Charles N. Kahn III
President and CEO

January 3, 2017

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445–G
Washington, DC 20201

RE: CMS-1656-FC and IFC, 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

Dear Acting Administrator Slavitt:

The Federation of American Hospitals ("FAH") is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay acute, inpatient rehabilitation, long-term acute care, psychiatric and cancer hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. The FAH appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services ("CMS") on the above final rule with comment period ("Final Rule") and interim final rule with comment period ("IFC") published in the Federal Register (81 Fed. Reg. 79,562) on November 14, 2016 and on implementation of section 16001 of the 21st Century Cures Act (Pub. L. 114-255).

Executive Summary

The FAH respectfully requests that CMS continue providing payment under the Outpatient Prospective Payment System ("OPPS") for all items and services in an excepted provider-based department ("PBD"). The FAH supports CMS's decision to decline to adopt the service line limitations articulated in its CY 2017 OPPS proposed rule in light of the significant administrative and operational issues associated with such limitations. As discussed in our detailed comments below, any limitation on the volume or types of services furnished in an excepted PBD and reimbursed under OPPS would be administratively burdensome, run contrary to Congress' intent, and not readily implementable based on claims data. Any such limitation would be particularly problematic for excepted PBDs that began operations shortly before the enactment of the Bipartisan Budget Act of 2015.

The FAH appreciates and supports CMS's development of a process for directly paying hospitals for items and services furnished in nonexcepted, off-campus PBDs under a special Medicare Physician Fee Schedule ("MPFS") rate. The FAH, however, urges CMS to adjust its methodology to use the full, non-facility practice amount under the MPFS and to adjust for the impact of packaging when setting the special MPFS rate. These adjustments support a higher payment rate of 64 percent of the OPPS rate, rather than the 50 percent provided for in the IFC. The special MPFS amount for ambulatory procedure code ("APC") 8010 (Mental Health Services Composite) should also be adjusted to mirror the reimbursement amount for partial hospitalization program ("PHP") services furnished in nonexcepted, off-campus PBDs.

The FAH further requests that CMS issue further sub-regulatory guidance on the implementation of Section 15001 of the 21st Century Cures Act, which deems PBDs for which a provider-based attestation was submitted prior to December 2, 2015 to be excepted PBDs for CY 2017 and establishes an alternative exception for mid-build departments in CY 2018 and thereafter. Because the deadline to complete the requirements for the alternative exception will run to February 13, 2016, the FAH requests that CMS clarify its expectations with regard to the required certification statement and document retention obligations through sub-regulatory guidance. In addition, the FAH urges CMS to clarify that the mid-build requirement is met where the signed written contract with an unrelated third party is contained in a lease with build-out obligations for the lessor, an agreement with a contractor for physical renovations, or a construction agreement with a developer.

Lastly, the FAH requests that CMS decline to link eligibility for payment for PHP services to the provision of 20 hours of therapeutic services per week. The 20-hour requirement is a prospective eligibility requirement based on the plan of care, and payment should not be denied where that requirement was met but, due to unforeseen circumstances, the beneficiary did not receive 20 hours of services in a given week.

The FAH requests that CMS Continue to Provide Payment Under the OPPS for All Items and Services Furnished in an Excepted PBD Regardless of the Volume or Types of Services Previously Furnished in the Excepted PBD

The FAH appreciates and supports CMS's decision in the Final Rule not to limit service line expansions in excepted, off-campus PBDs due to operational complexities and

administrative burdens on hospitals, CMS, and CMS contractors. ***The FAH further urges CMS to maintain this policy and decline to impose any additional restrictions on excepted PBDs while it monitors provider behavior over the coming years in ways that do not unreasonably burden hospitals or patients.*** The enactment of Section 603 on November 2, 2015 itself has significantly curtailed the acquisition of physician practices and the creation of new, off-campus PBDs in accordance with Congress' intent. Efforts to further restrict the ability of providers to serve their communities through existing, excepted PBDs would be inconsistent with Congress' intent and would unduly burden providers and the communities they serve. In particular, any limitations on service volumes or types would improperly penalize those providers with excepted PBDs that were not operating at capacity during any baseline period used to prospectively limit service volumes or types.

A. The Statutory Language of Section 603 Precludes the Imposition of Limits on Service Volumes or on the Types of Services Furnished in Excepted PBDs.

The FAH continues to maintain that Congress did not authorize limitations on the service lines or volumes furnished by an excepted PBD and respectfully urges CMS to decline to impose limitations on the volume or types of OPPS-reimbursable items and services furnished in excepted PBDs in accordance with the language and intent of Section 603. CMS has asserted that it has 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" and "limit the volume of services furnished to the level that was furnished prior to the date of enactment." 81 Fed. Reg. at 79,707. This assertion, however, is in tension with the statute's focus on excepted *departments* rather than excepted *items and services* and Congress' express direction that the term "department of a provider" maintains the definition in effect on November 2, 2015.

Section 603 defines "off-campus outpatient department of a provider" to exclude a "department" that was billing under OPPS with respect to covered outpatient department services furnished prior to November 2, 2015. Social Security Act § 1833(t)(21)(B)(ii). This provision expressly focuses on the excepted status of the off-campus PBD itself, not the excepted status of individual items or services provided in the PBD. To treat a PBD as excepted one day but not the next, or for certain types of items and services but not others, runs contrary to the statutory language itself. Instead, the plain language of the statute fully exempts PBDs billing under OPPS before November 2, 2015, from Section 603's site neutrality rule, regardless of any increase in the PBD's service volumes or changes to the its service mix. Along these lines, Congress specifically considered and rejected distinctions based on the services furnished by an excepted department when, through a floor amendment, Congress choose to except dedicated emergency departments in their entirety rather than only excepting a select group of emergency services. ***The FAH strongly urges CMS to give effect to Congress' clear intent by continuing its current policy, under which any item or service furnished in an excepted, off-campus PBD is furnished in a department that is not an "off-campus outpatient department of a provider" under Section 603 and may be paid under OPPS regardless of whether the volume of items and services furnished at that PBD has increased compared to a baseline period or whether that type of item or service was furnished to a Medicare patient prior to November 2, 2015***.

