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September 24, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (CMS-1695-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) 2019.¹ 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.

¹ 83 Fed. Reg. 37,046 (July 31, 2018).

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.

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 Wholesale Acquisition Cost (WAC) plus 3 percent for new drugs and biologicals that do not yet have adequate Average Sales Price (ASP) data;
- Not finalize its proposal to reduce payment for separately payable drugs purchased under the 340B program at nonexcepted hospital off-campus provider-based departments (PBDs);
- Not finalize its proposal to reduce reimbursement to 40 percent of the OPPS rate for certain clinic visits furnished at excepted off-campus PBDs;
- Not finalize its proposal to reduce reimbursement to 40 percent of the OPPS rate for service line expansions at excepted off-campus PBDs;
- Clarify how hospitals should bill for furnishing certain outpatient services related to Chimeric Antigen Receptor T-cell (CAR-T) therapies and ensure that hospitals are paid appropriately for furnishing these therapies; and
- Ensure that any model based on the Competitive Acquisition Program (CAP) authority is voluntary for all participants, preserves patient access to treatment and provider flexibility, and promotes cost-efficiency through more effective distribution and delivery of drugs and biologicals rather than utilization management tools.

We will address these recommendations in greater detail below.

I. CMS should not finalize its proposal to reduce reimbursement to WAC plus 3 percent for separately payable new drugs and biologicals that do not yet have adequate ASP data.

For CY 2019, CMS proposes to reduce Medicare reimbursement for separately payable drugs and biologicals that do not yet have adequate ASP data to calculate the usual ASP plus 6 percent reimbursement rate.² ACCC is deeply concerned about the unintended effects that this proposal would have on adoption of new and innovative drugs, and we urge CMS not to finalize it.

² 83 Fed. Reg. at 37,122-23.

The Medicare statute authorizes CMS to establish payment for drugs and biologicals based on WAC during an initial sales period in which the manufacturer does not have adequate data on the sales prices for the drug or biological to calculate the usual ASP-based rate. In the past, CMS has reimbursed providers for such drugs and biologicals at WAC plus 6 percent, which matches the 6 percent add-on to ASP used once ASP data are available. The WAC plus 6 percent rate reflects the provider's acquisition cost and related expenses that providers incur for drugs and biologicals but that may not be reflected in the ASP or WAC. CMS now proposes to reduce the reimbursement for drugs and biologicals without adequate ASP data to WAC plus 3 percent "whenever WAC-based pricing is used."³ Although the Proposed Rule does not explain the reasons for its proposal, CMS made a similar proposal in the CY 2019 Physician Fee Schedule (PFS) proposed rule based on the recommendation of a June 2017 Medicare Payment Advisory Commission (MedPAC) report. The MedPAC report identified certain concerns with WAC-based payment during the initial sales period, including that WAC-based payment sometimes fails to take account of discounts that providers received and that ASP-based payment, once available, tends to be lower than WAC-based payment.

ACCC urges CMS not to finalize its proposal and instead to continue reimbursement at WAC plus 6 percent for new drugs and biologicals that do not yet have adequate ASP data. We believe that the proposed reduction in reimbursement would result in lower utilization of new drugs by hospitals and outpatient facilities. As new drugs and biologicals enter the market, the current WAC plus 6 percent rate gives providers assurance that they will be adequately reimbursed for the drug or biological and associated costs like pharmacy services and storage and handling. Reducing reimbursement for therapies that are just becoming available will make providers less willing and able to administer new treatments. Although the reduced reimbursement rate would last only until the new drug or biological can be reimbursed based on its ASP, even a delay of a few months can be deeply harmful to a cancer patient who might benefit from a new therapy. Moreover, ACCC is concerned that the proposal ultimately will make it less attractive for manufacturers to develop new and innovative therapies in the first place, delaying the availability of potentially life-saving treatment for patients who do not have time to wait. We urge CMS not to finalize this change.

II. CMS should not finalize its proposal to reduce payment for separately payable drugs purchased under the 340B program at nonexcepted hospital off-campus PBDs.

CMS proposes to reduce payment for separately payable drugs without pass-through status for nonexcepted hospital off-campus PBDs under the 340B Drug Discount Program from ASP plus six percent to ASP minus 22.5 percent in CY 2019. With this proposal CMS is expanding upon the already devastating 340B cuts that went into effect in CY 2018 through the OPPI Proposed Rule, with its goal to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs." The proposed rate of ASP minus 22.5 percent is based on a MedPAC analysis, and ACCC is concerned again with the implementation of these cuts due to the alarming inconsistency in tackling the correct policy and political implications of the 340B Drug Discount Program.

³ *Id.* at 37,050.

ACCC members provide cancer care in private practices and hospitals, both academic and community-based, and for-profit and not-for-profit. The diversity of our membership and vantage point of all care settings for cancer care uniquely positions ACCC to comment on this proposal and the necessary broader reforms needed to sustain the 340B program.

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 cancer patients. Our expectation and understanding is that our members reinvest the 340B savings they realize from the discounted pricing into the provision of a full array of services that result in high quality cancer care to these beneficiaries, including social services, nutrition counseling, and psychosocial support. Most of these services are not separately payable, and many of our members participating in the program have said that they could not continue to provide these services without the savings from the 340B program.

At the same time, we recognize based on some member concerns that the 340B program may no longer be serving the populations it originally intended. These members have pointed out that some hospitals eligible for the 340B program are using the savings achieved to expand care delivery into areas that are not underserved, that may result in market and delivery distortions. Moreover, these members, which represent both physician offices and non-participating cancer programs, indicate they also treat underserved cancer patients, yet do not have access to the 340B program.

