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Submitted electronically via *www.regulations.gov*

December 29, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, NW
Washington, DC 20201

Re: CY 2017 Outpatient Prospective Payment System (OPPS) Interim Final Rule with Comment, (File Code: CMS-1656-IFC)

Dear Mr. Slavitt:

The Association of American Medical Colleges (the AAMC or Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or Agency's) interim final rule with comment entitled, "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 Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital," 81 Fed. Reg. 79562 (November 14, 2016).

The AAMC is a not-for-profit association representing all 145 accredited U.S. and 17 accredited Canadian medical schools; more than 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs Medical Centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their nearly 160,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The AAMC appreciates that in response to serious concerns raised by stakeholders, CMS made significant changes to its original plan for an alternative payment system for nonexcepted off-campus provider-based departments (PBDs). The policies adopted in the interim final rule with comment (IFC) will at a minimum ensure some level of payment for nonexcepted items and services furnished in these PBDs. However, the Association continues to be concerned about CMS's IFC policy for new payment rates for nonexcepted PBDs and comments made by CMS

about the limitation on service expansion and volume of services. Below we outline our concerns on these topics.

- **Alternative payment system for nonexcepted items and services furnished in off-campus provider-based departments.** The current alternative payment system will not adequately compensate hospitals and will result in rates that are insufficient to ensure access to care. CMS should not continue this alternative payment system at the current rate of 50 percent of the OPPS for 2017 and 2018 much less for 2019 and beyond without a thorough analysis of robust claims data in order to determine that payment for items and services provided in hospital outpatient departments (HOPDs) that fall under section 603 provisions to ensure that care will not be compromised for patients served by these HOPDs. As we explain further below, paying for nonexcepted items and services furnished in off-campus provider-based departments based on either the full non-facility practice expense payment under the Medicare physician fee schedule (MPFS) or the difference between the non-facility and facility amounts would clearly provide inadequate payment to hospitals for outpatient services.
- **Limitations on clinical service line expansion and volume of services**. In the preamble to the rule, CMS indicates that in the future it may impose the "family of services" limitation from the July 14, 2016 proposed rule (81 Fed. Reg. 45604) and also that the Agency may consider imposing limits on the growth of services in excepted HOPDs. As described below, the AAMC is concerned about these potential proposals as they go far beyond the changes that were contemplated when Congress enacted section 603 of the Bipartisan Budget Act of 2015.

The AAMC is also concerned that CMS has stated that "we believe the payment policy under this provision should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible . . ." The Association does not believe that was the intent of the legislation. Nowhere does section 603 use this terminology or indicate that Medicare's payment under section 603 is required or even intended to be site neutral to the amount Medicare would pay if the same service were done in a physician office. Section 603 merely directs the Secretary not to pay for services provided in a new off-campus outpatient department subject to its provisions under the OPPS and instead pay for these services under the "applicable payment system."

Even as payment for services provided in nonexcepted PBDs is less than for services provided at other HOPDs, nonexcepted PBDs, particularly those associated with teaching hospitals, continue to be substantially different from physician offices in the services they provide and the patients they treat. Regardless of whether an outpatient department is located on the campus of a hospital, off the campus of a hospital or at a remote location, and regardless of whether payment is under the OPPS or the alternative payment system for nonexcepted PBDs, these sites are frequently the sole sources of care for low-income and underserved populations, including Medicare beneficiaries, who may otherwise face difficulty being seen in physician offices. These HOPDs are obligated to meet the myriad of regulatory requirements, including compliance with hospital conditions of participation, and must provide stand-by care not provided in a physician's office. In short, both HOPDs and nonexcepted PBDs are comprehensive and coordinated care settings serving patients with chronic and complex medical conditions.

CMS Should Increase Payment Rates for Nonexcepted Items and Services for Calendar Years 2017 and 2018

The AAMC appreciates that CMS has recognized that the proposal in the July 14, 2016 proposed rule which would have provided nonexcepted PBDs with no payment in 2017 for items and services furnished to Medicare beneficiaries should not have been finalized. CMS's policy as specified in the interim final rule to use the MPFS as the basis for the payment system for nonexcepted PBDs will provide some level of payment for services at these locations in the coming year. Moreover, the approach to pay nonexcepted PBDs using OPPS payment policy helps smooth the transition to a new payment scheme in such a short period of time.

