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Christian G. Downs, JD, MHA

September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
P.O. Box 8013
Baltimore, MD 21244-1850

BY ELECTRONIC DELIVERY

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals (CMS-1717-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) 2020.¹ 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. 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, 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.

¹ 84 Fed. Reg. 39398 (Aug. 9, 2019).

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

- Not finalize its proposal to reduce reimbursement to 40 percent of the OPPS rate for certain clinic visits furnished at excepted off-campus provider-based departments (PBDs) and reverse the policy that was implemented in CY 2019;
- Finalize the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommendation to apply a status indicator of Q1 to CAR-T codes to enable them to be separately payable when no other service is performed;
- With respect to proposed change to the laboratory date of service rule:
 - Not finalize its proposal to require a physician to determine whether a the results of the molecular pathology test or advanced diagnostic laboratory test (ADLT) are intended to guide treatment provided during any potential future hospital outpatient encounter;
 - Not finalize its proposal to remove molecular pathology tests from the laboratory date of service billing exception for molecular pathology tests and certain ADLTs; and
 - Finalize its proposal to exclude blood banks and centers from the laboratory date of service exception for molecular pathology tests and certain ADLTs;
- Finalize its proposal regarding changes in the level of supervision of outpatient therapeutic services in hospitals and CAHs but provide clear guidance on how the new supervision rules apply to chemotherapy and radiation oncology services;
- Not finalize its proposal to require hospitals to make public lists of gross charges and payer-specific negotiated rates; and
- Not finalize its proposal to require prior authorization for certain outpatient department services.

We will address these recommendations in greater detail below.

I. CMS should not finalize its proposal to reduce reimbursement to 40 percent of the OPPS rate for certain clinic visits furnished at excepted off-campus PBDs.

CMS proposes to complete the phase-in of the payment reduction, finalized in the CY 2019 OPPS final rule, for clinic visits at off-campus departments that are excepted from Section 603 of the Bipartisan Budget Act of 2015.² Under the proposal, payment for these services

² 84 Fed. Reg. at 39,528.

would be reduced to 40 percent of the standard OPSS rate in CY 2020, after being paid at 70 percent of the standard OPSS rate in CY 2019. ACCC strongly opposes this proposal and we urge CMS not to finalize it.

Most importantly, CMS should not finalize the proposed completion of the phased-in payment reduction because it is unlawful. On September 17, 2019, the U.S. District Court for the District of Columbia ruled that CMS exceeded its authority in the CY 2019 OPSS final rule when it reduced payment to certain excepted off-campus PBDs by 30 percent.³ The court determined that the method developed by CMS to cut costs is impermissible and violates its obligations under the statute and the CY 2019 OPSS final rule is therefore *ultra vires* with respect to the payment reduction to excepted off-campus PBDs. Notably, the ruling is not limited to the 30 percent payment reduction for CY 2019 but to the policy as a whole, meaning that finalizing the implementation of the 60 percent payment reduction in CY 2020 is unlawful, as is continuing the 30 percent payment reduction from CY 2019. Therefore, CMS should not finalize its proposal and should also reverse the 30 percent payment reduction that was implemented in CY 2019.

Second, as we have previously expressed, we are deeply concerned about the harmful effects that the implementation of the entire payment reduction could have on cancer care if implemented. Clinic visits are a central part of cancer care, and patients rely on hospitals, including their off-campus departments, to provide these services, especially in areas with few physician practices. Off-campus departments allow patients to be treated in convenient locations that are integrated with the main hospital. Significantly reducing payment for these services will, without a doubt, hurt hospitals' ability to provide care in these settings. Indeed, the purpose of this proposal is to reduce utilization of clinic visits in excepted off-campus departments.