After continuous and careful review, ACCC believes CMS's proposal is flawed because it assumes all eligible providers are acting in an inappropriate manner which we fundamentally disagree with. CMS's focus should not be on reducing payment rates to all eligible providers but instead should be to identify who should remain eligible for this program and who the bad actors are that should not in the future. ACCC wants a 340B program that supports and encourages all providers – both physician offices and hospital-based cancer programs – to serve low-income Medicare beneficiaries, Medicare-only, Medicaid, uninsured, and dual-eligible cancer patients. As written, CMS's proposal does not accomplish this goal.

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. Previous MedPAC reports and industry experts have highlighted that for different sites of service for care, such as hospitals, payment level should be ASP plus 20 percent to account for the additional costs these programs incur. ACCC is very alarmed that despite a lack of accurate data to inform this policy and lack of addressing the core of this program CMS plans to move forward with these cuts again.

A. CMS does not have a clear understanding of the impact on Medicare beneficiaries or the cancer delivery infrastructure.

We also believe that instead of finalizing this policy and continued cuts to the 340B drug discount program, the agency should better understand the impact this proposal will have on

underserved populations, including low-income Medicare beneficiaries, Medicare-only, and dual-eligible cancer patients, particularly given that these patients tend to be treated more often in programs that are targeted for reduced reimbursement under this proposal. The agency should also understand the potential negative impact this proposal will have on independent community practices and their Medicare patients if some providers were able to offer Part B drugs at ASP minus 22.5 percent while others had to bill at ASP plus six percent.

These continued cuts to the 340B Drug Discount Program for nonexcepted off-campus PBDs do not address the transparency concerns that have filled the policy and political debate surrounding this program. Instead of doing direct work to address those transparency concerns, the continued cuts to 340B programs will directly impact cancer programs across the country and their most vulnerable patients. ACCC fully agrees that transparency is needed within the 340B Drug Discount Program to account for where the savings are going, and the populations being served. To that end, we fully support the agency tracking and auditing existing eligible providers rather than making such broad payment cuts. To make cuts without having first assessed the true magnitude of the problem is inappropriate. Moreover, the savings procured through the program should continue to go to underserved cancer programs and their patients to optimize cancer delivery for our country's most vulnerable populations.

B. The proposal only further exacerbates payment differentials.

In proposing differential drug payment rates for various sites of service based on 340B participation, CMS's proposal would create even more complexity in an already complex OPDS system and only further exacerbate payment differences between physician offices and hospital outpatient departments, as drug reimbursement will continue to be ASP plus six percent in the physician office compared to the proposed ASP minus 22.5 percent for drugs purchased through the 340B program in the hospital outpatient setting. CMS's proposal is in direct conflict with the agency's stated goal of promoting equitable payment between physician offices and hospital outpatient departments reflected in this Proposed Rule and previous rulemaking.

These proposed cuts only further exacerbate the fact that cancer care delivery as functioning today is not a modern system of healthcare delivery. With the cuts to the 340B Drug Discount Program that would go into effect in 2019 with the finalization of this proposal, CMS is not doing their part to include all sites of service across the country treating cancer patients when developing these policies. Certain sites of service have continually been left out of the healthcare delivery structure, and this further disincentivizes treating the most vulnerable cancer patients often seeking care at 340B facilities. CMS is continuing to support a healthcare delivery system that leaves out conversation about how to treat our most vulnerable populations at all sites of care – physician offices and hospital systems alike.

C. Savings from the 340B Drug Discount Program require transparency, not further cuts.

ACCC strongly opposes CMS finalizing this proposal and believes that the savings from the 340B program should always be used to help clinicians provide more and better care to underserved patients, including Medicare beneficiaries. While ACCC strongly opposes finalizing this proposal and we believe redistributing the savings across all outpatient services

defeats the clear intent by Congress and HRSA that these savings be used to expand care for underserved patients, at the very least, we believe any savings produced from this proposal should remain in the OPPS system. Further, the fact that CMS does not yet know how any savings from this proposal would be reallocated in a way that would not negatively impact low-income Medicare beneficiaries is another reason this proposal should not be finalized. ACCC strongly encourages CMS not to finalize its proposal to reduce payment for separately payable drugs purchased under the 340B program. Instead, we strongly believe that HRSA and Congress need to take steps to better align the program with its original intent and ensure that savings from the program are benefiting underserved patients, but this cannot be accomplished if covered entities see a 28.5 percent reduction in drug reimbursement (from ASP plus six percent to ASP minus 22.5 percent) on January 1st. ACCC stands willing to work with fellow stakeholders and policymakers to achieve comprehensive reform of the 340B program, which serves a critical role in serving underserved patients in the cancer care delivery system.

III. 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 use its authority under section 1833(t)(2)(F) of the Social Security Act (SSA) to reduce reimbursement for certain clinic visits furnished at excepted off-campus PBDs to 40 percent of the OPPS rate.⁴ ACCC strongly opposes this proposal, and we urge CMS not to finalize it. We are deeply concerned about the harmful effects that this proposal could have on cancer care if implemented. Our analysis of the likely impact of the proposal indicates that, although fewer than half of all hospitals bill for services in off-campus PBDs, almost 500 ACCC members (about two-thirds) have such departments and would be affected by the proposed reduction. We are disappointed that CMS chose to propose such a drastic reduction in reimbursement without thorough analysis to verify the data underlying CMS's proposal and its estimated impact, to test the validity of the agency's conclusion that the increase in volume for clinic visits is "unnecessary," to assess whether the proposed payment rates appropriately reflect the cost of care in hospital outpatient departments, to measure potential effects on providers like our member hospitals, and to examine the legal authority for these proposals. Notably, CMS's own Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommended that CMS not implement the proposal at this time and continue to study the reasons for changes in outpatient volume.⁵ We urge CMS to follow the HOP Panel's recommendation and not finalize this proposal without further study and analysis.

