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September 6, 2016

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**BY ELECTRONIC DELIVERY**

**Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program (CMS-1656-P)**

Dear Administrator Slavitt:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment (OPPS) proposed rule (the "Proposed Rule") for calendar year (CY) 2017.<sup>1</sup> ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 23,000 cancer care professionals from approximately 2,000 hospitals and private practices nationwide. These include Cancer Program Members, Individual Members, and members from 32 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 are often associated with considerable

<sup>1</sup> 81 Fed. Reg. 45604 (July 14, 2016).

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 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 request for comments by the Centers for Medicare & Medicare Services (CMS). In our comments below, we recommend that:

- With the exception of allogeneic hematopoietic stem cell transplantation (HSCT), CMS should wait until the effects of current policies have been thoroughly evaluated before expanding packaging to additional items and services;
  - CMS should finalize its proposal to create a new comprehensive ambulatory payment classification (C-APC) for allogeneic HSCT, but revise how the payment rate is calculated;
  - CMS should retain its current packaging logic based on date of service;
  - CMS should continue its current unrelated laboratory test exception, but finalize its proposal to broaden the exception to apply to all advanced diagnostic laboratory tests and revise the date of service rule for specimens analyzed using separately payable tests;
  - CMS should not increase its packaging threshold for drugs and biologicals;
  - CMS should not package payment for newly created CPT code 963XX;
- CMS should continue to reimburse hospitals for acquisition cost of separately payable drugs at Average Sales Price (ASP) plus six percent;
- CMS should assign a separate healthcare common procedure coding system (HCPCS) code for each biosimilar product;
- CMS should review the proposed decreases in payment for certain drug administration services;
- CMS should finalize its proposals regarding transitional pass-through status for devices, drugs and biologicals;
- CMS should rescind its proposals to implement Section 603 of the Balanced Budget Act of 2015 (BBA) that place restrictions on a provider based department's (PBD's) excepted status and delay the effective date of policies to implement Section 603 of the BBA until January 1, 2018;
  - CMS should not finalize its proposed restrictions on expansions or relocations of excepted PBDs;
  - CMS should not limit the scope of items and services that are reimbursed under the OPSS at excepted off-campus PBDs;

- CMS should delay the effective date of policies to implement Section 603 of the BBA until January 1, 2018 or until such time that CMS can propose, seek comment on, and finalize methods of implementing the statute that impose minimal burdens on hospitals, physicians, and beneficiaries;
- CMS should ensure that proposed quality measures effectively measure and influence the behaviors CMS intends;
- CMS should develop C-APCs for pathology services that are billed on a claim without another separately payable service; and
- CMS should revise the timing of the summer meeting and reinstate the winter Advisory Panel on Hospital Outpatient Payment (“HOP Panel” or “Panel”) meeting to provide CMS, the Panel, and stakeholders vital opportunities to discuss refinements to the OPPTS.

We discuss these recommendations in depth below.

**I. With the exception of allogeneic HSCT, CMS should wait until the effects of current policies have been thoroughly evaluated before expanding packaging to additional items and services.**

ACCC urges CMS to evaluate the effects of its recently-implemented packaging policies before considering further expansions of these policies. For CY 2017, CMS proposes to further expand its packaging policies by: creating 25 new C-APCs;<sup>2</sup> changing the logic for conditionally packaged services to apply to services billed on the same claim, rather than on the same day;<sup>3</sup> terminating the unrelated test exception to the laboratory packaging policy;<sup>4</sup> and increasing the packaging threshold for drugs and biologicals to \$110.<sup>5</sup> These proposals are part of CMS’s efforts to make “payments for all services paid under the OPPTS more consistent with those of a prospective payment system and less like those of a per service fee schedule.”<sup>6</sup> Although we understand CMS’s goals, we continue to be concerned about the effect of rapid changes to the OPPTS on access to care. We therefore urge CMS to evaluate the effects of its recently-implemented policies before considering further expansions of its packaging policies and to delay any expansions in packaging and new C-APCs for at least one year.

CMS’s proposed packaging proposals follow the substantial packaging changes to the OPPTS implemented in 2014, 2015, and 2016. 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

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<sup>2</sup> Id. at 45618.

<sup>3</sup> Id. at 45629.

<sup>4</sup> Id. at 45628.

<sup>5</sup> Id.

<sup>6</sup> Id. at 45627-28.

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 OPSS 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 OPSS 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 OPSS 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.<sup>7</sup> ACCC thus strongly supports the recent recommendation of the HOP Panel that CMS "provide further information and data for stakeholders to review on how comprehensive APCs are created and their effects [and that] CMS provide more time for the public to review the information and make proposals to the Panel."<sup>8</sup> Again, we urge CMS to carefully evaluate the effects of all its recently-implemented policies in aggregate before considering further packaging expansions.

