September 11, 2017

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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1678-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) 2018.[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] 82 Fed. Reg. 33,558 (July 20, 2017).

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

- CMS should wait until the effects of current packaging policies have been thoroughly evaluated before implementing additional Comprehensive Ambulatory Payment Classifications (C-APCs) and expanding packaging to additional items and services;
- CMS should not finalize its proposal to package payment for ambulatory payment classification (APC) Level 1 and Level 2 drug administration services with other separately payable services;
- The agency should adopt its proposed payment adjustment to certain cancer hospitals as final;
- CMS should continue to reimburse hospitals for the acquisition cost of separately payable drugs and biologicals at average sales price (ASP) plus six percent;
- CMS should not finalize its proposal to reduce payment for separately payable drugs purchased under the 340B program;
- CMS should work to ensure that transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals expires as close to three years as possible for both products with existing pass-through payment status and those established in the future;
- CMS should take steps to address the rising packaging threshold for certain drugs, biologicals, and therapeutic radiopharmaceuticals;
- The agency should adopt separate payment rates and Healthcare Common Procedure Coding System (HCPCS) codes for each individual biosimilar product;
- CMS should not finalize its proposal to reduce payment for services provided in off-campus provider-based departments to 25 percent of the OPPS rates;
- CMS should finalize its proposed revisions to the 14 day rule for molecular pathology and advanced diagnostic laboratory tests (ADLTs); and
- CMS should proceed cautiously regarding any proposals drastically impacting future reimbursement because it often takes hospitals years of planning to accommodate these changes and adjust to changes in technology and payment systems.

We will address these recommendations in greater detail below.

I. CMS should wait until the effects of current packaging policies have been thoroughly evaluated before implementing additional C-APCs and expanding packaging to additional items and services

For CY 2018, CMS is not proposing any additional C-APCs to be paid under the existing C-APC payment policy.[2] ACCC applauds this decision and urges CMS to wait until the effects of current packaging policies have been thoroughly evaluated before implementing additional C-APCs and expanding packaging to additional items and services. We understand CMS's

[2] *Id.* at 33,576.

"overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule"; however, we continue to be concerned about the effect of rapid changes to the OPPS on patient access to care.

ACCC asks CMS to employ a measured, gradual approach to any additional changes and move prudently to incorporate new packaging proposals. CMS, hospitals, and other stakeholders need time to learn from their experience with the newest policies before additional packaging proposals are implemented. Hospitals, specifically, need the assurance of predictable, appropriate payments in order to plan for the future and invest in the personnel and technologies that are essential to providing high-quality cancer care.

Careful analysis of the Proposed Rule's policies and rates is needed to ensure that the proposed payment rates appropriately reflect the costs of providing cancer care and to mitigate the need for future adjustments to offset any rate-setting errors. CMS needs to consider not only the effects of its proposals on access to each category of packaged services, but also on the full spectrum of cancer care. We are particularly concerned about hospitals' ability to provide the extensive support services that allow patients to achieve the full benefits of their treatment regimens. In addition to managing the course of treatment, our member hospitals offer social services, including planning for home care, hospice and long-term care; community agency referrals and referrals for transportation assistance; and nutrition services, including evaluating the patient's nutritional status, providing information about diet and cancer, and developing nutrition plans to meet the individual patient's needs. Cancer therapy support services also include patient and family education, which entails educating newly diagnosed patients and their families about their cancer, treatment options, support resources, self-care techniques, new prescribed treatments, and coping with and managing treatment side effects. Hospitals also provide psychosocial support to address the psychological and emotional aspects of cancer and cancer treatment. Many of these services were not fully reimbursed under the OPPS prior to the expansion of packaging, and it remains to be seen whether the new payment rates will harm hospitals' ability to furnish these services.

Moreover, the OPPS is a complicated system, and each change to the packaging policies raises questions about whether the proposed rates truly reflect the historic costs of care and whether they will be sufficient to protect access to care in the future. These questions can be difficult to answer, not only because the OPPS rate calculations are challenging to replicate, but also because the effects of a new payment policy are not reflected in the claims data until well after they are implemented.[3] Accordingly, we applaud CMS for not proposing additional C-

[3] CMS acknowledged this reality in the CY 2016 proposed rule, when it discusses its analysis of 2014 claims data and its discovery of "excess packaged payment" for laboratory services and found it necessary to implement a 2.0 percent reduction to the conversion factor for CY 2016 to offset this $1 billion error. *See* 80 Fed. Reg. 70298, 70357 (Nov. 13, 2015). We are troubled by the possibility that CMS may again err in the packaging of costs of other services and create additional payment reductions in the future to offset these errors.