⁴ *Id.* at 37,142.

⁵ CMS Advisory Panel on Hospital Outpatient Payment, August 20, 2018, Recommendation 3, *available at* <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2018-08-20-HOP-Panel-Meeting-Agenda.zip> ("The Panel recommends that CMS not implement the proposals for reduction in payment for outpatient clinic visits or restrictions to service line expansions. The Panel recommends that CMS study the matter to better understand the reasons for increased utilization of outpatient services.").

- A. *The Proposed Rule does not provide any data or analysis to support CMS’s conclusion that there has been an “unnecessary increase” in the volume of outpatient clinic visits, as CMS is required to show under SSA section 1833(t)(2)(F).*

SSA section 1833(t)(2)(F) authorizes CMS to “develop a method for controlling unnecessary increases in the volume of covered OPD services.” But the Proposed Rule includes no data or analysis to support CMS’s assumption that there has been an “unnecessary increase” in the volume of services furnished in the hospital outpatient setting. CMS should not proceed with any reduction in reimbursement for clinic visits furnished by off-campus PBDs – let alone a drastic reduction of 60 percent – without developing the data and analysis to support a conclusion that the volume of services furnished through an off-campus PBD is rising at an inappropriate rate.

It is particularly important for CMS to provide data and analysis showing that there has been an “unnecessary” increase in the volume of outpatient services in light of the many changes taking place in how care is provided in the United States. Changes in patient demographics and clinical needs, technological advances, and changing economic incentives from CMS and other payers all are playing a role in shifting care between settings, and could explain increases in the volume in hospital outpatient services that might appear, at first glance, to be driven solely by different reimbursement rates. Indeed, CMS appears to recognize the need for a careful, data-driven approach by asking a series of questions in the Proposed Rule about how “unnecessary” and “increase” should be defined for other outpatient services, what factors the method of controlling such increases should consider, potential alternatives to CMS’s proposed method, potential reasons to pay a higher rate for OPPS services that can be performed in lower cost settings, what exceptions the agency should allow, and what impact the method of controlling unnecessary increases might have on beneficiaries.

CMS should and must engage in a similarly rigorous analysis of whether there has been an “unnecessary increase” in the volume of outpatient clinic visits before the agency implements the proposed reduction in payment for those services as well. All of the questions that CMS asks stakeholders to consider and comment upon are important questions for the agency to consider when deciding whether and how to control the increase in use of outpatient clinic visits. Instead, the Proposed Rule assumes that a beneficiary “can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives.”⁶

The most that the Proposed Rule offers in terms of concrete support for its proposal is a reference to the Medicare Payment Advisory Commission (MedPAC) Report to Congress in March 2018 and other earlier MedPAC reports.⁷ But these reports do not show that there has been an “unnecessary” increase in the volume of clinic visits. For example, MedPAC’s 2018 report was focused on growth in spending, not unnecessary increases in volume, and in any case the MedPAC report relies on an unsupported assertion that a source of increased outpatient spending “appears to have been” the result of the shift of services from the physician office

⁶ 83 Fed. Reg. at 37,142.

⁷ *Id.* at 37,140.

setting to the hospital outpatient setting.⁸ In addition, the MedPAC report did not identify this shift of services as “unnecessary,”⁹ although the Proposed Rule incorrectly quotes the report as using that word.¹⁰ In short, the MedPAC reports fall far short of providing the kind of supporting data and analysis required to support CMS’s conclusion that there has been an “unnecessary increase” in outpatient service volume.

Until CMS provides an adequate explanation of the data and reasoning on which the agency relied in reaching this conclusion and allows providers and other stakeholders an opportunity to test the validity of the agency’s data and reasoning, the statutory requirement of an “unnecessary increase” will not be met. Just as important, CMS’s failure to provide adequate support for its proposal does not allow stakeholders to assess and meaningfully comment on whether the proposal is the right approach for patients and the Medicare program.

B. The Proposed Rule does not provide any data or analysis to support CMS’s proposal to pay for outpatient clinic visits at 40 percent of the OPSS rate.

Even if CMS had provided support for its conclusion that there has been an “unnecessary increase” in clinic visits furnished in off-campus PBDs, and that this increase was due to an inappropriate disparity in payment for those services under the OPSS, there is no support in the Proposed Rule for the agency’s conclusion that 40 percent of the OPSS rate is the appropriate payment for such clinic visits. CMS states that office visits furnished by a physician under the PFS are the “same service” as an outpatient clinic visit reimbursed under the OPSS and compares the PFS and OPSS rates as if the two services are the same, but provides no data or analysis to show that this is an appropriate comparison.¹¹

It is not accurate or appropriate to derive a payment rate for clinic visits at excepted off-campus PBDs directly from the PFS rate for physician office visits, which is what CMS proposes to do by using the 40 percent relativity adjuster that it has adopted for nonexcepted PBDs. The 40 percent adjustment to OPSS rates for nonexcepted off-campus PBDs was based primarily on a comparison of OPSS and PFS rates for clinic visits. Yet CMS itself has acknowledged that payment rates for clinic visits under the OPSS and PFS “are not entirely comparable” because of the “more extensive packaging that occurs under the OPSS for services provided along with clinic visits” compared to the PFS.¹² Similarly, in the OPSS final rule for CY 2017, CMS determined that the PFS payment rate for the 25 most frequently billed services at off-campus PBDs ranged from 0 percent and 137.8 percent of the OPSS rate.¹³ Ultimately, CMS continues to lack a solid rationale or adequate supporting data to claim that payment for any outpatient service at 40 percent of the OPSS rate is equivalent to the PFS payment for that service or is otherwise adequate or appropriate reimbursement for the service provided.