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<sup>7</sup> 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.

<sup>8</sup> CMS Advisory Panel on Hospital Outpatient Payment, Recommendation 6 (August 2016), available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

**A. CMS should finalize its proposal to create a new C-APC for allogeneic HSCT, but revise how the payment rate is calculated.**

For CY 2017, CMS proposes to create 25 new C-APCs, including a C-APC for allogeneic HSCT.<sup>9</sup> ACCC supports CMS's proposal to assign CPT®<sup>10</sup> code 38240 (hematopoietic progenitor cell (HPC); allogeneic transplantation per donor) to C-APC 5244 (Level 4 Blood Product Exchange and Related Services);<sup>11</sup> however, ACCC asks that CMS adopt the HOP Panel's recommendation that CMS refine the applied rate-setting logic to more accurately capture the complete costs associated with furnishing allogeneic HSCT services. At the August 2016 HOP Panel meeting, the Panel recommended that CMS only use claims that include both CPT code 38240 and revenue code 0819, Organ Acquisition: Other Donor, to calculate the payment rate for C-APC 5244.<sup>12</sup>

Analysis of the claims data used to set the proposed payment rate found that a significant number of claims for these services did not include a charge for donor search and acquisition costs, an essential, but costly, component of these services. Omission of those costs causes CMS to significantly underestimate the total costs of allogeneic HSCT services. Using only correctly coded claims would produce a more appropriate estimate of costs and a payment rate that comes closer to hospitals' actual costs. Under this revised methodology, the geometric mean cost of C-APC 5244 would change from about \$15,989 to \$29,093 because the donor search and cell acquisition costs, accounted for by the inclusion of revenue code 0819, would be more fully factored into the rate-setting. We urge CMS to adopt the HOP Panel's recommendation and calculate a payment rate using only correctly coded claims that include both CPT code 38240 and revenue code 0819.

Although this approach to setting payment for C-APC 5244 would produce an improved payment rate over the current CY 2016 rate, ACCC urges CMS continue to closely monitor the claims and cost data for allogeneic HSCT as the proposed payment rate is still substantially lower than the costs of furnishing this service to Medicare beneficiaries and access to it as a hospital outpatient may be compromised as a result. We believe the new cost center CMS proposes to capture acquisition costs related to allogeneic HSCT will be helpful in this regard and encourage CMS to finalize its proposal. We also ask CMS to consider invoice data for donor search and acquisition costs and adjust rates, as needed, to ensure that hospitals' full costs are reimbursed.

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<sup>9</sup> 81 Fed. Reg. at 45618.

<sup>10</sup> CPT is a registered trademark of the American Medical Association (AMA).

<sup>11</sup> Proposed Rule Addendum B (APC) and Addendum A (APC Title), *available at* <https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-P-OPPS-Addenda.zip>.

<sup>12</sup> CMS Advisory Panel on Hospital Outpatient Payment, Recommendations 3, 4 (August 2016).

**B. CMS should retain its current packaging logic based on date of service.**

For CY 2017, CMS proposes to change the packaging logic for all of the conditional packaging status indicators so that packaging would occur at the claim level and not based on the date of service.<sup>13</sup> ACCC strongly opposes this proposal and recommends that CMS retain the current practice of conditionally packaging payment for some items and services based on date of service date and for other items and services based on whether or not they appear on the same claim. First, CMS's proposal would systemically increase the amount of packaging. Second, it is problematic for many of our members who continue to submit claims for chemotherapy and radiation therapy monthly, as permitted by CMS's guidance, rather than for each patient visit.<sup>14</sup> In fact, in a recent survey of our members, about 75 percent of them said they billed for multiple days of hospital outpatient services on a single claim. The proposed policy could result in items and services being packaged although they are not ancillary to another service. Changing hospitals' billing practices would take time, and the short period of time between issuance of the final rule and its effective date is not sufficient for providers to change their billing practices. Should CMS seek to propose and implement such a change, sufficient notice must be provided so that providers have time to appropriately modify their billing practices.