For calendar year (CY) 2017, CMS has finalized the MPFS as the "applicable payment system" for the majority of nonexcepted items and services provided in nonexcepted PBDs. CMS adopted a set of payment rates for nonexcepted items and services that are based on a 50 percent reduction to the OPPS payment rates (inclusive of packaging). The 50 percent payment rate was derived from two factors: the difference between the OPPS payment rate and applicable MPFS practice expense payment rate for the most commonly billed services by off-campus hospital outpatient departments and also the ASC payment level.

For most services CMS defines the applicable MPFS payment rates as the difference between the non-facility and facility MPFS rates. For services with both technical and professional components, the applicable MPFS payment rates reflect the MPFS practice expense payment for the non-facility rate of the technical component. In instances where Medicare's MPFS payment is not differentiated by facility and non-facility, the full MPFS practice expense payment is used as the applicable MPFS rates. In Table X.B.1 of the rule, CMS illustrated the OPPS payment rates and the applicable MPFS payment rates for the 22 most frequently billed services by off-campus HOPDs. In the table, CMS computed a MPFS to OPPS payment ratio for each code. The Agency concluded that on average MPFS payments are 45 percent of OPPS payment rates for services provided in off-campus HOPDs. After considering data limitations of their own analysis and referencing the ASC to OPPS payment ratio of 55 percent, CMS established the CY 2017 MPFS payment rates at 50 percent of the OPPS payment rates – a mid-point between the 45 percent of the MPFS to OPPS payment rate ratio and the 55 percent ASC to OPPS payment ratio.

CMS acknowledged in the rule that the 45 percent MPFS to OPPS payment ratio is not directly comparable because the "OPPS payment rates include the costs of packaged items or services billed with the separately payable code" while the MPFS payment does not. Analysis conducted by our data consultant, Watson Policy Analysis (WPA), shows that the costs of packaged services account for approximately 20 percent of the total costs of performing these selected procedures at off-campus HOPDs. **Based on this analysis, a more reasonable approximation is to reduce OPPS payment rates by 20 percent to account for the cost of packaging, thereby making OPPS payment rates more comparable to MPFS payment rates. This adjustment will increase the MPFS to OPPS payment ratio from 45 percent to 56 percent, which is a more accurate representation of payment relativity between the applicable MPFS payment rates (as defined by CMS) and the OPPS payment rates.**

The table below shows estimated costs of packaging as a share of total costs for each of the 22 codes based on single procedure claims used in the CY 2017 OPPS Final Rule rate setting

process. This WPA analysis replicates CMS's logic in establishing APC weights. On average, packaging costs (weighted by claim line volume times rate) represent 20 percent of total costs for the 22 codes.

Another shortcoming of CMS's analysis is that in many cases the OPPS payment rates were compared to the difference between the non-facility and facility MPFS rate and not the full MPFS payment for practice expenses. **We believe the full MPFS payment for practice expenses in a non-facility setting is more appropriate for the analysis of payment relativity between the MPFS and the OPPS as a hospital continues to incur indirect costs when a service is provided in its nonexcepted PBD.**

Based on WPA's analysis, if CMS were to use the full amount that Medicare pays for practice expenses as the applicable MPFS rates and also take into consideration the cost of packaging, the MPFS to OPPS payment ratio would increase to 64 percent. We believe 64 percent of the OPPS payment rates, as opposed to 50 percent proposed by CMS, is a more appropriate and justifiable payment level for nonexcepted services provided by nonexcepted PBDs.