⁸ MedPAC, *Report to Congress: Medicare Payment Policy* 73 (Mar. 2018).

⁹ *Id.*

¹⁰ 83 Fed. Reg. at 37,140.

¹¹ *Id.*

¹² 81 Fed. Reg. 79,562, 79,723 (Nov. 14, 2016).

¹³ *Id.* at 79,724.

C. The Proposed Rule fails to account for numerous harmful effects that the proposal will have on patient access to care.

CMS's proposal also fails to analyze or account for the proposal's likely effects on effective delivery of care and patient access. ACCC is deeply concerned that reducing reimbursement for clinic visits furnished at off-campus PBDs will further fragment the delivery of care for cancer and other complex conditions. In the context of cancer care, we believe that the proposed reduction could significantly undermine a provider's ability to provide full-service cancer care in settings that are convenient for patients. It is likely that providers will be forced to scale back services or close off-campus PBDs, requiring patients receiving treatment at the hospital to seek all of their care at the main hospital, instead of at a PBD closer to home. In addition, many of our members are participating in new delivery models such as the Oncology Care Model (OCM) and Accountable Care Organizations (ACOs), created by the Center for Medicare & Medicaid Innovation (CMMI) to achieve better care for patients, better health for our communities, and lower costs through improvement of our health care system. These reforms will be hampered if hospitals are not given the flexibility to adapt use of PBDs to better meet their patients' needs. The Proposed Rule does not consider or address any of these potential negative effects on patient access to care and on the effective delivery and coordination of care.

We believe it is necessary for CMS to provide its supporting reasoning and data before finalizing the proposed reduction in payment for clinic visits. In particular, we urge CMS to analyze the effects of the same payment reduction in nonexcepted PBDs. That change took effect on January 1, 2018, following a year of payment at 50 percent of the OPPS rate. CMS presents no data or analysis in the Proposed Rule explaining how these payment rates affected utilization of clinic visits or other services, nor has it solicited comment from hospitals and other stakeholders on the effect this reduction had on them and on their patients. Without an analysis of the effect that the 40 percent payment adjustment has had on the volume of clinic visits in nonexcepted PBDs, it is premature to conclude that applying the same reduction to excepted departments would not harm access to care.

D. CMS's proposal is contrary to Congress's intent to protect excepted off-campus PBDs from precisely the kind of payment reduction that CMS proposes.

CMS's proposal is also troubling because it contravenes Congress's clear intent to preserve excepted off-campus PBDs from CMS authority to reimburse outpatient services at reduced rates. Section 603 of the Bipartisan Budget Act of 2015 excludes certain grandfathered off-campus PBDs that were "billing under [OPPS] with respect to covered OPD services furnished prior to the date of the enactment of" section 603. Despite this clear exception, CMS proposes to use its authority under section 1833(t)(2)(F) of the SSA to make payment to excepted and nonexcepted off-campus PBDs the same. Indeed, CMS seems to openly acknowledge that it seeks to use section 1833(t)(2)(F) as a way to impose payment reductions on the very PBDs that Congress explicitly excepted from such reductions: "While the changes required by the section 603 amendments to section 1833(t) of the Act address some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting, the majority of hospital off-campus departments continue to receive full OPPS payment

(including . . . excepted off-campus departments of a hospital)”¹⁴ Excepted off-campus PBDs do continue to receive full OPSS payment – and this is because Congress expressly instructed that they should not be subject to the type of reduction that CMS now proposes. CMS’s proposal would circumvent this clear congressional intent.

E. CMS should not make the proposed reduction in a non-budget-neutral manner and lacks the authority to do so.

Finally, ACCC is disappointed by CMS’s proposal not to make the proposed reduction in payment for outpatient clinic visits budget neutral, which will result in an overall reduction in funding for outpatient services. We believe that this proposal, if implemented, would exacerbate the harmful effects of the proposed reduction on patient access to care by forcing providers to cut services offered at PBDs or close those PBDs completely. In addition, CMS does not appear to have the statutory authority to implement its proposal in a non-budget-neutral manner. CMS states that it has this authority because SSA section 1833(t)(9)(B), which generally requires budget neutrality for changes under the OPSS, “does not apply to the volume control method” under SSA section 1833(t)(2)(F), but only to “wage and other adjustments.”¹⁵ But the legislative history of section 1833(t) directly contradicts this interpretation: the House conference report instructs that “adjustments [to the OPSS] made by the Secretary would be made in a budget neutral manner.”¹⁶ Congress also included a special authorization in SSA section 1833(t)(9)(C) for CMS to adjust the conversion factor to account for unnecessary increases in the volume of outpatient services, which Congress would not have done if it had intended to give CMS the authority to make other non-budget-neutral adjustments to the OPSS. Finally, CMS’s interpretation is not consistent with the significant grant of congressional authority that non-budget-neutral changes to the OPSS require. Given the broad requirement of budget neutrality in section 1833(t)(9)(B) and the importance of budget neutrality to the overall structure of the OPSS, it is a strained interpretation to conclude that CMS would have excepted changes under section 1833(t)(2)(F) from that requirement simply by referring to those changes as “methods” rather than “adjustments.”

