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October 5, 2020

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Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1734-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

BY ELECTRONIC DELIVERY

**Re: Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (CMS-1734-P)**

Dear Administrator Verma:

The Association of Community Cancer Centers (ACCC) appreciates the opportunity to comment on the proposed rule regarding the Medicare Physician Fee Schedule (PFS) for Calendar Year (CY) 2021 (Proposed Rule).<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 and payments to the physicians that furnish them, including during the COVID-19 public health emergency (PHE).

<sup>1</sup> 85 Fed. Reg. 50,074 (Aug, 17, 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:

- Mitigate the detrimental impact of increased payment for office/outpatient evaluation and management (E/M) visits, which have been offset by reductions to surgery and radiology oncology services, among others, by seeking a balanced approach to payment for all services.
- Abandon the proposal to assign certain section 505(b)(2) drug products to multiple source drug codes for purposes of Part B payment, which would not lower prices for providers and would create uncertainty about reimbursement rates.
- Finalize its proposals to increase flexibilities for telehealth services and communication technology-based services (CTBS), which expand access to services for patients in need.

We will address these recommendations in greater detail below.

**I. ACCC urges CMS to mitigate the detrimental impact of increased payment for office/outpatient E/M visits which have been offset by reductions to surgery and radiology oncology services, among others, by seeking a balanced approach to payment for all services**

As a multidisciplinary organization that represents all the service lines and specialists critical to high quality cancer care delivery, ACCC is deeply concerned about the offset reductions impact on radiation oncology and surgery. ACCC urges CMS to reconsider a more balanced approach that preserves these important parts of the cancer care team.

In the CY 2020 PFS final rule, CMS finalized substantial increases in the relative value units (RVUs) for office/outpatient E/M visits (Current Procedural Terminology (CPT) codes 99202–99215), which will become effective on January 1, 2021.<sup>2</sup> Under the PFS, if increases or decreases in RVUs cause estimated expenditures for the year to change by more than \$20 million, CMS must offset those changes with other adjustments to preserve budget neutrality.<sup>3</sup> Consequently, this year, CMS proposes to reduce the CY 2021 conversion factor, which converts RVUs to payment rates, by more than 10 percent.<sup>4</sup> The increases in RVUs for office/outpatient E/M visit codes together with the conversion factor will cause a significant redistribution of payment away from non-E/M services, with a disproportionate and negative impact on specialties like surgery and radiation oncology.<sup>5</sup>

As CMS recognized last year, the extent of the negative impact on specialties is “primarily driven by the extent to which those specialties bill using the office/outpatient E/M code set,” meaning that specialties that use these codes less are likely to see the most significant negative financial impact.<sup>6</sup> And that negative financial impact has become apparent this year as the agency’s own CY 2021 financial impact analysis for changes in the rule as a whole predicts a 6 percent decrease in Medicare PFS payments for radiation oncology and radiation treatment centers and an 11 percent decrease for radiology.<sup>7</sup> All of the surgical specialties included in this analysis would face a decrease in total allowed charges if CMS’s proposals are implemented.<sup>8</sup>

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<sup>2</sup> See 84 Fed. Reg. 62,568, 62,854 (Nov. 15, 2019).

<sup>3</sup> Social Security Act (SSA), § 1848(c)(2)(B)(ii)(II).

<sup>4</sup> 85 Fed. Reg. at 50,373.

<sup>5</sup> *Id.* at 50,375–76.

<sup>6</sup> See 84 Fed. Reg. at 63,157.

<sup>7</sup> 85 Fed. Reg. at 50,375–76.

<sup>8</sup> *Id.*

ACCC is alarmed by the extent of the expected combined financial impact for these specialties and therefore urges CMS to adopt a regulatory solution to mitigate their effect. ACCC understands from its members that these cuts in payments come at a time when they are already facing substantial losses in revenue due to the COVID-19 PHE, which has caused many Medicare beneficiaries to forego or postpone needed medical care. Last year, in response to concerns from commenters regarding the disproportionate impact on specialists that do not frequently bill E/M visits, CMS stated that it “w[ould] consider strategies [] mitigat[ing] the redistributive effects of [the budget neutrality] adjustment associated with revaluing of the office/outpatient E/M visit code set as part of future rulemaking.”<sup>9</sup>

For example, CMS could phase in the changes in values for E/M , which could eliminate the need for any budget neutrality adjustment or make smaller the adjustment that would apply in a given year. For CY 2019, CMS adopted a four-year phase-in of practice expense pricing updates “to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs . . . .”<sup>10</sup> ACCC urges CMS to adopt a similar solution in the CY 2021 PFS final rule. ACCC further encourages CMS to consider seeking additional legislative solutions, such as seeking legislative authority to exempt the office/outpatient E/M increases from budget neutrality requirements. ACCC urges CMS to follow through on its promise and encourages CMS to seek a balanced approach to payment for all PFS services in the CY 2021 final rule.

## **II. ACCC opposes CMS’s proposal to assign certain section 505(b)(2) drug products to multiple source drug codes for purposes of Part B payment, which would not lower prices for providers and would create uncertainty about reimbursement rates**

ACCC urges CMS not to finalize its proposal to assign certain drugs approved under the section 505(b)(2) pathway of the Federal, Food, Drug and Cosmetic Act to the multiple source drug payment methodology established under section 1847A of the Social Security Act for purposes of determining payment under Medicare Part B.<sup>11</sup>

The organization is concerned that this proposal would not lower prices through increased competition, and, most importantly from a provider perspective, would create uncertainty and confusion about reimbursement rates, which would hinder innovation and efficiency and cause delays in access to new therapies.

Under CMS’s proposed policy and regulation certain section 505(b)(2) drug products would be treated as multiple source drugs under Medicare Part B where CMS determines that “an existing multiple source drug code descriptor describes the section 505(b)(2) drug product.”<sup>12</sup> CMS states that the determination will be based on factors that include:

- “The active ingredient and drug name of the section 505(b)(2) drug product and other drug products paid in an existing multiple source drug code;”<sup>13</sup>

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<sup>9</sup> 84 Fed. Reg. at 62,856.

<sup>10</sup> 83 Fed. Reg. 59,452, 59,475 (Nov. 23, 2018).

<sup>11</sup> See 85 Fed. Reg. at 50,261–65.

<sup>12</sup> *Id.* at 50,397 (to be codified at proposed 42 CFR § 414.904(k)).

<sup>13</sup> *Id.* at 50,263.

- “The drug description and indications, particularly whether differences such as the salt form, additional ingredients, or uses exist;”<sup>14</sup>
- “The labeling information (and if necessary [certain] other materials . . .)” for the drug;<sup>15</sup> and
- “The dosage and administration, pharmacokinetics, indications, contraindications, warnings, drug interactions, and adverse reactions.”<sup>16</sup>

Section 1847A(c)(6)(C) of the SSA defines a “multiple source drug” as:

[A] drug for which there are 2 or more drug products which—(I) are rated as *therapeutically equivalent* (under the Food and Drug Administration’s [(FDA’s)] most recent publication of ‘Approved Drug Products with Therapeutic Equivalence Evaluations’), (II) . . . are *pharmaceutically equivalent and bioequivalent*. . . and as determined by the [FDA], and (III) are sold or marketed in the United States during the [calendar] quarter.”<sup>17</sup>

The statute also provides for one exception to this rule—namely single source drugs and biologicals that were treated as part of the same billing and payment code as of October 1, 2003, which are also to be treated as multiple source drugs.<sup>18</sup> Payment for drugs under Medicare Part B is based on the average sales price (ASP) for a single source drug and a volume-weighted average of reported ASPs for a multiple-source drug for all drugs included in a particular billing and payment code.<sup>19</sup>

Under CMS’s proposal, CMS would treat a 505(b)(2) drug as a multiple source drug whenever a billing and payment code has already been established under Medicare Part B that governs reimbursement for two or more therapeutically, bioequivalent, and pharmaceutically equivalent drugs under the statute. The statute does not permit CMS to establish a substitute process for identifying a multiple source drug and were it to do so it could significantly skew reimbursement for the health care professionals administering a drug.

Moreover, ACCC believes that, even if this proposal could be implemented consistent with the statute, that it will not achieve CMS’s stated goal of “encourage[ing] competition among products that are competitors” or the Administration’s “efforts to curb drug prices while limiting opportunities to ‘game the regulatory process and the patent system in order to unfairly maintain monopolies.’”<sup>20</sup> First, the policy would apply only to drugs approved through the section 505(b)(2) approval pathway, which is a very narrow subset of drugs on the U.S. market. Second, CMS does not provide any evidence that drugs adopted through this pathway have high drug prices, thus raising questions about the need for the policy in the first place.

For all of these reasons, ACCC urges CMS not to finalize the proposal to treat certain 505(b)(2) drugs as multiple sourced drugs.

### **III. ACCC supports CMS’s proposals to increase flexibilities for telehealth services and CTBS, which expand access to services for patients in need**

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<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at 50,263-64.

<sup>16</sup> *Id.* at 50,264.

<sup>17</sup> SSA § 1847A(c)(6)(C)(i) (emphasis added).

<sup>18</sup> *Id.* § 1847A(c)(6)(C)(ii).

<sup>19</sup> *Id.* § 1847A(b)(1)–(4).

<sup>20</sup> *Id.* at 50,264.

ACCC supports the additional telehealth flexibilities that CMS proposes to adopt on a temporary or permanent basis for CY 2021, to the extent these services are provided via telehealth consistent with the medical judgment of an appropriate health care professional. Specifically, ACCC supports CMS's proposals to add additional services to the Medicare Telehealth Services List on a permanent Category 1 basis, as well as its proposal to create a new Category 3 for telehealth codes to be added to the Medicare Telehealth Services List on a temporary basis during the PHE while CMS considers whether to add them permanently.<sup>21</sup> ACCC believes that these proposals will help more patients gain access to necessary medical services and reduce disparities in care, including in rural areas consistent with the U.S. Department of Health and Human Services Rural Action Plan.<sup>22</sup>

ACCC also supports CMS's proposals to expand the scope of communication technology-based services (CTBS) covered by Medicare, which can facilitate timely access to health care, save money for beneficiaries and the Medicare program, and promote effective coordination of care. Specifically, ACCC supports CMS's proposals to adopt a policy to allow the following CTBS codes to be billed by licensed clinical social workers and clinical psychologists, as well as physical therapists, occupational therapists and speech-language pathologists who bill Medicare directly for their services:

- G2061 (Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes),
- G2062 (Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes), and
- G2063 (Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes).<sup>23</sup>

In addition, ACCC supports CMS's proposals to adopt two new G codes, which parallel the existing G codes for remote evaluation of downloadable images/recorded video (G2010) and for virtual check-in (G2012), but which would allow billing for these services by certain nonphysician practitioners who cannot independently bill for E/M services, namely:<sup>24</sup>

- G20X0 (Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.)
- G20X2 (Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion).

ACCC believes that providing separate payment for CTBS services when they are provided by non-physician practitioners as well as when they are provided by physicians will help to improve patient access to and

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<sup>21</sup> *Id.* at 50,097, 50101-02.

<sup>22</sup> Rural Action Plan, U.S. Dept. of Health and Human Servs. (Sept. 2020), available at <https://www.hhs.gov/sites/default/files/hhs-rural-action-plan.pdf>.

<sup>23</sup> 85 Fed. Reg. at 50,112.

<sup>24</sup> *Id.*

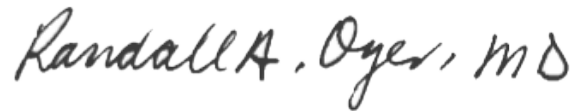
communication with their care team, reduce costs by reducing the need for more expensive in person services, improve care coordination among members of the patient's care team, and increase the quality of care provided. For all of these reasons, ACCC supports CMS's CTBS proposals.

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ACCC greatly appreciates the opportunity to comment on the 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, flowing style.

President  
Association of Community Cancer Centers