Moreover, CMS's proposed rule is fundamentally in tension with its previous interpretation of a "department" of a provider. As CMS notes, Section 603 refers to the regulatory definition of a "department of a provider" that was in place as of November 2, 2015. *E.g.*, 81 Fed. Reg. at 79,702. CMS's operative guidance at that time made clear that the PBD and the service lines offered by a PBD are distinct, clarifying in express terms that the PBD is the site-specific department, not any group or cluster of clinical services offered in the PBD. In its program memorandum on provider-based status, CMS states, **"The provider-based rules *do not apply to specific services*; rather these rules are *site-specific*."** CMS, Transmittal A-03-030, Provider-Based Status On or After October 1, 2002, Part E(1) (April 18, 2003) (emphasis added). CMS further clarifies that a provider seeking to attest for its PBDs would attest for each of its "facilities," which may be "an entire building, two or more buildings, or defined areas within a building." *Id.* Thus, as of November 2, 2015, neither the expansion of service volumes nor the addition of new service lines to an existing PBD created a new PBD. This interpretation of the regulation defining "department of a provider" was the operative interpretation as of November 2, 2015, and as CMS concludes, Congress adopted CMS's existing definition and interpretation of PBD for Section 603 purposes. Thus, CMS lacks congressional authority to deny OPPS payments to excepted, off-campus PBDs that render items and services not previously offered by that PBD.

In the Final Rule, CMS highlights the reference to "personnel and equipment needed to deliver the services at the facility" in the regulatory definition of "department of a provider" at 42 C.F.R. § 413.65(a)(2). In context, however, it is clear that changes in equipment, personnel, or services do not create a new or different PBD. To our knowledge, CMS has never required or advised providers that a change in personnel, equipment or services at an existing PBD requires any changes to the hospital's enrollment or warrants the submission of a new, voluntary provider-based attestation. *See* 42 C.F.R. § 424.516(e), CMS, Form 855A § 4, Medicare Enrollment Application, Institutional Providers; CMS, Transmittal A-03-030, Provider-Based Status On or After October 1, 2002, Part E(1) (April 18, 2003). Instead, the statement that a provider-based department is comprised of the "personnel and equipment needed to deliver the services at that facility" as well as the "specific physical facility" clarifies that the personnel and equipment must be under the main provider's financial and administrative control. Instead, existing PBDs have been free to add new service lines or increase service volumes without becoming new PBDs as long as the services are "of the same type as those furnished by the main provider." 42 C.F.R. § 413.65(a)(2).

Finally, the imposition of volume or service line limitations on a PBD is inconsistent with Congress' clear direction that a PBD's excepted status under Section 603 is based on the date it began furnishing covered outpatient department services billed under OPPS. The plain language of Section 603—consistent with CMS's interpretation—only requires that a PBD have furnished a single, covered outpatient department item or service to a Medicare beneficiary prior to November 2, 2015 and timely billed for that item or service under OPPS in order for the PBD to be excepted under section 1833(t)(21)(B)(ii). Thus, a PBD could have begun operations on the afternoon of November 1, 2015 and be excepted to the same extent as a PBD that had been in operations for many years and was operating at capacity. This is true even though the newer PBD was not furnishing the full volume and range of items and services that it was designed to furnish prior to November 2, 2015. Congress' passage of the 21st Century Cures Act, Public Law 114-255 further confirms its intent that an excepted PBD's service volumes or types should

not be restricted based on prior performance. Under section 16001 of Public Law 114-255 ("Section 16001"), a PBD is deemed to be excepted in 2017 based exclusively on the date it submitted its provider-based attestation. Section 16001 also creates an alternative exception for PBDs that were mid-build prior to November 2, 2015, as long as the provider adds the PBD to its hospital enrollment and timely submits a provider-based attestation and certification of mid-build status. A limitation on excepted items and services based on volume or on service types would wholly undo Congress' clear intent to exempt newer PBDs to the same extent as existing PBDs. ***The FAH, therefore, respectfully urges CMS to decline to implement any service volume or line limitations for excepted PBDs, recognizing Congress' intent to curtail the creation of new PBDs rather than limit the operation of existing or mid-build PBDs.***

B. A Limitation on Service Volumes or Types Would Produce Unacceptable Variability in a Medicare Beneficiaries' Copayment Rates at a Single PBD

Adopting any limitation on the particular items and services rendered at an excepted PBD would result in Medicare beneficiaries facing vastly different copayment obligations at a single hospital outpatient department, producing beneficiary confusion and inequity. For example, if CMS were to adopt an annual volume cap on services, a Medicare beneficiary that undergoes an outpatient procedure on December 15th might incur a copayment obligation that is approximately double that of a Medicare beneficiary receiving the same procedure on the next day. Similarly, if CMS adopted limitations based on service types, a Medicare beneficiary might face one copayment rate for an x-ray and another copayment rate for an MRI furnished in the same hospital imaging department. ***The FAH urges CMS to minimize beneficiary confusion by treating all items and services rendered at an excepted PBD as excepted under 42 C.F.R. section 419.48.***

C. A Limitation on Service Volumes Would Improperly Penalize Newer, Excepted PBDs, Contrary to Congress' Intent.

In its comments on the proposed rule of July 14, 2016, CMS–1656–P (81 Fed. Reg. at 45,604), however, the Medicare Payment Advisory Committee ("MedPAC") suggests limiting the volume of OPPS-reimbursable services furnished by an excepted PBD by imposing a volume cap from a baseline time period and then switching from OPPS to MPFS reimbursement once the cap is met in a year. This approach cuts against Congress' clear intent by differentiating between newer and older excepted PBDs based on whether the PBD was established enough to operate at capacity during the baseline period. It also penalizes providers that temporarily suspended or reduced services at an excepted PBD during the baseline period in order to make needed renovations or repairs or due to difficulties in recruiting needed health professionals to replace professionals that retire or relocate. In addition, the proposed policy would disincentive innovations that improve efficiency in outpatient departments because excepted PBDs would be unable to benefit from the increased capacity generated by the more efficient delivery of care. It would also constrain a provider's ability to reshuffle service lines among excepted PBDs to consolidate complimentary services in ways that improve the accessibility of existing service lines. Finally, a volume-based cap on the OPPS-reimbursable items and services rendered in an excepted PBD would improperly fail to differentiate between providers that organically grow to meet community needs through existing, excepted PBDs and providers that acquire new physician practices to establish new, off-campus PBDs. Population growth or demographic

changes may naturally increase the volume of services rendered by the excepted PBD, and a policy that penalizes providers for responding to changing community needs is contrary to both the language and intent of Section 603.