We continue to believe that the proposed payment rates for clinic visits of 40 percent of the OPSS rates would be inadequate to support access to these important services. Although the payment rate for services in a particular ambulatory payment classification (APC) may be more or less than a hospital's cost for a procedure within that APC, the system is intended to provide appropriate reimbursement, on average. In contrast to this usual method, CMS proposes to ignore its data on the cost of providing clinic visits and set payment at 40 percent of the geometric mean cost calculated from its claims data. This rate is not based on hospital cost data, and CMS has not provided a solid rationale supporting payment at anything less than the average cost, much less payment at 40 percent of the OPSS rate.

Moreover, because the proposed reduction would be implemented in a non-budget neutral manner, the cut in payment for these services would not be balanced by increases in payment for other services. If these cuts are fully implemented, hospitals would need to consider reducing access to care at off-campus departments, increasing burdens on patients who would need to

³ *Am. Hosp. Assoc'n et al. v. Azar*, 1:18-cv-02841 (D.D.C. Sept. 17, 2019).

travel farther to the main hospital campus and potentially causing delays in treatment as hospitals adjust to treating more patients on campus.

Even if the court had not found these cuts to be unlawful, we believe it would be premature to complete the phase-in of these payment reductions until the effects of the payment reductions implemented to date have been thoroughly analyzed. CMS presents no data on how a similar payment reduction affected access to care in non-excepted departments, beginning on January 1, 2018, following a year of payment at 50 percent of the OPPS rate. CMS has not provided any analysis of the anticipated effect of the payment reduction, the amount of services that it would consider to be “necessary,” or an adequate justification for its belief that the proposed payment rate will not harm access to care. Notably, CMS’s own HOP Panel recommends that CMS freeze the payment policy for off-campus clinic visits at calendar year 2019 rates and evaluate whether beneficiary access has been compromised and whether the volume of outpatient services has decreased.⁴

Thus, CMS should not finalize its proposal to complete the phase-in of the 60 percent reduction of payment to certain non-excepted PBD, and should instead reverse the policy that was adopted in CY 2019 and pay applicable non-excepted PBDs at 100 percent of the OPPS for CY 2020.

II. CMS should not finalize its proposal to continue to pay ASP minus 22.5 percent for separately payable drugs purchased under the 340B Program, including drugs furnished in nonexcepted hospital off-campus PBDs.

CMS proposes to pay ASP minus 22.5 percent for separately payable drugs without pass-through status acquired under the 340B Program, including 340B drugs furnished in nonexcepted off-campus PBDs, in CY 2020. With this proposal, CMS is continuing its already devastating changes to 340B program that went into effect in CY 2018 and expanded to nonexcepted off-campus PBDs in CY 2019.

ACCC is extremely concerned about how continuing this payment architecture impacts rural and underserved providers of cancer care where the bulk of the beneficiaries are Medicare or dual eligible. We urge CMS to return to paying ASP plus 6 percent for separately payable drugs purchased under the 340B Drug Pricing Program.

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 continued 340B

⁴ Aug. 19, 2019 Recommendations, Advisory Panel on Hospital Outpatient Payment, CMS.gov, *available at* <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

reimbursement cuts undermine this goal and negatively impact the provision of essential healthcare to underserved populations.

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. While ACCC recognizes, based on some member concerns, that certain 340B-eligible hospitals use the program savings to expand care delivery to areas that are not underserved, we believe this issue can best be addressed in the regulatory framework provided by the enabling statute.

Our expectation and understanding is that our members use their 340B savings to provide an array of services, 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.

Rather than reducing 340B reimbursement rates, CMS should look for ways to identify covered entities who knowingly and repeatedly violate the rules of the program and penalize these entities, not the providers (and ultimately their patients) who utilize 340B savings as intended. ACCC fully supports transparency achieved through required public reporting from covered entities on the savings accrued from the program, and how these savings are spent.