**C. CMS should continue its current unrelated laboratory test exception, but finalize its proposal to broaden the exception to apply to all advanced diagnostic laboratory tests and revise the date of service rule for specimens analyzed using separately payable tests.**

ACCC is troubled by CMS's proposal to discontinue the unrelated laboratory test exception using the "L1" modifier. CMS instead proposes to package any and all laboratory tests if they appear on a claim with other hospital outpatient services.<sup>15</sup> Although the use of the "L1" modifier has been operationally burdensome in some cases, the ability to identify unrelated laboratory tests on claims is critical as is seeking separate payment for these services. It is not uncommon for cancer patients to come to hospital for their treatment and, during the same encounter, seek to have tests performed that are unrelated to their cancer care. Cancer patients often do not feel well and spend a lot of time traveling to appointments to receive their care. It is understandable why they want to consolidate appointment dates and lab tests whenever possible. Our members want to accommodate them and provide the best, patient-centered care. CMS should reimburse them appropriately in these circumstances and should continue the current unrelated laboratory test exception accordingly. If CMS's proposal to eliminate the "L1" modifier is motivated by a need for administrative relief, ACCC suggests that CMS explore alternatives to the "L1" modifier and seek comments on those alternatives before discontinuing its use entirely.

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<sup>13</sup> 81 Fed. Reg. at 45629.

<sup>14</sup> Claims Processing Manual, ch. 1, § 50.2.2.

<sup>15</sup> 81 Fed. Reg. at 45628.

Separate and apart from CMS's proposed treatment of unrelated lab tests, ACCC greatly appreciates CMS's forethought in proposing an expansion of the laboratory packaging exception to apply to all advanced diagnostic laboratory tests (ADLTs). ACCC agrees with CMS's findings that these services are "generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged," and are thus not appropriate candidates for policy packaging.<sup>16</sup> We ask CMS to finalize this ADLT proposal and encourage the agency to carefully consider all similar tests and expand this exception as appropriate.

In addition to implementing the proposal to pay separately for ADLTs, we ask CMS to revise its date of service rule for tests that are excluded from the packaging requirements. CMS's date of service rule, 42 C.F.R. § 414.510, generally treats the date the specimen was collected as the date of service for lab tests ordered within 14 days of discharge from the hospital. Under this rule, the hospital where the specimen was collected must bill for the test, even if the hospital does not perform the test.

This has created significant challenges for hospitals that need to obtain analysis of specimens, yet are uncomfortable billing for services they did not provide themselves. This requirement is different from Medicare's rules in other settings, which generally require diagnostic tests to be billed by the entity that performs them, and is different from the rules of Medicare Advantage plans and other payers. To align policies across payers and to simplify administration for hospitals, we ask CMS to revise the date of service rule to recognize the date the test is performed as the date of service for all laboratory tests that are excluded from the packaging requirements.

**D. CMS should not increase its packaging threshold for drugs and biologicals.**

ACCC also is deeply troubled by CMS's proposal to increase the packaging threshold for drugs, biological and radiopharmaceuticals from \$100 to \$110 per day.<sup>17</sup> If finalized, CY 2017 would be the second consecutive year that the packaging threshold would be increased. This proposal would result in an expansion of packaging, as more drugs would fall under the threshold. Combined with packaging of laboratory tests and reductions in drug administration reimbursement, expanded packaging of drugs will increase hospitals' financial strain. ACCC cautions against the expansion of packaging policies at this time, not only for the above explained reasons, but also given the miscalculation in CY 2014 regarding packaging of laboratory services and subsequent correction in CY 2016. Given the propensity for error with respect to packaging proposals, CMS should establish a clear process for addressing incorrect projections.

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<sup>16</sup> Id. at 45629.

<sup>17</sup> Id. at 45660-61.

ACCC strongly believes that CMS's ever expanding packaging policies disregard the clear language of the statute and Congressional intent, and that they make it increasingly difficult for hospitals to furnish critical therapies to patients. ACCC urges CMS to fully evaluate the effects of its recently-implemented policies before considering further expansions of its packaging policies and recommends that CMS delay any expansions in packaging and new C-APCs for at least one year to allow stakeholders and CMS more time to verify the accuracy of the agency's calculations.

**E. CMS should not package payment for newly created CPT code 963XX.**

CMS proposes to package payment for newly created CPT code 963XX (Application of on-body injector (includes cannula insertion) for timed subcutaneous injection). ACCC opposes this proposal because this code identifies a new, innovative method of providing a drug that is a common part of cancer treatment. It should be separately reimbursed like almost all other drug administration codes in order to ensure that hospitals are paid appropriately for this service.

**II. CMS should continue to reimburse hospitals for acquisition cost of separately payable drugs at ASP plus six percent.**

To maintain stable and predictable reimbursement for important cancer therapies and other drugs, we ask CMS to finalize its proposal to continue to reimburse the acquisition cost of separately payable drugs at ASP plus six percent.<sup>18</sup> This payment rate helps ensure that hospitals can continue to provide high quality cancer care to Medicare beneficiaries. In addition, because this payment rate is equivalent to the rate provided for drugs in the physician office setting, it removes incentives to select one setting over another and helps protect access to care in the most clinically appropriate setting for each beneficiary. We thus also ask that separate payment be made for all drugs with HCPCS codes just as payment is made for these drugs in physicians' offices. To the extent that certain drugs continue to be packaged, CMS should require hospitals to bill for them using HCPCS codes and revenue code 636.

