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September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically at <https://www.regulations.gov/>

Re: File Code CMS-1772-P. 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

Dear Administrator Brooks-LaSure:

The Association of Community Cancer Centers (ACCC) appreciates the opportunity to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the calendar year (CY) 2023 Hospital Outpatient Prospective Payment System (OPPS) proposed rule, published in the Federal Register on Tuesday, July 26, 2022 (87 Fed. Reg. 44502).

ACCC is the leading education and advocacy organization for the multidisciplinary cancer care community including physicians, nurses, social workers, pharmacists, researchers, hospital executives, administrators, financial navigators, and other oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 30,000 cancer care professionals from over 1,700 private practices, hospital-based cancer programs, large healthcare systems, and major academic centers across the country, as well as members from 35 state oncology societies.

ACCC respectfully offers the following comments to CMS in response to the CY 2023 OPPS proposed rule. In summary, we recommend that CMS:

- Consider allowing brachytherapy to be reported through the traditional ambulatory payment classification (APC) methodology, or reassign brachytherapy CPT codes 57155 and 58346 to comprehensive APC 5416 for Level 6 Gynecologic Procedures;

- Not finalize its proposal to add APC 5611 to the 2 times rule exception list and evaluate whether it remains appropriate to include these codes in the same APC;
- Consider extending pass-through status for drugs and biologicals whose pass-through payment status is expiring in CY 2023 by at least a full year;
- Finalize a rate of average sales price plus 6 percent for 340B-acquired drugs and engage in a formal rulemaking process with opportunities for public comment prior to finalizing any potential remedies to retroactively address the cuts made in CYs 2018-2022; and
- Refrain from expanding its hospital outpatient department prior authorization process in future rulemaking cycles without significant collaboration with and buy-in from both provider and patient stakeholder groups.

We will address these recommendations in greater detail below.

* * *

Comprehensive Ambulatory Payment Classifications (C-APCs)

CMS proposal (87 Fed. Reg. 44513): First implemented in CY 2015, a C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this payment policy, CMS provides a single payment for a hospital outpatient claim including a primary service (identified by the status indicator “J1”) along with all other items and services reported on the claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service, representing components of a complete comprehensive service. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

In the CY 2023 OPSS proposed rule, CMS continues to assign CPT codes 57155 and 58346, describing gynecologic brachytherapy procedures used in the treatment of cervical cancer, to C-APC 5415 for Level 5 Gynecologic Procedures. This C-APC is expected to be reimbursed at a rate of \$4,712.62.

ACCC comment: In general, ACCC is concerned with the C-APC payment policy and how it impacts the provision of radiation therapy, particularly the delivery of brachytherapy in the treatment of cervical cancer. The C-APC payment methodology lacks the appropriate charge capture mechanisms to ensure that reimbursement is commensurate with services rendered. We are concerned about C-APC 5415, in particular, because cervical cancer disproportionately impacts women from disadvantaged and underserved communities and women of color. These women are less likely to have access to screening and preventive services that would allow intervention before more invasive and later-stage cervical cancers emerge. Undervaluing the provision of brachytherapy procedures risks exacerbating existing disparities in treatment.

ACCC urges CMS to consider allowing brachytherapy to be reported through the traditional APC methodology rather than a C-APC. However, if the agency is committed to the C-APC payment methodology, we recommend that it move brachytherapy for cervical cancer treatment to C-APC 5416 for Level 6 Gynecologic Procedures. This C-APC is expected to be reimbursed at a rate of \$7,039.90 for CY 2023.

Proposed APC Exceptions to the 2 Times Rule

CMS proposal (87 Fed. Reg. 44549): Under the APC payment methodology, all services associated with the APC are reimbursed at the same rate. However, CMS established a “2 times rule” such that if the highest calculated cost of an individual procedure categorized to any given APC exceeds two times the calculated cost of the lowest-costing procedure categorized to that same APC, CMS must adjust the placement of codes to other APCs that better match updated resource costs or create a new APC for identified services. However, the agency can exempt any APC from the 2 times rule for any of the following reasons:

- Resource homogeneity
- Clinical homogeneity
- Hospital outpatient setting utilization
- Frequency of service (volume)
- Opportunity for upcoding and code fragments

Based on the CY 2021 claims data available for this proposed rule, CMS found 23 APCs with violations of the 2 times rule. However, upon application of the above criteria, the agency found that all of the 23 identified APCs met the criteria for an exception. CMS proposes, therefore, not to address the 2 times rule violation for those 23 APCs.

In addition to APCs 5612 for Level 2 Therapeutic Radiation Treatment Preparation and 5627 for Level 7 Radiation Therapy, which were on the 2 times rule exception list in previous years, CMS proposes to apply an exception to APC 5611 for Level 1 Therapeutic Radiation Treatment Preparation. CMS proposes a payment rate of \$135.80 for APC 5611 for CY 2023.

ACCC comments: ACCC is concerned with CMS’ proposal to add APC 5611 to the 2 times rule exception list. The highest-cost service in APC 5611 is radiation therapy planning (77299), and the actual cost of the service is 163% higher than the lowest cost service, 77331 special radiation dosimetry, and 102% higher than the proposed rate for the APC itself.