A. CMS should reverse the payment cuts so as not to complicate further any appropriate legal remedy.

As CMS notes in the Proposed Rule, the “CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs are the subject of ongoing litigation.”⁵ The United States District Court for the District of Columbia found the Secretary exceeded his statutory authority with these payment cuts. CMS is appealing this decision, but due to the extreme complexities involved in devising an appropriate remedy, the Agency is already seeking public input on an appropriate remedy “in the event of an unfavorable decision on appeal.”⁶ However, if the Court of Appeals does not release its final decision by March 1, 2020,⁷ CMS will continue these 340B cuts in CY 2020, further complicating any remedy that would be required should CMS ultimately receive an adverse decision from the Court of Appeals. CMS should reverse the payment cuts now to avoid further complications relating to an appropriate legal remedy.

B. An appropriate remedy should minimize administrative complexities for providers.

As already noted, CMS is seeking public input on an appropriate remedy should the Court of Appeals agree with the District Court and decide the Secretary did indeed exceed his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B

⁵ 84 Fed. Reg. at 39,504.

⁶ *Id.* at 39,504.

⁷ *Id.* at 39,505.

Program to ASP minus 22.5 percent. “CMS is soliciting initial public comment on how to formulate a solution that accounts for all of the complexities that the district court recognized.”⁸

Realizing the complexity of the issue, ACCC encourages CMS to consider options that minimize administrative complications for providers. This consideration is particularly important for cancer programs with scarce resources that, by definition, would be the ones to receive the 340B claims adjustments.

C. The OPPS payment rate for 340B-acquired drugs should be set at ASP plus 6 percent.

CMS is seeking public comment on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP plus 3 percent could be an appropriate remedial payment amount, both for CY 2020 and for determining a remedy for CYs 2018 and 2019.⁹ ACCC appreciates CMS proactively seeking input on these payment rates. However, it has been well established over several years and many studies that the statutory payment rate of ASP plus 6 percent is an appropriate minimum payment level for all providers. In fact, previous MedPAC reports and industry experts have highlighted that, for different sites of service for care, such as hospitals, the payment level should be ASP plus 20 percent to account for the additional costs these programs incur.

To maintain consistency with reimbursement rates that were in place prior to the payment cuts, and to ensure providers have access to 340B savings in order to provide comprehensive cancer services to underserved patients, a rate of ASP plus 6 percent is an appropriate remedial payment, both for CY 2020 and for determining a remedy for the previous 2 years.

Once CMS has returned to a rate of ASP plus 6 percent, the Agency should work with stakeholder groups to determine a long-term 340B reform strategy. ACCC strongly believes that HRSA and Congress should take steps to better align the program with its original intent and ensure the savings from the program are benefiting underserved patients. Additionally, HRSA should seek stakeholder input to clarify the definition of eligible patient, so that providers understand clearly which patients qualify for the program. ACCC stands willing to work with fellow stakeholders and policymakers to achieve comprehensive reform of the 340B Program, which plays a critical role in serving underserved patients in the cancer care delivery system.

III. CMS should finalize the HOP Panel’s recommendation to apply a status indicator of Q1 to CAR-T codes to enable them to be separately payable when no other service is performed.

In Addendum B to the Proposed Rule, CMS proposes to continue to assign status indicator “B” to three Category III Current Procedural Terminology (CPT®)¹⁰ codes that the American Medical Association (AMA) created to describe services related to CAR-T therapies,

⁸ *Id.* at 39,504.

⁹ *Id.* at 39,504.

¹⁰ CPT is a registered trademark of the American Medical Association.

effective January 1, 2019. CAR-T therapies present an exciting and transformative new approach to treating certain cancers, and ACCC wishes to ensure that when hospitals furnish outpatient services related to CAR-T therapies, they are paid appropriately for furnishing those therapies.

We support the HOP Panel's recommendation that CMS apply a status indicator (SI) of Q1 to CPT codes 0537T (Chimeric antigen receptor t-cell (car-t therapy) harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day), 0538T (Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage)), and 0539T (Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration), enabling them to be separately payable when no other service is performed.¹¹ CMS should implement this recommendation in the final rule to ensure that Medicare payment for these services is appropriate and adequate to reflect the service furnished.