In sum, the FAH strongly opposes the imposition of any limitation on the volume of services furnished by an excepted PBD because such a policy is not statutorily authorized, unduly penalizes excepted PBDs that were operating below capacity during the baseline period, disincentivizes efficiency-oriented innovations that improve the capacity of excepted PBDs, penalizes the reorganization of existing outpatient services among excepted PBDs in ways that better serve the community, and improperly conflates organic growth with acquisition-fueled growth.

From an operational standpoint, MedPAC's proposal to cap service volumes from a baseline period is likewise administratively complex and unduly burdensome. As CMS has noted, claims data is not adequate to identify those services provided in a particular PBD. This precludes the establishment of a service volume cap for each excepted PBD. CMS did not require submission of the "PO" modifier that identifies services furnished in off-campus PBDs until January 1, 2016 or nearly two months after sections 603 was enacted. In addition, the annual adjustments to the service volume cap for an excepted PBD would need to take into account the service mix furnished at that PBD and the varying impact of the OPPS payment rate updates for the relevant service lines. This calculation would be particularly complex as the assignment of APCs and the bundling of services continues to evolve in ways that have varying impacts on different PBDs. ***In light of the operational difficulties associated with imposing and adjusting any service volume cap on PBDs, the FAH urges CMS to decline to impose any such cap.***

Should CMS nonetheless propose or adopt any cap on OPPS-reimbursable services rendered by an excepted PBD, ***the FAH strongly opposes the use of the baseline period proposed by MedPAC.*** MedPAC's comments proposed using the 12-month period that preceded November 2, 2015 (*i.e.*, November 2, 2014 through November 1, 2015) as a baseline for volume caps. This approach would effectively bar excepted PBDs that began operations any time during the year before the enactment of Section 603 from being fully excepted from Section 603, contrary to the plain text of Section 603. In addition, providers have undertaken capacity-building improvements to excepted PBDs since the enactment of Section 603 without notice that CMS would limit service volumes based on pre-November 2, 2015 service volumes, and these providers should not be penalized by the use of a baseline period that predates the effective date of any policy limiting service volume expansions. ***Instead, the FAH respectfully requests that any baseline period run no earlier than the 12-month period immediately prior to the effective date of the policy, or, for excepted PBDs that began operations within the 5-year period prior to the effective date of the policy, the 12-month period following the PBD's fifth year of operations.*** This approach provides a greater assurance that each excepted PBD was operating at or near capacity during the baseline period.

In addition, any cap would need to be adjusted for any excepted PBDs that, for various reasons, were operating below capacity during the baseline period. This may be due to workforce issues or renovations during a time that later becomes a baseline reference period. The renovation of PBDs is wholly permissible and consistent with the language and purpose of

Section 603. Likewise, Congress did not intend to penalize those providers that were unable to fill essential positions during a baseline reference period. However, absent an exceptions process, any cap would retroactively penalize providers that made needed investments in their excepted PBDs and therefore operated at less than full capacity during the baseline period. ***Therefore, if CMS proposes a cap on service volumes, the FAH strongly urges CMS to adopt a robust exceptions process to address situations where service volumes during the baseline period are inconsistent with the excepted PBD's actual capacity.***

Finally, the FAH requests that any dollar-based cap on OPPS-reimbursable services furnished in an excepted PBD be adjusted annually, not only based on market basket increases to the OPPS payment rates, but also based on changes in utilization among Medicare beneficiaries, demographic changes in the community served by the excepted PBD, and efficiency improvements in certain service lines. These national- and facility-specific adjustment are necessary to attempt to differentiate between natural reimbursement growth due to increased rates, demand, or efficiency and acquisition-fueled growth.

D. A Limitation on Service Types or Clinical Families is Unworkable.

CMS also requests comments addressing how a limitation on lines of service would work in practice. The FAH reiterates its concerns that limiting OPPS reimbursement to particular "clinical families of services" or imposing any other limitation on the types of services furnished by excepted PBDs is unworkable and administratively burdensome. As described in the FAH's September 6, 2016 comment letter on the Proposed Rule (incorporated here by reference), providers and CMS would face difficulties in identifying the excepted items and services because, *inter alia*, (1) claims for PBDs do not necessarily identify the particular excepted PBD in which the service was furnished, (2) the dynamism around APCs and bundling creates uncertainty as to those items and services that are excepted, (3) the American Medical Association modifies the Healthcare Common Procedure Coding System ("HCPCS") codes comprising APCs on a regular basis, and (4) medicine evolves, creating new procedures or enabling providers to furnish procedures on an outpatient basis. In addition, as the FAH's comment letter on the proposed rule explains, the list of clinical families proposed by CMS does not cover the full range of items and services that might be rendered by an outpatient department and misclassifies certain items and services. ***The FAH therefore urges CMS to decline to impose any limitation on the lines of service furnished by an excepted PBD.***

Payment Policy for Outpatient Services Furnished in Nonexcepted, Off-Campus PBDs

The FAH thanks CMS for responding to the significant concerns expressed by the FAH and others by finding an option to allow hospitals to bill for nonexcepted, off-campus PBD items and services using the institutional claim form (UB04/837I) and to be directly paid for these services. Hospitals deserve to be paid at a reasonable rate for the critical and high-quality care they provide to Medicare beneficiaries, including care furnished in nonexcepted, off-campus PBDs. ***Paying individual health care professionals for the hospital's services was an untenable policy, and the FAH fully supports CMS's decision in the IFC to directly pay hospitals for items and services furnished in nonexcepted, off-campus PBDs.*** In addition, the FAH supports CMS's use of the institutional claim for these items and services and recommends its continued use for nonexcepted items and services. As nonexcepted, off-campus PBDs remain

part of the hospital, it is appropriate for these sites to continue using the institutional claim form. As CMS notes in the IFC, use of the institutional claim will appropriately facilitate accurate cost reporting and coordination with the Provider Statistical and Reimbursement ("PS&R") Report, which uses institutional claims as its source.