		Mean Costs based on singles used in rate-setting			
HCPCS	**Short Descriptor**	**Procedure**	**Packaging**	**Procedure plus packaging**	**Percentage packaging**
	Total: Top 22	***$ 162.88***	***$39.55***	***$202.43***	***20%***
96372	Ther/proph/diag inj sc/im	$ 47.02	$33.61	$80.63	42%
71020	Chest x-ray 2vw frontal&latl	$ 63.67	$5.68	$69.35	8%
93005	Electrocardiogram tracing	$ 33.08	$49.42	$82.50	60%
96413	Chemo iv infusion 1 hr	$ 171.54	$189.03	$360.56	52%
93798	Cardiac rehab/monitor	$ 198.04	$0.05	$198.09	0%
96375	Tx/pro/dx inj new drug addon	$ 50.84	$0.03	$50.87	0%
93306	Tte w/doppler complete	$ 485.20	$11.57	$496.77	2%
77080	Dxa bone density axial	$ 98.73	$12.18	$110.91	11%
77412	Radiation treatment delivery	$ 205.71	$33.34	$239.05	14%
90853	Group psychotherapy	$ 107.39	$0.08	$107.47	0%
96365	Ther/proph/diag iv inf init	$ 140.92	$121.14	$262.06	46%
20610	Drain/inj joint/bursa w/o us	$ 262.99	$95.31	$358.31	27%
11042	Deb subq tissue 20 sq cm/<	$ 410.21	$91.54	$501.75	18%
96367	Tx/proph/dg addl seq iv inf	$ 69.52	$0.09	$69.61	0%
93017	Cardiovascular stress test	$ 215.77	$58.90	$274.66	21%
77386	Ntsty modul rad tx dlvr cplx	$ 567.49	$15.06	$582.55	3%
78452	Ht muscle image spect mult	$ 743.17	$536.90	$1,280.06	42%
74177	Ct abd & pelv w/contrast	$ 291.26	$111.55	$402.81	28%
71260	Ct thorax w/dye	$ 175.31	$92.51	$267.81	35%
71250	Ct thorax w/o dye	$ 134.51	$11.07	$145.58	8%
73030	X-ray exam of shoulder	$ 71.42	$21.16	$92.58	23%
90834	Psytx pt&/family 45 minutes	$ 148.40	$0.44	$148.85	0%

Clarity Needed When Some Services Are Provided in an Excepted HOPD and Others Are Provided in a Nonexcepted PBD

CMS states that OPPS payment policies, such as comprehensive APCs (C-APCs) and conditionally and unconditionally packaged items and services, will be incorporated into the newly established MPFS rates for PBDs. This means laboratory, drug, and, ancillary services that are packaged under OPPS will continue to be packaged under the newly established MPFS rates for nonexcepted items and services.

In the IFC, CMS does not specify how to apply OPPS payment policies (*e.g.*, C-APCs and packaging) when a portion of the items and services bundled into an APC are provided in excepted hospital outpatient departments while the balance are provided in an off-campus,

nonexcepted provider based department. Below are three scenarios to further illustrate this problem:

1. *The primary service is provided in an excepted HOPD and a portion of the packaged services is provided at a nonexcepted, off-campus PBD*. The patient has a primary procedure coronary artery angiography (CPT 93456) at an excepted HOPD and two days later has a clinic visit (CPT G0463) at a nonexcepted, off-campus PBD, or is referred to the emergency department on the main campus for an observation service lasting more than 8 hours. Under the current OPPS policy, the clinic visit or observation service will be packaged into the primary procedure – angiography, APC 5191. With section 603, the IFC does not explicitly address whether a service provided at a nonexcepted, off-campus PBD subject to the MPFS can be packaged into a service paid under another payment system—the OPPS.

2. *Services that trigger C-APCs are provided both by the excepted HOPD as well as the nonexcepted, off-campus PBDs*. The patient has an outpatient clinic visit for assessment and management (CPT G0463) at a nonexcepted, off-campus PBD, and then is referred by the doctor to the emergency department on the main campus for an observation stay lasting more than 8 hours. Under the current OPPS policy, the combination of a clinic visit and the observation stay of more than 8 hours will trigger C-APC 8011 – comprehensive observation services. The clinic visit is subject to payment under the MPFS in 2017 but it would normally trigger payment under the OPPS and then be packaged. Is the clinic visit paid separately as it is subject to payment under the MPFS? If so, it would not trigger the C-APC payment for observation services although it is possible the C-APC could be triggered for other reasons such as billing of code G0379 (Direct Referral for Observation Services).

