

The leading education and advocacy  
organization for the cancer care community



October 5, 2020

**OFFICERS**

**President**

Randall A. Oyer, MD  
Ann B. Barshinger Cancer Institute  
Lancaster, Pennsylvania

**President-Elect**

Krista Nelson, MSW, LCSW, OSW-C  
Providence Cancer Institute  
Portland, Oregon

**Treasurer**

David R. Penberthy, MD, MBA  
Southside Regional Medical Center  
Petersburg, Virginia

**Secretary**

Olalekan Ajayi, PharmD, MBA  
Welch Cancer Center  
Sheridan, Wyoming

**Immediate Past President**

Ali McBride, PharmD, MS, BCOP  
The University of Arizona Cancer Center  
Tucson, Arizona

**TRUSTEES**

Nadine J. Barrett, PhD, MA, MS  
Duke Cancer Institute  
Durham, North Carolina

Amy Ellis

Northwest Medical Specialties, PLLC  
Tacoma, Washington

Jorge J. Garcia, PharmD, MS, MHA, MBA, FACHE  
Baptist Health South Florida  
Miami, Florida

Amanda Henson, MSHA, MBA, FACHE  
Baptist Health  
Louisville, Kentucky

Una Hopkins, RN, FNP-BC, DNP  
Montefiore Medical Center  
Bronx, NY

Jeff Hunnicutt  
Highlands Oncology Group, PA  
Fayetteville, Arkansas

Barbara Jensen, RN, BSN, MBA  
Skagit Regional Health  
Mount Vernon, Washington

Michelle Shiller, DO, MSPT  
Baylor Scott & White Cancer Center  
Dallas, Texas

Lawrence David Wagman, MD  
City of Hope  
Rancho Cucamonga, California

Wendi L. Waugh, RT(R)(T), CMD, CTR  
Southern Ohio Medical Center Cancer Center  
Portsmouth, Ohio

**EXECUTIVE DIRECTOR**

Christian G. Downs, JD, MHA

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1736-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

BY ELECTRONIC DELIVERY

**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:

The Association of Community Cancer Centers (ACCC) appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment System (OPPS) proposed rule (the Proposed Rule) for calendar year (CY) 2021.<sup>1</sup> ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 23,000 cancer care professionals from approximately 1,100 hospitals and more than 1,000 private practices nationwide. These include cancer program members, individual members, and members from 34 state oncology societies. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

ACCC is committed to preserving and protecting the entire continuum of quality cancer care for our patients and our communities, including access to appropriate cancer therapies in the most appropriate setting, including during the COVID-19 public health emergency (PHE). Advanced cancer treatments often are associated with considerable risk, and many are available only in the hospital setting. Hospital outpatient departments are a critical component of the cancer care delivery system. Hospitals face growing numbers of patients requiring cancer care, while also dealing with the challenges of the PHE, and their ability to continue to provide care will depend on appropriate Medicare payment rates for oncology services, including chemotherapy drugs, radiation oncology, and other important services.

<sup>1</sup> 85 Fed. Reg. 48,772 (Aug. 12, 2020).

ACCC is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comments. In our comments below, we recommend that CMS:

- Protect rural and underserved providers and patients by not finalizing further reductions in payment under the 340B Program.
- Finalize the proposed changes in the level of supervision of Non-Surgical Extended Duration Therapeutic Services (NSEDTS) so long as hospitals retain the flexibility to determine how best to staff these services, both with respect to the individuals who may be providing the services and how the hospital chooses to meet the supervision requirements.
- Reverse, not extend, the requirement for prior authorization for certain outpatient department services.

We will address these recommendations in greater detail below.

**I. To protect rural and underserved providers and beneficiaries, CMS should not finalize its proposal to further reduce the payment rate for separately payable drugs acquired under the 340B Program.**

CMS proposes to pay ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent for CY 2021 and subsequent years for separately payable drugs without passthrough status acquired under the 340B program.<sup>2</sup> With this proposal, CMS is lowering the payment rate for 340B drugs well below the already devastating payment rate of ASP minus 22.5 percent that went into effect in CY 2018.

ACCC is extremely concerned about how lowering the reimbursement rate to ASP minus 28.7 percent impacts rural and underserved providers of cancer care where the bulk of the beneficiaries are Medicare or dual eligible. We urge CMS not to further reduce the payment rate for separately payable drugs purchased under the 340B Drug Pricing Program.