IV. CMS should not finalize its proposals with respect to the clinical laboratory date of service rule except that it should allow blood banks and centers to continue to bill hospitals.

In the CY 2018 OPPI/ASC final rule with comment period, CMS established an additional exception at 42 C.F.R. § 414.510(b)(5) for the hospital outpatient setting so that the date of service (DOS) for molecular pathology tests and certain ADLTs is the date the test is performed (instead of the date of specimen collection).¹² As CMS is aware, this has important implications for determining which entity bills for the service—either the hospital where the specimen was collected or the laboratory that performs the test. If all of the criteria for the exception at § 414.510(b)(5) are satisfied, then the laboratory that performs the molecular pathology test or applicable ADLT would bill Medicare for the test. CMS adopted this new exception because ADLTs are performed by a single laboratory and molecular pathology tests are often performed by one or only a few laboratories, and because hospitals may be reluctant to bill a Medicare for a complex test that it does not have the technical ability to perform and would not typically (or never) perform.¹³

In the Proposed Rule, CMS proposes to revise the exception for molecular pathology tests and certain ADLTs in three ways: (1) by requiring the ordering physician to determine whether the results of the molecular pathology test or ADLT are intended to guide treatment provided during any potential future hospital outpatient encounter; (2) by removing molecular pathology tests from the exception altogether such that the ordering of the test would need to comply with the 14-day rule in order for the laboratory to bill for the test; and (3) by excluding

¹¹ Aug. 19, 2019 Recommendations, Advisory Panel on Hospital Outpatient Payment, *supra* n.4.

¹² 84 Fed. Reg. at 39,599.

¹³ *Id.* at 39,600.

blood banks and centers from the exception.¹⁴ ACCC disagrees with the first two proposals and supports the third.

First, CMS's proposal to require the ordering physician to certify that the molecular pathology test or applicable ADLT will not be used for any future hospital outpatient encounter presents several problems, including that it adds significant administrative burden to clinicians and increases the opportunity for error. This proposal places additional burdens on physicians, which contradicts the agency's initiative to put patients over paperwork. Separately, the ordering physician may not know whether the test will be used to guide a future hospital outpatient encounter. Physicians cannot predict whether or where patients may seek further treatment. Requiring a physician to certify to the use of the test for a potential future unknown service in order to determine which entity will bill for the service would create unnecessary and confounding administrative burdens. This, in turn, may make physicians unwilling to make such a certification or to favor certifying that the test could guide a future hospital outpatient encounter, resulting in the test not being separately payable. It also would be very difficult to establish and apply standards for whether the physician's determination was reasonable and well-founded.

Second, ACCC disagrees with CMS's proposal to remove molecular pathology tests from the exception. This proposal will effectively eliminate the availability of the exception for most precision medicine diagnostics by limiting the exception to a very small subset of tests designated as "Advanced" by CMS. This is problematic because it could lead to delays in patient care. Physicians would be required to wait 14 days after a patient is discharged to order the test in order to comply with the 14-day rule and enable the performing laboratory to bill for the test. This would result in a return to unnecessary and potentially harmful delays in care, and disruption in patient access to timely targeted treatments, which were the basis for changing the rule last year. Furthermore, despite CMS's assertion that many molecular pathology tests can be performed in a hospital laboratory, that assertion is certainly not true for sophisticated precision medicine diagnostics which are frequently performed in only one lab, thereby undercutting CMS's rationale for revising the exception.

ACCC supports CMS's third proposal, which is to exclude blood banks and centers from the exception and to define a blood bank and center as an entity whose primary function is the collection, storage and dissemination of blood products. It is appropriate to exclude blood banks and blood centers from the exception and to enable them to bill hospitals directly because they perform molecular pathology tests to identify the most compatible blood product for a patient, and not for diagnostic purposes.