3. *The primary services are provided by a nonexcepted, off-campus PBD and a portion of the packaged services are provided at an excepted HOPD*. The patient has an outpatient clinic visit for assessment and management (CPT G0463) at a nonexcepted, off-campus PBD, and then the patient has a laboratory test the next day at an excepted HOPD. Under the current OPPS policy, the laboratory service will be packaged with the clinical visit into APC 5012.

To satisfy the statute's requirements of section 603 as well as that of OPPS, CMS can carve out nonexcepted services from the rest of the services with the "PN" modifier on the claim and apply standard OPPS payment policies on excepted and nonexcepted services separately. The IFC does provide support for this policy where it indicates "we consider these rates to be site-of-service specific rates for the technical component of MPFS services." (81 FR 79716). Following the logic that each site is treated independently would mean that conditionally packaged services would always be paid separately if there is no other separately paid service provided in that same site billed on a single claim.

It Is Premature to Finalize an Alternative Payment System for Calendar Year 2019 and Beyond

For 2019 and subsequent years, CMS indicates that it is considering continuing its current methodology (a special MPFS rate that is a percentage of the OPPS payment) or paying based on the MPFS itself. The IFC indicates that where CMS will pay based on the MPFS, payment will equal Medicare's full non-facility practice expense payment for technical component and "incident to" services where payment is not made under the MPFS in the facility site. In other

cases, Medicare's payment would equal the difference between the MPFS' non-facility and facility payment. (p. 797928)

In Table X.B.1 of the IFC (and shown above), CMS provides the MPFS payment amounts that would be used for 22 services if CMS adopted a policy to pay non-excepted off-campus PBDs using the MPFS. For those services where Medicare would pay the full non-facility practice expense payment, the reductions could be as much as 82 percent (CPT code 93017). For services where Medicare pays the difference between the non-facility and facility MPFS amounts, the reductions would be even higher and the payments would be clearly insufficient. For example, Medicare would pay a non-excepted off-campus PBD only $0.36 for CPT code 90834 (Psychotherapy, 45 minutes). Paying $0.36 for 45 minutes of use of a hospital outpatient department is clearly unreasonable and insufficient. (pp. 79724 -79725)

Hospital outpatient clinic visits are the most commonly furnished services in off-campus PBDs. While Medicare uses CPT codes to pay for clinic visits under the MPFS, it uses G0463 to pay for outpatient clinic visits. The discussion in the rule (p. 79723) suggests that if CMS were to use the MPFS to pay for the most commonly furnished clinic visits, payment could decline from $102.12 to $29.02 for 99214 and to $21.86 for 99213—reductions of 71 and 79 percent respectively. We believe reductions of this magnitude would set the rates well below the hospital's costs of providing outpatient clinic visits and would be inadequate.

For payments in CY 2019, we encourage CMS to undertake additional analysis that includes sufficient claims data with the "PN" modifier in order to best determine payment policies for nonexcepted PBDs. CMS should not finalize a permanent alternative payment system without soliciting comprehensive feedback through notice and comment rulemaking to ensure that patients that seek care in nonexcepted PBDs are not disadvantaged by gross underpayment for services rendered. As a guiding principle, the AAMC favors proposals that will minimize the burden on hospitals' administrative operations and reduce the risks of disruption of access to care.

CMS Should Not Limit Services Provided at Excepted Off-Campus PBDs and Should Not Resurrect the "Family of Services" Proposal

In the preamble to the final rule CMS states "We disagree that section 603 does not provide us the authority to adopt a policy that would limit OPPS payment to the type of services that had been furnished and billed at an off-campus PBD prior to enactment of Public Law 114-74. Further, we believe the statute give us the authority to limit the volume of services furnished to the level that was furnished prior to the date of enactment." (p. 79707)

The AAMC strongly disagrees with both statements and urges CMS to not re-propose the "family of services" proposal that was not finalized in this rule, nor to try to limit the volume of services should there be growth in services at excepted HOPDs. Since CMS has finalized a rule that, except under very narrow circumstances, prohibits relocated excepted HOPDs from being paid under OPPS, these sites may have little choice to but to add new services and services lines to better serve their communities and to offer new treatments that were not previously available. Unlike CMS, the AAMC believes that the "family of services" policy would, indeed, hinder access to needed services in the community. Volume growth also is to be expected over time.