The FAH, however, is concerned that CMS's methodology for calculating the special MPFS rate unnecessarily depresses payment for nonexcepted items and services. When using the full, non-facility MPFS and adjusting for packaging as well as the indirect costs of operating a hospital department, the FAH's analysis supports a MPFS-based payment at 64 percent of OPPS rather than the 50 percent set forth in the IFC. The FAH, therefore, urges CMS to increase the special MPFS rate to 64 percent of OPPS for CY 2017. Further refinements to the transitional payment methodology for nonexcepted items and services may be warranted in CY 2019 and subsequent years, once data becomes available. At this stage, however, the FAH supports the continued use of a special MPFS rate based on a percentage reduction in the OPPS rate rather than an exclusively MPFS-based payment rate because MPFS data is flawed, particularly when applied to the hospital outpatient context.

A. The FAH Strongly Urges CMS to Increase the Special MPFS Rate Paid to Nonexcepted, Off-Campus PBDs for CY 2017 and CY 2018 to 64 Percent of the OPPS (a Payment Reduction of 36 Percent) and Opposes any Further Reduction in Payment Below 50 Percent of OPPS

In the IFC, CMS establishes the MPFS as the "applicable payment system" under Section 603 for items and services furnished in nonexcepted, off-campus PBDs. CMS also conducted analyses of the relationship between OPPS rates and the MPFS and ambulatory surgery center rates, adopting an interim final payment rate to be used for nonexcepted items and services furnished by off-campus PBDs. In general, these locations will receive a special MPFS rate that equates to 50 percent of the OPPS payment. Reimbursement for items and services that are already paid under other Medicare Part B payment systems (*e.g.*, separately payable drugs and laboratory services) are unaffected by Section 603 and will continue to be paid under those other (non-OPPS) payment systems and rates.

CMS determined this 50 percent adjustment by analyzing the 22 HCPCS codes that were most commonly billed with the "PO" modifier used for off-campus PBDs between January 1 and August 26, 2016, and determining a ratio between the OPPS payment rate and an estimate of the amount that would have been paid to the physician in the office setting under the MPFS for practice expenses not associated with the professional component of the service. CMS presented their analysis in Table X.B.1 of the rule, and based on this table, estimated that the weighted average ratio between the estimated MPFS technical payment amount and the OPPS payment rate was 45 percent, when using national payment rates. They used this figure in concert with an ASC-to-OPPS payment ratio of 55 percent to establish an interim final payment rate of 50 percent of OPPS for nonexcepted, off-campus PBDs. (81 Fed. Reg. at 79,722 – 79,725).

1. The FAH Recommends that CMS use the Full Non-Facility Practice Amount to Compare MPFS and OPPS Payments

We believe it is important to note that CMS's comparison was often based on a portion of the non-facility MPFS rate and not the full payment rate that Medicare makes under the MPFS for practice expenses in a physician's office. For services where Medicare's MPFS payment is undifferentiated between facility and non-facility, the full MPFS payment for practice expenses was used in this comparison. However, where the MPFS payment is differentiated by facility and non-facility, CMS used the difference between the non-facility and facility payment to make the comparison. Thus, in many cases, CMS is not using the full Medicare payment under the MPFS for practice expenses for the comparison. Instead CMS used an amount that represents only the direct costs of the service and includes no compensation for the indirect costs that a hospital continues to incur when a service is provided in the hospital outpatient department, irrespective of whether it is subject to section 603.

The FAH recommends using the full non-facility MPFS practice expense payment in all cases as a hospital continues to incur indirect costs when a service is provided in the off-campus outpatient department. Section 603 does not require that CMS implement site-neutral payment between physician offices and nonexcepted, off-campus PBDs or even reference site neutrality. Instead, Section 603 merely directs the Secretary not to pay for services provided in a nonexcepted, off-campus PBDs under the OPPS and instead pay for these services under the "applicable payment system." If CMS used the full amount that Medicare makes for practice expenses, the MPFS payment as a percent of the OPPS payment would be substantially higher than the 45 percent weighted average ratio between the estimated MPFS technical payment amount and the OPPS payment rate.

In the following table, we illustrate how the comparison of the estimated MPFS technical payment amount and the OPPS rate would change if the full MPFS practice expense payment amount were used rather than the difference between the non-facility and the facility amount for the 5 procedures[1] among the 22 where the MPFS payment is differentiated between facility and non-facility sites. In addition, we have also included the two most common evaluation and management services (current procedural terminology ("CPT") codes 99213 and 99214) to the table. Although CMS did not include these codes when calculating the weighted average, CMS considered its estimate of the MPFS payment rate for these services (calculated at 21 and 28 percent of the OPPS rate) in ultimately arriving at the interim final payment rate of 50 percent of the OPPS rate. In each case, the inclusion of the full MPFS practice expense rate increases the estimated MPFS payment rate by between 3.4 and 21.4 percentage points.

[1] Table X.B.1 indicates six procedure codes where CMS used the difference between the non-facility and facility MPFS amount in the comparison but payment is not differentiated by non-facility and facility for one of these procedure codes (96365).

Table 1 - MPFS Non-Facility Practice Expense as a Percent of the OPPS

Code	Title	CY 2016 MPFS Payment Amount Used by CMS	CY 2016 OPPS Payment Rate	MPFS as % of OPPS	CY 2016 MPFS Full Non-Facility Practice Expense	Revised MPFS as % of OPPS	Percentage Point Difference
93798	Cardiac rehab/monitor	$ 11.10	$ 103.92	10.7%	$ 14.68	14.1%	3.4%
90853	Group psychotherapy	$ 0.36	$ 69.65	0.5%	$ 3.94	5.7%	5.1%
20610	Drain/inj joint/bursa w/o us	$ 13.96	$ 223.76	6.2%	$ 28.64	12.8%	6.6%
11042	Deb subq tissue 20 sq cm/<	$ 54.78	$ 225.55	24.3%	$ 77.70	34.4%	10.2%
90834	Psytx pt&/family 45 minutes	$ 0.36	$ 125.04	0.3%	$ 11.10	8.9%	8.6%
99213	Office/outpatient visit est	$ 21.86	$ 102.12	21.4%	$ 36.16	35.4%	14.0%
99214	Office/outpatient visit est	$ 29.02	$ 102.12	28.4%	$ 50.84	49.8%	21.4%

The five codes for which CMS's analysis uses the difference between the facility and non-facility MPFS amounts to estimate the MPFS technical payment amount constitute the five codes with the lowest ratios between the MPFS estimate and the OPPS payment amount, skewing the weighted average toward the lower end. Altering the methodology used to estimate the MPFS technical payment amount moderates the extent to which these codes depress the weighted average percentage calculated by CMS.