Maintaining appropriate reimbursement rates for drugs and biologicals is critical to ensuring patient access to them. We agree with CMS's conclusion that payment at ASP plus six percent "represents the combined acquisition and pharmacy overhead payment for drugs and biologicals" To this end, proposals to reduce this payment rate, such as the proposed Part B Drug Payment Model, will result in a payment rate that does not reflect the acquisition costs of these therapies and will likely jeopardize the availability of these medicines for the patients who need them to treat complex, chronic conditions, such as cancer. As such, ACCC urges CMS to finalize OPDS payment for drugs at ASP plus six percent and not decrease that rate for CY 2017 for any reason.

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<sup>18</sup> Id. at 45664–65.

**III. CMS should assign a separate HCPCS code for each biosimilar product.**

ACCC continues to support CMS’s proposals to pay for biosimilar biological products at their physician office rates and to allow these therapies to be eligible for pass-through status.<sup>19</sup> ACCC supports the development of biosimilar biologics, which may provide greater access to innovative cancer treatment at lower costs to beneficiaries, providers, and the Medicare program.

CMS, however, proposes to continue its reimbursement policy for biosimilar products under Part B that assigns all biosimilars with the same reference product to a single HCPCS code, and reimburse for that code based on the volume-weighted ASP of all products under the code plus 6 percent of the reference product’s ASP.<sup>20</sup> ACCC reiterates its concerns that this policy will continue to impose unfair administrative burdens and care-compromising financial pressures on providers. ACCC suggests that ACCC adopt a reimbursement methodology that assigns each biosimilar product to a separate HCPCS code and calculates reimbursement separately for each biosimilar product. This approach will ensure effective monitoring of the safety of each biosimilar product following approval and encourage providers to focus on providing the best and most appropriate beneficiary care.

**IV. CMS should review the proposed decreases in payment for certain drug administration services.**

For CY 2017, several drug administration services that are essential to cancer care would be reduced 17.5 to 43 percent due to changes in APC assignments. We are concerned about these dramatic changes in payment and ask that CMS review these proposed changes to verify that they correctly reflect hospitals’ costs, including the costs of packaged drugs.

**Comparison of Hospital OPPS Drug Administration Rates, July 2016 to Proposed 2017 with decreases greater than ten percent**

HCPCS Code	Short Descriptor	Proposed 2017 Rates			Q3 2016 Rates			Change 2016-2017
		SI	APC	Payment Rate	SI	APC	Payment Rate	
96375	Tx/pro/dx inj new drug addon	S	5691	\$34.89	S	5692	\$42.31	-17.5%
96401	Chemo anti-neopl sq/im	S	5692	\$52.69	S	5693	\$92.40	-43.0%
96411	Chemo iv push addl drug	S	5692	\$52.69	S	5693	\$92.40	-43.0%
96422	Chemo ia infusion up to 1 hr	S	5693	\$180.19	S	5695	\$280.27	-35.7%

<sup>19</sup> Id. at 45664.

<sup>20</sup> Id.

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96423	Chemo ia infuse each addl hr	S	5691	\$34.89	S	5692	\$42.31	-17.5%
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ACCC cautions that CMS's revision of drug administration rates should not result in reduced overall payments for providers. Providers depend on stable payment rates to ensure their ability to provide high quality care to patients.

**V. CMS should finalize its proposals regarding transitional pass-through status for devices, drugs and biologicals.**

ACCC applauds CMS's proposals to allow for quarterly expiration of pass-through status for devices, drugs and biologicals and to standardize the duration of pass-through status to as close to three full years as possible.<sup>21</sup> ACCC believes that this policy will improve the predictability and equity of pass-through status irrespective of when pass-through status first is awarded. We ask CMS to clarify that it will adjust payment rates for APCs related to use of pass-through devices and policy-packaged drugs when that status expires in the middle of the year. Currently, pass-through status expires at year-end, and new rates are implemented through the annual rulemaking process at the same time. If pass-through status expires on the quarter, and CMS does not adjust payment rates promptly to include the costs of drugs and devices no longer receiving pass-through payments, hospitals will not be reimbursed for the additional costs of those innovative technologies. We ask CMS to ensure that it updates payment rates promptly to include the costs of drugs and devices that are packaged upon expiration of pass-through status mid-year.