For all the reasons above, ACCC strongly opposes the proposal to set payment at 40 percent of the OPSS rate for outpatient clinic visits at excepted off-campus PBDs and urges CMS not to finalize it.

IV. CMS should not finalize its proposal to reduce reimbursement to 40 percent of the OPSS rate for service line expansions at excepted off-campus PBDs.

CMS also proposes to reduce reimbursement to 40 percent of the OPSS rate for services furnished by excepted off-campus PBDs if those services are not part of a “clinical family of services” that the PBD had been providing during a baseline period prior to November 1, 2015.¹⁷ The proposal to reduce payment for service line expansions suffers from many of the same

¹⁴ 83 Fed. Reg. at 37,141.

¹⁵ *Id.* at 37,142.

¹⁶ See Balanced Budget Act of 1997, H.R. Rep. No. 105-217, at 784 (Conf. Rep.).

¹⁷ 83 Fed. Reg. at 37,148-49.

defects as the proposal to reduce payment for clinic visits at excepted off-campus PBDs. The proposal also would have a meaningful negative impact on ACCC members. Our analysis indicates that, in 2017, 30 ACCC hospitals added drug administration and clinical oncology services to an excepted off-campus PBD, 13 ACCC hospitals added radiation oncology services, and 15 ACCC hospitals added imaging services. This proposal would harm hospitals like these and limit their patients' access to care. We urge CMS to heed the HOP Panels' recommendation and not finalize the proposal.

As with the agency's proposal to reduce payment for clinic visits, CMS does not provide adequate data or reasoning to support its conclusion that 40 percent of the OPPS rate is an appropriate payment for the various services that an excepted off-campus PBD might provide through a service line expansion. As noted above, the 40 percent PFS relativity adjuster was based primarily on a comparison of OPPS and PFS rates for clinic visits. That comparison is inadequate to support the accuracy of a payment rate at 40 percent of the OPPS rate, even for clinic visits themselves. The comparison of rates across payment systems is even more unreliable for other types of services, including many services in the "clinical families" of drug administration and clinical oncology, radiation oncology, and imaging. CMS has provided no data and no reasoning to support its conclusion that 40 percent of the OPPS rate is an accurate equivalent of the PFS rate for each of these services, nor could it possibly do so. Services furnished under the PFS and services furnished under the OPPS often are not directly comparable, and even when a comparison may be made, CMS's own analysis of the top 25 billed services found that the PFS rate varies from 0 percent to 137.8 percent of the OPPS rate.¹⁸

CMS's proposal to reduce payment for new service lines also will create new barriers to patient access and effective coordination and delivery of care, especially for complex conditions like cancer. Comprehensive cancer care often requires the involvement of multiple specialties and types of services, including imaging, drug administration, and radiation oncology. Many of ACCC's members provide a mixture of these services at off-campus PBDs throughout their communities, and they report that offering a variety of services at a single location is essential to providing quality care. In addition, most patients prefer it. CMS's proposal to reduce payment under the OPPS to the clinical families a facility billed for before November 1, 2015, could deny a hospital the ability to update its services and facilities to meet patients' needs. Effectively, hospitals providing cancer care would be frozen in time, unable to expand or shift the availability of certain services to different locations because they would receive inadequate payment for those services.

CMS's proposal also contradicts Congress's clear intent that excepted off-campus PBDs not be subject to the kind of payment reductions that the agency proposes, and therefore goes beyond the agency's authority. As many stakeholders have pointed out during previous rulemaking on this issue, CMS lacks the statutory authority to impose payment reductions on "new clinical families of services," or indeed to create the concept of a "clinical family of services" in the first place. Congress established an exception for certain off-campus PBDs of a hospital, based on the date that PBD was "billing under [section 1833(t)] with respect to covered OPD services," not the type of services for which the excepted PBD billed. Indeed, when Congress wanted to identify certain services that would or would not be subject to CMS's

¹⁸ 81 Fed. Reg. at 79,724.

authority to reduce payment from the OPSS rate, it knew how to do so, as it did when it excepted emergency department services under section 1833(t)(21)(A). If Congress had wanted to give CMS the authority to subject certain services furnished by excepted PBDs to payment under a non-OPSS rate, it would have said so clearly.

Finally, as CMS recognized when it first implemented Section 603, applying the payment reduction to expansions of services in certain clinical families would be “operationally complex and could pose an administrative burden to hospitals, CMS, and our contractors to identify, track, and monitor billing for clinical services.” This contradicts CMS’s stated intent to reduce administrative burden for providers by adding yet another layer of documentation simply to avoid a drastic 60 percent payment cut for affected services.

For all the reasons above, ACCC firmly opposes the proposal to set payment at 40 percent of the OPSS rate for new lines of service at excepted off-campus PBDs and urges CMS not to finalize this proposal.

V. CMS should clarify how hospitals should bill for furnishing certain outpatient services related to CAR-T therapies and ensure that hospitals are paid appropriately for furnishing these therapies.