APCs for CY 2018 and urge the agency to carefully evaluate the effects of all its recently-implemented policies in aggregate before considering further packaging expansions.

II. CMS Should Not Finalize Its Proposal to Package Payment For APC Level 1 and Level 2 Drug Administration Services With Other Separately Payable Services

CMS proposes to make a significant change in how it pays for APC 5691, Level 1, and 5692, Level 2, drug administration services as part of the Proposed Rule by conditionally packaging payment for some of these services with separately payable services instead of paying for them as a distinct, primary service.[4] CMS asserts that this would make billing for these services under the OPPS more consistent with billing under the Medicare Physician Fee Schedule (PFS) and that packaging these services aligns payment for them with CMS's ancillary services payment policies.[5] ACCC believes that CMS's proposal would do the exact opposite of what it intends, making the OPPS and PFS even more inconsistent, and, moreover, would classify services as ancillary that instead should be treated as primary. In addition, CMS's proposal would create an unnecessarily large cost burden on hospitals by forcing them to swallow the bulk of the costs for providing drug administration services without providing adequate reimbursement.

First, in the Proposed Rule, CMS states that packaging drug administration services would "promote equitable payment between the physician office and hospital outpatient department"[6] on the grounds that "physicians are not eligible to receive payment for an office visit when a drug administration service is provided."[7] Although it is true that Current Procedural Terminology (CPT®)[8] code "99211 cannot be paid if it is billed with a drug administration service . . . when a medically necessary, significant and *separately identifiable E/M [evaluation and management] service (which meets a higher complexity level than CPT code 99211)* is performed in addition to one of those drug administration services," CMS allows a complex evaluation and management (E/M) code to be billed using modifier -25.[9] It therefore is not the case that physicians cannot bill for drug administration services in addition to other types of services. CMS allows physicians to do so where the services are supported by significant and distinct clinical requirements, precisely because it wishes to adequately compensate physicians when they perform distinct services. In addition, packaging drug administration services is inconsistent with how drugs and biologicals are reimbursed under the PFS, where they are separately payable at ASP plus six percent or the actual charge on the claim, whichever is lower.[10] The OPPS already packages many of the drugs it covers, including "policy packaged" drugs and those under the $120 proposed packaging threshold. To package drug

[4] 82 Fed. Reg. at 33,585.
[5] *Id*.
[6] *Id*.
[7] *Id*.
[8] CPT is a registered trademark of the American Medical Association.
[9] Medicare Claims Processing Manual (MCPM), ch. 12, § 30.6.7(D) (emphasis added).
[10] 42 C.F.R. § 414.904.

administration services as well only further exacerbates difference in reimbursement between the PFS and the OPPS.

Second, CMS's proposal would package many APC Level 1 and Level 2 drug administration services as "ancillary," that, by its own definition, should be treated as primary, distinct services. CMS has adopted packaging policies for ancillary services that are "integral, ancillary, supportive, dependent, or adjunctive to a primary service."[11] In making this statement, CMS assumes that every time a patient visits a hospital the patient must be there for a single primary service. But when a patient visits a hospital, she may be there for multiple distinct services, and the administration of a drug is generally distinct from those other services, requiring a provider to prepare the drug for administration, administer it, and monitor the patient carefully. For example, a beneficiary being treated for cancer may receive a chemotherapy administration and an imaging service on the same day. The drug administration is a unique service, not ancillary to the imaging service.

The drug administration services proposed to be packaged also do not qualify as add-on codes, defined by CMS as follows:

> Add-on codes describe procedures that are always performed in addition to a primary procedure. CPT defines add-on codes as codes that describe "procedures [that] are commonly carried out in addition to the primary procedure performed," and also states that "[a]dd on codes are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code" (2013) CPT Codebook Professional Edition, page xi).[12]

As noted above, the drug administration services proposed to be packaged can qualify as stand-alone codes, requiring a distinct set of activities and techniques from the provider to achieve them. They therefore should not be packaged as under CMS's proposed policy.

Third, CMS's proposal would undercompensate hospitals for drug administration services and force them to absorb the costs of providing them. To determine payment rates for separately payable services, CMS uses the average cost for the items and services that are part of that payment rate. CMS therefore includes payment for "multiple interrelated items and services . . . packaged into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility."[13] Under CMS's proposed policy, payment for drug administration services would be packaged into other separately payable services and those services would include the cost of the drug administration service in proportion to the frequency with which the two services are billed together. Under this methodology, the payment for the separately payable service necessarily will account for less than the cost of the full drug administration service.