*A. The proposal to further reduce payment for 340B drugs fails to account for the numerous harmful effects it will have on patient access to care.*

As CMS considers reforms and changes to the 340B Program, the Agency should support policies that encourage medical oncology providers to treat underserved populations, including low-income Medicare beneficiaries, Medicare-only, Medicaid, uninsured, and dual-eligible cancer patients. The 340B Program should assist all providers, both physician offices and hospital-based cancer programs, in serving these populations. The Agency's additional cuts to 340B reimbursement undermine this goal and negatively impact the provision of essential healthcare to underserved populations.

CMS believes "it is appropriate for the Medicare program to pay for SCODs [Specified Covered Outpatient Drugs] purchased under the 340B program at a rate that approximates what hospitals actually pay to acquire the drugs."<sup>3</sup> CMS is proposing to lower the reimbursement rate for 340B drugs based on methodologically suspect survey data, which "confirm that the ASP minus 22.5 percent rate is generous to 340B hospitals, and... supports an even lower payment rate."<sup>4</sup>

However, the 340B Program serves a critical role in the delivery of cancer care and helps many of our members provide comprehensive cancer services to high numbers of low-income Medicare beneficiaries. Our expectation and understanding is that our members use their 340B savings to provide an array of services,

---

<sup>2</sup> 85 Fed. Reg. at 48890.

<sup>3</sup> *Id.* at 48884.

<sup>4</sup> *Id.* at 48882-83.

including social services, nutrition counseling, and psychosocial support to underserved populations. Many of our members cannot provide these services without the savings from the 340B Program.

The initial payment cuts that went into effect in CY 2018 have already had a devastating impact on the 340B savings that are needed for our members to provide essential patient care services. Additional cuts will only serve to multiply the harmful effects of the initial payment cuts.

*B. Rather than further reducing payment rates, CMS should continue its current policy of paying ASP minus 22.5 percent for 340B drugs.*

As an alternative to reducing the payment rate for 340B drugs to ASP minus 28.7 percent, CMS is proposing to continue its “current policy of paying ASP minus 22.5 percent for 340B-acquired drugs as we prevailed on appeal to the D.C. Circuit in the litigation.”<sup>5</sup> ACCC continues to oppose the payment reductions that began in CY 2018 and are the subject of the referenced litigation, and urges CMS to return to paying ASP plus 6 percent for 340B drugs.

However, until payment rates for 340B-acquired drugs can be returned to their pre-CY 2018 levels, ACCC urges CMS not to further reduce the payment rate for separately payable drugs acquired under the 340B Program, and instead maintain the reimbursement rate for 340B-acquired drugs at ASP minus 22.5 percent.

**II. ACCC supports the proposal regarding changes in the level of supervision of NSEDTS so long as hospitals retain the flexibility to determine how best to staff these services, both with respect to the individuals who may be providing the services and how the hospital chooses to meet the supervision requirements**

For CY 2020, CMS finalized a proposal to amend the regulation at 42 C.F.R. § 410.27(a)(1)(iv) 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 critical access hospitals (CAHs) in order to align the supervision requirements between the two provider types, including for chemotherapy and radiation therapy services.<sup>6</sup> Then, as part of an interim final rule (IFR) with comment period published in the federal register on April 6, 2020, in response to the COVID-19 pandemic, CMS “assigned, on an interim basis, a minimum required supervision level of general supervision for NSEDTS services, including during the initiation portion of the service” for the duration of the public health emergency.<sup>7</sup> Previously, direct supervision had been required for these services during the initiation phase but general supervision was permitted thereafter.<sup>8</sup> CMS is now proposing to make the change adopted in the IFR permanent, so that the minimum required supervision level is general supervision for all phases of NSEDTS.<sup>9</sup>

ACCC supports this proposal and agrees with CMS that it “would be beneficial to patients and outpatient hospital providers as it would allow greater flexibility in providing these services and reduce provider burden, and thus, improve access to these services in cases where the direct supervision requirement may have otherwise prevented some services from being furnished due to lack of availability of the supervising physician or nonphysician practitioner.”<sup>10</sup> CMS goes on to note, however, “that the requirement for general supervision for an

---

<sup>5</sup> *Id.* at 48891.

<sup>6</sup> 84 Fed. Reg. 61,142, 61,363 (Nov. 12, 2019).

<sup>7</sup> 85 Fed. Reg. at 48,935. *See also* 85 Fed. Reg. 19,230, 19,266 (Apr. 6, 2020).

<sup>8</sup> 85 Fed. Reg. at 48,935.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

entire NSEDTS does not preclude these hospitals from providing direct supervision for any part of a NSEDTS when the practitioners administering the medical procedures decide that it is appropriate to do so” and that “[m]any outpatient therapeutic services including NSEDTS may involve a level of complexity and risk such that direct supervision would be warranted even though only general supervision is required.”<sup>11</sup> ACCC agrees that there may be circumstances in which direct supervision of NSEDTS is necessary, at either the initiation phase or otherwise, and therefore supports continued flexibility for hospitals in staffing these services, both with respect to the health care professionals providing the care and with respect to how supervision is provided.

### III. **CMS should reverse, not extend, its requirement for prior authorization for certain outpatient department services**

As part of the CY 2020 OPPTS final rule, CMS finalized a prior authorization process for five categories of services under Medicare Part B and Medicare Advantage: Blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.<sup>12</sup> ACCC opposed this change in its comments on the CY 2020 OPPTS proposed rule. CMS is now proposing to add two new service categories to the list of services subject to prior authorization: implanted spinal neurostimulators and cervical fusion with disc removal.<sup>13</sup> ACCC continues to oppose the use of prior authorization in Medicare Part B and Medicare Advantage and urges CMS to reverse its decision to permit prior authorization for services under these programs.

As discussed in last year’s comments, a report by the American Medical Association (AMA) has documented the increased use of prior authorization as a utilization management tool in recent years and the corresponding increased administrative burden on physicians.<sup>14</sup> While focused on physician practices and not hospitals, the AMA reported that, in a survey of 1,000 practicing physicians, “[m]edical practices spend an average of two business days a week per physician to comply with health plans’ inefficient and overused prior-authorization [] protocols,” and a “practice will complete 29.1 [prior authorization] requests per physician per week that take 14.6 hours to process.”<sup>15</sup>

In an updated survey of physicians from 2019, the AMA found that 48 percent of physicians reported that prior authorization always or often leads to delays in care and an additional 43 percent reported that it sometimes leads to delays in care.<sup>16</sup> Twenty-four percent of physicians reported that delays in prior authorization have led to an adverse event for their patients and 16 percent reported that these delays have led to hospitalizations.<sup>17</sup> ACCC member institutions similarly continue to experience increases in unnecessary and burdensome prior authorization, delaying patient care and increasing the administrative burden on hospitals. To protect patients, CMS should reverse its prior authorization policies finalized last year instead of extending them to additional service categories.

With respect to cancer care, ACCC member institutions have further seen significant delays in patient access to intravenous cancer treatment in Medicare Advantage. Life threatening diseases, including cancer, need quick access to therapies for patients. CMS thus far has not required prior authorization for cancer care services,

---

<sup>11</sup> *Id.*

<sup>12</sup> 84 Fed. Reg. at 61,450-51, 61,456.

<sup>13</sup> 85 Fed. Reg. at 49,028-29.

<sup>14</sup> Andis Robeznieks, *Why Prior Authorization Was a White-Hot Issue in 2018*, Am. Med. Assoc’n, <https://www.ama-assn.org/practice-management/sustainability/why-prior-authorization-was-white-hot-issue-2018> (Dec. 6, 2018).

<sup>15</sup> *Id.*

<sup>16</sup> AMA, 2019 AMA Prior Authorization Physician Survey, <https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf> (2020).

<sup>17</sup> *Id.*

however, ACCC remains concerned that the agency will eventually do so and that prior authorization for cancer services could put patient lives at risk.

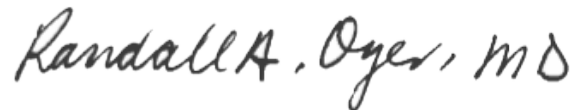
Finally, we believe that prior authorization requirements are inconsistent with the Trump Administration's Patients Over Paperwork initiative, which seeks to reduce administrative burden for providers, increase efficiencies, and improve the patient experience. For all these reasons, ACCC urges CMS to reverse its prior authorization policy for services under Medicare Part B and Medicare Advantage and not to extend it to additional service categories.

\* \* \*

ACCC greatly appreciates the opportunity to comment on the OPSS Proposed Rule. ACCC reiterates its commitment to promoting access to effective cancer treatments for all Medicare beneficiaries who need them. If you have any questions about our comment letter or would like to discuss our comment in further detail, please contact Christian Downs at [cdowns@acc-cancer.org](mailto:cdowns@acc-cancer.org) or (301) 984-9496.

Respectfully submitted,

Randall A. Oyer, MD

A handwritten signature in black ink that reads "Randall A. Oyer, MD". The signature is written in a cursive style with a large, prominent "R" and "O".

President  
Association of Community Cancer Centers