FEDERAL REGISTER

Vol. 81 Thursday,
No. 135 July 14, 2016

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 416, 419, 482, *et al.*
Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Proposed Rule

shift of some Medicare beneficiaries from an inpatient TKA procedure to an outpatient TKA procedure in the BPCI and CJR model pricing methodologies, including target price calculations and reconciliation processes. Some of the issues CMS faces include the lack of historical data on both the outpatient TKA episodes and the average episode spending for beneficiaries who would continue to receive the TKA procedure on an inpatient basis. Because historically the procedure described by CPT code 27447 has been on the IPO list, there is no claims history for beneficiaries receiving TKA on an outpatient basis. In addition, we are seeking public comment on the postdischarge care patterns for Medicare beneficiaries that may receive an outpatient TKA procedure if it were removed from the IPO list and how this may be similar or different from these beneficiaries' historical postdischarge care patterns. For example, Medicare beneficiaries who are appropriate candidates for an outpatient TKA procedure may be those who, in the past, would have received outpatient physical therapy services as follow-up care after an inpatient TKA procedure. CMS would need to develop a methodology to ensure model target prices account for the potentially higher risk profiles of Medicare beneficiaries who would continue to receive TKA procedures in inpatient settings.

X. Proposed Nonrecurring Policy Changes

A. Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

1. Background

In recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physician's services in a hospital setting. When a Medicare beneficiary receives services in an off-campus department of a hospital, the total payment amount for the services made by Medicare is generally higher than the total payment amount made by Medicare when the beneficiary receives those same services in a physician's office. Medicare pays a higher amount because it generally pays two separate claims for these services—one under the OPPS for the institutional services and one under the MPFS for the professional services furnished by a physician or other practitioner. Medicare beneficiaries are responsible for the cost-sharing liability, if any, for both of these claims, often resulting in significantly higher total beneficiary cost-sharing than if the service had been furnished in a physician's office.

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under section 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered covered OPD services as defined under section 1833(t)(1)(B) for purposes of payment under the OPPS and will instead be paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, in this proposed rule, we refer to an ''off-campus outpatient department of a provider,'' which is the term used in section 603, as an ''off-campus outpatient provider-based department'' or an ''off-campus PBD.''

As noted earlier, section 603 of Public Law 114–74 made two amendments to section 1833 of the Act—one amending paragraph (t)(1)(B) and the other adding new paragraph (t)(21). The provision amended section 1833(t)(1)(B) by adding a new clause (v), which excludes from the definition of ''covered OPD services'' applicable items and services (defined in paragraph (t)(21)(A)) that are furnished on or after January 1, 2017 by an off-campus PBD, as defined in paragraph (t)(21)(B). The second amendment added a new paragraph (t)(21), which defines the terms ''applicable items and services'' and ''off-campus outpatient department of a provider,'' requires the Secretary to establish a new payment policy for such applicable items and services furnished by an off-campus PBD on or after January 1, 2017, provides that hospitals shall report on information as needed for implementation of the provision, and establishes a limitation on administrative and judicial review on certain determinations and information.

In defining the term ''off-campus outpatient department of a provider,'' section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015, the date of enactment of Public Law 114–74) that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility. Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of ''off-campus outpatient department of a provider,'' for purposes of paragraphs (1)(B)(v) and (21)(B), an off-campus PBD that was billing under subsection (t) with respect to covered OPD services furnished prior to the date of enactment of paragraph (t)(21), that is, November 2, 2015. We are proposing to refer to this exception as providing ''excepted'' status to certain off-campus PBDs and certain items and services furnished by such excepted off-campus PBDs, which would continue to be paid under the OPPS. Moreover, as noted earlier, because the definition of ''applicable items and services'' specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b) and the definition of ''off-campus outpatient department of a provider'' does not include PBDs located on the campus of a hospital or within the distance (described in the definition of campus at 413.65(a)(2)) from a remote location of a hospital facility, the items and services furnished by these excepted off-campus PBDs on or after January 1, 2017 will continue to be paid under the OPPS.

In this proposed rule, we are making a number of proposals to implement section 603 of Public Law 114–74. Broadly, we are proposing to do three things: (1) Define applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services shall instead be made under section 1833(t)(21)(C) of the Act; (2) define off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) establish policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, in this rule, we are proposing policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; establish the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBD and for the items and services furnished by such

excepted off-campus PBDs); and describe the applicable payment system for nonexcepted items and services. In addition, we are soliciting public comments on information collection requirements for implementing this provision in accordance with section 1833(t)(21)(D) of the Act.

There is no legislative history on record regarding section 603 of Public Law 114–74. However, the Congressional Budget Office estimated program savings for this provision of approximately $9.3 billion over a 10-year period. In January 2016, we posted a notice on the CMS Web site that informed stakeholders that we expected to present our proposals for implementing section 603 of Public Law 114–74 in the CY 2017 OPPS/ASC proposed rule. Because we had already received several inquiries or suggestions from stakeholders regarding implementation of the section 603 provision, we provided a dedicated email address for stakeholders to provide information they believed was relevant in formulating these proposals. We have considered this stakeholder feedback in developing this proposed rule.

