DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

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September 6, 2016

BY ELECTRONIC SUBMISSION

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments to CMS-1656-P

Dear Acting Administrator Slavitt:

On behalf of the more than 1,400 gastroenterologists and other physician specialists whose independent medical practices are members of the Digestive Health Physicians Association ("DHPA"), we want to thank you for the opportunity to comment on the Outpatient Prospective Payment System ("OPPS") Proposed Rule for Calendar Year 2017.[1] We focus our comments on the steps CMS has proposed to implement the site neutrality provisions of section 603 of the Bipartisan Budget Act of 2015 ("BBA"),[2] which limits new hospital off-campus provider-based departments from billing under the OPPS. We agree with CMS that Congress acted in section 603 of the BBA "to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services."[3] And, we believe that most of CMS's proposals effectuate that Congressional intent.

However, in implementing section 603 of the BBA, we believe CMS must consider the wider trend of hospital acquisition of independent medical practices and ambulatory surgery centers in recent years. This vertical consolidation has increased the cost of healthcare services in many communities. In response—and consistent with Congress's purpose in enacting section 603 of the BBA—CMS should modify certain of its proposals to be sure that existing, vertically consolidated systems, which are excepted from the site neutrality rules, may receive payment under the OPPS *only* if they actually furnish items and services

[1] 81 Fed. Reg. 45604 (July 14, 2016).

[2] Public Law 114-74 (2015).

[3] 81 Fed. Reg. at 45684.

"as they were being furnished on the date of enactment."[4] Specifically, we provide the following recommendations:

- We disagree with CMS's proposal that an excepted provider-based department ("excepted PBD") should be reimbursed under the OPPS for any services in the same "clinical family" as items and services the excepted PBD provided at any point before November 2, 2015. Instead, excepted PBDs should only be reimbursed under the OPPS for those items and services that were actually provided in the twelve months prior to November 2, 2015.
- We believe CMS should finalize its proposal to require an excepted PBD to maintain its precise location as of November 2, 2015, as a condition of maintaining its "excepted" status. Any exception to this general rule should be extremely narrow and only apply in those circumstances when the Secretary has determined that a *bona fide* public health emergency exists.
- CMS proposes a "transitional policy" for 2017, under which services provided by non-excepted PBDs will be paid under the MPFS rate for non-facility services (or under the ASC fee schedule with respect to recently-acquired ambulatory surgery centers); we agree with this policy and believe it should be made permanent.

I. Digestive Health Physicians Association

DHPA formed in 2014 to promote and protect the high quality, cost-effective and coordinated care furnished in independent gastroenterology practices. DHPA is the only national medical association that exclusively represents the voices of those gastroenterologists who have chosen to care for patients in the independent practice setting. In its first two years, DHPA has grown to include 62 member gastroenterology practices from 31 states in every region of the country. Our more than 1,400 physicians provide care to approximately 2.5 million patients annually in more than 3.5 million distinct patient encounters. Our physician members are on the front lines of providing innovative treatments for serious diseases and chronic conditions such as colon cancer, Crohn's disease, and ulcerative colitis.

II. CMS's Interpretation of Section 603 of the BBA Correctly Reflects Congress's Intent to Prevent Hospital-Based Consolidation That Raises the Cost of Essential Healthcare Services for Patients and the Medicare Program.

Section 603 of the BBA is Congress's response to one of Medicare's most severe payment imbalances. Prior to its passage, hospitals that purchased physician practices or ambulatory surgery centers could enroll them as "provider-based" locations eligible to receive inflated reimbursement for identical services under the OPPS. Neither the Medicare program nor beneficiaries (who are responsible for out-of-pocket, cost-sharing payments) received greater value to justify these increased costs. This policy fueled provider consolidation and undermined competition in many communities, which has implications far beyond the Medicare program. Indeed, the HHS Office of Inspector General ("OIG") found that CMS could not justify the

[4] Id. at 45685; id. at 45684.

benefits of "provider-based" status, and in fact many hospitals did not even attest to meeting the extremely limited standards necessary to achieve this status.[5] As a result, Medicare beneficiaries and the Medicare program needlessly paid higher prices for identical healthcare services that they have been receiving outside the hospital setting. This is why the OIG, the U.S. Government Accountability Office ("GAO"), and MedPAC all called for an end to this unnecessary reimbursement disparity.[6]

Gastroenterologists are particularly concerned about these heightened costs. The shift of care into the more expensive hospital setting—including for colonoscopies—results in higher beneficiary out-of-pocket costs that, over time, could impact screening rates for colon cancer (the second leading cause of cancer death in the United States). In 2016, Medicare pays hospitals $793 for a lesion removal colonoscopy and diagnostic colonoscopy, but independent ASCs just $429 for exactly the same procedures. Hospitals receive $747 for an upper GI endoscopy biopsy, yet independent ASCs receive just $404 from Medicare for that procedure. In short, the same procedure, same equipment, same physician, and same medical outcome result in nearly twice the cost in the hospital setting.[7]

We are concerned that off-campus PBDs pass their artificially high costs on to Medicare beneficiaries in the form of increased coinsurance payments, which may discourage patients from utilizing important preventative services. This is particularly concerning for services such as colonoscopy where Medicare payment policy can make out-of-pocket costs unpredictable. Medicare beneficiaries pay a coinsurance fee equal to 20% of the Medicare allowable charge for most services.[8] Although this coinsurance payment is waived for *preventative* procedures (including screening colonoscopies), the payment still applies to other diagnostic and therapeutic procedures (including biopsy and/or removal of lesions during colonoscopy). Practically speaking, it is impossible for a gastroenterologist to know whether a polyp or lesion exists prior to conducting a screening colonoscopy. As a result, a beneficiary who schedules a screening service may face unexpected out-of-pocket costs if a potentially cancerous polyp or lesion is found. And, because these payments are based on a percentage of the underlying procedure, as a practical matter, the higher cost of care in PBDs has the potential to translate into greater out-of-pocket costs for Medicare beneficiaries. This disparity requires patients to pay increased amounts for services that they may obtain more affordably in independent endoscopy centers. Worse, the risk of incurring such heightened, unexpected out-of-pocket costs may cause patients to delay or avoid these necessary cancer screening services.[9]

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[5] HHS Office of Inspector General, *CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain*, OEI-04-12-00380 (June 2016) ("OIG Report"), p. 10.

[6] Id. See also MedPAC, *March 2014 Report to Congress* ("MedPAC Report"), p. 75 and Government Accountability Office, *Medicare: Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform*, GAO-16-189 (December 2015) ("GAO Report"), p. 1.

[7] Comparing the OPPS Addendum B and ASC Addendum BB, regarding facility fees only.

[8] See 42 C.F.R. §§ 410.152(l)(5); 410.160(b)(7) and 42 U.S.C. § 1395l(b)(1).

[9] Numerous independent studies have demonstrated that increased out-of-pocket costs are associated with lower patient use of colonoscopy and other available preventative services, particularly among lower-income patients. See e.g., Khatami S, Xuan L, et al., *Modestly Increased Use of Colonoscopy When*

Moreover, gastroenterology practices are an attractive target for hospital acquisitions because of the range of services necessary to deliver comprehensive GI care. For example, many gastroenterologists deliver care at endoscopy centers where they perform screening and therapeutic colonoscopies as well as other endoscopic procedures. Also, many independent GI practices incorporate diagnostic imaging services such as ultrasound, computed tomography, and magnetic resonance imaging to assist in diagnosis and management of gastrointestinal diseases and chronic conditions. Finally, many gastroenterologists incorporate drug infusion into their practices to treat complicated medical conditions such as inflammatory bowel disorder ("IBD"). In many cases, hospitals enjoy remarkably high profits for these ancillary services because they receive purchasing incentives in addition to the higher reimbursement under the OPPS. For example, MedPAC estimates that about 50% of hospitals are eligible to purchase outpatient drugs at steep discounts under the 340B program, with an average discount of 22.5% on such drugs.[10]

The following table demonstrates the total cost differential to the Medicare program for common services between hospital out-patient departments ("HOPDs") and physician offices or non-hospital-based ambulatory surgical centers. The payment differentials illustrate the incentive that hospitals have to expand GI services furnished in existing off-campus PBDs in order to bill for such services under the OPPS:

Copayments Are Waived, Clinical Gastroenterology and Hepatology, 2012;10:761–766 and Dorn SD, Wei D, et al., *Impact of the 2008–2009 Economic Recession on Screening Colonoscopy Utilization Among the Insured*, Clinical Gastroenterology and Hepatology, 2012;10:278–284. See also Trivedi AN, Rakowski W, and Ayanian JZ, M.D., M.P.P., *Effect of Cost Sharing on Screening Mammography in Medicare Health Plans*, N Engl J Med 2008;358:375-83 (finding that high cost sharing was associated with significantly lower rates of mammography rates).

[10] MedPAC, June 2015 Report to the Congress, p. 70.

HCPCS Code	MPFS Professional Payment in Physician Office or ASC[11]	Total Payment in a Physician Office or ASC[12]	Total Payment in an HOPD[13]	% By Which Totally Payment in HOPD Exceeds Total Payment in Physician Office or ASC
45380 – Colonoscopy, with biopsy, single or multiple (performed in an ASC)	$216.62	$687.18	$969.38	41%
45385 – Colonoscopy, with removal of tumor, polyp, or lesion (performed in an ASC)	$273.54	$744.10	$1026.30	38%
99203 – New patient E&M visit	$108.85	$108.85	$186.55	71%
96413 – Remicade iv infusion 1 hr	$136.41	$136.41	$416.68	305%
74182 – MRI Abdomen w/ dye	$88.44	$456.86	$542.76	19%

The steps CMS is taking to implement section 603 of the BBA are critical to stemming the tide of vertical consolidation that has resulted in higher costs for GI and other services when they are furnished in the hospital setting. And, those steps are consistent with the purpose of section 603—**"to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services."**[14] The purpose of the statute

[11] This column includes the *facility* PC in every case other than for CPT Code 99203 (which uses the non-facility value to represent office E&M visits). Note that the professional fees for CPT Codes 96413 and 74182 do not change between facility and non-facility settings.

[12] The amounts shows in this column combine the professional fee and the relevant ASC facility fee or office TC (if any).

[13] The amounts shown in this column combine physician payments and relevant OPPS facility fees.

[14] 81 Fed. Reg. at 45684.

cannot be fully achieved, however, unless CMS modifies certain of its proposals to avoid creating loopholes that would undermine the goals of a site-neutral payment policy for non-excepted, off-campus PBDs.

III. CMS Should Act to Restrict the Large Numbers of Existing Off-Campus PBDs from Expanding their Capacity or the Items or Services Offered in each Location.

As stated above, section 603 of the BBA will only prevent provider-based departments from billing at the OPPS rate if they were enrolled *after* November 1, 2015. Therefore, although section 603 will significantly reduce the concerns raised above, it will do little to address the large number of vertically consolidated systems that already exist. According to the OIG, half of the country's hospitals own at least one off-campus PBD (and some own many more).[15] In recent years, the number of vertically consolidated hospitals, volume of Medicare services provided in hospital outpatient departments (including PBDs), and the number of physicians practicing in HOPDs have grown rapidly.[16] As of 2013, nearly half of physician practices were owned by hospitals, and just 41% were wholly owned by physicians.[17] Moreover, nearly half of hospital markets are now "highly concentrated," in part because of the significant incentives that hospital systems have to absorb physician practices and other providers.[18]

As a result, we believe it is appropriate—and entirely consistent with Congressional intent—for the Agency to implement section 603 of the BBA in a manner that limits the expansion of existing off-campus PBDs. Although the statute permits off-campus PBDs that were in place prior to November 2, 2015, to continue billing under the OPPS, we believe that CMS must take a strict view of the scope of this exception. Unless the Agency can place effective limits on the expansion of these excepted PBDs, they will continue to serve as a platform for further consolidation of physician practices into hospital systems (at higher payment rates), thereby undermining the goals of section 603.

A. The Proposed Rule Correctly Limits Excepted PBDs to Their Pre-BBA Locations.

We agree with CMS's proposal to restrict "excepted PBD" status only to those locations that were enrolled as provider-based locations prior to November 2, 2015. We echo CMS's concerns that, if excepted off-campus PBDs could relocate at will, "hospitals would be able to relocate excepted off-campus PBDs to larger facilities, purchase additional physician practices, move these practices into the larger relocated facilities, and receive OPPS payment for services furnished by these physicians."[19] We also agree that this is exactly the outcome that Congress

[15] OIG Report p. 10. In one case, the OIG discovered that a hospital operated 84 locations as off-campus PBDs.

[16] Id. at 1; GAO Report, pp. 1 and 9.

[17] Cutler DM, Morton FS, *Hospitals, Market Share, and Consolidation*, JAMA, 2013;310(18):1964-1970. In 2013, about 10% of physician practices were wholly or partly owned by entities that were not physicians or hospitals.

[18] Id.

[19] 81 Fed. Reg. at 45684.

"intended to preclude" through section 603.[20] Thus, CMS appropriately proposes that an excepted PBD would retain that status if it provides services only at the "physical address that was listed on the provider's hospital enrollment form as of November 1, 2015," and that "the unit number is considered part of the address."[21] We believe this is the right decision—it is a clear and effective way to end the incentive for hundreds of existing PBDs to expand through the continued acquisition of physician practices and ASCs. **As such, we urge CMS to finalize this proposal.**

CMS asks whether it should create limited exceptions to this rule to allow for relocations in the event of natural disasters or other emergencies. DHPA is certainly concerned about preserving patient access to care in such emergencies, but any such exception that the Agency constructs should be extremely limited and rely on the Secretary's existing authority to declare bona fide public health emergencies.[22] Moreover, CMS should establish fraud and abuse safeguards and monitoring standards to detect and penalize any hospitals that use such an "emergency" exception to increase the size of the excepted PBDs.

B. CMS Should Establish Stronger Limits on Excepted PBDs' Ability to Offer Additional Items and Services.

CMS proposes limits to the kinds of "items and services" for which an excepted PBD may seek reimbursement under the OPPS. We agree with the Agency that "[Section 603] excepts off-campus PBDs and the items and service that are furnished by such excepted off-campus PBDs . . . ***as they were being furnished on [November 2, 2015]***."[23] We also agree with CMS's overall proposal that an "excepted off-campus PBD would be limited to seeking payment under the OPPS for the provision of items and services ***it was furnishing prior to the date of enactment*** of [Section 603] only."[24] This is a common-sense rule that would prevent an excepted PBD from modifying its services to earn greater reimbursement under the OPPS.

We are concerned, however, that CMS's implementation of this policy deviates from the Agency's stated goal by allowing excepted PBDs substantial latitude to define the "items and services" that were offered prior to November 2, 2015. Specifically, CMS's proposal (1) grants excepted PBDs the ability to expand services within "clinical families" of services that were offered by the entity prior to November 2, 2015, regardless of the volume of services offered or the differences in reimbursement within a clinical family; and 2) does not specify a time period during which such services must have been offered. **As a result, we are concerned that CMS's proposal may allow excepted PBDs to expand their scope of services in material ways while continuing to bill under the OPPS.**

[20] Id.

[21] Id.

[22] See 42 U.S.C. § 247d (concerning the Secretary's power to declare such an emergency).

[23] 81 Fed. Reg. at 45685 (emphasis added).

[24] Id. (emphasis added).

CMS created the concept of "clinical families" solely for the purpose of this Proposed Rule. Under CMS's proposal, an excepted PBD would be reimbursed under the OPPS for *any* service—including services the PBD never furnished in the past—as long as the service is within the same "clinical family" as a service that the excepted PBD provided before November 2, 2015.[25] CMS also proposes that an excepted PBD could expand services within a given clinical family *regardless* of the volume of services it provided within that clinical family prior to November 2, 2015.[26]

This is troubling—and not in keeping with the letter or spirit of section 603 of the BBA—because the newly constructed clinical families are extremely broad. For example, the gastroenterology clinical family covers eight separate APCs with more than 250 CPT Codes.[27] Thus, under the Proposed Rule, an excepted PBD that performed *any* services grouped under APC 5311 (Level 1 Lower GI Procedures) with facility reimbursement of $492.45 per procedure would be entitled to receive reimbursement under the OPPS, even if it began to provide much higher-intensity services under APC 5331 (Complex GI Procedures) with facility reimbursement of $3,613.57 per procedure.[28] In addition, CMS's list of clinical families does not account for many of the advanced imaging codes that are relevant to gastroenterology. It is therefore unclear whether, for example, CMS intends to allow an HOPD that previously performed x-ray exams of the colon (CPT Code 74280, reimbursed at a rate of $191.97 under APC 5523, and covered under the "Advanced Imaging" clinical family) to integrate far more expensive advanced imaging services relevant to gastroenterology (for example, GI PET exams reimbursed at a rate of $332.65 under APC 5591) while retaining its reimbursement advantage under the OPPS.[29] These examples are troubling because CMS is "proposing not to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish"[30] As a result, an excepted PBD could rely upon a small volume of services that happen to share a clinical family with a highly reimbursed APC to justify a significant change in the types of clinical services offered by the excepted PBD (and reimbursed under the OPPS).

Our concerns with this proposal are compounded by the fact that CMS does not place a time limit on the period during which an "item or service" must have been provided to justify expansion within an applicable "clinical family." In other words, under the Agency's current proposal, an excepted PBD could introduce an entirely new and higher-cost service line based upon a small number of services furnished in a given clinical family many years before November 2, 2015.

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[25] Id.

[26] Id.

[27] Id. at 45686. The APCs are 5301–03, 5311–13, 5331, and 5341. *See also* 2016 OPPS Final Rule Data Addendum B, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-FC.html.

[28] Id. and 2016 OPPS Final Rule Data Addendum B.

[29] Id.

[30] 81 Fed. Reg. at 45685.

We do not believe a proposal that would give excepted PBDs this degree of flexibility to expand the scope of their services, while retaining payment advantages under the OPPS, is in keeping with the purpose of section 603 of the BBA. Instead, we believe CMS should adhere to the plain language of the statute (and its own characterization of Congressional intent), to ensure that excepted PBDs may only receive reimbursement under the OPPS for the specific items and services they provided prior to November 2, 2015.

We believe two policy revisions are necessary to achieve this goal. First, CMS should not implement its concept of "clinical families." Rather, **excepted PBDs should be reimbursed under the OPPS *only* for the actual items and services that were present on claims submitted by the excepted PBDs prior to November 2, 2015.** Second, CMS should not allow an excepted PBD an indefinite "look-back" period to assert that it previously provided a service that should be reimbursed under the OPPS. Instead, **CMS should require that an excepted, off-campus PBD may only bill under the OPPS for those items and services for which it submitted claims at some point from November 1, 2014 through November 1, 2015.**

IV. CMS Should Clarify That Non-Excepted, Off Campus PBDs Will Not Receive Greater Reimbursement Than Other Comparable Entities Following Its "Transitional" Policy for 2017.

We ask CMS to provide additional clarity regarding the scope of its "transitional policy" for 2017, and we ask the Agency to ensure that non-excepted, off-campus PBDs will not receive greater reimbursement than equivalent, non-hospital entities in the future. Section 603 of the BBA states that payment for items and services furnished by a non-excepted, off-campus PBD must be "made under the applicable payment system" other than the OPPS.[31] We believe that CMS has correctly identified that, in many instances, the appropriate "applicable payment system" should be the Medicare Physician Fee Schedule ("MPFS"), but we note that in some cases the "applicable payment system" should be the ASC fee schedule instead.[32] This is because most off-campus PBDs were independent physician practices or physician-owned ASCs that hospitals acquired and converted to provider-based departments.[33] However, CMS is unclear about the Agency's long-term plans—beyond 2017—to specify the "applicable payment system." Rather, CMS states that its policy to reimburse non-excepted PBDs on the basis of the non-facility MPFS rate is only a "transitional policy."

We are concerned about the Agency's plan to develop a new provider type for non-excepted off-campus PBDs.[34] We ask the Agency to confirm that reimbursement for any new off-campus PBD provider type will continue to be equal to reimbursement for physician practices or ASCs under the MPFS or ASC fee schedule, respectively. In other words, even after 2017, a non-excepted, off-campus PBD providing physician services should be reimbursed at the same rate as any other physician practice under the MPFS (in both its professional and technical components),

[31] 42 U.S.C. § 1395l(t)(21)(C).

[32] 81 Fed. Reg. at 45688.

[33] Note that CMS also gives hospitals the opportunity to re-enroll PBDs as other provider types where appropriate (for example, ambulatory surgical centers). See id.

[34] Id. at 45688-89; id. at 45690.

even if this PBD is technically enrolled as a newly-developed "off-campus PBD" provider type. Likewise, just as CMS identified the MPFS as the applicable payment system for acquired physician practices, the ASC fee schedule should remain the applicable payment system for hospital-acquired ASCs.

VI. Request for Action

Through its proposals to implement Section 603 of the BBA, CMS is taking important steps towards ending the payment disparity—and the corresponding increases in health care costs for the federal government, Medicare beneficiaries, and other patients—that have resulted from vertical consolidation of physician practices into hospital systems. However, we believe that certain of CMS's proposals should be modified in light of the Agency's own statement that section 603 of the BBA only excepts off-campus PBDs and the items and services furnished by those PBDs ***"as they were being furnished on the date of enactment."***[35] In order to adhere to that correct reading of the statute, CMS should make the following changes in the Final Rule:

- CMS should only allow excepted PBDs to bill under the OPPS for those items and services that the excepted PBD actually provided at some point during the twelve months prior to November 2, 2015. The Agency should *not* finalize its proposal to allow excepted PBDs to be paid under the OPPS for additional services that are in the same "clinical family."
- Rather than only being a "transitional policy" for 2017, the MPFS non-facility rate should serve as the permanent standard for reimbursement of services provided by non-excepted, off-campus PBDs that were formally physician practices, just as the ASC fee schedule should remain the payment system that would apply to non-excepted, off-campus PBDs that were formerly independent ASCs.

At the same time, CMS should finalize its proposal to require an excepted, off-campus PBD to maintain its existing location (including the same unit number within a medical office building) as a condition of retaining its "excepted" status and offer flexibility to this rule only for genuine public health emergencies.

[35] Id. at 45685 (emphasis added).

DHPA—with its more than 1,400 gastroenterologists who prevent, detect and treat serious gastrointestinal disease and chronic conditions on a daily basis—looks forward to serving as a resource to CMS as it works to finalize the OPPS Proposed Rule for 2017. Please reach out with any questions to DHPA's Chair of Health Policy, Dr. Lawrence Kim (lkim@gutfeelings.com, 303-788-8888), or to DHPA's legal counsel, Howard Rubin (Howard.Rubin@kattenlaw.com, 202-625-3534).

Sincerely,

Fred Rosenberg, M.D.
President

Lawrence Kim, M.D.
Chair, Health Policy

cc: Howard Rubin, Esq., Katten Muchin Rosenman LLP
Kevin Harlen, DHPA Executive Director