furnished at off-campus provider-based outpatient departments (PBD) that previously were excepted or grandfathered from site-neutral payment policies. For CY 2023, CMS proposes to continue the policy of paying the Medicare Physician Fee Schedule (PFS)-equivalent rate of 40% of the OPPS payment rate for hospital outpatient clinic visits coded under HCPCS G0463 when delivered by a previously excepted off-campus PBD. CMS proposes to now exempt services furnished by excepted off-campus PBDs of rural sole community hospitals.

ASCO opposes the continued policy of site neutral payments for clinical visits at off-campus provider-based departments. CMS should not implement policies that have the effect of diminishing patient access to cancer services in any setting of care. ASCO urges CMS to reverse this policy.

ASCO supports the proposal to exempt services furnished by excepted off-campus PBDs of rural sole community hospitals. We urge CMS to finalize this policy.

In general, ASCO has found that site neutral payment policies are based on flawed methodologies. Under this site neutral policy the agency proposes to continue, Medicare has established a relationship between the OPPS payment methodology and Medicare Physician Fee Schedule (PFS) rates. There is no logical basis for this relationship. These two Medicare payment systems are based on two different data sets for rate setting that are then further influenced by distinct policies that set annual payment updates which also vary from the hospital outpatient to the office setting. This policy imposes significant financial strain on these departments as they struggle to maintain the same level of patient access to cancer services—or would reduce the services provided. For additional information, please see the American Society of Clinical Oncology’s Policy Statement on Site-Neutral Payments in Oncology.¹

Instead of pursuing and promoting the flawed site neutral policy, CMS should focus on a payment policy that supports quality, value, and cost effectiveness. These policies should also address disparities in oncology care. We urge CMS to allocate resources, although not at the expense of other outpatient hospital services, that fully compensate all sites, including hospital outpatient departments (HOPDs), for the services provided. Changes in reimbursement for oncology services should be based on a patient-

centric approach that ensures adequate reimbursement—regardless of the setting of care—to support the full scope of medical and ancillary services required to provide Medicare beneficiaries with high-quality, high-value care.

Rural sole community hospitals play an important and unique role in maintaining access to needed health services for Medicare beneficiaries in isolated communities. Congress and other policy makers have recognized that these facilities may have above average costs for their patient mix. ASCO was pleased to see that CMS has recognized these unique circumstances by exempting such facilities from this policy.

**Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status (340B) (Section V, page 44644)**

In June 2022, the Supreme Court ruled that the Department of Health and Human Services (HHS) may not vary reimbursement rates for drugs and biologicals among groups of hospitals without conducting a survey of hospital acquisition costs. Given the timing of the Supreme Court decision, CMS was unable to adjust its proposed payment rates and budget neutrality calculations to account for the decision before issuing its proposal. CMS anticipates that it will finalize a rate of average sales price (ASP) plus 6% to such drugs and biologicals beginning in January 2023. CMS also seeks comments on remedies for the payment cuts made in CYs 2018–2022.

ASCO supports CMS’ intent to finalize a payment rate of ASP +6% in the final rule. We urge CMS to come to a swift decision and implementation timeline regarding reimbursement for payment cuts because of the ASP -22.5% policy in 2018-2022. Reimbursement remedies should not penalize other facilities as a result.

Since the implementation, ASCO has objected to the agency’s policy that set a differential Medicare payment rate for separately covered outpatient drugs purchased under the 340B program. We are pleased that CMS is proposing to revert to its pre-2018 policy of ASP +6% for 340B drugs. The discounted purchase price combined with the higher reimbursement rate allowed hospitals to realize significant savings on high-cost drugs, which in turn would be used to support uncompensated care costs and other safety net programs. When CMS drastically cut reimbursement rates, the capacity of these facilities to provide these services was put significantly at risk and this increased risk was disproportionately borne by the most vulnerable patients. Restoration of the payment rate is a relief to these institutions and the patients they serve.

ASCO joins other stakeholders in agreeing that the decision announced in the proposed rule is an important first step by the agency. We eagerly await further details on how CMS will remedy reimbursement cuts from previous years. ASCO believes it is critical that the agency make facilities whole for the previous lower payments from multiple years. While we urge swiftness, we also appreciate action must be taken in a judicious manner that does not penalize other facilities as a result.
Proposed Payment Adjustments for NIOSH-Approved Domestic Surgical N95 Respirators (Section XIII, page 44869)

In the fiscal year 2023 Inpatient Prospective Payment System proposed rule, CMS requested public comments on potential IPPS and OPPS payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH) approved surgical N95 respirators. CMS is proposing to make a payment adjustment under the OPPS and IPPS to compensate hospitals for the additional resource costs of acquiring domestically made NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023.