2. Defining Applicable Items and Services and an Off-Campus Outpatient Department of a Provider as Set Forth in Sections 1833(t)(21)(A) and (B) of the Act

a. Background on the Provider-Based Status Rules

Since the beginning of the Medicare program, some hospitals, which we refer to as ''main providers,'' have functioned as a single entity while owning and operating multiple departments, locations, and facilities. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments under the OPPS for services provided at the provider-based facility and may also increase the coinsurance liability of Medicare beneficiaries receiving those services. The current criteria for provider-based status are located in the regulations at 42 CFR 413.65.

When a facility or organization has provider-based status, it is considered to be part of the hospital. The hospital as a whole, including all of its PBDs, must meet all Medicare conditions of participation and conditions of payment that apply to hospitals. In addition, a hospital bills for services furnished by its provider-based facilities and organizations using the CMS Certification Number of the hospital. One type of facility or organization that a hospital may treat as provider-based is an off-campus outpatient department. In order for the hospital to do so, the off-campus outpatient department must meet certain requirements under 42 CFR 413.65, including, but not limited to:

- It generally must be located within a 35-mile radius of the campus of the main hospital;
- Its financial operations must be fully integrated within those of the main provider;
- Its clinical services must be integrated with those of the main hospital (for example, the professional staff at the off-campus outpatient department must have clinical privileges at the main hospital, the off-campus outpatient department medical records must be integrated into a unified retrieval system (or cross reference) of the main hospital), and patients treated at the off-campus outpatient department who require further care must have full access to all services of the main hospital;
- It is held out to the public as part of the main hospital.

Section 603 makes certain distinctions with respect to whether a department of the hospital is ''on'' campus or ''off'' campus and also excludes from the definition of ''off-campus outpatient department of a provider'' a department of a provider within the distance from a remote location of a hospital facility. Below, we provide some details on the definitions of the terms ''campus'' and ''remote locations.''

Section 413.65(a)(2) of the regulations defines a ''campus'' as ''[T]he physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS Regional Office, to be part of the provider's campus.''

In developing the provider-based rules, CMS also recognized that many hospitals operated fully integrated, though geographically separate, inpatient facilities. While the initial scope of provider-based rulemaking primarily concerned situations with outpatient departments, we believed the policies set forth were equally applicable to inpatient facilities. Therefore, CMS also finalized a regulatory definition for a ''remote location of a hospital'' at 42 CFR 413.65(a)(2) as ''a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term 'remote location of a hospital' does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.''

Under the provider-based rules, we consider these inpatient ''remote locations'' to be ''off-campus,'' and CMS reiterated this position in the FY 2003 IPPS/LTCH PPS final rule (67 FR 50081 through 50082). Hospitals that comprise several sites at which both inpatient and outpatient care are furnished are required to designate one site as its ''main'' campus for purposes of the provider-based rules. Thus, any facility not located on that main campus would be considered ''off-campus'' and must satisfy the provider-based rules in order to be treated by the main hospital as provider-based.

For Medicare purposes, a hospital that wishes to add an off-campus PBD must submit an amended Medicare provider enrollment form detailing the name and location of the provider-based facility within 90 days of adding the new facility to the hospital. In addition, a hospital may ask CMS to make a determination that a facility or organization has provider-based status by submitting a voluntary attestation to its MAC, for final review by the applicable CMS Regional Office, attesting that the facility meets all applicable provider-based criteria in the regulations. If no attestation is submitted and CMS later determines that the hospital treated a facility or organization as provider-based when the facility or organization did not meet the requirements for provider-based status, CMS will recover the difference between the amount of payments actually made to the hospital and the amount of payments that CMS estimates should have been made for items and services furnished at the facility in the absence of compliance with the provider-based requirements for all cost reporting periods subject to reopening. However, if the hospital submits a complete attestation of compliance with the provider-based status requirement for a facility or organization that has not previously been found by CMS to have

been inappropriately treated as provider based, but CMS subsequently determines that the facility or organization does not meet the requirements for provider-based status, CMS will recover the difference between the amount of payments actually made to the hospital since the date the attestation was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements.

Historically, PBDs billed as part of the hospital and could not be distinguished from the main hospital or other PBDs within the claims data. In CY 2015 OPPS/ASC final rule with comment period (79 FR 66910 through 66914), CMS adopted a voluntary claim modifier ''PO'' to identify services furnished in off-campus PBDs (other than emergency departments, remote locations and satellite locations of the hospital) to collect data that would help identify the type and costs of services typically furnished in off-campus PBDs. Based on the provision in the CY 2015 OPPS/ASC final rule with comment period, use of this modifier became mandatory beginning in CY 2016. While the modifier identifies that the service was provided in an off-campus PBD, it does not identify the type of PBD in which services were furnished, nor does it distinguish between multiple PBDs of the same hospital. As discussed later in this section, we are soliciting public comments on the type of information that would be needed to identify nonexcepted PBDs for purposes of section 603, although we are not proposing to collect such information for CY 2017.

b. Proposed Exemption of Items and Services Furnished in a Dedicated Emergency Department or by an Off-Campus PBD as Defined at Sections 1833(t)(21)(B)(i)(I) and (II) of the Act (Excepted Off-Campus PBD)

(1) Dedicated Emergency Departments (EDs)

Section 1833(t)(21)(A) of the Act specifies that, for purposes of paragraph (1)(B)(v) and [paragraph [21] of section 1833(t), the term ''applicable items and services'' means items and services *other* than items and services furnished by a dedicated emergency department (as defined in 42 CFR 489.24(b)). Existing regulations at § 489.24(b) define an ED as any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

- It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;
- It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or
- During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

Accordingly, based on existing regulations, an ED may furnish both emergency and nonemergency services as long as the requirements under § 489.24(b) are met. In accordance with section 1833(t)(21)(A) of the Act and regulations at § 489.24(b), we are proposing that all services furnished in an ED, whether or not they are emergency services, would be exempt from application of sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act, and thus continue to be paid under the OPPS. Moreover, we are proposing to define ''applicable items and services'' to which sections 1833(t)(1)(B)(v) and (t)(21)(A) of the Act apply to include all items and services not furnished by a dedicated ED as described in the regulations at 42 CFR 489.24(b).