The largest increases are for CPT codes 99213 and 99214, which CMS considered in establishing the interim final rate but excluded when calculating the weighted average percent difference between the estimated MPFS technical payment amount and the OPPS payment rate. CMS's exclusion of these codes from the calculation in Table X.B.1 was based on its recognition that the MPFS and OPPS rates are not comparable given the "extensive packaging" that occurs under the OPPS for services provided along with clinic visits. (81 Fed. Reg. at 79,723.) Hospital outpatient clinic visits, however, have overwhelming utilization in the Medicare claims. CMS indicates 6.7 million claim lines (81 Fed. Reg. at 79,723) for evaluation and management services compared to 338,44 claims lines (81 Fed. Reg. at 79,724) for the highest volume service among the 22 used by CMS in its comparison. As described below, even if these codes are included in the final analysis, they nonetheless support a higher payment rate if there is some accounting for the impact of packaging.

2. <u>The FAH Strongly Urges CMS to Adjust for Packaging Differences Between the MPFS and the OPPS</u>

In the IFC, CMS writes: "As noted with the clinic visits, we recognize that there are limitations to our data analysis including that OPPS payment rates include the costs of packaged items or services billed with the separately payable code, and therefore the comparison to rates under the MPFS will not be a one-to-one comparison." (81 Fed. Reg. at 79,725.) CMS's calculation of the weighted average percentage of OPPS payment reimbursed for the technical component of the most common off-campus PBD items and services under the MPFS, however, makes no adjustment for packaging other than the exclusion of evaluation and management services.

We examined this known limitation in CMS's analysis to estimate the amount of packaging included in the 22 codes listed in Table X.B.1. Using the same single procedure claims that were used to determine CY 2017 OPPS Final Rule weights, we estimated the amount of packaging for the codes on the table was approximately 20 percent of the total cost. Table 2 below shows the calculations of packaging percentages for single procedure claims used in rate-setting for the Final Rule.

Table 2– MPFS as a Percentage of OPPS Adjusted for Packaging Estimate Mean Procedures Costs and Mean Packaging Costs

HCPCS	Short Descriptor	Procedure Costs	Packaging Costs	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%

Notes:

- Uses the same 22 procedures codes used by CMS listed on page 79724 of the final rule.
- Calculations based on CY 2015 data used for CY 2017 rate-setting.
- CY 2017 Final Rule data and policies were followed.
- Based on costs for single procedure claims used in rate setting.
- Costs have been standardized to account for wage index.
- Means are arithmetic.

The table above shows a mean packaging portion of 20 percent with a range from a low of 0 percent to a high of 60 percent. We believe that to do a more appropriate comparison between MPFS and OPPS rates, the CMS analysis needs to adjust the OPPS payment amounts to address packaging. Therefore, as a reasonable approximation, we recommend adjusting the OPPS denominator to be 80 percent of the value (to account for the 20 percent of packaging), which will adjust the calculated percentage that CMS reported for the MPFS-to-OPPS comparison from 45 percent to 56 percent.

This analysis also excludes evaluation and management services, consistent with CMS's methodology, but in light of the extensive packaging under OPPS for these services, the inclusion of these services would be consistent with a higher payment rate, assuming the same 20 percent adjustment for packaging would raise the MPFS-to-OPPS percentage for CPT codes 99213 and 99214 to 44 and 62 percent, respectively. The inclusion of these codes, however, might also increase the packaging adjustment above 20 percent, further increasing the weighted average MPFS-to-OPPS ratio.

Based on this analysis, and, importantly, further refining the methodology to use the full non-facility practice expense payment for the same 22 codes to account for the indirect costs associated with off-campus hospital department services, raises this percentage to nearly 64 percent. The FAH, therefore, strongly urges CMS to increase the payment rate to 64 percent of OPPS for nonexcepted items and services furnished in off-campus PBDs.

3. The FAH Strongly Recommends Against Any Further Increase of the Percentage Payment Reduction

CMS states in the IFC that it considers the 50 percent reduction from OPPS rates to be "a transitional policy until such time that we have more data to better identify and value nonexcepted items and services furnished by nonexcepted, off-campus PBDs and billed by hospitals." (81 Fed. Reg. at 79,725). To the extent that CMS suggests it may apply a percentage

payment reduction that exceeds the 50 percent reduction adopted in the IFC, the FAH strongly urges against such a payment reduction. As noted above, not using the full MPFS payment for non-facility practice expenses and failing to correct for packaging underestimates the MPFS-to-OPPS payment ratio. Adjusting CMS's methodology to account for these factors would produce a smaller percent reduction. Thus, even if CMS does not adopt our suggestion to use a 36 percent reduction (or paying 64 percent of the OPPS rate), the above analysis suggests that the reduction in payment for off-campus outpatient departments subject to section 603 should not exceed a maximum of 50 percent for CY 2017 or future years.

The FAH therefore recommends increasing the special MPFS rate paid to nonexcepted, off-campus PBD subject to section 603 to 64 percent of the OPPS rather than 50 percent of the OPPS. Even if CMS does not adopt this recommendation, the FAH recommends that CMS not increase the reduction above the 50 percent adopted in the IFC.