Additionally, ACCC strongly supports CMS's proposals to calculate device offset amounts for transitional pass-through status at the HCPCS code level as opposed to the APC level. Because the offset amount reduces the pass-through payment by the amount that CMS otherwise pays for the device through the OPPS, ACCC agrees with CMS's belief that the improved granularity of calculation will better reflect the device-specific costs associated with pass-through devices and ensure that all technologies are equitably and appropriately reimbursed.<sup>22</sup> ACCC also supports CMS's proposal to use the "Implantable Devices Charged to Patients" cost to charge ratio (CCR) to calculate transitional pass-through payments for devices instead of the average hospital-wide CCR.

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<sup>21</sup> Id. at 45643, 45657.

<sup>22</sup> Id. at 45654-56.

**VI. CMS should rescind its proposals to implement Section 603 of the BBA that place restrictions on a PBD's excepted status and delay the effective date of policies to implement Section 603 of the BBA until January 1, 2018.**

For CY 2017, CMS proposes to implement Section 603 of the BBA relating to payment for items and services furnished by certain off-campus outpatient departments of a provider.<sup>23</sup> ACCC disagrees with CMS's interpretation of the requirements of the BBA, as proposed, and is very concerned that CMS's proposal will undermine hospitals' ability to provide beneficiaries access to critical, community-based outpatient cancer care.

ACCC has numerous concerns pertaining to CMS's proposals with respect to implementation of Section 603 of the BBA, including CMS's interpretation of Congress' intent, the scope of items and services eligible for excepted status, the operational challenges and uncertainties of providing payment for non-excepted items and services under the Medicare Physician Fee Schedule (MPFS), and the resulting compliance concerns arising from CMS's proposal and lack of operational detail. For the above reasons, explained fully below, ACCC recommends that CMS:

1. Not finalize its proposed restrictions on expansions or relocations of excepted PBDs;
2. Not finalize its proposed restrictions on items and services furnished by excepted PBDs; and
3. Delay the effective date of policies to implement Section 603 of the BBA until January 1, 2018 or until such time that CMS can propose, seek comment on, and finalize methods of implementing the statute that impose minimal burdens on hospitals, physicians, and beneficiaries.

**A. CMS should not finalize its proposed restrictions on expansions or relocations of excepted PBDs.**

CMS proposes that the excepted status of an off-campus PBD – meaning that off-campus PBD that could continue be paid under the OPFS as of January 1, 2017 – would terminate with respect to all services provided by that PBD under the following circumstances:

- The excepted off-campus PBD relocates to a location that is different from the physical location the off-campus PBD occupied on or prior to the November 2, 2015;
- The excepted off-campus PBD expands or relocates to spaces at the same physical address occupied by the off-campus PBD on or prior to November 2, 2015;<sup>24</sup> or
- The ownership of the excepted off-campus PBD changes independently of the main provider.

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<sup>23</sup> *Id.* at 45681.

<sup>24</sup> CMS proposes that the physical address include a unit number and that expansion to new units within the same building would terminate excepted status. *See* 81 Fed. Reg. at 45684.

ACCC strongly disagrees with CMS's belief that excepted status was intended to limit the prospective opportunities for excepted PBDs to relocate or expand existing locations. These moves or expansions might be essential to a hospital's ability to continue to provide critical outpatient cancer services to beneficiaries. Typically, a smaller hospital cannot offer all services from the outset of operations at an off-campus PBD. Instead, as volumes and needs of patients grow, additional services are added. For example, an off-campus PBD might need to expand into another suite at the same address to fulfill increased demand for chemotherapy administration services, or it might need to relocate to a new building, with a new radiation therapy vault, when it replaces radiation therapy equipment with newer technology. The changes proposed by CMS would hinder the ability to grow organically to meet patients' needs, especially in smaller and rural communities. CMS concedes that "there is no legislative history on record regarding Section 603 of Public Law 114-74"<sup>25</sup> but nonetheless takes the position that "we believe that Section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs as they existed at the time [the BBA] was enacted."<sup>26</sup> We do not think that Congress intended to limit beneficiaries' access to care simply because a provider expanded or moved its location.

CMS's proposal to impose such restrictive limits on the excepted status of PBDs is arbitrary and arguably incongruent with the fact that Congress provided for an excepted status in the first place. The limitation of new services also is counter to the innovation that our members are being asked to deliver as they look at new models of care. These rules potentially stifle the creativity needed to deliver value based care by limiting how that care is reimbursed. ACCC urges CMS not to finalize the proposed restrictions on expansions of current PBDs. ACCC also urges CMS not to finalize the proposed termination of the excepted status of PBDs due to expansion or relocation of the department.