(2) On-Campus Locations

As noted earlier, section 1833 (t)(21)(B)(i) of the Act defines the term ''off-campus outpatient department of a provider'' for purposes of paragraphs (t)(1)(B)(v) and (t)(21) as a department of a provider (as defined at 42 CFR 413.65(a)(2) as that term is in effect as of November 2, 2015), that is not located on the campus of that provider or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility (as defined in § 413.65(a)(2)). We believe that the statutory language refers to such departments as defined by the regulations at § 413.65 as they existed at the time of enactment of Public Law 114–74. The existing regulatory definition of a ''department of a provider'' includes both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. We used the existing regulatory definition of a department of a provider as a guide in designing our proposals to implement section 603 of Public Law 114–74.

We are not proposing to change the existing definition of ''campus'' located at § 413.65(a)(2) of our regulations and believe hospitals can adequately determine whether their departments are on-campus, including by using the current provider-based attestation process described in § 413.65(b) to affirm their on-campus status. Currently, the CMS Regional Offices review provider-based attestations to determine whether a facility is within full compliance of the provider-based rules, and hospitals that ask for a provider-based determination are required to specify whether they are seeking provider-based status for an on-campus or off-campus facility or organization. If a CMS Regional Office determines that a department is not in full compliance with the provider-based rules, hospitals may utilize the reconsideration process described under § 413.65(j) and the administrative appeal process described at 42 CFR part 498. As we gain experience under section 603 of Public Law 114–74, we may consider issuing further guidance regarding provider-based attestations if needed.

In accordance with section 1833(t)(21)(B)(i)(I) of the Act, we are proposing that on-campus PBDs and the items and services provided by such a department would be excepted from application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act.

(3) Within the Distance From Remote Locations

In addition to the statutory exception for off-campus PBDs located on the campus of a provider, section 1833(t)(21)(B)(i)(II) of the Act excepts from the definition of off-campus PBDs those that are not located within the distance (as described in the definition of campus at § 413.65(a)(2)) from a ''remote location'' (as also defined at § 413.65(a)(2)) of a hospital facility. The ''distance'' described in the definition of ''campus'' at § 413.65(a)(2) is 250 yards. While hospitals that operate remote locations are referred to as ''multicampus'' hospitals, as discussed previously, under current provider-based rules, a hospital is only allowed to have a single ''main'' campus for each hospital. Therefore, when determining whether an off-campus PBD meets the exception set forth at section 1833(t)(21)(B)(i)(II) of the Act, we are proposing that the off-campus PBD must be located at or within the distance of

250 yards from a remote location of a hospital facility. Hospitals should use surveyor reports or other appropriate documentation to ensure that their off-campus PBDs are within 250 yards (straight-line) from any point of a remote location for this purpose.

c. Applicability of Exception at Section 1833(t)(21)(B)(ii) of the Act

Section 1833(t)(21)(B)(ii) of the Act states that, for purposes of sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act, the term ''off-campus outpatient department of a provider'' shall not include a department of a provider (that is, an off-campus PBD) (as so defined) that was billing under this subsection, that is, the OPPS, with respect to covered OPD services furnished prior to November 2, 2015. We are proposing that, as provided in section 1833(t)(21)(B)(ii) of the Act, if an off-campus PBD meets this exception, sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act do not apply to that department or to the types of items and services furnished by that department (to be discussed in greater detail below) that were being billed under the OPPS prior to November 2, 2015.

A major concern with determining the scope of the exception set forth at section 1833(t)(21)(B)(ii) of the Act for purposes of applying sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act is determining how relocation of the physical location or expansion of services lines furnished at the ''excepted'' off-campus PBD affects the excepted status of the off-campus PBD itself and the items and services furnished by that excepted off-campus PBD.

We have heard from some providers that they believe that section 1833(t)(21)(B)(ii) of the Act specifically excepted off-campus PBDs billing for covered OPD services furnished before November 2, 2015, and that these excepted departments should remain excepted, regardless of whether they relocate or expand services, or both. These providers noted that the exception for certain off-campus PBDs states that section 1833(t)(21)(B)(ii) of the Act does not include an off-campus PBD (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph. These providers argued that, because the statute does not include a specific limitation on relocation or expansion of services, no limitation should be applied.

Providers also have suggested that off-campus PBDs should be able to relocate and maintain excepted status as long as the structure of the PBD is substantially similar to the PBD prior to the relocation. Some stakeholders have suggested that the criteria for defining substantially similar could be based on maintaining similar personnel, space, patient population, or equipment, or a combination of these factors.