This highlights an underlying flaw with the APC methodology: it does not provide an accurate representation of costs for radiation oncology services. Rather than providing an exception for APC 5611, ACCC recommends that CMS evaluate whether it remains appropriate to include these codes in the same APC.

Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2023

CMS proposal (87 Fed. Reg. 44630): New drugs, biologicals, and radiopharmaceuticals are granted pass-through status by Medicare as a means of establishing a transitional payment until enough data is acquired to determine if the new agent is to be paid separately or packaged into an APC. For CY 2023, CMS proposes to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the average sales price (ASP) methodology, which is proposed at ASP plus 6 percent, as CMS considers these to be drugs under the OPPTS.

CMS proposes to continue pass-through payment status in CY 2023 for 32 drugs and biologicals, including those approved for pass-through payment status with effective dates beginning between April 1, 2021, and April 1, 2022. CMS proposes to end pass-through payment status for 43 drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2020, and January 1, 2021. The agency proposes to continue to update pass-through payment rates on a quarterly basis on the CMS website.

ACCC comment: In the CY 2022 OPPS final rule, CMS exercised its equitable adjustment authority under section 1833(t)(2)(E) of the Social Security Act to extend pass-through status for products affected by the COVID-19 pandemic.¹ Since that final rule was issued in late 2021, the COVID-19 pandemic has continued to adversely impact patients and their timely access to screening and diagnostic services for cancer. To this date, the nationwide public health emergency determination as the result of the COVID-19 pandemic is still in effect. ACCC therefore encourages CMS to again exercise its equitable adjustment authority to extend pass-through status for products affected by the ongoing COVID-19 pandemic whose pass-through payment status is due to expire in CY 2023.

Like many patients during the COVID-19 pandemic, those in need of screening, diagnosis, and treatment for cancer have experienced challenges accessing necessary services. Significant declines in rates of cancer screening and diagnosis during the pandemic have been well documented in available medical literature. Extensive clinical research has already demonstrated how breast cancer screening and diagnosis, for example, has plummeted during the pandemic, and that the impact has been particularly pronounced among historically underserved racial and ethnic groups.^{2,3,4} The pandemic continued throughout CY 2021, and even after vaccinations became available mid-way through the year, many providers were still unable to provide pre-pandemic levels of screening and diagnostic services, whether because of patient access challenges or because of patient hesitancy toward seeking medical intervention overall.

As a result of this suppressed patient access to cancer screening and diagnostic services in 2021, many novel drugs with pass-through status during that calendar year had limited uptake and adoption by cancer care providers. We believe that the COVID-19 pandemic continues to impact utilization of several drugs and biologicals whose pass-through payment status is due to expire in the coming year, and we are concerned that the agency may not have accurate depiction of utilization from CY 2021 claims data upon which to base payment rates for these drugs and biologicals in CY 2023. For these reasons, we request that CMS consider using its equitable adjustment authority to extend pass-through status for drugs and biologicals whose pass-through status is expiring in CY 2023 by at least a full year. This will help to ensure that claims data will

¹ 86 Fed. Reg. 63458, 63755 (Nov. 11, 2021).

² Patel, Manali I., Jacqueline M. Ferguson, Eida Castro, Cristina D. Pereira-Estremera, Guillermo N. Armaiz-Peña, Ysabel Duron, Fay Hlubocky et al. "Racial and Ethnic Disparities in Cancer Care During the COVID-19 Pandemic." *JAMA Network Open* 5, no.

³ Grimm, Lars J., Cindy Lee, Robert D. Rosenberg, Judy Burleson, Michael Simanowith, Tom Fruscillo Jr, Casey E. Pelzl, Sarah M. Friedewald, Linda Moy, and Margarita L. Zuley. "Impact of the COVID-19 Pandemic on Breast Imaging: An Analysis of the National Mammography Database." *Journal of the American College of Radiology* (2022).

⁴ Cairns, Ashley, V. Morgan Jones, Kelly Cronin, Margaret Yocobozzi, Clifford Howard, Nadja Lesko, Akiko Chiba, and Marissa Howard-McNatt. "Impact of the COVID-19 Pandemic on Breast Cancer Screening and Operative Treatment." *The American Surgeon* 88, no. 6 (2022): 1051-1053.

accurately reflect utilization rates when the agency determines payment for these novel therapies through future rulemaking.

OPPS Payment Methodology for 340B Purchased Drugs

CMS proposal (87 Fed. Reg. 44647): Under the OPSS, CMS establishes payment rates for separately payable drugs and biologicals without pass-through status, including for specified covered outpatient drugs purchased at discount prices under the Health Resources and Services Administration’s 340B Drug Pricing Program. In the CY 2018 OPSS final rule, CMS finalized a policy to reimburse 340B-acquired drugs at a rate of ASP minus 22.5 percent. This was a significant change from the previous rate of ASP plus 6 percent.