B. The FAH Recommends Applying the OPPS Claims Processing Logic for Packaging Separately to Those Items and Services with the PN Modifier Attached and Those Items and Services Without the PN Modifier

In the IFC, CMS indicates that a hospital that is subject to section 603 will be required to bill for all nonexcepted items and services billed by a hospital on an institutional claim with modifier "PN." (81 Fed. Reg. at 79,710.) Elsewhere in the IFC, CMS indicates that nonexcepted services provided at an off-campus, outpatient, provider-based department of a hospital will be paid under the MPFS at 50 percent of the OPPS rate (81 Fed. Reg. at 79,725) and that all OPPS payment adjustments will apply (*i.e.*, packaging, multiple procedure payment reduction and comprehensive APCs). (81 Fed. Reg. at 79,726.) The IFC, however, does not address what occurs when there are mix of services billed on the same claim where some of the services are furnished in a mix of excepted and nonexcepted PBDs. For example, it is possible to have a primary service that is separately paid with a modifier of "PN" indicating on the same claim as a conditionally packaged service that does not have modifier "PN". The reverse is also possible (*i.e.*, the packaged service has modifier "PN" while the separately paid service is unmodified).

The FAH recommends that CMS process all services on a claim reported with the PN modifier separately from those services reported without the PN modifier. The IFC does not explicitly address this question, but Section 603 itself does not authorize CMS to apply payment reductions to services furnished in excepted PBDs. Therefore, it is appropriate to apply the packaging logic separately to PN and non-PN items and services billed on the same claim form. In other words, CMS would apply its packaging logic to all of the claimed items and services reported with the PN modifier and pay for these items and services at the special MPFS rate. The remaining items and services reported without the PN modifier would then be paid according to the usual OPPS packaging payment policies at the final CY 2017 OPPS payment rates.

C. The Nonexcepted Payment Rate for the Mental Health Services Composite APC 8010 Should be Increased to the Full Nonexcepted Payment Rate Established by CMS for PHP Services

The FAH thanks CMS for responding to the FAH's concerns regarding payment for nonexcepted PHP services by establishing a payment rate for nonexcepted PHP services rather than requiring nonexcepted PBDs offering PHP services to separately enroll as Community Mental Health Centers ("CMHCs"). In the IFC, CMS establishes the payment rate for PHP mental health services furnished in a nonexcepted, off-campus PBD at the CMHC rate (APC 5853), which is $121.48.

CMS, however, has a policy that caps the aggregate payment for specified non-PHP mental health services at the payment rate for PHP services. Under this policy, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service exceeds the maximum per diem payment rate for PHP services provided by a hospital, those specified mental health services will be assigned to composite APC 8010 (Mental Health Services Composite). In CY 2017, the payment rate for APC 8010 is set at $207.27 under OPPS, which is the same as the rate for new APC 5863 (PHP (3 or more services per day)).

Under the IFC where services are furnished in a nonexcepted, off-campus PBD, the OPPS payment rate for APC 8010 would be reduced by 50 percent to $103.63 (the special MPFS rate). This rate, however, is less than the PHP rate that CMS established for PHP services furnished by nonexcepted, off-campus PBDs ($121.48). Thus, the application of the special MPFS rate methodology to the composite OPPS rate for mental health services produced an unintentional departure from CMS's longstanding policy to pin the composite mental health services rate to the PHP payment rate. ***The FAH therefore recommends correcting for this anomaly by setting Medicare payment for APC 8010 in the nonexcepted off-campus PBD at $121.48 rather than $103.63 for CY 2017 and prospectively tying the amount paid under APC 8010 for services furnished in a nonexcepted, off-campus PBD to the nonexcepted, off-campus PHP payment amount.***

D. Data to Use in CY 2018, CY 2019 and Future Years

In the IFC, CMS indicates that it anticipates continuing to use the same methodology to determine MPFS payment amounts for nonexcepted items and services furnished by nonexcepted, off-campus PBDs for CY 2018. Again, we strongly recommend against reducing the percentage of the OPPS paid to nonexcepted, off-campus PBDs below 50 percent and also urge CMS to raise to 64 percent the percentage in CY 2018.

CMS sets out two potential alternatives for CY 2019 and subsequent years. Under the first alternative, CMS would make payment using traditional MPFS rates (as opposed to special MPFS rates set based on a percentage of the OPPS rates). For most services provided in nonexcepted, off-campus PBDs, the MPFS-based rate would equal the non-facility payment under the MPFS minus the facility payment. For other services where payment is not differentiated between sites (such as "incident to" services and the technical component of a diagnostic test where Medicare does not make payment in the facility setting under the MPFS), Medicare would make the full non-facility MPFS practice expense payment. Under the second alternative, CMS would continue to make payment using a methodology similar to that being used for CY 2017 and CY 2018—that is, paying at a percentage of standard OPPS rates that reflects the relative resources involved in furnishing the services.

At this stage, ***the FAH recommends that CMS continue to base payment to nonexcepted, off-campus PBDs on a percentage of the OPPS amount, subject to our comments above.*** Because this payment policy has not yet been applied, there is no data on its operational impact on hospitals and its impact on access to outpatient care, particularly in underserved communities and health professional shortage areas. Without at least one year of data under the Section 603 payment policy, detailed comments on alternative methodologies for CY 2019 and subsequent years is premature.

The FAH, however, has significant concerns with CMS's suggestion that it might set the payment rate for nonexcepted, off-campus PBD services based on the difference between the PFS non-facility and facility rate or, for some services, the non-facility MPFS practice expense payment. Such an approach would be problematic for the following reasons:

1. Nonexcepted PBDs Remain Hospital Outpatient Departments. Section 603 explicitly retains the PBD's status as a hospital outpatient department and only indicates that the site cannot be paid under the OPPS. As nonexcepted, off-campus PBDs continue to constitute hospital outpatient departments, OPPS cost and charge data remain the best source of data for setting nonexcepted, off-campus PBD payment rates.

2. Hospitals have Higher Infrastructure Costs than Physician Offices. Hospital outpatient departments, unlike physician offices, must meet health and safety regulations—Conditions of Participation—that do not apply to physician offices. These requirements impose higher infrastructure costs hospitals as compared to physician offices providing the same services. Paying the difference between the non-facility and facility payment under the MPFS means the hospital is only being compensated for the direct costs of furnishing a service (*i.e.,* clinical labor, medical equipment and medical supplies) and Medicare would not be not making ***any*** payment for the hospital's institutional infrastructure costs despite the hospital having higher indirect costs than the physician office.