We believe that section 1833(t)(21)(B)(ii) of the Act excepted 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. Thus, as noted above, we have developed our proposals in defining the scope of the excepted off-campus PBD and the items and services it furnishes based on the existing regulatory definition of department of a provider, which speaks to both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program and the personnel and equipment needed to deliver the services at that facility.

Below we are making a number of proposals regarding the scope of the exception at section 1833(t)(21)(B)(ii) of the Act for purposes of applying sections 1833(t)(1)(B)(v) and (t)(21) of the Act. These proposals are made in accordance with our belief that section 603 of Public Law 114–74 is intended to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services.

(1) Relocation of Off-Campus PBDs Excepted Under Section 1833(t)(21)(B)(ii) of the Act

In considering how relocation of an excepted off-campus PBD could affect application of sections 1833(t)(1)(B)(v) and (t)(21) of the Act, we are concerned that if we propose to permit excepted off-campus PBDs to relocate and continue such status, hospitals would be able to relocate excepted off-campus PBDs to larger facilities, purchase additional physician practices, move these practices into the larger relocated facilities, and receive OPPS payment for services furnished by these physicians, which we believe section 603 of Public Law 114–74 intended to preclude.

As previously stated, we believe that section 603 of Public Law 114–74 applies to off-campus PBDs as they existed at the time of enactment and only excepts those items and services that were being furnished and billed by off-campus PBDs prior to November 2, 2015.

After reviewing the statutory authority, and the concerns noted earlier, we are proposing that, for purposes of paragraphs (t)(1)(B)(v) and (t)(21) of section 1833 of the Act, excepted off-campus PBDs and the items and services that are furnished by such departments would no longer be excepted if the excepted off-campus PBD moves or relocates from the physical address that was listed on the provider's hospital enrollment form as of November 1, 2015. In the case of addresses with multiple units, such as a multi-office building, the unit number is considered part of the address; in other words, an excepted hospital PBD could not purchase and expand into other units in its building, and remain excepted. Once an excepted off-campus PBD has relocated, we are proposing that both the off-campus PBD itself and the items and services provided at that off-campus PBD would no longer be excepted, that is considered to be an excepted off-campus PBD for which the items and services furnished are covered OPD services payable under the OPPS, and instead, would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act.

Hospitals have expressed concern that there may be instances when an excepted off-campus PBD may need to relocate, including, for example, to meet Federal or State requirements, or due a natural disaster. We recognize that there may be circumstances beyond the hospital's control where an excepted off-campus PBD must move from the location in which it existed prior to November 2, 2015. We are soliciting public comments on whether we should develop a clearly defined, limited relocation exception process, similar to the disaster/extraordinary circumstance exception process under the Hospital VBP program (as implemented in the FY 2014 IPPS/LTCH PPS final rule; 78 FR 50704) for hospitals struck by a natural disaster or experiencing extraordinary circumstances (under which CMS allows a hospital to request a Hospital VBP Program exception within 90 days of the natural disaster or other extraordinary circumstance) that would allow off-campus PBDs to relocate in very limited situations, and that mitigate the potential for the hospital to avoid application of sections 1833(t)(1)(B)(v), and (t)(21)(C) of the Act. In addition, we are seeking public comments on whether we should consider exceptions for any other circumstances that are completely beyond the control of the hospital, and, if so, what those specific circumstance would be.

(2) Expansion of Clinical Family of Services at an Off-Campus PBD Excepted Under Section 1833(t)(21)(B)(ii) of the Act

We have received questions from some hospitals regarding whether an excepted off-campus PBD can expand the number or type of services the department furnishes and maintain excepted status for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. As mentioned earlier in the relocation discussion, we have heard that some providers believe that section 1833(t)(21)(B)(ii) of the Act specifically excepted *departments*, pointing out that the statute is not written with any limiting language and that excepted departments should remain excepted, regardless of whether these departments expand either the number of services or the types of services they provide. Under this interpretation, section 1833(t)(21)(B)(ii) of the Act would limit only the number of excepted off-campus PBDs a hospital can have to the number of off-campus PBDs that were billing Medicare for covered OPD services furnished prior to enactment of Public Law 114–74.

We believe that section 1833(t)(21)(B)(ii) of the Act excepts off-campus PBDs and the items and services that are furnished by such excepted off-campus PBDs for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as they were being furnished on the date of enactment of section 603 of Public Law 114–74, as guided by our regulatory definition of department of a provider. Thus, we are proposing that the excepted off-campus PBD would be limited to seeking payment under the OPPS for the provision of items and services it was furnishing prior to the date of enactment of section 603 of Public Law 114–74 only. Moreover, we are proposing that items and services that are not part of a clinical family of services furnished and billed by the excepted off-campus PBD prior to November 2, 2015 would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act, that is, not payable under the OPPS.

As noted earlier, we believe that the amendments to section 1833(t) of the Act were intended to address items and services furnished at physicians' offices that are converted to hospital off-campus PBDs on or after November 2, 2015 from being paid at OPPS rates. One issue we contemplated in considering how expanded services should affect excepted status is how it could affect payment to physicians' offices purchased *after* the date of enactment of section 603. We are concerned that if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe these amendments to section 1833(t) of the Act are intended to address.