In Addendum B to the Proposed Rule, CMS proposes to assign status indicator “B” to four Category III Current Procedural Terminology (CPT®)¹⁹ codes that the American Medical Association (AMA) created to describe services related to CAR-T therapies, 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 are concerned about the lack of clarity from CMS on how to bill for the services described by these codes. A status indicator of “B” represents that the code is not paid under the OPSS, but that an alternate code that is recognized by OPSS when submitted on an outpatient hospital Part B bill may be available. However, it is not clear what alternate code a hospital should use for CAR-T related services or how else the hospital might bill Medicare for those services in the hospital outpatient setting. Hospitals already are providing these treatments and will continue to do so as the use of these innovative therapies expands. CMS should make clear in the final rule how hospitals should bill for such services and should ensure that Medicare payment for these services is appropriate and adequate to reflect the service furnished.

VI. CMS should ensure that any model based on the CAP authority is voluntary for all participants, preserves patient access to treatment and provider flexibility, and promotes cost-efficiency through more effective distribution and delivery of drugs and biologicals rather than utilization management tools.

The Proposed Rule includes a Request for Information (RFI) issued by CMMI seeking input on a potential CMMI model that would leverage CMS’s existing authority under the CAP

¹⁹ CPT is a registered trademark of the American Medical Association.

established under section 1847B of the SSA to test new methodologies and processes for distributing and reimbursing drugs and biologicals covered under Medicare Part B.²⁰

ACCC supports new and more cost-efficient approaches to delivering and paying for health care, including meaningful conversation about how those new approaches might reduce the cost of drugs. However, we are concerned about any CMMI model that would rely on the CAP authority because of the significant challenges in providing drugs to patients under the prior version of the program, as well as concerns about whether reimbursement for drug administration and other services will be sufficient to cover the full costs of treating patients. As originally implemented, the CAP often resulted in delays in patient access to medications and inhibited provider flexibility in adopting patient treatment regimens. These issues would be difficult to overcome in any updated version of the CAP, particularly with respect to cancer drugs. However, we also understand that some practices may desire an alternative to the current model for acquiring Part B drugs through the Medicare program, provided that alternative is voluntary, appropriately structured to protect patients, and will reimburse them for the true cost of providing quality cancer care. Should HHS choose to move forward with a model based on the CAP authority, ACCC urges the agency to structure the model so that it is voluntary for all participants (and does not impose penalties on those who do not participate), ensures timely patient access to necessary medications, maintains provider flexibility to choose appropriate treatments, and does not seek cost savings simply by inserting yet another middleman between manufacturers and providers.

A. General Comments on a Potential CAP-Based Model

The cancer care delivery infrastructure is a fragile construct of hospital outpatient departments and physician offices working together to provide care to patients in their communities. Physicians and providers face growing numbers of patients requiring cancer care, and their ability to provide appropriate care depends on several factors, including adequate Medicare payment rates for chemotherapy drugs, radiation oncology, and other important oncology services. 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.

ACCC also understands that the United States health care system is shifting fundamentally toward a payment and delivery paradigm based on value, and community cancer centers are part of this reform effort. We fully support the overarching goal of this shift to bend the cost curve by improving care, providing the right care at the right time, reducing over-treatment and under-treatment, and reducing hospital admissions and readmissions. ACCC members have a long history of working with CMS on meaningful payment reform, including by partnering with CMMI to achieve a shared goal of improving care and reducing costs for cancer patients through the OCM. We also recognize the need for a broad, national conversation about pharmaceutical pricing and strategies to rein in drug costs for the Medicare program and its beneficiaries. However, this conversation needs to consider the relative costs and benefits of all

²⁰ 83 Fed. Reg. at 37,212-17.

aspects of health care, rather than focusing narrowly on reducing drug costs to the detriment of quality, access, and innovation.

Further, any policy solution to rein in drug costs must preserve patients' access to – and ability to afford – quality cancer care and, relatedly, mitigate any impact on already reduced payment rates for cancer care providers. Many of our members are already challenged to provide care in their communities at reduced payment rates due to sequestration, decreasing drug administration rates, and under- or unreimbursed services required to provide quality cancer care. Additionally, ACCC's members strive to provide the best care possible to their patients, including the most appropriate drug therapies, with the choice of treatment being guided by clinical evidence and the patient's needs, regardless of cost. While it is our responsibility to ensure appropriate utilization and to provide the right drug to the patient at the right time, ACCC physicians and providers have no control over drug prices. Any policy approach to lower drug costs should not hold patients or providers accountable for a problem they did not create.

B. There are significant barriers to effective provider participation in a CAP-based model.

Few provider practices were interested in consistently participating in the first version of the CAP, and there are significant barriers to providers participating effectively in a new model based on the CAP authority. The original CAP experienced a high rate of turnover of physician participants from year to year, likely as physicians discovered that the CAP did not work for them.²¹ Providers probably would face similar barriers to effective participation in a new model based on the CAP, for a number of reasons.

First, any CAP-based model that requires physicians to obtain each dose of a drug for a specific patient would impose administrative burdens that could have a negative impact on a provider's ability to provide the best patient care and ensure that patients are getting the drugs they truly need. Second, providers are unlikely to want to participate in a CAP-based model if they are not assured that reimbursement for the other items and services they provide will be sufficient to cover the costs of providing quality care. Currently, reimbursement for drugs helps practices provide patient support services and pharmacy services that are essential to providing the drug and quality patient care but are not adequately reimbursed as separate services. Relevant social services include assistance with navigating the process of financing cancer care services, including communicating with insurers, social services, transportation services, dietary guidance, and chaplain support, all of which are unreimbursed and yet fundamental to providing patients with support during their illness. Pharmacy service costs for cancer treatment providers include the costs of furnishing clean rooms, maintaining supplies, solutions, hoods, and storage, and other administrative costs associated with managing chemotherapy inventory and preparing drugs for administration. Practices would incur many of these costs even if they were no longer responsible for purchasing the drugs themselves. These services are only going to become more essential as cancer treatments become more complex.