ASCO supports payments for domestically made NIOSH approved surgical N95 respirators. We urge CMS to finalize this proposed policy.

Our nation’s recent experience with the COVID-19 pandemic has brought to the forefront the importance of domestic manufacturing and distribution of personal protective equipment (PPE) such as N95 respirators. The pandemic demonstrated potential limitations of globalized supply chains. Federal policy actions such as the payment adjustment proposed by CMS can support efforts to bolster domestic manufacturing. ASCO strongly supports this proposal, which encourages hospitals to buy domestic N95 equipment. This effort to support domestic manufacturing will help prevent future shortages of lifesaving PPE by helping to sustain the domestic supply chain. Hospitals often face the choice of purchasing more expensive domestic N95s versus the less expensive foreign made masks. The payment adjustment will enable purchase of the more expensive domestically manufactured masks.

While ASCO was pleased to see this proposal in the CY 2023 OPPS proposed rule, we were disappointed there was not a similar proposal in the CY 2023 Medicare PFS Proposed Rule. Oncology practices and other types of physician practices also must purchase N95s and other PPE. We have included language in our comments to the CY 2023 PFS proposed rule urging CMS to implement a similar policy for the physician fee schedule.

Proposed Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process (Section XX, page 44802)

For CY 2020, CMS finalized a policy whereby hospitals must seek provisional affirmation of coverage before select outpatient services are furnished to beneficiaries and before a claim can be submitted for processing. This prior authorization requirement initially applied to only five categories of services. In the CY 2021 rulemaking cycle, CMS expanded the services subject to prior authorization, adding two new categories of services for dates of service on or after July 1, 2021. CMS did not change the list of services subject to prior authorization in CY 2022, holding steady with the previously established seven categories. For CY 2023, CMS is proposing an additional service category consisting of facet joint injections, medial branch blocks and facet joint nerve destruction.
ASCO did not support the CMS policy in 2020 to establish a prior authorization (PA) process for certain outpatient department services, and we continue strong opposition to CMS' proposal for expansion of PA requirements in 2023. We urge the agency to review the current program to assess its impact on utilization, patient access to care and the administrative burden it generates.

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 remains concerned, both about negative impacts certain PA policies have had on patient access to care and escalating administrative burden for providers—all without evidence of clear benefit.

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.

A recent report by the American Medical Association illustrates the heavy burden of PA on physician practices. This report, released in February 2022, found that 93% of physicians report care delays, 40% of physicians have been forced to hire staff who work exclusively on prior authorization, and 34% of respondents report that prior authorization has led to a serious adverse event for their patient.

---

including hospitalization, life-threatening event, or disability. Studies such as this one provide growing evidence that expanded implementation of PA is impeding patient access to care and increasing administrative burden for providers, drawing resources and clinician time away from patient care and—since most care eventually is approved—without a clear benefit.

We appreciate that the agency has implemented certain modifications, including gold carding as part of its PA process. However, we still believe that the PA process established by CMS fails to meet the principles noted above. It lacks transparency, CMS has failed to provide information on how its policies are evidence-based, and significant concerns remain related to both 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 pandemic and related public health emergency.

We urge the Agency to work with physicians and other stakeholders to address these critical issues and design a system that ensures safe, timely delivery of appropriate and high-quality care to its beneficiaries.

**ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies (Section XIII, page 44717)**

In 2022, CMS finalized a policy to unpackage and pay separately at ASP plus 6% for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS. CMS proposes four products that are eligible for this reimbursement for 2023: C9290 (Inj, bupivacaine liposome); J1097 (Phenylephrine ophth soln); J1096 (Dexamethasone ophth insert 0.1 mg); and C9089 (Bupivacaine implant, 1 mg).

*ASCO supports CMS’ proposal to cover these non-opioid pain management drugs. We urge the agency to finalize this proposal.*

ASCO supports the use of non-opioid alternatives when these policies are appropriately designed. It is clear that there is an opioid epidemic in the United States (U.S.), which may have been exacerbated during the COVID-19 pandemic. State and federal actions to address opioid misuse and abuse is laudable. While these are important policies in general, ASCO reiterates its previous position that cancer patients should continue to be exempt from opioid-related restrictions, even if non-opioids are available.