After reviewing the statutory authority and the concerns raised by commenters noted above, we are proposing, for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act, that excepted status of items and services furnished in excepted off-campus PBDs is limited to the items and services (defined as clinical families of services below) such department was billing for under the OPPS and were furnished prior to November 2, 2015. We are proposing that if an excepted off-campus PBD furnishes services from a clinical family of services that it did not furnish prior to November 2, 2015, and thus did not also bill for, these new or expanded clinical families of services would not be covered OPD services, and instead would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as described in section X.A.1.c. of this proposed rule. We note that we are proposing not to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish.

In summary, our proposals related to expansion of clinical families of services are as follows: We are proposing that service types be defined by the 19 clinical families of hospital outpatient service types described in Table 21 below. Moreover, we are proposing that if an excepted off-campus PBD furnished and billed for any specific service within a clinical family of services prior to November 2, 2015, such clinical family of services would be excepted and be eligible to receive payment under the OPPS. However, we are proposing that if an excepted off-campus PBD furnishes services from a clinical family of services that such department did not furnish and bill for prior to November 2, 2015, those services would be subject to sections 1833(t) (1)(B)(v) and (t)(21) of the Act in CY 2017 and subsequent years. We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for which HCPCS codes map to each clinical family of services. If we add a new HCPCS code or APC in future years, we will provide mapping to these clinical families of services, where relevant.

In addition, we considered, but are not proposing in this proposed rule, to specify a specific timeframe in which service lines had to be billed under the OPPS for covered OPD services furnished prior to November 2, 2015. We are seeking public comment on whether we should adopt a specific timeframe for which the billing had to occur, such as CY 2013 through November 1, 2015.

TABLE 21—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical families	APCs
Advanced Imaging	5523–25, 5571–73, 5593–4.
Airway Endoscopy	5151–55.
Blood Product Exchange	5241–44.
Cardiac/Pulmonary Rehabilitation	5771, 5791.
Clinical Oncology	5691–94.
Diagnostic tests	5721–24, 5731–35, 5741–43.
Ear, Nose, Throat (ENT)	5161–66.
General Surgery	5051–55, 5061, 5071–73, 5091–94, 5361–62.
Gastrointestinal (GI)	5301–03, 5311–13, 5331, 5341.
Gynecology	5411–16.
Minor Imaging	5521–22, 5591–2.
Musculoskeletal Surgery	5111–16, 5101–02.
Nervous System Procedures	5431–32, 5441–43, 5461–64, 5471.
Ophthalmology	5481, 5491–95, 5501–04.
Pathology	5671–74.

TABLE 21—PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION—Continued

Clinical families	APCs
Radiation Oncology	5611–13, 5621–27, 5661.
Urology	5371–77.
Vascular/Endovascular/Cardiovascular	5181–83, 5191–94, 5211–13, 5221–24, 5231–32.
Visits and Related Services	5012, 5021–25, 5031–35, 5041, 5045, 5821–22, 5841.

Under our proposal, while excepted off-campus PBDs would not be eligible to receive OPPS payments for expanded clinical families of services, such excepted off-campus PBDs would continue to be eligible to receive OPPS payment for clinical families of services that were furnished and billed prior to that date. We discuss later in this section how we are proposing to pay for expanded items and services that are furnished at excepted off-campus PBDs, that is, are nonexcepted items and services.

We are seeking public comments on these proposals. In addition, we are seeking public comments on our proposed categories of clinical families of services, and our proposal not to limit the volume of services furnished within a clinical family of services that the hospital was billing prior to November 2, 2015.

d. Change of Ownership and Excepted Status

Under current policy, provider-based status is defined as the relationship between a facility and a main provider. If a Medicare-participating hospital, in its entirety, is sold or merges with another hospital, a PBD's provider-based status generally transfers to new ownership as long as the transfer would not result in any material change of provider-based status. A provider-based approval letter for such a department would be considered valid as long as the new owners accepted the prior hospital's provider agreement, consistent with other hospital payment policies.

We have received inquiries regarding whether excepted off-campus PBDs would maintain excepted status if a hospital were purchased by a new owner, if a hospital merged with another provider, or if only an excepted off-campus PBD were sold to another hospital.

We are proposing that excepted status for the off-campus PBD would be transferred to new ownership only if ownership of the main provider is also transferred and the Medicare provider agreement is accepted by the new owner. If the provider agreement is terminated, all excepted off-campus PBDs and the excepted items and services furnished by such off-campus PBD would no longer be excepted for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. We are proposing that individual excepted off-campus PBDs cannot be transferred from one hospital to another and maintain excepted status. We are soliciting public comments on these proposals.

e. Comment Solicitation for Data Collection Under Section 1833(t)(21)(D) of the Act

Hospitals are required to include all practice locations on the CMS 855 enrollment form. Beginning in March 2011 and ending in March 2015, in accordance with section 1866(j) of the Act, CMS conducted a revalidation process where all actively enrolled hospitals were required to complete a new CMS 855 enrollment form to (1) initially enroll in Medicare, (2) add a new practice location, or (3) revalidate existing enrollment information.

Collection and retention of Medicare enrollment data have been authorized through a Paperwork Reduction Act notice in the **Federal Register**. The authority for the various types of data to be collected is found in multiple sections of the Act and the Code of Federal Regulations; specifically, in sections 1816, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act, and 42 CFR Chapter IV, Subchapter A.