²¹ RTI International, Evaluation of the Competitive Acquisition Program for Part B Drugs, at 59 (2010) [hereinafter Evaluation of the CAP for Part B Drugs], available at https://www.cms.gov/Research-Statistics-Data-andSystems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.

Moreover, should HHS create a new CAP-based model, providers who participate likely would face additional administrative costs and could need to hire at least one additional full-time equivalent (FTE) employee to manage drug inventory purchased through the model and ensure it gets to the right patient. Practices would have to hire an additional FTE, instead of using an existing one, because they would continue to purchase drugs not available under the model, including drugs for their non-Medicare patients, through the regular drug distribution system and would be paid for them under other reimbursement methods.

In addition, practices are already facing financial restraints due to sequestration's reduction in reimbursement for drugs and services. Further reducing practices' revenue under a new CAP-based model would leave providers with even less to cover patient support services and pharmacy services, as well as the additional administrative costs incurred under the model. If CMMI chooses to move forward with a new CAP-based model, it should ensure that it adopts a mechanism to ensure that providers will be appropriately compensated for all of the services they provide. For example, CMMI could consider adopting a new inventory management fee under the model to cover the costs of these services, similar to the Monthly Enhanced Oncology Services payment available under the OCM.²²

C. It will be difficult to overcome the distribution and access issues of the original CAP.

The original version of the CAP faced significant challenges that will be difficult to overcome when implementing a CAP-based model. For example, the laws governing the CAP and requirements imposed by vendors often delayed the delivery of a CAP covered drug to providers (and consequently to patients) because:

- Physicians had to submit a prescription to a CAP vendor before the vendor could deliver the drug to the physician,²³ or
- Physicians could not transfer drugs across multiple practice locations except pursuant to their agreement with the CAP vendor.²⁴ In ACCC's experience, these agreements led to restrictions on the ability of physicians to transfer drugs to the practice's location that was most convenient for the beneficiary. Physicians therefore had limited ability to work around the delays imposed by needing to order each dose of a drug for a specific patient and location from the CAP vendor.

This lack of flexibility guarantees that a provider will face difficulties in tailoring treatment regimens to specific patients under the CAP authority. For example, if a patient has an adverse reaction to a particular medication and needs to quickly switch prescriptions, her physician would face additional administrative burdens having to obtain or restock the drug the patient needs under the CAP, compared to using a drug out of the physician's own supply and billing for it. In addition, any drugs the physician ordered from the CAP vendor but could not administer are at risk of being discarded if the physician and the vendor cannot process a new

²² CMS, Oncology Care Model: OCM Performance-Based Payment Methodology Version 3.2, at 7 (Dec. 27, 2017).

²³ SSA § 1847B(b)(4)(E).

²⁴ 42 C.F.R. § 414.908(a)(3)(xi).

prescription to use the drug for another patient. This process imposes cost burdens on the physician and the vendor as they seek to avoid wasting drugs.

The lack of flexibility in the delivery of drugs was particularly problematic for cancer patients under the original CAP. After CMS postponed implementation of the CAP effective December 31, 2008, it hired RTI International to perform an analysis of the program to determine its successes and failures.²⁵ This evaluation found that physicians particularly relied on certain emergency measures in the CAP to timely dispense the appropriate dosage form and strength of a drug to patients. These measures included the emergency restocking provision²⁶ and the “furnish as written” provision.²⁷ The former permitted physicians to use a drug in their own inventory and then immediately resupply it with a drug purchased through the CAP in situations where the drugs were immediately necessary, the physician could not have predicted she would need the drug, the vendor could not supply it fast enough, and the situation qualified as an emergency.²⁸ Under the latter, a physician could purchase a drug through the ASP reimbursement system if a dosage form or strength of a drug was not available through the CAP.²⁹

Under the CAP, physicians used the emergency restocking provisions for breast, prostate, colorectal, and other cancers and tumors 16 percent of the time in 2006 and 21.7 percent of the time in 2007.³⁰ In 2006 and 2007, they used the emergency restocking provisions for chemotherapy 26.5 and 25.5 percent of the time respectively.³¹ Finally, they used the emergency restocking provisions for lung, upper digestive tract, and other severe cancers 28.1 and 27.8 percent of the time in 2006 and 2007 respectively.³²

In addition, under the CAP in 2006 and 2007, physicians used the “furnish as written” provision for breast, prostate, colorectal, and other cancers and tumors 3.9 and 5.4 percent of the time respectively.³³ They used the “furnish as written” provision for chemotherapy 5.4 and 8.9 percent of the time respectively.³⁴ They used the “furnish as written” provision for lung, upper digestive tract, and other severe cancers 3.5 and 3.6 percent of the time respectively.³⁵ These categories of codes were among the top 20 that most used the emergency restocking and “furnish as written” provisions.³⁶

²⁵ Evaluation of the CAP for Part B Drugs at 9.

²⁶ 42 C.F.R. §§ 414.902, 414.906(e).

²⁷ *Id.* § 414.908(a)(3)(xiv).