**B. CMS should not limit the scope of items and services that are reimbursed under the OPSS at excepted off-campus PBDs.**

ACCC disagrees with CMS's proposal to limit the applicability of excepted status to certain items and services. CMS proposes that excepted items and services be determined on a PBD-by-PBD basis according to whether or not an item or service is in the same proposed clinical family as items or services provided by off-campus PBD prior to November 2, 2015. CMS proposes to define 19 clinical families, including advanced imaging, clinical oncology, general surgery, minor imaging, pathology, radiation oncology, and visits and related services, by APCs.<sup>27</sup> An excepted PBD would continue to be paid under the OPSS only for the clinical families of services it provided prior to November 2, 2015. Any expanded services would be paid under the MPFS.

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<sup>25</sup> 81 Fed. Reg. at 45682.

<sup>26</sup> Id. at 45684.

<sup>27</sup> Id. at 45685-86.

The proposed limitation could significantly undermine a provider's ability to provide full-service cancer care in settings that are convenient for patients. Cancer care often requires 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 their 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. Limiting payment under the OPSS to the clinical families a facility billed for as of November 2, 2015, could deny a PBD the ability to update its services and facilities to meet patient's needs. It likely will lead to less convenient care for patients, as patients increasingly would be required to travel between locations for care or would need 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 and Accountable Care Organizations, created by the Center for Medicare & Medicaid Innovation 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 flexibility to adapt service lines and facilities to better meet their patients' needs.

Furthermore, CMS's proposal to define clinical families by APCs is confusing and does not reflect the way hospitals operate. Hospitals do not define their service lines by APCs; they define them by clinical specialties and patients' needs. Although they do identify their services by CPT codes, the APC assignments and packaging status of codes can change from year to year, as CMS illustrates in every OPSS rule. CMS's proposal to define clinical families by APCs thus is not clear to hospitals and might not result in coherent definitions of related services that align with the care patients need.

As above, we strongly disagree with CMS's belief that excepted status was intended to apply only to certain items and services and we urge CMS not to finalize the proposed limitations on excepted items and services according to clinical families.

**C. CMS should delay the effective date of policies to implement Section 603 of the BBA until January 1, 2018 or until such time that CMS can propose, seek comment on, and finalize methods of implementing the statute that impose minimal burdens on hospitals, physicians, and beneficiaries.**

ACCC is concerned by CMS's admitted challenges in operationalizing the proposal to implement Section 603 of the BBA starting January 1, 2017. As required by the BBA, CMS proposes that payment for non-excepted off-campus provider-based departments or non-excepted items or services at excepted off-campus PBDs would be made under the MPFS at non-facility rates.<sup>28</sup> CMS admits, however, that it currently does not have a mechanism to allow off-campus PBDs to be paid directly under the MPFS and that "there is no straightforward way to do that

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<sup>28</sup> Id. at 45689.

before January 1, 2017.”<sup>29</sup> Although CMS plans to adapt its systems to permit these payments by January 1, 2018, for CY 2017, CMS proposes that these locations enroll in Medicare as another supplier type, such as a group practice, in order to be paid for non-excepted services. Furthermore, since facilities may not be able to receive payment under the MPFS, CMS proposes, as a temporary measure, to make payment for these services, effective January 1, 2017, to the physician or practitioner who performs the service at non-facility rates under the MPFS.<sup>30</sup>

ACCC is deeply concerned that the plethora of operational and administrative challenges associated with CMS’s proposal will create a significant burden for providers especially given that CMS plans to implement new mechanisms to provide payment under the MPFS for 2018. CMS’s proposal would give hospitals less than two months from the release of the final rule to the effective date of Section 603 to form contractual arrangements with physicians and non-physician practitioners to collect the payments that hospitals are entitled to under the statute. As CMS notes, these arrangements could be subject to extensive rules, such as the reassignment rules, the anti-markup prohibition, the physician self-referral rules, and the anti-kickback statute.<sup>31</sup> Hospitals would face considerable challenges negotiating compliant contracts in such a short amount of time, and they would face additional burdens unwinding these agreements if they are no longer needed one year later, when CMS plans to have mechanisms in place to pay hospitals directly for services that are payable under the MPFS. Ironically, although Section 603 might have been drafted with concerns about vertical consolidation in mind,<sup>32</sup> the legal challenges posed by CMS’s proposed implementation could encourage more hospitals to employ physicians to avoid having to form and unwind arrangements with physicians twice in the coming years.