Sections 1833(t)(21)(A) and (B) of the Act exempt both certain off-campus PBDs and the items and services furnished in certain types of off-campus PBDs from application of sections 1833(t)(1)(B)(v) and (21) of the Act. However, while the Medicare enrollment process requires that a hospital identify the name and address of each of its off-campus PBDs, such departments bill under the CMS Certification Number of the hospital, rather than a separate identifier. Accordingly, at this time, we are unable to automate a process by which we could link hospital enrollment information to claims processing information to identify items and services to specific off-campus PBDs of a hospital. In order to accurately identify items and services furnished by each off-campus PBD (exempt or not) and to actively monitor the expansion of clinical family of services at excepted off-campus PBDs, we are seeking public comments on whether to require hospitals to self-report this information to us (via their MAC) using the authority under section 1833(t)(21)(D) of the Act to collect information as necessary to implement the provision.

Specifically, we are seeking public comments on whether hospitals should be required to separately identify all individual excepted off-campus PBD locations, the date that each excepted off-campus PBD began billing and the clinical families of services (shown earlier in Table 21) that were provided by the excepted off-campus PBD prior to the November 2, 2015 date of enactment. If we were to require hospitals to report this information, we would expect to collect this information through a newly developed form which would be available for download on the CMS Web site.

3. Payment for Services Furnished in Off-Campus PBDs to Which Sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act Apply (Nonexcepted Off-Campus PBDs)

a. Background on Medicare Payment for Services Furnished in an Off-Campus PBD

As previously noted, under existing policies, Medicare generally makes two types of payments for items and services furnished in an off-campus PBD: (1) Payment for the items and services furnished by the off-campus PBD (that is, the facility) where the procedure is performed (for example, surgical supplies, equipment, and nursing services); and (2) payment for the physician's professional services in furnishing the service(s).

The first type of payment is made under the OPPS. Items and services furnished in an off-campus PBD are billed using HCPCS codes and paid under the OPPS according to the APC group to which the item or service is assigned. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this proposed rule. Section 1833(t)(1)(B) of the Act generally outlines what are covered OPD services eligible for

payment under the OPPS. Sections 1833(t)(1)(B)(i) through (iii) of the Act provide for Medicare payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by community mental health centers (CMHCs)), certain items and services that are furnished to inpatients who have exhausted their Part A benefits or who are otherwise not in a covered Part A stay, and certain implantable items. Section 1833(t)(1)(B)(iv) and new subsection (v) list those items and services that are not covered OPD services and, therefore, not eligible for Medicare payment under the OPPS.

The second type of payment for services furnished in an off-campus PBD is for physicians' services and is made under the MPFS at the MPFS ''facility rate.'' For most MPFS services, Medicare maintains two separate payment rates: One that assumes a payment is also made to the facility (the facility rate); and another that assumes the professional furnishes and incurs the full costs associated with furnishing the service (the nonfacility rate). The MPFS facility rate is based on the relative resources involved in furnishing a service when separate Medicare payment is also made to the facility, usually through an institutional payment system, like the OPPS. The MPFS nonfacility rate, which reflects all of the direct and indirect practice expenses involved in furnishing the particular services, is paid in a variety of settings such as physician offices, where Medicare does not make a separate, institutional payment to the facility.

Under Medicare Part B, the beneficiary is responsible for paying cost-sharing, which is generally about 20 percent of both the OPPS hospital payment amount and the MPFS allowed amount. Because the sum of the OPPS payment and the MPFS facility payment for most services is greater than the MPFS nonfacility payment for most services, there is generally a greater cost to both the beneficiary and the Medicare program for services furnished in facilities paid through both an institutional payment system like the OPPS and the MPFS.

The incentives for hospital acquisition of physician practices and the resultant higher payments for the same types of services have been the topic of several reports in the popular media and by governmental agencies. For example, the Medicare Payment Advisory Commission (MedPAC) stated in its March 2014 Report to Congress that Medicare pays more than twice as much for a level II echocardiogram in an outpatient facility ($453) as it does in a freestanding physician office ($189) (based on CY 2014 payment rates). The report determined that the payment difference creates a financial incentive for hospitals to purchase freestanding physicians' offices and convert them to HOPDs without changing their location or patient mix. (MedPAC March 2014 Report to Congress, Chapter 3.) The Government Accountability Office (GAO) also published a report in response to a Congressional request about hospital vertical consolidation. Vertical consolidation is a financial arrangement that occurs when a hospital acquires a physician practice and/or hires physicians to work as salaried employees. In addition, the Office of Inspector General (OIG) published a report in June 2016 entitled ''CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain'' (OEI–04–12–00380), in which it highlighted concerns about provider-based status in light of the higher costs to both the Medicare program and Medicare beneficiaries relative to when the same services are furnished in the physician office setting. These types of reports highlight the types of concerns we believe Congress may have been trying to address when it legislated section 603 of Public Law 114–74. As we developed our proposal to implement section 603, we took into consideration the concerns described above, the specific statutory language, and the available discretion found in that statutory language.

As described in detail above and below, section 603 of Public Law 114–74, through amendments to section 1833(t) at paragraphs (1)(B)(v) and (21), provides that items and services furnished by nonexcepted off-campus PBDs and certain items and services furnished by excepted off-campus PBDs are not covered OPD services under the OPPS, and that payment shall be made for those applicable items and services under the applicable payment system if the requirements for such payment are otherwise met. However, the statutory amendments do not reference or define a specific applicable payment system under which payment shall be made.