²⁸ *Id.* § 414.906(e). An emergency situation is defined as “an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of” the rule are met. *Id.* § 414.902.

²⁹ *Id.* § 414.908(a)(3)(xiv).

³⁰ Evaluation of the CAP for Part B Drugs at 53.

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

These data make clear that the only way for physicians to make the CAP work when treating cancer patients was to circumvent the CAP's standard procedures and rely on the emergency restocking and "furnish as written" provisions, likely to accommodate changes in patient scheduling or changes in a planned course of treatment. These obstacles are so fundamental to the nature of the CAP that they may be difficult to overcome in any new CAP-based model.

D. If CMMI moves forward with a new CAP-based model, it must take steps to protect patient access and preserve provider flexibility.

Should CMMI choose to move forward with a new model based on the CAP authority, it should consider either excluding cancer drugs from this program, as the above data suggests that they clearly are not suited for it, or CMMI must develop a means of streamlining the CAP distribution system to avoid the above issues. As part of any streamlined CAP system, CMMI must maintain and improve the emergency restocking and "furnish as written" provisions to make drugs available to patients when needed, accommodate changes that frequently need to be made at a moment's notice in response to a patient's evolving health and comorbidities, and preserve provider and patient choice with respect to their prescriptions. These changes should also include a mechanism for physicians to disenroll from the CAP model mid-year if it turns out that the model is adversely affecting their patients, instead of requiring physicians to participate for a full year.³⁷

Finally, to further maintain patient and provider access to the drug of their choice, CAP vendors should not be permitted to adopt closed formularies under which a vendor might actually get to exclude or threaten to exclude a drug from coverage and should not be permitted to adopt utilization management tools, such as prior authorization requirements and step therapy, as suggested by MedPAC for its proposed drug value program (DVP).³⁸ As discussed further below, these measures might reduce or delay patients' access to drugs that they truly need.

E. Providers should not be forced to participate in any CAP-based model and CMMI should not impose payment penalties that effectively require provider participation.

ACCC also urges CMMI not to make any new CAP-based model mandatory or to take any measures that would effectively make the model mandatory by forcing providers to choose between participating in the model or risking financial ruin. As mentioned above, MedPAC recently proposed a DVP, which the RFI suggests could be used as a potential framework for a CAP-based model.³⁹ As proposed by MedPAC, the DVP would incentivize provider participation in the CAP by gradually phasing out the 6 percent payment given to providers in

³⁷ 42 C.F.R. § 414.906(a).

³⁸ MedPAC, Report to the Congress: Medicare and the Health Care Delivery System at 32 (June 2017) [hereinafter "MedPAC Report"], available at http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0.

³⁹ 83 Fed. Reg. at 37,214-15.

addition to ASP under the traditional reimbursement system.⁴⁰ In practice, reducing the additional 6 percent payment to ASP would serve only to penalize providers who choose not to participate in the model and would not encourage improvements in care. Without adequate reimbursement for the full array of services needed to provide quality care under either the standard reimbursement system or a CAP-based model, providers would be caught between two bad choices, neither of which would be sustainable or result in better care for patients. For these reasons, ACCC urges CMMI not to use punitive measures under the current ASP system as a tool to force provider participation in a new CAP-based model.

F. A CAP-based model should not authorize vendors to use formularies or any form of utilization management.

The RFI seeks comment on whether a CAP-based model should allow CAP vendors to use “formulary and/or utilization management strategies, such as step therapy.”⁴¹ ACCC strongly opposes the use of step therapy or any form of utilization management as part of any CAP-based model. Giving CAP vendors the authority to establish step therapy or other limits on utilization would severely limit patient access and create new barriers for patients seeking care from a provider who has chosen to participate in the model. For providers treating patients with cancer or other complex and life-threatening conditions, it is simply unacceptable for drugs to be delayed or unavailable due to the administrative burdens of a CAP vendor’s utilization management decisions. For example, patients with cancer are often subject to complex, multi-drug treatment regimens that evolve quickly over time in response to the progression or regression of the patient’s cancer and changes in the patient’s comorbid conditions. It is critical that providers who prescribe Part B drugs continue to have the flexibility to choose the drug regimen that is most clinically appropriate for each patient’s treatment, without the dangerous obstacle of utilization management standing in the way. We appreciate the Administration’s commitment to reducing administrative burden and placing patients above paperwork. Utilization management tools always are coupled with significant provider burden. We urge CMMI to keep this in mind as it develops any new CAP-based model.

Moreover, there are already numerous group purchasing organizations (GPOs) and other intermediaries between manufacturers of Part B drugs and providers, and these intermediaries have successfully obtained significant reductions in the cost of Part B drugs. We believe these existing intermediaries are in the best position to press manufacturers for discounts on Part B drugs that save money for the Medicare program, providers, and patients, and that adding CAP vendors as new middlemen with the authority to impose new and additional limits on providers would do more harm than good by hamstringing providers and limiting patient access without incurring significant additional cost savings. We urge CMMI not to include utilization management authority as part of any CAP-based model, and instead to rely on CAP vendors to drive cost-efficiency through helpful innovations in the distribution and delivery system for drugs.

⁴⁰ MedPAC Report at 58.

⁴¹ 83 Fed. Reg. at 37,217.

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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 Blair Burnett at (301) 984 9496 x213 or bburnett@acc-cancer.org.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Thomas A. Gallo". The signature is written in a cursive, flowing style.

Thomas A. Gallo, MS, MDA
President, Association of Community
Cancer Centers