Given the patient populations that they serve, hospitals must be able to retain the flexibility to offer services in locations that best meet the needs of their patients.

Ensure that Outpatient Outcomes Measures are reviewed under the NQF SES Trial Period

In the CY 2017 OPPS final rule, CMS finalized two claims-based outcomes measures for inclusion into the Hospital Outpatient Quality Reporting (OQR) program starting CY 2020:

- Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Treatment (OP-35)
- Hospital Visits after Hospital Outpatient Surgery (OP-36)

The AAMC objects to the fact that these two measures were finalized for public reporting without full consideration of the influence of patient populations' socioeconomic status (SES) on the measures' outcomes. In response to stakeholder comments to the proposal, in the final rule CMS provided the results of its own analysis after examining the impact of SES on the measures' outcomes. While the AAMC appreciates that the Agency took this step, we believe that at this time the National Quality Forum (NQF) trial period is the appropriate venue to evaluate and make a determination regarding a measure-level SES adjustment. CMS noted that OP-35 had been submitted to the NQF for review under the trial period. However, CMS did not submit OP-36 for SES review by NQF since the measure was endorsed before the trial period started. CMS explained that "because the 2015 NQF Surgery Project's measure submission deadline was January 14, 2015, both the developer and the Surgery Standing Committee conformed to the pre-trial policy regarding inclusion of SDS factors in the risk-adjustment approach. Thus, OP–36 was not part of NQF's SDS trial."

The AAMC does not think that CMS has provided a sufficient rationale for failure to submit a measure for SES review by NQF since the Agency has the ability to submit any metric (either NQF-endorsed or not) to NQF at any point during the trial period, which ends in April 2017. Consideration of the impact of SES is crucial as provider performance on these measures may be heavily influenced by factors outside of the hospital's direct control. For example, patient populations who do not have assistance at home, or ready access to pharmacies for needed medications may be more likely to return to the ED or be admitted as an inpatient as compared with patients who have access to these benefits.

At a minimum, before a final determination is made as to whether there is a conceptual and empirical relationship between the measures' outcomes and SES factors, CMS's SES analysis of OP-35 and OP-36 should be shared with the relevant NQF committees during the trial period. An opportunity for stakeholder review and feedback also should be provided. Until these committees have had the opportunity to make such a determination, CMS should withhold finalizing these two measures for public reporting.

Nonexcepted PBDs Should Be Able to Participate in the 340B Drug Pricing Program

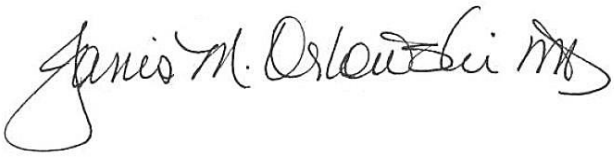
The AAMC appreciates CMS's clarification that the 340B Drug Pricing Program will not be impacted as CMS works to implement section 603. We do not believe it was the intent of

section 603 to change this important program. AAMC-member teaching hospitals and their clinical faculty, residents, and students are committed to this safety net mission in expanding access to care for underserved and vulnerable patients. In addition, as major referral centers with highly specialized expertise, these academic medical centers serve a sicker, more complex, and more vulnerable patient population – patients who often are unable to seek the necessary care elsewhere. As CMS moves to developing a new payment methodology under section 603, we urge CMS to continue to ensure that the 340B program is not negatively impacted. Any changes that limit hospitals' ability to purchase drugs under the 340B program would cut services to under-served communities.

CONCLUSION

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Ivy Baer, J.D., M.P.H., at 202.828.0499 or ibaer@aamc.org and Mary Mullaney at 202.909.2084 or mmullaney@aamc.org regarding Section 603 implementation, Susan Xu, M.P.A, M.S., at 202.862.6012 or sxu@aamc.org regarding payment issues, and Scott Wetzel at 202.862.0495 or swetzel@aamc.org regarding quality issues.

Sincerely,



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