We have established and maintained institutional Medicare payment systems based on specific statutory requirements and on how particular institutions provide particular kinds of services and incur particular kinds of costs. The rules regarding provider and supplier enrollment, conditions of participation, coverage, payment, billing, cost reporting, and coding vary across these institutional payment systems. While some of the requirements are explicitly described in statute and others are captured in CMS regulatory rules or subregulatory guidance, the requirements are unique to the particular type of institution.

Section 1833(t)(21)(C) of the Act provides for the availability of payment under other payment systems for items and services furnished by nonexcepted off-campus PBDs and for certain items and services furnished by excepted off-campus PBDs that are not covered OPD services under the OPPS (for example, expanded clinical families of services). We refer to these items and services collectively as ''nonexcepted items and services.'' Section 1833(t)(21)(C) of the Act provides that payments for these nonexcepted items and services furnished by an off-campus outpatient department of a provider shall be made under the applicable payment system under Medicare Part B (other than under this subsection, that is OPPS), if the requirements for such payment are otherwise met.

While we intend to provide a mechanism for an off-campus PBD to bill and receive payment for furnishing nonexcepted items and services under an applicable payment system that is not the OPPS, at this time, there is no straightforward way to do that before January 1, 2017. At a minimum, numerous complex systems changes would need to be made to allow an off-campus PBD to bill and be paid as another provider or supplier type. For example, currently, off-campus PBDs bill under the OPPS for their services on an institutional claim, whereas physicians and other suppliers bill under the MPFS on a practitioner claim; and there are numerous systems edits designed to be sure that entities enrolled in Medicare bill for their services only within their own payment systems. The Medicare system that is used to process professional claims (the Multi-Carrier System or ''MCS'') was not designed to accept nor process institutional OPPS claims. Rather, OPPS claims are processed through an entirely separate system referred to as the Fiscal Intermediary Standard System or ''FISS'' system. To permit an off-campus PBD to bill under a different payment system than the OPPS would require significant changes to these complex systems as well as other systems involved in the processing of Medicare Part B claims. We are not suggesting these operational issues are insurmountable, but they are multifaceted and will require time and care to resolve. As such, we are not able to propose at this time a mechanism for an off-campus PBD to bill and receive

payment for nonexcepted items and services furnished on or after January 1, 2017, under an applicable payment system that is not the OPPS.

As described in greater detail below, in order to begin implementing the requirements of section 603 of Public Law 114–74, we are proposing to specify that the applicable payment system for purposes of section 1833(t)(21)(C) of the Act is the MPFS. While we do not believe there is a way to permit off-campus PBDs to bill for nonexcepted items and services they furnish under the MPFS beginning January 1, 2017, we are actively exploring options that would allow off-campus PBDs to bill for these services under another payment system, such as the MPFS, and be paid at the applicable rate under such system beginning in CY 2018. We are soliciting public comment on the changes that might need to be made to enrollment forms, claim forms, the hospital cost report, as well as any other operational changes that might need to be made in order to allow an off-campus PBD to bill for nonexcepted items and services under a payment system other than the OPPS in a way that provides accurate payments under such payment system and minimizes burden on both providers and Medicare beneficiaries. Accordingly, we intend the policy we are proposing in this proposed rule to be a temporary, 1-year solution until we can adapt our systems to accommodate payment to off-campus PBDs for the nonexcepted items and services they furnish under the applicable payment system, other than OPPS.

b. Proposed Payment for Applicable Items and Services Furnished in Off-Campus PBDs That Are Subject to Sections 1833(t)(1)(B)(v) and (21) of the Act

(1) Definition of ''Applicable Payment System'' for Nonexcepted Items and Services

In this section, we describe our interpretation and proposed implementation of section 1833(t)(21)(C) of the Act, as it applies to nonexcepted items and services for CY 2017 only. Section 1833(t)(21)(C) of the Act requires that payments for nonexcepted items and services be made under the applicable payment system under Medicare Part B (other than under this subsection; that is, the OPPS) if the requirements for such payment are otherwise met. While section 1833(t)(21)(C) of the Act clearly specifies that payment for nonexcepted items and services shall not be made under subsection (t) of section 1833 (that is, the OPPS), it does not define the term ''applicable payment system.'' In analyzing the term ''applicable payment system,'' we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several other payment systems under which payment is made for similar items and services, such as the ASC payment system, the MPFS, or the CLFS.

As noted above, many off-campus PBDs were initially enrolled in Medicare as freestanding physician practices, and were converted as evidenced by the rapid growth of vertical hospital consolidation and hospital acquisition of physician practices.[4] Before these physician practices were converted to off-campus PBDs, the services furnished in these locations, were paid under the MPFS using an appropriate place of service code that identified the location as a nonfacility setting. This would trigger Medicare payment under the MPFS at the nonfacility rate, which includes payment for the ''practice expense'' resources involved in furnishing services. Many physician practices that were acquired by a hospital became provider-based to the hospital in accordance with the regulations at 42 CFR 413.65. Once a hospital-acquired physician practice became provider-based, the location became an off-campus PBD eligible to bill Medicare under the OPPS for its facility services, while physicians' services furnished in the off-campus PBD were paid at the facility rate under the MPFS. Because many of the services furnished in off-campus PBDs are identical to those furnished in freestanding physician practices, as discussed later in this section, we are proposing to designate the applicable payment system for the payment of the majority of nonexcepted items and services to be the MPFS. Specifically, we are proposing that, because we currently do not have a mechanism to pay the off-campus PBD for nonexcepted items and services, the physician or practitioner would bill and be paid for items and services in the off-campus PBD under the MPFS at the nonfacility rate instead of the facility rate.