In addition to these issues, CMS’s proposals would require hospitals to contend with other legal challenges presented by Section 603. CMS notes, for example, that a PBD “would still be considered to be part of the hospital and that the hospital as a whole would continue to be required to meet all applicable conditions of participations and regulations governing its provider-based status” but the PBD also would have to “meet all the applicable MPFS requirements” to be paid for its non-excepted services.<sup>33</sup> This statement raises questions for hospitals about how to reconcile these requirements. One area of confusion is compliance with the incident to rules with regard to services and supplies paid for by the hospital, but billed, under CMS’s proposal, by physicians working at the PBD. CMS’s rules on payment for items and services provided incident to physicians’ services require that those “services or supplies must represent an expense incurred by the physician or legal entity billing for the services or

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<sup>29</sup> Id. at 45687.

<sup>30</sup> Id. at 45681–91.

<sup>31</sup> Id. at 45689-90.

<sup>32</sup> Id. at 46687.

<sup>33</sup> Id. at 45690.

supplies.”<sup>34</sup> To qualify as provider-based, the costs of the hospital department must be reported on the hospital’s cost report<sup>35</sup> and patients must be billed the same way they would be at the main provider.<sup>36</sup> For 2017, CMS proposes for physicians to bill for services and supplies provided in off-campus PBDs, yet the costs of those services and supplies were incurred by the hospital, not the physician, and patients at the main hospital would not be billed by physicians for those items and services. If this proposal were to be implemented, additional guidance would be needed to reconcile these requirements and reassure hospitals and physicians about billing for their services.

CMS also must address the fact that many services currently provided in off-campus PBDs do not have payment rates under the MPFS. Many surgical procedures are valued in the MPFS for the facility setting only. The lack of payment is not only a concern for hospitals and physicians, but also for beneficiaries. A PBD would continue to be a clinically appropriate setting for these procedures, but if there is no payment for them, patients might be sent to the main provider for care instead.

For these reasons, ACCC recommends the CMS delay effective date of policies to implement Section 603 of the BBA until January 1, 2018 or until such time that CMS can make proposals regarding operationalization that do not create burdensome administrative and logistical challenges and unnecessary compliance risks. CMS proposes to delay implementation of the payment provisions related to appropriate use criteria in the MPFS due to similar administrative challenges,<sup>37</sup> and we urge CMS to delay implementation of Section 603, as well.

## **VII. CMS should ensure that proposed quality measures effectively measure and influence the behaviors CMS intends.**

Starting in CY 2020, CMS proposes to adopt quality measure, OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy, proposes to remove three questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) regarding pain management from the Value-Based Purchasing Program, and solicits comments on a future potential measure regarding the safe use of opioids.<sup>38</sup> Generally, ACCC supports initiatives that seek to improve the quality of care for cancer patients, many of whom undergo surgery or chemotherapy and are prescribed opioid medications for their pain. ACCC also strongly supports initiatives that align stakeholder incentives to provide comprehensive and high-value care.

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<sup>34</sup> Benefit Policy Manual, ch. 15, § 60.1.

<sup>35</sup> 42 C.F.R. § 413.65(d)(3).

<sup>36</sup> *Id.* at § 413.65(d)(4).

<sup>37</sup> 81 Fed. Reg. 46162, 46389 (July 15, 2016).

<sup>38</sup> 81 Fed. Reg. at 45711-14, 45721, 45756.

ACCC, however, remains concerned that CMS's proposals send mixed messages about treatment of pain and other complications of cancer care. CMS notes the need to ensure that its quality measurements do not have unintended consequences for opioid prescribing practices,<sup>39</sup> yet it also proposes a new measure that looks at admissions due to poorly managed pain, as well as other side effects of cancer treatment. We urge CMS to review all of its measures together to ensure that they provide the right incentives to provide the most appropriate care.

Moreover, the proposed quality measure OP-35 is poorly calibrated for the intended outcome. For example, the listed causes for admissions and ED visits for cancer patients are not exclusive sequelae of outpatient chemotherapy. This undermines the sensitivity and specificity of this measure. Furthermore, the measure's 30-day timeframe is misaligned with the presentation of conditions such as febrile neutropenia, a common cause of hospitalization among patients receiving chemotherapy. For these reasons, ACCC urges CMS not to finalize this measure as proposed and instead engage stakeholders to fine tune this important measure that could yield improved health outcomes for chemotherapy patients.