ASCO does wish to highlight the special situation of cancer-related pain. Opioids remain an essential part of pain treatment plans for cancer patients. We are encouraged to see that many of the new laws, guidelines, and regulations limiting opioid prescribing specifically exempt cancer patients under active treatment, as this reflects the recognition that cancer patients represent a special population

---

undergoing often drastic treatment for severe, often life-threatening diseases. In designing its policies, ASCO urges CMS to maintain this posture of exempting cancer patients from opioid limiting policies, to ensure that those Medicare beneficiaries experiencing cancer-related pain continue to have appropriate access to opioids for their pain treatment plans.

Rural Emergency Hospitals (REH) Payment Policies (Section XVIII, page 44774)

The Consolidated Appropriations Act of 2021 created a new type of Medicare hospital called the Rural Emergency Hospital (REH). This classification is designed to help meet the needs of rural communities that cannot adequately support a full-service hospital, but that otherwise would lack emergency services. CMS is proposing to consider all covered outpatient department services (that is, services that would otherwise be paid under the OPPS) as REH services. CMS proposes to pay REHs 105% of OPPS payments for services furnished to program beneficiaries, and to make a substantial supplemental monthly facility payment at $268,294 for CY 2023.

ASCO supports efforts to improve access in rural/underserved areas. We urge CMS to provide these resources but not at the expense of other hospital outpatient services.

ASCO is dedicated to reducing disparities and improving outcomes for patients and survivors of cancer who live in rural communities. To this end, in 2019 the Society created a new task force to address the rural cancer care gap. Patients living in rural areas often are diagnosed with more advanced cancer and have recently been shown to have higher mortality. Persistent issues with access to screening and treatment, as well as higher rates of behavioral risk factors, may be key contributors to this disparity.

Patients with cancer residing in rural areas face several challenges. Longer travel distances have been associated with worse outcomes in patients with cancer, including later stage at time of diagnosis, less timely receipt of chemotherapy, and delaying or declining treatment. Increased travel distance has also been associated with a lower likelihood of receiving radiation therapy. Patients with cancer from rural areas also incur greater financial burden associated with travel and lodging costs.

REHs have the potential to address and help mitigate some of the challenges faced by Medicare beneficiaries residing in rural areas. ASCO believes the allocation of resources dedicated towards addressing disparities in the care of rural Medicare beneficiaries is vital, but it should not be implemented at the cost of compromising resources dedicated to other hospital outpatient services.

**Request for Information on Use of CMS Data to Drive Competition in Healthcare Marketplaces (Section XIX, page 44800)**

On July 9, 2021, President Biden issued an Executive Order on Promoting Competition in the American Economy (EO 14036). In response to that EO, CMS seeks information from the public on how data collected by CMS can be used to promote competition across the healthcare system. The EO identifies hospital consolidation as a significant concern that has left many localities and patients without good options for convenient and affordable healthcare service. This is especially true for rural communities. While hospital consolidation and mergers may reduce access to services in rural areas; consolidation in rural and urban areas may increase prices for hospital services. Both scenarios can have a negative impact on patient care.

The impact of consolidation can be found among medical oncology practices. A recent study found that medical oncologists in the US are increasingly working in large practices. In fact, by 2022 more than 40% of all practicing medical oncologists were employed at the largest 5% of practices. The impact of this consolidation on patient care must be better understood.

ASCO has long expressed concern on local care. Patients should receive services where they live and work. The association supports the agency efforts in this area. We strongly support efforts to collect and share data that can provide better insight on the impact of our rapidly evolving healthcare landscape. Better evidence will allow CMS, policymakers, and providers to better understand the impact of consolidation on both costs and quality. Improving the ease of access to information should be part of the Agency’s strategy, as practices and health systems navigate this change. This type of insight will allow the government to establish more responsive policies and allow providers, patients and other stakeholders to make more informed decisions. We look forward to greater details on these efforts by CMS in future rulemaking.

* * * * * * *

We appreciate the opportunity to comment on the 2023 Hospital Outpatient Prospective Payment System proposed rule. Please contact Gina Hoxie (gina.baxter@asco.org) with any questions or for further information.

---

10 Milligan, Michael; Erfani Parsa, Orav, E. John; Gabriel A. Brooks, and Lam, Miranda; Practice consolidation among U.S. medical oncologists over time.; *Journal of Clinical Oncology* 2022 40:16_suppl, e13627-e13627.
Sincerely,

Lori Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology