December 29, 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–FC and IFC

Dear Acting Administrator Slavitt:

On behalf of LUGPA, we thank you for the opportunity to comment on the Outpatient Prospective Payment System ("OPPS") Final Rule for 2017 issued by the Centers for Medicare and Medicaid Services.[1] Our comments focus on CMS's implementation of Section 603 of the Bipartisan Budget Act of 2015 ("BBA").[2] This law mandates that an off-campus provider-based department ("PBD") will no longer be reimbursed under the OPPS, but instead under another "applicable payment system," unless the PBD was in operation prior to November 2, 2015.[3] As CMS recognized in the OPPS Proposed Rule issued in July, Section 603 "is intended to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services."[4]

LUGPA commends CMS for finalizing many provisions of the Proposed Rule in a manner that reflects Congress's important site-neutrality goals. Unfortunately, in certain important respects, the Final Rule departs from the Proposed Rule in ways that contradict the language and purpose of Section 603 of the BBA. Without certain revisions, we believe that "the exceptions will swallow the rule" and CMS will have failed to implement a site-neutral payment structure as Congress directed. We are particularly concerned with the following:

- The Final Rule appears to remove *all* limitations on the services for which an "excepted PBD" may bill under the OPPS—even if these services are entirely different from the types of services the PBD provided prior to November 2, 2015; and

[1] 81 Fed. Reg. 79562 (Nov. 14, 2016).
[2] Public Law 114-74 (2015).
[3] 42 U.S.C. § 1395L(t)(1)(B) and (21).
[4] 81 Fed. Reg. 45604, 45684 (July 14, 2016).

- The Final Rule creates a new payment system for "nonexcepted PBDs" that will perpetuate the dramatic payment disparity Congress sought to remedy in Section 603 of the BBA. **The data we present in this comment letter shows that, if left unchecked, this payment disparity could approach *half a billion dollars annually* with respect to commonly performed urologic services alone**.

The Final Rule lays out two options for future refinements to the site neutrality payment rules that CMS intends to implement in 2019: (1) fully equalizing payment rates between physician offices and PBDs for each CPT Code; or (2) continuing to base PBD reimbursement on a percentage of the relevant OPPS payment. As we explain below, we support the first of these two options. We believe that the creation of a site neutral reimbursement for each CPT Code is the only way to achieve Congress's goal of curbing the practice of hospital acquisition of physician practices; a practice that results in additional out-of-pocket costs for Medicare beneficiaries and greater expenses for the healthcare system as a whole.

I. LUGPA

In 2008, when physician leaders of large urology group practices began to recognize the need for a formal association to help meet the challenges of the future, LUGPA was initially established with the purpose of enhancing communication between large urology groups, allowing for benchmarking of operations, promoting quality clinical outcomes, developing new business opportunities, and improving advocacy and communication in the legislative and regulatory arenas. Since that time, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 135 urology group practices in the United States, with more than 2,100 physicians who, collectively, provide approximately 30% of the nation's urology services.[5]

Integrated urology practices are able to monitor health care outcomes and seek out medical "best practice" in an era increasingly focused on medical quality and the cost-effective delivery of medical services, as well as better meet the economic and administrative obstacles to successful practice. LUGPA practices often include advanced practice providers and other specialists, such as pathologists and radiation oncologists, who work as teams with urologists to coordinate and deliver care through a convenient one-stop shop for the patient. LUGPA's mission is to provide urological surgeons committed to providing integrated, comprehensive care the means to access resources, technology, and management tools that will enable them to provide all services needed to care for patients with acute and chronic illnesses of the genitourinary system, including men with prostate, kidney and bladder cancer, in an efficient, cost-effective, and clinically superior manner, while using data collection to create parameters that demonstrate quality and value to patients, vendors, third party payors, regulatory agencies, and legislative bodies.

[5] Centers for Medicare and Medicaid Services, *Medicare Provider Utilization and Payment Data: Physician and Other Supplier*, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html.

II. CMS Has Modified Its Original Proposal In Ways that Undermine Congress's Goals of Achieving Site-Neutral Payments.

In the Proposed Rule, CMS accurately described the policy rationale that led Congress to enact Section 603 of the BBA, stating that the legislation was **"intended to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services."**[6] Congress's desire to establish a site-neutral payment structure was based, in part, on studies by the HHS Office of Inspector General ("OIG"), the Government Accountability Office ("GAO"), and MedPAC showing, in recent years, that (i) utilization has increasingly shifted from the physician office to the more-expensive hospital outpatient setting;[7] (ii) the number of Medicare services provided in more expensive HOPDs increased by a third;[8] (iii) the number of vertically consolidated hospitals grew by about 20%;[9] and (iv) the number of physicians practicing in HOPDs nearly doubled.[10] In general, the Proposed Rule contained policies that would have been powerful correctives to this serious reimbursement disparity. Unfortunately, the Final Rule represents a worrisome retreat from CMS's proposals, providing hospitals with many of the same incentives they previously had to purchase physician practices.

A. CMS Should Not Allow an Excepted PBD Unlimited Latitude to Expand the Services It Provides.

We agreed with CMS's statement in the Proposed Rule that Section 603 was intended to "except[] off-campus PBDs **as they existed at the time that Public Law 114-74 was enacted**, including those items and services furnished and billed by such a PBD prior to that time."[11] Consistent with that statement, CMS took the reasonable position that even an "excepted PBD," which had billed for covered services under the OPPS prior to November 2, 2015, should not be allowed to retain this substantial reimbursement advantage if it changes the nature of the services it offers.[12] To that end, the Agency proposed that an excepted PBD could only bill the OPPS for services in the same "clinical family" as the services it billed prior to November 2, 2015.[13] In our comments to the Proposed Rule, we argued that even this expansion undercut Congress's intention of developing a site neutral payment structure and that excepted PBDs should be limited to billing under the OPPS only for those services the excepted PBD *actually provided* in the twelve months prior to November 2, 2015.[14]

In the Final Rule, CMS states that it is unable to implement the "clinical families" concept, in part due to concern that it "could be operationally complex and could pose an administrative burden to hospitals."[15] Instead, the Agency eliminates any limitation on the items and services that can be offered in an excepted PBD.[16] Thus, an excepted PBD will retain the right to bill

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[6] 81 Fed. Reg. at 45684.
[7] Government Accountability Office, *Medicare: Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform*, GAO-16-189 (December 2015) ("GAO Report"), pp. 1, 9; see also 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. 1; MedPAC, *March 2014 Report to Congress* ("MedPAC Report"), p. 75.
[8] OIG Report, p. 1.
[9] GAO Report p. 9
[10] *Id*. at 1.
[11] 81 Fed. Reg. at 45684 (emphasis added).
[12] *Id*. at 45685.
[13] *Id*.
[14] See LUGPA Comments to 2017 OPPS Proposed Rule.
[15] 81 Fed. Reg. at 79707.
[16] *Id*.

under the OPPS for *any* item or service it offers at any point in the future, as long as it retains its "excepted PBD" status which only requires that the PBD not relocate.[17]

We strongly disagree with this major change in policy. CMS is allowing excepted PBDs to expand the types of items and services furnished—or change the very nature of the items and services furnished—while continuing to collect higher reimbursement under the OPPS. The number of existing, excepted PBDs is very high—in 2015, the HHS OIG found that a majority of hospitals had at least one off-campus PBD in place.[18] This kind of open-ended commitment to support higher payments to excepted PBDs means that the hundreds of hospitals that have already absorbed physician practices and converted them into PBDs will continue to enjoy an unfair reimbursement advantage, even if such expansion completely alters the nature of services provided in these pre-existing PBDs. Not only does this policy change continue to undermine the competitive balance between hospitals and independent practices, but it comes with higher costs for Medicare beneficiaries and the healthcare system. Clearly, perpetuating these cost imbalances cannot be what Congress envisioned by legislating a "site-neutral" payment system.

B. Even Without "Clinical Families," CMS Can Operationalize a Method to Ensure "Excepted PBD" Status is Not Abused.

CMS states that its policy towards excepted PBDs is necessary because of operational limitations, including the difficulty of identifying services previously provided in a PBD and classifying these into clinical families.[19] However, as articulated in our comments to the Proposed Rule, we believe CMS can adopt a more straightforward, and less operationally complex, alternative to achieve the goals of Section 603. Specifically, we believe that CMS already has the data it needs to restrict excepted PBDs to billing under the OPPS only for those items and services that were in place at the time Section 603 of the BBA was enacted—November 2, 2015.

We acknowledge that CMS has faced historical limitations on identifying the services provided in a specific off-campus PBD. This is because PBDs were not previously required to report their PBD status. Instead, PBDs submitted claims using a general "place of service" code associated with hospital outpatient departments. However, this changed in 2016 because PBDs are now required to include on claims a new place of service code identifying their status as PBDs.[20] Consequently, CMS now has a clear source of claims data setting out the items and services provided through PBDs. As a result, it should be operationally feasible to develop a list of "grandfathered" items and services for which the PBD may continue to bill under the OPPS. Conversely, PBDs would be required to bill for any new services under the same site neutral rules as "nonexcepted PBDs."

Although CMS only has specific PBD data beginning in 2016, we believe this approach is still more consistent with Section 603 than the policy set forth in the Final Rule that gives excepted PBDs the authority to change or expand the scope of their services while continuing to bill under the OPPS. We acknowledge that using 2016 data would present a potential gap of roughly two months' worth of data (November and December 2015). However, if CMS is concerned that this gap would present an improperly limited baseline, the Agency could hone this process by comparing the 2016 PBD claims to each hospital's historic claims from HOPDs (including for the period prior to November 2, 2015). By definition, because PBDs are a type of HOPD, if an item or service was not delivered through any of a hospital's HOPDs, it also could not have been delivered through any PBD.

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[17] *Id*.
[18] OIG Report at p. 10.
[19] 81 Fed. Reg. at 79707.
[20] 81 Fed. Reg. at 45683.

Accordingly, we urge CMS to modify the portion of the interim final rule that would enable excepted PBDs to bill under the OPPS for any and all items and services and to adopt, instead, a policy that would limit PBD's to billing under the OPPS for those items and services delivered in HOPDs in the year prior to November 2, 2015, and delivered within the specific, excepted PBD in 2016.

III. CMS's Proposal to Adopt a Modified Version of the MPFS as the "Applicable Payment System" for Nonexcepted PBDs Contradicts the Purpose of Section 603 of the BBA and Undermines Congress's Goal of Establishing a Site Neutral Payment Structure.

As noted above, we are concerned that the Final Rule's treatment of "excepted" PBDs will enable existing HOPDs to continue benefiting from inappropriately inflated reimbursement in the future. However, one might at least expect the Final Rule to prescribe genuine site neutral payments for *nonexcepted* PBDs. Nonexcepted PBDs are outpatient departments that either were built on or after November 2, 2015 or expanded in a way that caused the PBD to lose its "excepted" status (e.g., by changing its location). Section 603 of the BBA clearly states that payments to nonexcepted PBDs must be made "under the applicable payment system under [the Medicare statute] if the requirements for such payments are otherwise met."[21] As such, nonexcepted PBDs are precisely the entities for which Congress intended to reduce reimbursement to a level equal to that of physician practices. This would seem to be the *only* method by which CMS could achieve Congress's objective of "curb[ing] the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services."[22] **Yet, surprisingly, CMS has issued an interim final policy that would continue to reimburse nonexcepted PBDs far more than physician practices for providing identical services.** We disagree with this approach and urge CMS to adopt a truly site-neutral payment policy consistent with Section 603 of the BBA.

A. The Interim Final Policy Will Continue to Incentivize Hospitals to Purchase Physicians Practices and Raise Costs for the Medicare Program.

We agree with CMS's decision to treat the MPFS as the "applicable payment system" for most services provided in nonexcepted PBDs.[23] But, the Final Rule goes on to state that, because "hospitals that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is a currently separately valued technical component," the Agency will "establish a new set of payment rates under the MPFS that reflects the relative resource costs of furnishing the technical component of a broad range of services to be paid under the MPFS specific to one site of service (the off-campus PBD of a hospital) with packaging (bundling) rules that are significantly different from MPFS rules."[24] The effect of this policy is clear: **nonexcepted off-campus PBDs will continue to receive a separate facility fee that is not available to physician practices, in direct contravention of Congress's intent in passing Section 603 of the BBA**. This facility fee will continue to inflate the cost of items and services provided within PBDs.

This aspect of the Final Rule contradicts the basic site neutrality principle that lies at the heart of Section 603. The fact that this reimbursement will be made under the MPFS rather than the OPPS is immaterial—the ultimate effect will be a continuation of preferential reimbursement for PBDs, which is ultimately borne by beneficiaries and the Medicare system as a whole. As such,

[21] 42 U.S.C. § 1395L(t)(21)(C).
[22] 81 Fed. Reg. at 45684.
[23] 81 Fed. Reg. at 79721.
[24] *Id*.

this interim final policy will leave intact many of the incentives that hospitals have to acquire physician practices, even for those PBDs that have failed to comply with the minimal standards for "excepted" status established in the Final Rule.

Moreover, it is not evident that CMS has truly established the MPFS as the "applicable payment system" under this interim final policy, because the Agency essentially creates a parallel payment structure under the MPFS that is only available to hospitals and is heavily based on the OPPS. Section 603 is very clear that nonexcepted off-campus PBDs are to be paid "under the applicable payment system . . . **if the requirements for such payment are otherwise met**."[25] Yet in this interim final policy, CMS effectively incorporates core elements of the OPPS into the MPFS to facilitate less administratively burdensome payments to hospitals. In effect, rather than making a payment under the MPFS where "the requirements of such payment are otherwise met," CMS modifies MPFS standards to allow the Agency to make payments to PBDs using OPPS standards. This is inconsistent with the clear instructions of Section 603.

Under the interim final policy, claims submitted by a nonexcepted PBD (to be paid under the MPFS) will be processed by CMS in almost exactly the same manner as those submitted by an excepted PBD (to be paid under the OPPS). The nonexcepted PBD will continue to submit an institutional, rather than a professional, claim to CMS.[26] The Agency will then apply the same bundling rules used under the OPPS to assign the relevant CPT codes on the claim to an Ambulatory Payment Classification ("APC").[27] This APC will be distinct from—and generally will cover many more items and services than—the MPFS non-facility "technical component" payment available to physician offices.[28] Indeed, the interim final policy would allow a nonexcepted PBD to receive a facility fee even when physician offices are unable to claim payment for a similar "technical component" for the same services.[29] The sole difference between the OPPS process for excepted PBDs and the MPFS process for nonexcepted PBDs is that the Agency will then apply an adjustment to this APC, such that the nonexcepted PBD will receive a facility fee that is 50% lower than it would receive under the OPPS.[30] The application of OPPS bundling rules, the use of the hospital/institutional claim form, and the use of an APC-based payment methodology makes it extremely difficult to view this interim final policy as a genuine payment "under the MPFS."

The effect on payments from the Medicare program is potentially staggering. Even the discounted APC rates will result in markedly higher reimbursement for non-excepted PBDs than for physician practices for the majority of CPT codes, eliminating any semblance of a site neutral payment structure. The ongoing payment disparity is illustrated in the following two tables, which show the anticipated 2017 cost differential between the physicians' office, hospital outpatient departments (including excepted PBDs) and non-excepted PBDs (NEPBDs) for the five 5 most commonly performed office procedures and evaluation & management (E&M) services for urology:[31]

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[25] 42 U.S.C. § 1395L(t)(2)(C) (emphasis added).
[26] 81 Fed. Reg. at 79716.
[27] *Id*.
[28] *Id*. at 79722.
[29] *Id*. "[T]he new payment rates for the nonexcepted items and services billed by hospitals under the MPFS will establish a means to report the technical aspect of all applicable items and services under the MPFS, not merely the ones with currently separate values for the component rates."
[30] *Id*. at 79725.
[31] The cost differential reflected in Tables 1 and 2 is based on 2017 reimbursement amounts and 2014 utilization data, which is the most current, publicly available data.

CPT	Descriptor	Number of Services[32]	MPFS[33] Non-Facility Reimbursement	MPFS Facility Reimbursement	APC (OPPS)[34]	Total OPPS[35]	Total NEPBD[36]	Differential, OPPS-Office[37]	Differential, NEPBD-Office[38]
52000	Cystoscopy	680,302	167.97	105.52	549.21	654.73	380.12	331,144,753.94	144,330,423.23
51798	Measurement of PVR urine	1,829,179	19.74	-	54.53	54.53	27.27	63,638,052.00	13,774,632.46
55700	Biopsy of prostate	74,172	253.38	136.02	1,643.96	1,779.98	958.00	113,230,952.95	52,263,052.39
51728	Cystometrogram w/vp	48,307	321.22	-	549.21	549.21	274.61	11,013,730.31	(2,251,613.42)
52281	Cystoscopy and urethral dilation	46,824	279.22	158.27	1,643.96	1,802.23	980.25	71,313,453.02	32,825,061.50
							Total Cost Differential for In-Office Procedures:	**$590,340,942.22**	**$240,941,556.15**

Table 1: Projected Cost Differential for top 5 In-Office Procedures based on 2014 Medicare Expenditures

CPT	Descriptor	Number of Services	MPFS Non-Facility Reimbursement	MPFS Facility Reimbursement	APC (OPPS)	Total OPPS	Total NEPBD	Differential, OPPS-Office	Differential, NEPBD-Office
99214	Follow-Up, Moderate	2,340,774	108.75	79.68	106.56	186.24	132.96	181,384,486.06	56,668,036.69
99213	Follow-Up, Intermediate	3,474,172	73.93	51.68	106.56	158.24	104.96	292,901,196.24	107,797,306.75
99204	New Patient, Moderate	481,351	166.17	131.72	106.56	238.28	185.00	34,708,102.67	9,061,721.39
99203	New Patient, Intermediate	332,391	109.46	77.88	106.56	184.44	131.16	24,921,613.53	7,211,821.05
99215	Follow-up, Complex	207,113	146.43	112.69	106.56	219.25	165.97	15,082,672.84	4,047,692.20
							Total Cost Differential for In-Office Procedures:	**$548,998,071.34**	**$184,786,578.08**

Table 2: Projected Cost Differential for top 5 In-Office E & M Codes based on 2014 Medicare Expenditure

[32] Centers for Medicare and Medicaid Services, Medicare Provider Utilization and Payment Data: Physician and Other Supplier, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html. 2014 Data; CPT codes represent highest expenditures for office-based services excluding imaging, laboratory and Part B drugs.

[33] 2017 Medicare Physician Fee Schedule Final Rule, CMS 1654-F, Appendix B; note that the MPFS facility reimbursement reduces or eliminates the practice expense component of the RVU calculation for that CPT code

[34] 2017 Medicare Outpatient Prospective Payment System Final Rule with Comment Period and Interim Final Rule with Comment Period, CMS-1656-FC and IFC.

[35] Total OPPS fee (which is the same as excepted PBDs) is the sum of the OPPS APC fee plus the MPFS facility reimbursement for each CPT code.

[36] Total NEPBD fee is the sum of the 50% of the OPPS APC fee plus the MPFS facility reimbursement for each CPT code.

[37] OPPS-Office cost differential is the product of the number of cases and the difference between Total OPPS fee and MPFS non-facility reimbursement.

[38] NEPBD-Office cost differential is the product of the number of cases and the difference between Total NEPBD fee and MPFS non-facility reimbursement.

The data in Tables 1 and 2 illustrates how profound the incentive has been—and continues to be—for hospitals to acquire physician practices and convert them into off-campus PBDs. Prior to Congressional action in 2015, hospitals' continued acquisition of physician practices, if left unchecked, could have resulted in a potential increase in expenditures of over $1.1 *billion annually* for just the one specialty of urology.[39] The purpose of Section 603 of the BBA was to eliminate this economic incentive by establishing a site neutral payment structure between off-campus PBDs and physician practices. But, as Tables 1 and 2 show, there remains a massive payment disparity not only between physicians' offices and HOPDS (including excepted PBDs), but between physicians' offices and non-excepted PBDs as well. For example, two of the top five CPT codes by Medicare expenditure for urology in 2014 were biopsy of the prostate (CPT 55700) and cystoscopy with urethral dilation (CPT 52281); the practice expense component of these codes was $117.36 and $120.95, respectively.[40] If a hospital acquired an office that performed such procedures after passage of the BBA (creating a non-excepted PBD), the facility cost for these procedures would immediately increase to $821.98,[41] despite being performed by the same physicians using the same staff in the same location. Clearly, the payment disparity perpetuates the incentive for hospitals to continue acquiring physician practices. In fact, ***in examining 10 CPT codes in the field of urology alone there is a $425 million spread between what those services would cost in a non-excepted PBD and what they would cost in the physician office setting.***[42] There is nothing "neutral" about such a payment structure and clearly is not what Congress intended when it passed Section 603 of the BBA.

B. The Agency Has Not Provided Adequate Support for Its Interim Final Rule.

CMS provides little justification for this increased reimbursement. The Agency references "concerns regarding some of the information currently used to develop RVUs for payment rates under the MPFS," citing a discussion of the valuation of PE RVUs in the 2015 MPFS Final Rule.[43] Notably, in that instance, CMS ultimately *rejected* a proposal to link nonfacility PE RVU rates to OPPS or ASC facility payments, after "the vast majority" of commenters "urged [CMS] to withdraw the proposal."[44] In that case, CMS was "persuaded that the comparison of OPPS (or ASC) payment amounts to PFS payment amounts for particular procedures is not the most appropriate or effective approach to ensuring that PFS payment rates are based on accurate cost assumptions."[45] Yet, in the Final Rule, CMS adopts essentially the same position it previously rejected to justify a separate payment system within the MPFS for nonexcepted PBDs, stating that "the quality of the data currently used to develop payment rates under the OPPS, including hospital claims data and cost reporting, far exceeds the quality of data currently used for MPFS payments."[46]

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[39] The $1.1 billion estimate is based on the sum of the OPPS-Office cost differential for the top five most commonly billed in-office procedures of $590,340,942.22 and the OPPS-Office cost differential for the top five most commonly billed E&M codes of $549,998,071.34.

[40] The practice expense component of a procedure can be approximated by calculating the difference between the facility and non-facility MPFS reimbursement.

[41] Facility cost for nonexcepted PBDs are 50% of the OPPS APC for the procedure; CPT 55700 and 52281 both utilize APC 5373 – with OPPS rate of $1643.96.

[42] The estimate of $425 million is the sum of the NEPBD-Office cost differential for the top five most commonly billed in-office procedures of $240,941,556.15 and the NEPBD-Office cost differential for the top five most commonly billed E&M codes of $184,786,578.08. The 10 CPT codes included in Tables 1 and 2 account for 68.8% of all Medicare expenditures in urology (including imaging and laboratory but excluding Part B drugs).

[43] 81 Fed. Reg. 79722, citing 79 Fed. Reg. 67548, 67568 (Nov. 13, 2014).

[44] 79 Fed. Reg. at 67568.

[45] *Id*.

[46] 81 Fed. Reg. 79722.

In reality, CMS has very little historical data on the costs associated with operating a PBD, because the Agency's data systems have not allowed it to isolate and analyze these entities. Indeed, the HHS OIG found that "CMS's data systems were inadequate for managing provider-based status," because "CMS could not identify: (1) the number of hospitals denied provider-based status or (2) hospitals billing as provider-based."[47] Further, OIG determined that CMS was not able to "identify off-campus provider-based-facility billing" until January 2016, when the Agency mandated the use of new place of service codes representing PBD status.[48] Even so, the OIG determined that "CMS's inability to identify all facilities billing as provider-based limits its full enforcement of the [BBA]," because "[b]efore January 2016, CMS could not distinguish billing from on- and off-campus provider-based facilities owned by the same hospital, or among multiple off-campus provider-based facilities" such that "CMS cannot create a population of off-campus provider-based facilities that should be grandfathered (i.e., exempt) from [the BBA]."[49]

Even now that CMS is able to distinguish between these facilities, the data collected from the facilities might be suspect because non-compliance with PBD standards is extremely common. The OIG found that nearly two-thirds of hospitals with PBDs did not attest that all PBDs were compliant with CMS rules; and three-quarters of these non-attesting hospitals owned PBDs that failed to meet at least one PBD requirement.[50] Indeed, the OIG discovered that eight of the ten CMS regional offices responsible for assessing compliance with PBD regulations "reported challenges with the provider-based review process primarily because they experienced difficulties obtaining documentation from hospitals."[51] Taken together, these findings demonstrate that CMS has little ability to distinguish costs attributable to an off-campus PBD from those attributable to other kinds of HOPDs. It is therefore unlikely that allegedly "higher quality" hospital data could provide CMS with superior insights about the *specific* operational costs of most PBDs.

C. CMS Should Adopt the Site Neutral Policy it Proposes for Future Years and Ensure that Hospitals Do Not Receive an Unwarranted Financial Windfall Under the Interim Final Rule.

CMS requests comment on two alternative policies for future years. First, CMS proposes a more genuinely site neutral policy to take effect in 2019. Under this policy, CMS would pay nonexcepted off-campus PBDs "at a MPFS-based rate that would reflect the relative resources involved in furnishing the services."[52] This would be a true site-neutral policy, because it would equalize Medicare payments between PBDs and physician practices for most services. However, CMS currently believes it will be another two years until the Agency can operationalize this kind of modification. Second, the Agency sets forth an alternative approach similar to the interim final policy for 2017, whereby off-campus PBDs would be paid at a rate based on the OPPS.[53] CMS notes that this approach would attempt to equalize payment rates between off-campus PBDs and physician practices "in the aggregate," but that these rates may not equalize for certain "specialties, service lines, and nonexcepted off-campus PBD types."[54]

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[47] OIG Report at 7.
[48] *Id*. at 11.
[49] *Id*. at 12.
[50] *Id*. at 10, 13.
[51] *Id*. at 14.
[52] 81 Fed. Reg. 79728.
[53] *Id.*
[54] *Id.*

We support the first of these options—a truly site-neutral policy in which reimbursement for each CPT Code is equalized to the greatest degree possible. This proposed policy is the **only** method that achieves Congress's objective of ending payment disparities that create incentives for hospitals to purchase practices and results in greater costs for Medicare beneficiaries and the healthcare system as a whole. And CMS seems to agree, stating 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."[55] However, CMS does not believe it can implement this policy until 2019.

While we understand the operational challenges CMS faces, we are concerned that the Agency intends to maintain a policy in 2017 and 2018 that will continue to incentivize hospitals to acquire physician practices, placing a greater financial strain on the Medicare system. In effect, the Agency has provided hospitals with a *de facto* two year extension of the policy that Congress sought to curtail. Accordingly, we ask the Agency to consider ways in which it can mitigate the continuing incentives for hospitals to purchase physician practices over the next two years, including the adoption of a transitional policy for 2017 and 2018 that would allow a subset of certain items and services to be billed on a truly site neutral basis. Alternatively, we ask CMS to explore program integrity methods (such as audits and, where necessary, recoupments of overpayments made to PBDs) to ensure that hospitals are not abusing the interim period necessitated by the Agency's operational limitations. We believe a public commitment to this kind of review would be an effective counterbalance to the incentives that the Final Rule provides hospitals to continue purchasing physician practices over the next two years.

IV. Request for Action

We appreciate CMS's efforts to implement site neutrality standards that will bring greater parity to the healthcare system. However, we are greatly concerned by certain deviations in the Final Rule from positions that the Agency had taken in the Proposed Rule. These changes are so significant—and could come with such a potentially steep cost to the Medicare system (approaching half a billion dollars annually in the field of urology alone if hospital acquisition of physician practices were left unchecked)—that they risk undermining the entire purpose for which Congress enacted Section 603 of the BBA.

We urge the Agency to take the following steps to modify the Final Rule and enact policy that is more consistent with Congress's objectives:

- CMS should reverse its policy of allowing excepted PBDs to bill under the OPPS for *any* service, as long as the PBDs retain "excepted" status. Instead, the Agency should use the specific PBD data it has collected since January 2016 to identify the items and services billed through the PBD and restrict billing under the OPPS to these items and services.
- CMS should reverse its interim final policy of allowing nonexcepted PBDs to bill for a special, heightened facility fee under the MPFS. Without making such a change, the Agency cannot credibly claim that it is implementing a site neutral payment structure as required by Section 603 of the BBA.
- CMS should move forward with its proposal—targeted for implementation in 2019—to create a payment policy for nonexcepted PBDs that is more aligned with

[55] Id. at 79727-8.

physician office rates under the MPFS. The Agency should develop policies to mitigate the continuing incentives that hospitals have to purchase physician practices—thereby shifting care out of the more cost-efficient independent practice setting—until such a new payment policy takes effect.

On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the Final Rule. Please feel free to contact Dr. Kapoor at (516) 342-8170 or dkapoor@impplc.com, or Howard Rubin at (202) 625-3534 or howard.rubin@kattenlaw.com, if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,

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