On June 15, 2022, the U.S. Supreme Court ruled in *American Hospital Association v. Becerra* that the Department of Health and Human Services may not vary reimbursement rates for drugs and biologicals among groups of hospitals without conducting a survey of hospitals’ acquisition costs. This decision has retroactive implications for CYs 2018-2022 as well as the proposed CY 2023 rates. However, due to the timing of the Supreme Court decision, CMS did not have sufficient time to incorporate the adjustments to the proposed payment rates and budget neutrality calculations to account for that decision before issuing the CY 2023 OPSS proposed rule.

For that reason, CMS anticipates it will revert to its previous policy and finalize a rate of ASP plus 6 percent, regardless of whether a drug was acquired through the 340B program, for CY 2023. The agency has supplied “340B Alternate supporting files” to provide information on how this shift would impact payments for CY 2023 given budget neutrality constraints. CMS seeks comments on how to apply the Supreme Court’s decision to CYs 2018-2022.

ACCC comment: ACCC appreciates CMS’ action in response to the recent Supreme Court decision and supports the agency’s intent to finalize a payment rate of ASP plus 6 percent in the CY 2023 OPSS final rule. In our comments in response to the CY 2018 OPSS proposed rule, we strongly opposed CMS’ proposal to reduce payment for separately payable drugs purchased under the 340B program. Like other stakeholders, ACCC believes that this reversion to its pre-2018 reimbursement policy for 340B purchased drugs is a necessary step in recognizing the Supreme Court’s decision.

Historically, the 340B program has served a critical role in the delivery of cancer care. Today, the 340B program helps some of our members provide comprehensive cancer services to high numbers of low-income Medicare beneficiaries, Medicare-only, Medicaid, uninsured, and dual-eligible patients with cancer. In most cases, our members reinvest the 340B savings they realize from the discounted pricing into the provision of a full array of supportive oncology care services that result in high-quality cancer care for these beneficiaries, including social services, nutrition counseling, and psychosocial support. Most of these services are not separately payable, so the restoration of the payment rate to ASP plus 6 percent will be a relief to these institutions and the patients they serve.

In looking at potential remedies to address the cuts made in CYs 2018-2022, we urge the agency to engage in a formal rulemaking process with opportunities for public input prior to finalizing any decision around retrospective payments to 340B covered entities. Moreover, we strongly

request that CMS not attempt to recoup funds from other hospitals nor implement any policy change that will unfairly penalize non-340B facilities if it decides that CY 2018-2022 adjustments are necessary.

Proposed Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process

CMS proposal (87 Fed. Reg. 44802): In the CY 2020 OPSS final rule, CMS finalized a prior authorization process for certain hospital outpatient department services. Under this policy, 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, which was expanded to seven categories in the CY 2021 rulemaking cycle. For CY 2023, CMS proposes to require prior authorization for a new service category, Facet Joint Interventions, which would be effective for dates of service on or after March 1, 2023.

ACCC comment: While CMS's prior authorization process for hospital outpatient department services does not directly impact cancer care at this time, ACCC has strong concerns with this program overall and the precedent it sets for Medicare beneficiary access to care. As we have seen in commercial health insurance and the Medicare Advantage (MA) program, strenuous prior authorization requirements can act as a barrier for patients requiring timely access to necessary cancer care services and treatments.

Patients with cancer often require immediate treatment to prevent further spread of their cancer. Thus, delays caused by unnecessary and administratively burdensome prior authorization processes can have even greater irreversible consequences for these patients. When combined with a lack of transparency in the approval process and determinations made by personnel with limited knowledge of oncology, prior authorization requirements in MA and the commercial space have become a major hurdle for ACCC members and a worrisome impediment for their patients.

ACCC supports CMS' goal of reducing cost while preserving or increasing the overall quality of care for Medicare beneficiaries. However, we believe that utilization management tools like prior authorization should be implemented only when necessary and in a transparent and evidence-based manner. Moreover, we believe that these requirements should never hinder patient access to medically necessary cancer care.

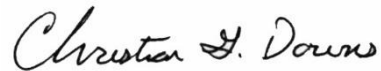
ACCC thanks the agency for not extending prior authorization requirements to oncology services in this rulemaking cycle. Additionally, we urge CMS to refrain from expanding its hospital outpatient department prior authorization process in the future without significant collaboration with and buy-in from both provider and patient stakeholder groups. Only through this level of stakeholder engagement can the agency ensure the timely delivery of necessary, high-quality care for Medicare beneficiaries.

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Administrator Brooks-LaSure
September 13, 2022

Thank you for this opportunity to share the oncology care provider perspective on the CY 2023 OPPS proposed rule. As the association representing the multidisciplinary cancer care team, ACCC is uniquely suited to participate in this dialogue with CMS in its efforts to maintain a stable and equitable Medicare payment system. If you have any questions on our comments, please feel free to contact Matt Devino, Director of Cancer Care Delivery & Health Policy, at mdevino@accc-cancer.org or (301) 263-3510.

Respectfully Submitted,

A handwritten signature in black ink that reads "Christian G. Downs". The signature is written in a cursive, flowing style.

Christian G. Downs, JD, MHA
Executive Director
Association of Community Cancer Centers (ACCC)