V. ACCC supports the proposal regarding changes in the level of supervision of outpatient therapeutic services in hospitals and CAHs but seeks clarification on how it will apply to chemotherapy and radiation oncology.

¹⁴ *Id.* at 39,601.

CMS proposes to amend the existing 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 CAHs in order to align the supervision requirements between the two provider types.¹⁵ As noted in the proposed rule, since 2010, there have been two different levels of supervision required for hospital outpatient therapeutic services: (1) direct supervision for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals and PBDs of hospitals (other than CAHs); and (2) general supervision for CAHs and small rural hospitals with 100 or fewer beds. Thus, there has essentially been a two-tiered system of physician supervision requirements for hospital outpatient therapeutic services.

ACCC appreciates that CMS's proposal is intended to ensure consistency in supervision requirements for hospital outpatient therapeutic services, and generally supports the proposal. Establishing the minimum level of supervision as general supervision would help many hospitals, particularly in rural and underserved areas, where it can be difficult to schedule enough physicians to provide direct supervision. However, it is unclear how the proposal would apply to chemotherapy and radiation oncology services, which may warrant a higher level of supervision than other outpatient therapeutic services. Therefore, if CMS finalizes its proposal, we request that CMS also provide clear guidance on how the general supervision requirement for services furnished by all hospitals and CAHs will apply to chemotherapy and radiation oncology services and whether there are any circumstances when direct supervision would be expected notwithstanding the general rule.

VI. CMS should not finalize its proposal to require hospitals to make public lists of gross charges and payer-specific negotiated rates.

ACCC strongly opposes CMS's proposed expansive new public disclosure requirements that would require all non-federally owned or operated hospitals to publicly display gross and payer-specific negotiated charges for all items and services with the intention of making such services "shoppable" to patients.¹⁶ While ACCC members believe that price transparency for patients is important and that patients should not be surprised by cost of care, CMS's current proposal has many negative consequences that will harm patients more than help them. Financial counseling performed at ACCC member institutions includes discussions of potential expected costs, but in a way that is designed to ensure maximum patient understanding with the least amount of additional burden. CMS's proposal disregards the special nature of cancer care and could have devastating consequences. Furthermore, ACCC believes that CMS's proposal exceeds its authority and is, therefore, unlawful.

With respect to cancer care specifically, there is an urgency and unpredictability to receiving treatment that may not be present for other services. For elective procedures, patients may have the time and energy (and lack of medical urgency) to "shop" around, but with cancer

¹⁵ *Id.* at 39,526.

¹⁶ *Id.* at 39,575.

care there is not as much choice. Cancer patients do not have the luxury to comparison shop for treatment to determine the most cost-effective course of treatment. Often the course of treatment required for cancer care is complex and patients should not need to feel additionally responsible for price comparison, especially when they are provided with standard charges for services that would not adequately reflect what the patient would be charged in the first place. Furthermore, cancer care requires quick adaptation to changing patient response to treatment, meaning that even if patients could “shop” for services at the beginning of care, it would be very difficult to do so mid-treatment.

Giving patients comprehensive charge information would not help guide the course of cancer care because the course of treatment and regimen that most patients receive will not be “shoppable” or comparable. What is paramount for cancer patients are the discussions they have with their care team about the best course of treatment, and second opinions they acquire about those recommendations. It is extremely rare for a patient to seek a second opinion about a proposed course of cancer treatment with respect to cost; the discussions almost always revolve around the most effective treatment to enable that patient to continue to live or have a certain quality of life. Furthermore, ACCC is very concerned that this proposal will directly interfere with the delicate balance of the collaborative nature of a multi-disciplinary cancer care team and the care coordination required. The proposal has the potential to disrupt coordination of care and suggest that cancer patients insist on the least costly care rather than the care that is most likely to have a positive clinical outcome for the patient.