3. Payment to Hospitals Using the MPFS will be Inadequate. In Table X.B.1, CMS provides the MPFS payment amounts that would be used for 22 services if CMS adopted a policy to pay nonexcepted, 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 nonexcepted, 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.

   For outpatient clinic visits that are currently paid $102.12, the MPFS approach would result in Medicare reducing payment by 71 percent to $29.02 for CPT code 99214 and 79 percent to $21.86 for CPT code 99213—payment amounts that would be well below the hospital's costs of providing outpatient clinic visits.

4. Hospital Data is Better than Physician Data. In the IFC, CMS states: "We believe that, for nonexcepted items and services furnished by an off-campus PBD, 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 used for MPFS payments." Given CMS's statement that the quality of the OPPS data "far exceeds" the quality of the MPFS data, we believe CMS should not use the MPFS data to pay hospital outpatient departments. Medicare's MPFS payments are based on a combination of estimates of direct expenses by a panel of physicians (the Relative Value Update Committee) and a very limited number of responses to the Physician Practice Information Survey that is nearly 10 years old. Meanwhile, more than 5,000 hospitals are submitting hospital charge data and Medicare cost reports annually that CMS uses to determine OPPS rates. ***The FAH concurs with CMS's assessment that OPPS data is far superior to MPFS data and urge CMS to continue using hospital data to set the special MPFS rates for nonexcepted, off-campus PBDs in CY 2019 and subsequent years.***

Using Data on Claims Reported with the PN Modifier in Future Ratesetting

The IFC does not indicate whether claims for services in nonexcepted, off-campus PBDs with modifier "PN" will be used for ratesetting. Any policy proposal on this issue would be premature until adequate data is available, but, once such data is available, the FAH respectfully request that CMS address this issue in future notice-and-comment rulemaking. Although PBDs subject to section 603 remain hospital outpatient departments and bill for Medicare services in the same way as all other hospital outpatient services, these PBDs are being paid at discounted rates even though there is no evidence that the costs for these PBDs is any less than other hospital outpatient departments. At this time, it is unclear how hospitals will allocate costs and charges for outpatient services provided in PBDs subject to section 603 under the discounted rates that they will be paid. Thus, it is unclear how including claims from 603 departments will affect the ratesetting process.

The FAH recommends that CMS fully analyze hospital cost allocation and charging practices for nonexcepted, off-campus PBDs relative to all other hospital outpatient departments before proposing a policy on this issue. As Section 603 takes effect in CY 2017, claims from PBDs subject to section 603 will not be available until 2018 for the CY 2019 rulemaking. However, data from Medicare cost reports take an additional two years before being ready for use in the ratesetting process. Thus, CMS may not have adequate data with which to propose an appropriate policy on this issue until CY 2021. ***Once CMS has done this analysis, the FAH urges CMS to solicit stakeholder feedback on its analysis and proposed policy through notice and comment rulemaking.***

Implementation of the Mid-Build Exception

With the enactment of the 21st Century Cures Act (Pub. L. 114-225) on December 13, 2016, Congress responded to the situation of providers that had new, off-campus PBDs in construction when Section 603 was enacted. Section 16001 of Public Law 114-225 ("Section 16001") amends Section 603 by deeming some PBDs excepted or grandfathered in 2017 based solely on the date of their provider-based attestation and creating an alternative exception under

which mid-build PBDs may receive payment under OPPS starting in 2018. The statute permits CMS to implement deemed treatment and the alternative exception through "program instruction or otherwise." On December 23, 2016, CMS posted preliminary guidance on implementation of Section 16001.[2] ***The FAH supports the issuance of sub-regulatory guidance and urges CMS to issue further such guidance, particularly with regard to the deemed treatment provision, the process for satisfying the requirements of the alternative exception, and documentation retention expectations for providers with PBDs that are deemed excepted in 2017 or are covered by the alternative exception in 2018 and after.*** Because providers need to be able to assess whether they qualify for deemed treatment on January 1, 2017 and to fulfill the procedural requirements for the alternative exception on or before February 13, 2017, prompt guidance is of critical importance. In addition, document retention guidance is necessary to assist provider in preparing for audits of PBDs receiving the alternative exception under Section 16001.

A. Deemed Treatment in 2017

With the enactment of Section 16001, a PBD is deemed to be excepted under section 1833(t)(21)(B)(ii) if a provider-based attestation was received by CMS prior to December 2, 2015. ***The FAH supports CMS's confirmation that the submission of a provider-based attestation prior to December 2, 2015 alone qualifies a PBD for deemed treatment as an excepted PBD and that a PBD deemed excepted under this provision would not use modifier "PN" in 2017.*** The plain text of Section 16001 establishes that, even if an off-campus PBD did not furnish any covered outpatient department items or services prior to November 2, 2015, the PBD will be treated as excepted in 2017 by virtue of the provider's submission of a provider-based attestation on or before December 1, 2015. The statute does not require that the PBD meet the mid-build requirement or that the provider undertake any additional procedural steps to receive deemed treatment. ***The FAH also urges CMS to confirm that retention of CMS's written acknowledgment of its receipt of the attestation should satisfy any documentation obligations for providers with PBDs receiving deemed treatment in 2017.***

B. Alternative Exception Beginning with 2018

Section 16001 also creates an alternative exception in 2018 and after for those PBDs that qualify as mid-build as long as the provider submits a timely provider-based attestation and certification statement and adds the PBD to the provider's enrollment. On December 23, 2016, CMS confirmed that the 60-day deadline for the submission of the attestation and certification statement runs to February 13, 2017. ***The FAH supports CMS's sub-regulatory guidance clarifying that the provider-based attestation and certification statement are timely for purposes of the alternative exception if received by the Medicare Administrative Contractor on or before February 13, 2017.***

1. The requirements for provider-based attestations should not be altered for purposes of the alternative exception for mid-build PBDs

[2] CMS, Note Regarding Implementation of Sections 16001 and 16002 of the 21st Century Cures Act (Dec. 23, 2016), *at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Sections-16001-16002.pdf.