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[11] *See, e.g.*, 79 Fed. Reg. 66,770, 66,776 (Nov. 10, 2014).
[12] 78 Fed. Reg. 74,826, 74,942 (Dec. 10, 2013).
[13] 82 Fed. Reg. at 33,584.

For example, CPT code 96372, therapeutic, prophylactic, or diagnostic injection,[14] is currently a separately payable drug administration service that may be billed multiple times during a single hospital visit. Under CMS's proposal, this service would be packaged with other separately payable services, including, for example, CPT code 99281, for an evaluation and management (E/M) emergency department visit.[15] For CY 2018, CMS proposes to reimburse hospitals for CPT code 96372 at $56.24, and this code has a geometric mean cost of $103.82.[16] The geometric mean cost for CPT code 99281 is $69.94.[17] Yet, under CMS's proposal, if CPT code 96372 is billed with CPT code 99281, these services would be reimbursed at the CPT code 99281 payment rate of $67.24, and it appears that this rate would not vary no matter how many times CPT code 96272 is billed during a single emergency department visit. It is unclear whether CMS has even accounted for billing for multiple drug administration codes during a single visit as part of its determination of payment rates under its proposed packaging policy.

As another example, CPT code 96401, for chemotherapy administration, subcutaneous or intramuscular; non hormonal anti-neoplastic,[18] may be billed under CMS's proposal with the code for the separately payable service of intravenous infusion, hydration, initial, 31 minutes to 1 hour, CPT code 96360.[19] CPT code 96401 has a payment rate of $56.24 and a geometric mean cost of $103.02.[20] CPT code 96360 has a geometric mean cost of $162.55.[21] Yet under CMS's proposal, these services would be paid at the CPT code 96360 payment rate of $184.16.[22] This is particularly bizarre given that the primary reason for a chemotherapy service is for a patient to receive chemotherapy, and the hydration that accompanies it is merely a support to that service to help patients recover after chemotherapy administration. Yet CMS would treat hydration as the primary service and chemotherapy as secondary.

Based on these examples, and for the reasons outlined above, CMS should not finalize is proposed packaging policy for APC Level 1 and Level 2 drug administration services. Indeed, this is what the Hospital Outpatient Payment (HOP) Panel recommended after hearing stakeholder testimony and thoughtfully considering the issues raised. We ask CMS to follow the HOP Panel's recommendation in the final rule.

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[14] AMA, CPT 2017 Professional, at 660 (2017).
[15] *Id*. at 22.
[16] CMS's proposed payment rates for CPT codes for CY 2018 are available in Addendum B to the Proposed Rule available for download here: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-P.html. The CY 2018 Proposed Rule CPT Cost Statistics Files are available for download on the same page.
[17] *Id*.
[18] CPT 2017 Professional at 661.
[19] *Id*. at 659.
[20] Addendum B; CPT Cost Statistics Files.
[21] CPT Cost Statistics Files.
[22] Addendum B.

III. The Agency Should Adopt its Proposed Payment Adjustment to Certain Cancer Hospitals as Final

CMS is proposing to continue a policy of adjusting payment to the eleven cancer hospitals designated under Section 1886(d)(1)(B)(v) of the Social Security Act (SSA) to align the payment-to-cost ratio for cancer hospitals with those of the remaining hospitals under the OPPS.[23] Costs at these cancer hospitals are higher, relative to their payments, than at other OPPS hospitals, and for this reason ACCC supports this policy and asks that CMS adopt it as final.

IV. CMS Should Continue to Reimburse Hospitals for the Acquisition Cost of Separately Payable Drugs and Biologicals at ASP Plus Six Percent

ACCC supports CMS's policy of continuing to reimburse hospitals for the acquisition cost of separately payable drugs and biologicals at ASP plus six percent.[24] This policy is important to ensure that hospitals continue to receive stable and predictable reimbursement for the life-saving cancer therapies and drugs that they provide to patients and to maintain a high quality of cancer care. Continuing to reimburse for drugs and biologicals at ASP plus six percent also ensures that there is parity in payment between the Medicare PFS and the OPPS, removing financial incentives to choose one care setting over another. ACCC also asks that CMS make separate payment for all drugs with separate HCPCS codes, just as CMS does in the physician office setting. To the extent that certain drugs and biologicals continue to be packaged, CMS should require hospitals to bill for them using HCPCS codes and revenue code 636.