ACCC urges CMS to not finalize its proposal on requiring hospitals to make public a list of their standard charges for “shoppable services.” ACCC agrees that patients should receive information to enable them to make informed decisions about their healthcare, but the approach that CMS has put forward requires significant modification in order to strike a balance between the cost and quality of care. Furthermore, while this proposal may be appropriate for elective procedures, it is inappropriate for cancer care and fails to account for the urgent, personalized, and ever-changing nature of cancer care. If finalized, the proposal will place an additional burden on cancer patients that will interfere with timely and clinically appropriate treatment. Should CMS wish to implement a proposal that will provide charge information in a manner that is appropriate for cancer care, it should reach out to ACCC member institutions to determine current best practices.

We also note that we believe CMS’s proposal exceeds its authority. The statutory authority on which CMS relies for its proposal— Section 2718(e) of the Public Health Service Act (PHS Act)¹⁷—does not provide CMS with authority to require hospitals to make public their gross charge and payer-specific negotiated rates. Section 2718(e) authorizes CMS to require hospitals to “establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's *standard charges* for items and services provided by the

¹⁷ 42 U.S.C. § 300gg-18(e).

hospital, including for diagnosis-related groups established under section 1886(d)(4) of the [Medicare statute].”¹⁸ “Standard charges” has long been understood in the hospital industry to be a technical term of art that means a hospital’s usual or customary *chargemaster* charge; not payer-specific charges that are the result of negotiation and vary year-by-year and plan-by-plan. Additionally, Section 2718(e) authorizes *only one* list of standard charges — “a list” — whereas CMS would require hospitals to make public three lists: (1) a list of gross charges for inpatient and outpatient items and services; (2) a list of payer-specific negotiated rates for those same services; and (3) a list of payer-specific negotiated charges for shoppable services. For all of these reasons, we urge CMS to not finalize its proposal.

VII. CMS should not finalize its proposal to require prior authorization for certain outpatient department services.

In response to a recently completed analysis of the volume of covered outpatient department services, CMS proposes to implement a prior authorization requirement for five categories of services: Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, and Vein Ablation.¹⁹ ACCC opposes this proposal and remains extremely concerned about the use of utilization management tools in Part B and Medicare Advantage.

As reported by the American Medical Association (AMA) last year, the use of prior authorization as a utilization management tool has increased significantly in the last five years and resulted in substantial additional administrative burden.²⁰ While focused on physician practices and not hospitals, the AMA reports that in a survey of 1,000 practicing physicians, medical practices spend an average of two business days per week per physician to comply with health plans’ inefficient and overused PA protocols and a practice will complete 29.1 prior authorization requests per physician per week that take 14.6 hours to process. ACCC member institutions have experienced the same increase in unnecessary and burdensome prior authorization which often delays necessary patient care and increases administrative costs to the hospitals. CMS should not be compounding this already existing epidemic by adding additional prior authorization requirements under Medicare.

With respect to cancer care, the use of prior authorization has resulted in significant delays in patient access to intravenous treatment in Medicare Advantage. Life threatening diseases, including cancer, need quick access to therapies for patients. While CMS’s proposal does not include cancer, we are very concerned that it will eventually lead to prior authorization requirements for cancer care. We also observe that added prior authorization requirements is inconsistent with the Trump Administration’s Patients Over Paperwork initiative, which seeks to reduce administrative burden for providers so that they can focus on providing quality patient

¹⁸ *Id.* (emphasis added).

¹⁹ 84 Fed. Reg. at 39,604.

²⁰ 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).

care. ACCC urges CMS to not finalize its proposal and to instead address increasing utilization of certain services in a different manner.

* * *

ACCC greatly appreciates the opportunity to comment on the OPPS 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 301/984-9496 or cdowns@acc-cancer.org.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Ali McBride', with a stylized flourish at the end.

Ali McBride, PharmD, MS, BCOP
ACCC President