The statute requires submission of a provider-based attestation in accordance with 42 C.F.R. § 413.65(b)(3) for any PBD covered by the alternative exception. The process for preparing and submitting provider-based attestations is already established, and CMS has already issued sub-regulatory guidance on the attestation process in its April 18, 2003 Program Memorandum.[3] In light of existing guidance, the FAH does not believe that further guidance on the content provider-based attestations is necessary at this time and is concerned that any such guidance could generate confusion given the short time remaining for the preparation and submission of attestations.

2. The requirements for certification statements should be minimal, based on the plain text of the statute

The statute also requires the submission of a certification statement for mid-build PBDs proceeding under the alternative exception. ***The FAH supports CMS's clarification that this statement can be submitted by the chief executive officer or chief operating officer of the main provider (or equivalent if such titles are not used by the main provider) to the Medicare Administrative Contractor through e-mail or mail.*** The FAH, however, requests further guidance as to the content of the certification statement. ***Based on the plain text of the statute, the FAH urges CMS to confirm that the certification need only identify the PBD by its physical street address and practice location name and include a plain statement that the PBD met the mid-build requirement (e.g., "I hereby certify that the department met the mid-build requirement of section 1833(t)(21)(B)(v) of the Social Security Act.").*** Because the statute only requires the certification statement, the FAH is opposed to the imposition of any additional requirements, including the submission of supporting documentation. The off-campus, provider-based attestation process already requires the submission of significant documentation, and given the limited time for compliance, the addition of any other documentation or other requirements in connection with the certification would be unduly burdensome.

3. The Mid-Build Requirements of Section 1833(t)(21)(B)(v) are Satisfied by a construction agreement for renovations or a new building or a lease with build-out obligations.

The statute provides that a PBD met the mid-build requirement if, before November 2, 2015, the provider "had a binding written agreement with an outside unrelated party for the actual construction" of the mid-build PBD. Social Security Act 1833(t)(21)(B)(v). ***The FAH urges CMS to broadly interpret the statutory mid-build requirement to reflect Congress' intent to make the mid-build exception available to providers that had contractual commitments for the construction of a PBD, regardless of whether that commitment is contained in a lease with build-out obligations for the lessor, an agreement with a contractor for physical renovations, or a construction agreement with a developer.*** The statutory requirements clarify Congress' intent to exclude projects that were wholly internal (no contract with an outside unrelated party), non-binding, or limited to exploratory work rather than actual construction. A lease agreement

[3] CMS, Program Memorandum, Intermediaries, Provider-Based Status On or After October 1, 2002, Transmittal A-03-030, Change Request 2411 (Apr. 18, 2003), *at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/A03030.pdf.

that obligates the landlord to undertake physical improvements to the site meets these requirements and is consistent with Congress' intent, as long as the landlord is an outside unrelated party. Likewise, if a provider had an agreement with an outside unrelated party for physical improvements to a site (*e.g.*, renovations necessary to satisfy fire code or other requirements for hospital space), such an agreement should qualify as an agreement for actual construction in the same way that an agreement for the construction of entirely new space would so qualify.

C. Document Retention Expectations for Mid-Build PBDs Should be Clear and Straightforward Based on Statutory Requirements.

Section 16001 requires that CMS audit compliance with the alternative exception requirements no later than December 31, 2018. In light of the reimbursement impact of the mid-build exception and impending CMS audits of PBDs covered by the alternative exception, the FAH requests that CMS provide clear guidance concerning document retention requirements for mid-build PBDs. ***Based on the statutory requirements for the alternative exception, the documentation that should be retained and might be requested as part of an audit under section 1833(t)(21)(B)(vii) of the Social Security Act should be confined to copies of the provider-based attestation, certification statement, and written construction agreement and evidence that the provider added the PBD to its hospital enrollment*** (*e.g.*, a copy of section 4 of the Medicare Enrollment Application, CMS-855A, reporting the mid-build PBD as a new practice location or a report from PECOS confirming the addition of the PBD to the hospital's Medicare enrollment).

Payment for PHP Services Should Not be Denied or Reduced Where the Patient's Plan of Care Calls for 20 Hours of Therapeutic Services per Week, Even if the Patient Does Not Receive the Expected 20 hours of Therapeutic Services in a Given Week Due to Unforeseen Circumstances

In the Final Rule, CMS requests comments on the advantages, disadvantages, and potential challenges of strengthening the tie between payment and furnishing at least 20 hours of services per week to eligible beneficiaries in a PHP program. The Medicare Benefit Policy Manual (Pub. 100-02, ch. 6, § 70.3) currently provides that patients admitted to a PHP must "require a minimum of 20 hours per week of therapeutic services, as evidenced by their plan of care." This requirement is part of a prospective assessment of a patient's eligibility based on the plan of care and physician certification. ***The FAH urges CMS to decline to directly link the provision of 20 hours per week of therapeutic services and Medicare PHP payment.*** Medicare beneficiaries admitted to a PHP program by the physician are done so with the full expectation that the beneficiary will receive intensive outpatient therapeutic treatment that entails at least 20 hours of treatment per week. However, an individual Medicare beneficiary's ability to meet this requirement each and every week while in the PHP program can be impacted by circumstances, in many cases that are essentially out of the control of both the beneficiary and the hospital. Some examples are noted below:

- A beneficiary may require an Electro-Convulsive Therapy ("ECT") which might take clinical precedence over the PHP attendance the day of the ECT.

- A beneficiary may have a chronic or acute non-psychiatric medical condition with related symptoms or conditions that may limit their PHP participation during a particular treatment week.

- A beneficiary may have a medical appointment to diagnosis or treat a chronic or acute medical condition that takes precedence over their PHP treatment on a particular day

Because of the above types of circumstances, the FAH believes the 20-hour treatment requirement and payment should be mutually exclusive determinations. The FAH would be strongly opposed to any CMS policy that would systematically deny PHP payment for an entire week where the 20-hour treatment requirement was not met. As stated above, if a physician admission to the PHP program was done so with the full expectation that 20 hours of treatment would be met then full PHP payment for the week should follow accordingly. Any potential non-compliance with the PHP 20 hour per week eligibility requirement could be identified and addressed through currently available medical review policies and processes employed by the Medicare Administrative Contractor (MAC).

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The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or Steve Speil, Executive Vice President, at 202-624-1529.

Sincerely,