### **VIII. CMS should develop C-APCs for pathology services that are billed on a claim without another separately payable service.**

Under CMS's policy of conditionally packaging payment for clinical pathology services, these services are separately payable only if they are on the only service on the claim, and even then, only the single highest paying code is separately reimbursed. This policy severely limits payment for hospital pathology services provided to non-hospital patients, such as patients whose biopsies were performed in physician offices or ambulatory surgical centers. Although each specimen requires the same amount of resources to prepare and analyze, CMS's policy does not provide additional payment for reviewing more than one specimen. As a result, a hospital might be paid only a small fraction of the costs for analyzing these specimens. Hospital laboratories may be the only facilities available to analyze these specimens, but if they are not adequately paid for their services, they might not be able to continue to provide them to their communities.

ACCC supports the recommendations of the HOP Panel for CMS to:

- "take into consideration the comments regarding hospital pathology laboratories as it evaluates conditional packaging to determine whether an accommodation can be made," and
- "develop a composite ambulatory payment classification (APC) for pathology services when multiple pathology services are provided on a claim with no other payable services."<sup>40</sup>

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<sup>39</sup> Id. at 45756.

<sup>40</sup> CMS Advisory Panel on Hospital Outpatient Payment, Recommendations 1 (August 2016).

C-APCs for different numbers of specimens would provide much more appropriate payment for these services than the current conditional packaging policy.

We also thank CMS for clarifying during the Open Door Forum on August 30, 2016, that hospitals can appropriately bill for these services for non-hospital patients on a 14x type of bill. Because hospitals that bill correctly using this type of bill are paid under the OPPS,<sup>41</sup> it is critical that the OPPS provide appropriate payment for these services.

**IX. CMS should revise the timing of the summer HOP Panel meeting and reinstate the winter meeting to provide CMS, the Panel, and stakeholders vital opportunities to discuss refinements to the OPPS.**

ACCC requests that CMS and the HOP Panel take affirmative steps to ensure that the Panel's meetings continue to serve their intended purpose of discussing concerns about the OPPS in depth and developing useful recommendations for CMS. Recently, for example, the meeting agendas have been shortened, and the Panel has issued fewer recommendations than in the past. Furthermore, CMS has announced that the winter 2017 meeting has been cancelled. In order to continue to ensure that the Panel's meetings continue to serve their intended purpose, ACCC urges CMS to revise the timing of the summer meeting and reinstate the winter 2017 HOP Panel Meeting.

ACCC recommends that CMS revise the timing of the summer meeting to allow sufficient and reasonable time for stakeholders to analyze the OPPS data and CMS's proposals. ACCC asks CMS to schedule the summer meeting during the last week of the comment period and delay the HOP Panel testimony deadline as much as possible.

For the summer 2016 HOP Panel meeting, despite an extension of the testimony deadline from July 15, 2016 to July 18, 2016, stakeholders had only 12 days from release of the proposed rule to the HOP Panel testimony deadline to develop comments. Twelve days is simply not enough time to develop meaningful and detailed comments on CMS's extensive proposals. In reality, the few analysts who can replicate CMS's calculations to provide the necessary insight for the development of detailed and meaning comments need at least two weeks from receipt of the data to discuss questions with CMS staff, refine their models, and ultimately calculate payment rates under alternative scenarios. If these experts cannot begin to provide detailed analyses before the testimony deadline, then it is impossible for organizations such as ACCC to provide detailed, meaningful comments which undermines the intended purpose of the HOP Panel meeting. To this end, ACCC urges CMS to schedule the summer meeting during the last week of the comment period and delay the HOP Panel testimony deadline as much as possible.

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<sup>41</sup> See Claims Processing Manual, ch. 16, §§ 30.3, 40.3.

CMS has announced that the winter 2017 HOP Panel meeting has been cancelled. CMS and the Panel should reinstate the winter meeting and use that forum to report to the public the effects of prior expansions of packaging on use of items and services and access to care. Historically, the winter meeting has been the first, and usually only, opportunity to see CMS's updated cost data for each code and APC prior to the release of the proposed rule. This information provides important insights into changes in access to care and the appropriateness of APC assignments. We urge CMS and the Panel to continue to make this information available early in the year and to continue to discuss it with stakeholders at a winter Panel meeting.

By failing to reinstate the winter HOP Panel meeting, CMS and the Panel are depriving stakeholders of a crucial opportunity to engage in the rulemaking process, to offer insights and commentary on CMS's proposals and operationalization of implemented policies, and to pressure test the data on which CMS will make future proposals. Again, ACCC urges CMS and the Panel to re-instate the winter 2017 HOP Panel meeting.

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Thank you for this opportunity to comment on the OPPS Proposed Rule for CY 2017. ACCC encourages CMS to incorporate our recommendations into the final rule and protect patients' access to care in the most appropriate setting. We look forward to continuing to work with CMS to address these critical issues in the future. 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 these very important matters.

Respectfully submitted,



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President

Association of Community Cancer Centers