V. CMS Should Not Finalize its Proposal to Reduce Payment for Separately Payable Drugs Purchased Under the 340B Program.

CMS proposes to reduce payment for separately payable drugs without pass-through status that are purchased under the 340B Drug Pricing Program from average sales price (ASP) plus six percent to ASP minus 22.5 percent in CY 2018.[25] CMS says its goal is to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs."[26] The proposed rate of ASP minus 22.5 percent is based on a Medicare Payment Advisory Commission (MedPAC) analysis, and, although CMS acknowledges that it does not have acquisition cost data, it believes that this rate represents the "average minimum discount that a participating 340B hospital receives."[27]

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

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[23] 82 Fed. Reg. at 33,595.
[24] *Id.* at 33,630.
[25] 82 Fed. Reg. 33558, 33634 (July 20, 2017).
[26] *Id.*
[27] *Id*. at 33634.

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. In most cases, 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, other members have raised concerns that the 340B program is no longer serving the populations it originally intended. Instead, these members have pointed out that some hospitals eligible for the 340B program have expanded the program to include areas that are not underserved, causing market and delivery distortions. Moreover, many of these members, both physician offices and non-participating cancer programs, indicate they also treat underserved cancer patients, yet do not have access to the program.

After careful review, ACCC believes CMS's proposal is flawed because it focuses on payment rates to eligible providers rather than who should be eligible for this program. 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. Alternatively, CMS should use its resources to identify who eligible providers serve and where underserved Medicare beneficiaries reside. This would allow organizations like ACCC and others to direct our resources in those areas. In the meantime, ACCC will continue to work with stakeholders to reform the 340B program through the appropriate agency.

More specifically, ACCC strongly encourages CMS not to finalize its proposal to reduce payment for separately payable drugs purchased under the 340B program for the following reasons:

A. The proposal could limit fundamental reforms needed to modernize the 340B program.

For years our members have recognized that in order for the 340B program to remain sustainable and most appropriately fulfill the Congressional intent of the program to assist hospitals to reach more indigent patients, the Health Resources & Services Administration (HRSA) must promulgate regulations that offer clear, coherent and relevant direction, including a better definition of a "covered entity" to focus on programs treating patients in a reasonable catchment area and better definition of an "eligible patient" so that providers understand clearly which patients qualify for the program.

ACCC strongly believes that it would be inappropriate for CMS to fundamentally alter the 340B program without first having HRSA conduct a review or audit of the overall program and the participating providers. HRSA can and should use its authority to modernize the program, by revisiting the metric used to determine 340B eligibility, requiring transparency and public reporting of the savings accrued and how these savings are spent on services that benefit underserved patients, and creating a path for all oncology providers, regardless of site of care, to participate in the 340B program (see *ACCC Principles for 340B Drug Pricing Program Sustainability and Reform*).[28]

Not only does the Proposed Rule fail to achieve the fundamental reforms outlined in ACCC's principles, but it will significantly undermine any future efforts for meaningful reform. Simply put, CMS's proposal is premature before HRSA is given the authority to resolve the underlying challenges with the program they oversee.

B. *CMS's proposed payment rate of ASP minus 22.5% is based on significant data limitations.*

CMS also notes significant data limitations in the Proposed Rule, stating that Medicare OPPS claims data does not reflect where 340B drugs are being used (limiting our ability to know which patients are being served by this program) and the agency is unable to "precisely calculate" the discounts 340B hospitals receive. Despite not having access to accurate cost data, CMS proposes to move forward with an estimated average discount, calculated by MedPAC, while also citing significant data limitations in MedPAC's analysis. It has been well established over several years and many studies, that the statutory payment rate of ASP +6% is the most appropriate payment level for all providers. ACCC is very alarmed that despite a lack of accurate data to inform this policy, CMS plans to move forward.

C. *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, the agency should first and foremost 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.

[28] "ACCC Principles for 340B Drug Pricing Program Sustainability and Reform." Association of Community Cancer Centers (ACCC). September 2017. https://www.accc-cancer.org/advocacy/pdf/2017-ACCC-340B-principles.pdf

D. The proposal is counter to CMS's goal of reducing unnecessary burdens for clinicians.

CMS also proposes to require that a modifier be reported on all drug line items to convey that the drug in question was not purchased under the 340B discount program. This places the onus on all hospitals – both 340B and non-340B – to use a modifier to receive the higher (standard) reimbursement rate of ASP plus six percent. ACCC is very concerned about the precedent this sets, establishing the default reimbursement rate without the modifier at ASP minus 22.5 percent in the hospital outpatient setting. Additionally, while we appreciate and support CMS's need to gather more data (which should occur before, not in tandem with, CMS's proposal to reduce reimbursement to 340B hospitals), the modifier, as proposed, will create significant operational challenges for hospitals across the country, particularly as proposed, to be implemented January 1, 2018. In addition to the reasons listed above, from an operational standpoint, ACCC urges CMS not to finalize this proposal because cancer programs would need time to assess the budgetary impact of the proposed reductions and make appropriate changes to the services they offer, as well as time to modify and update their IT systems, particularly to accommodate the proposed use of a modifier on all non-340B drug claims. Notably, the use of a modifier, as proposed, also directly conflicts with CMS's call for information and stated goal of "reduc[ing] unnecessary burdens for clinicians" in this Proposed Rule.[29]

E. The proposal only further exacerbates payment differentials.

Furthermore, in proposing differential drug payment rates for hospitals based on 340B participation, CMS's proposal would create even more complexity in an already complex OPPS 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.

F. Any savings from this proposal should remain in the OPPS system.

CMS is also soliciting comments on the redistribution of savings if this proposal were to be finalized. For the reasons listed above, 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. In the Proposed Rule, CMS explores several options for redistributing the savings, including beyond simply increasing the conversion factor across all outpatient

[29] 82 Fed. Reg. at 34,172.

services. 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. We 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% reduction in drug reimbursement (from ASP plus six percent to ASP minus 22.5%) 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.

VI. CMS Should Work to Ensure that Transitional Pass-Through Payment for Drugs, Biologicals, and Radiopharmaceuticals Expires as Close to Three Years as Possible for Both Products with Existing Pass-Through Payment Status and Those Established in the Future

CMS proposes that the pass-through payment status for 19 drugs and biologicals would expire on December 31, 2017. [30] The agency also states that it intends to ensure that pass-through payment status expires for products with newly acquired pass-through payment status on the quarter that is as close to three years as possible.[31] ACCC supports these efforts but urges CMS to extend this policy to all existing products with pass-through payment status, not just those that CMS establishes in this year's final rule and after. In addition, ACCC supports continued payment for drugs and biologicals with pass-through payment status at ASP plus six percent, including for the 38 drugs and biologicals for which CMS proposes pass-through payment this year.[32]

VII. CMS Should Take Steps to Address the Rising Packaging Threshold for Drugs, Biologicals, and Therapeutic Radiopharmaceuticals

CMS's proposed packaging threshold for CY 2018 is $120.[33] Drugs, biologicals, and therapeutic radiopharmaceuticals with a per-day cost above this threshold would be classified as separately payable and those below this threshold would be packaged. This threshold has

[30] *Id*. at 33,621.
[31] *Id*.
[32] *Id*. at 33,622.
[33] *Id*. at 33,625.

increased dramatically since 2010 when it was set at $65,[34] with increases of $5 to $10 each year since. Congress historically has opposed packaging thresholds at these levels and, though it has not spoken specifically to this issue in recent years, this should not be interpreted as acceptance of a higher threshold. In 2005 and 2006, Congress had set the packaging threshold at $50 as a result of its objections to the $150 packaging threshold established by CMS in 2003.[35] CMS's ever expanding packaging policies make it increasingly difficult for hospitals to furnish critical therapies to patients. ACCC urges CMS to reconsider its packaging threshold and instead to pay separately for all drugs and biological with HCPCS codes as it does in the physician office setting, creating greater parity between these settings of care, as we discussed above.

VIII. The Agency Should Adopt Separate Payment Rates and HCPCS Codes for Each Individual Biosimilar Product

ACCC addresses CMS's proposals with respect to payment for biosimilars in more detail in comments submitted on the PFS. In brief, CMS proposes to continue paying for biosimilar biological products using only one HCPCS code at a payment rate calculated using ASP plus six percent for all national drug codes (NDCs) assigned to biosimilar products plus six percent of the reference biological product.[36] ACCC supports assignment of unique codes and payment rates for each biosimilar.

CMS's current policy imposes additional administrative burdens on providers who need to take extra time to ensure they are administering the correct product from among different biological products grouped under the same HCPCS code. The current policy also could encourage providers to choose the least costly biological product rather than the one that is most clinically appropriate, because all biological products in the same HCPCS code are reimbursed at the same rate. CMS's current policy also makes it more difficult for the Food and Drug Administration (FDA) to track safety information back to the manufacturer of the specific biosimilar product for which information is reported.

These unintended consequences of CMS's current payment policy stifle the market for biosimilars by creating potential barriers to uptake among providers. They also show that the current policy fails to recognize the "innate differences in biological products," as the Proposed Rule aptly puts it. Biosimilars are similar – but not identical – to other biological products with a common reference product, and CMS payment policy should recognize this fundamental aspect of biosimilars by establishing a separate code and separate payment for each product. This approach will ensure effective monitoring of the safety of each biosimilar product following approval and will encourage providers to focus on providing the best and most appropriate beneficiary care. We encourage CMS to propose and finalize such a policy at the earliest opportunity.

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[34] 74 Fed. Reg. 60,316, 60,487 (Nov. 20, 2009).
[35] Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-273, § 621(2), 117 Stat. 2210 (Dec. 8, 2003); 67 Fed. Reg. 66,718, 66,772 (Nov. 1, 2002).
[36] 82 Fed. Reg. at 33630; 82 Fed. Reg. 33950, 34090 (July 21, 2017).

IX. CMS Should Not Finalize Its Proposal to Reduce Payment for Services Provided in Off-Campus Provider-Based Departments to 25 Percent of the OPPS Rates

ACCC's primary comments on CMS's proposal with respect to payment for certain items and services furnished by certain off-campus provider departments are included in our comments on the PFS. ACCC strongly opposes CMS's proposal to reduce payment for these departments to 25 percent of the OPPS rate for the services provided in them. The proposed rate does not accurately reflect the cost of care in these departments, and it is inconsistent with Congressional intent for these sites to be reimbursed under a system other than the OPPS to create parity with physicians' offices. If implemented, these payment reductions would harm access to care and severely limit hospitals' ability to extend services at locations that would be more convenient for beneficiaries.

In brief, sections 1833(t)(1)(B)(v) and (t)(21) of the SSA established that certain items and services furnished by off-campus outpatient departments must be paid for under a system outside of the OPPS.[37] For CY 2017, CMS determined that the applicable payment system is the PFS, but due to differences in the services offered by these departments and physicians' offices and claims processing issues, CMS established new rates under the PFS at 50 percent of the OPPS rate.[38] CMS established this "relativity adjuster" after performing an evaluation of the most frequently billed services at provider-based departments and comparing payment for those services under the PFS and OPPS.[39] CMS determined that overall the PFS payment rate for the 25 most frequently billed services at provider-based departments ranged between zero percent and 137.8 percent of the OPPS, with a volume weighted average of 45 percent.[40] CMS recognized that this analysis was based on imperfect data, but decided to proceed anyway with a payment rate for these departments of 50 percent of the OPPS.[41]

If implemented, these rates would be far less than the PFS rates for many services that are essential to cancer care. For example, code 96413 (chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug) would be reimbursed at $143.60 in a physician office but only $71.65 in a non-excepted off-campus department, including payment for drugs that are not separately payable under the OPPS. Payment for code 74177 (Computed tomography, abdomen and pelvis; with contrast material(s)), including payment for the contrast agent that is packaged under the OPPS, would be only $84.79 in a non-excepted department, compared to payment of $221.34 for the technical component in a physician's office, plus separate payment for the contrast agent.

ACCC urges CMS to not implement the proposed 25 percent relatively adjuster because it would produce payments that are not representative of the payments that would be made under the PFS and would not fairly reflect the cost of care in these departments. In proposing to now

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[37] SSA §§ 1833(t)(1)(B)(v) and (t)(21)
[38] 81 Fed. Reg. 79,562, 79,723, 79,725 (Nov. 14, 2016).
[39] *Id.*
[40] *Id*. at 79,724.
[41] *Id*. at 79,725.

adopt a payment rate of 25 percent of the OPPS, CMS does not cite any new data or perform any additional analyses. In fact, CMS acknowledges that it is not able to study the CY 2017 claims data that might allow the agency to consider numerous factors that affect the comparison between PFS and OPPS rates, including OPPS packaging policies.[42] CMS bases its proposal on the evaluation of the OPPS payment rate for a single service—HCPCS code G0463, for certain clinic visits—instead of a more comprehensive review of payment at provider-based departments.[43] CMS bases its proposal on this evaluation despite recognizing in the CY 2017 final rule that "these payment rates are not entirely comparable" because of the "more extensive packaging that occurs under the OPPS for services provided along with clinic visits" compared to the PFS.[44] CMS provides no explanation for its apparent conclusion that a payment adjustment based on only these two codes is appropriate now when it was not appropriate last year.

Even if CMS is not yet prepared to perform a full analysis of what the payment rate for services at provider-based departments should be, it cannot arbitrarily reduce the payment rate for these departments by half compared to the rate in CY 2017 without justifying its reasons for doing so. It has presented no grounds for concluding that a payment rate of 50 percent of the OPPS is too high and therefore should not adopt the payment reduction for provider-based departments as final.

In addition, the proposed rates are entirely inconsistent with Congressional intent. Contrary to Congress's intent to establish parity between reimbursement for services provided in these departments and services provided in physicians' offices, this proposal would create large differences in payment between these settings of care. For example, drugs and biologicals currently paid for separately under the PFS often are packaged for purposes of the OPPS. When payment for these drugs is packaged into a drastically reduced payment for a drug administration, these drugs and biologicals would be reimbursed at a fraction of the payment available for them under the PFS, amounting to grossly inadequate reimbursement to hospitals for drugs and biologicals provided through these departments. This cannot be the intent of Congress in establishing an alternative payment system for off-campus outpatient departments, and we urge CMS not to finalize its proposal.

X. CMS Should Finalize its Proposed Revisions to the 14 Day Rule for Molecular Pathology and ADLTs

CMS proposes to modify the Medicare laboratory date of service (DOS) for molecular pathology tests and ADLTs. Currently, the DOS for laboratory tests performed on stored specimens collected during a patient's hospital stay is the date the test was performed *only if* the test is ordered more than 14 days following the patient's discharge from the hospital.[45] Otherwise, payment for the test is bundled with the hospital service. This requirement is known

[42] 82 Fed. Reg. at 33,983.
[43] *Id.* at 33,982–83.
[44] 81 Fed. Reg. at 79,723.
[45] 42 C.F.R. §§ 414.510(b)(2)(i)(A); 414.510(b)(3)(i).

as the "14 day rule." CMS is proposing not to apply the 14 day rule to molecular pathology tests and ADLTs performed on specimens collected during the patient's hospital stay so long as the test is ordered after the patient's discharge and the other requirements of the statute are met.[46] ACCC supports this proposal and asks that CMS finalize it as drafted for both molecular pathology tests and ADLTs.

CMS's designation of certain tests as ADLTs is new and still in the process of being implemented. Though there is some guidance about ADLTs from the Protecting Access to Medicare Act of 2014 and the regulations implementing it that address what qualifies as an ADLT,[47] CMS has yet to issue guidance on how to apply for ADLT status. We therefore cannot know what kinds of tests will ultimately receive ADLT status and how they will interact with hospital billing requirements. CMS should not establish restrictions that affect who may bill for these tests until we know more about which tests would qualify as ADLTs in practice. Doing so could unnecessarily delay the performance of laboratory services that a hospital may be unable to perform and thereby delay treatment decisions that are essential to planning patients' future care.

Regarding molecular pathology tests, although it is true that some hospitals may perform these tests using kits, as noted by CMS,[48] often hospitals cannot do so because the tests were developed in a laboratory or are performed by a small group of labs or single lab. If the hospital cannot perform these tests, then adopting a 14 day rule for them could again unnecessarily delay these services and ultimately delay important decisions about a patient's future course of treatment. Accordingly, ACCC supports CMS's proposal and requests that it be finalized as drafted for both molecular pathology tests and ADLTs.

XI. CMS Should Proceed Cautiously Regarding Any Proposals Drastically Impacting Future Reimbursement Because It Takes Hospitals Years of Planning to Accommodate These Changes and Adjust to Changes in Technology and Payment Systems

In the Proposed Rule, CMS issued a request for information (RFI) on the agency's "flexibilities and efficiencies" as a step toward starting a "national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families."[49] CMS explains that it aims "to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple and accessible."[50] ACCC thanks CMS for this opportunity to provide our recommendations on how to achieve these important goals.

Cancer diagnosis and treatment are continuously evolving, and we are at a time of particularly important advancements in the technologies available to treat cancer. Increasingly

[46] 82 Fed. Reg. at 33,653.
[47] SSA § 1864A(5)(A); 42 C.F.R. § 414.502.
[48] 82 Fed. Reg. at 33,653.
[49] *Id.* at 33,703.
[50] *Id.* at 33,703-04

personalized medicine and new gene therapies have the potential to exceed the efficacy of prior therapies, and oncology practices and hospitals need to continue to adapt to changing diagnostic and treatment protocols to use these tools most effectively. At the same time, our members are working to improve treatment using existing drugs, through expanded patient education and counseling, better coordination among specialists, participation in clinical trials, and prolonged office hours.

We also are experiencing significant changes in the systems used to pay for cancer care. CMS and other payers continue to move away from traditional fee-for-service models to value-based approaches. For example, half of the oncology practices participating in the Oncology Care Model (OCM) are ACCC members and these practices, along with ACCC, have dedicated considerable resources to making this model successful. Each participant in the OCM must analyze its patient population, the services it offers, and anticipated reimbursement and costs to identify ways to provide high quality care more efficiently over several years.

Many of our members have made investments in technology and staffing based on expected future reimbursement levels, but frequent changes in the conventional Medicare payment systems, including the PFS and the OPPS, that form the basis for the OCM and other new payment models, create challenges for participants in these models. For example, large reductions in payment for the drug administration and hydration services that are central to many cancer treatment regimens, whether through revaluation under the PFS, proposed expansions of packaging in the OPPS, or reductions in payment to nonexcepted off-campus departments, can upend a practice or hospital's plans to expand services over the coming years and complicate efforts to achieve the improvements in care that are the heart of the OCM and other new payment models.

It is difficult to plot a path forward toward new payment and care delivery models when CMS keeps changing the terrain. ACCC and its members want to continue to work with CMS to improve the quality and efficiency of care provided to Medicare beneficiaries. We embrace the opportunity to adopt new treatment options and develop new payment models, but we also recognize that stability and predictability in the payment systems that serve as the foundations for these models is essential to achieving these goals. We ask CMS to use its regulatory flexibilities to provide stable reimbursement throughout the transition to new payment models. For example, CMS should consider exempting participants in the OCM and other value-based models from proposed payment reductions, such as the reduction in payment for nonexcepted off-campus departments.

We also urge CMS to reinstate the HOP Panel's winter meeting and to use the Panel more effectively to discuss proposed changes to OPPS packaging and payment policies well in advance of their implementation. OPPS payments are calculated using complex formulas and packaging logic, and the results often vary from year to year based on changes in the underlying data on cost and claims frequency. When new packaging rules are proposed to be added this already complicated system, careful analysis is needed to verify that CMS's proposed rates are calculated correctly and provide appropriate incentives to hospitals. This analysis also needs to

be repeated over time to ensure that changes in the methodology will produce predictable results. The HOP Panel's expertise, combined with the opportunity for discussion with stakeholders, has been invaluable for questioning and refining many of CMS's proposals. The development and implementation of comprehensive APCs is one example; CMS delayed implementation for a year, following the HOP Panel's recommendation, to allow more time for the agency and stakeholders to assess the proposed methodology.

We urge CMS to use the HOP Panel this way for all potentially significant changes in the OPPS:

- announce a potential proposal in a proposed rule;
- discuss it at that summer's HOP Panel meeting;
- respond to comments in the final rule, but not implement the change;
- discuss the proposal and updated data at the winter HOP Panel meeting;
- issue a refined proposal in the next year's proposed rule; and
- use the HOP Panel and public comments to further refine the proposal prior to finalizing it.

This process not only would improve the development of new policies under the OPPS by ensuring that their methodologies and effects are fully considered, but it also would provide for more stability in reimbursement for participants in alternative payment models that use the OPPS as the basis for payment.

ACCC additionally asks that CMS reinstate the winter HOP Panel meetings because they proved the only opportunity for stakeholders in the past to see and discuss updated cost data for HCPCS codes and APCs before this data is released in the Proposed Rule. The release of this data during the winter HOP Panel meeting enabled stakeholders to see changes in access to care and the appropriateness of APC assignments early, and helps give them a meaningful opportunity to engage in the rulemaking process by offering commentary on how CMS's policies have been operationalized in practice.

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Thank you for this opportunity to comment on the OPPS Proposed Rule for CY 2018. ACCC appreciates CMS's continued work to improve the OPPS and encourages it to adopt ACCC's recommendations regarding OPPS issues. ACCC looks forward to working with CMS in future on its efforts to improve the OPPS. Please feel free to contact Leah Ralph, Director of Health Policy, at (301) 984-5071 if you have any questions or need any additional information. Thank you again for your attention to this very important matter.

Respectfully submitted,

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