When items and services similar to those often furnished by off-campus PBDs are furnished outside of a setting with an applicable Medicare institutional payment system, Medicare payment is generally made under the MPFS under one of several different benefit categories of Medicare benefit such as physician's services, diagnostic tests, preventive services, or radiation treatment services. Although section 1833(t)(1)(B)(v) of the Act specifically carves out from the definition of covered OPD services those items and services defined at section 1833(t)(21)(A) of the Act furnished by certain off-campus PBDs defined by section 1833(t)(21)(B) of the Act, the amendments to section 1833(t) of the Act do not specify that the off-campus outpatient departments of a provider are no longer considered a PBD part of the hospital. This nuance made it difficult for us to determine how to provide payment for the hospital-based portion of the services under MPFS because, as previously noted, Medicare payment processing systems were not designed to allow these off-campus PBDs to bill for their hospital services under a payment system other than OPPS.

Currently, a hospital (including a PBD) does not meet the requirements to bill under another payment system; that is, a hospital and its departments are enrolled as such in the Provider Enrollment, Chain and Ownership System (PECOS) and may only submit institutional claims for payment of covered OPD services under the hospital OPPS under the CMS Certification Number of the hospital. As explained above, there are several other Medicare payment systems for other types of providers and suppliers. Many of these are designed for particular kinds of institutional settings, are specifically authorized by law, and have their own regulations, payment methodologies, rates, enrollment and billing requirements, and in some cases, cost reporting requirements. While the services furnished in a PBD may be the same or similar to those that are furnished in other sites of service, for Medicare purposes, an off-campus PBD is considered to be part of the hospital that meets the requirements for payment under the OPPS for covered OPD services. There currently is no mechanism for it to be paid under a different payment system. In order to allow an off-campus PBD to bill under the MPFS for nonexcepted items and services, we believe it would be necessary to establish a new provider/supplier type (for nonexcepted off-

[4] The number of vertically consolidated hospitals and physicians increased from 2007 through 2013. Specifically, the number of vertically consolidated hospitals increased from about 1,400 to 1,700, while the number of vertically consolidated physicians nearly doubled from about 96,000 to 182,000. This growth occurred across all regions and hospital sizes, but was more rapid in recent years. (Government Accountability Office; GAO 16–189, December 2015; *http://www.gao.gov/products/GAO-16-189*)

campus PBDs) that could bill and be paid under the MPFS for nonexcepted items and services using the professional claim. At this time, we are not proposing new mechanisms to allow an off-campus PBD to bill and receive payment from Medicare for nonexcepted items and services as currently enrollment as a hospital based department. However, as described in detail later in this section, we are soliciting comment on changes that would need to be made in order to allow an off-campus PBD to bill for nonexcepted items services it furnishes under a payment system other than the OPPS.

Accordingly, for CY 2017, we are proposing the MPFS to be the applicable payment system for nonexcepted items and services that, but for section 603, would have otherwise been paid under the OPPS; and that payment would be made for applicable nonexcepted items and services to the physician or practitioner under the MPFS at the nonfacility rate because no separate facility payment would be made to the hospital. We note that the hospital may continue to bill for services that are not paid under the OPPS, such as laboratory services.

(2) Definition of Applicable Items and Services and Section 603 Amendment to Section 1833(t)(1)(B) of the Act and Proposed Payment for Nonexcepted Items and Services for CY 2017

(a) Background

Section 1833(t)(21)(A) of the Act defines the term ''applicable items and services'' for purposes of paragraph (t)(1)(B)(v) and paragraph (t)(21) to mean items and services (other than those furnished by a dedicated emergency department). Paragraph (1)(B)(v) then specifically carves out from the definition of covered OPD services, that is, those applicable items and services that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (t)(21)(B). Thus, such applicable items and services are not eligible for payment under the OPPS because they are not covered OPD services. Under our proposals, this would mean that all items and services furnished by a nonexcepted off-campus PBD and those nonexcepted items and services furnished by an excepted off-campus PBD (collectively references as nonexcepted items and services) are applicable items and services under the statute. Therefore, instead of being eligible for payment under the OPPS as covered OPD services, paragraph (t)(21)(C) requires that, for nonexcepted items and services, payment shall be made under the applicable payment system, other than OPPS, if the requirements for such payment are otherwise met. In other words, the payment requirement under paragraph (t)(21)(C) applies to items and services furnished by nonexcepted off-campus PBDs and for expanded clinical families of services furnished by excepted off-campus PBDs (nonexcepted items and services).

(b) Proposed Payment Policy for CY 2017

In accordance with sections 1833(t)(1)(B)(v) and 1833(t)(21)(C) of the Act, payment for nonexcepted items and services as defined in section X.A.2. of this proposed rule will no longer be made under the OPPS, effective January 1, 2017. Instead, we are proposing that, for items and services for which payment can be made to a billing physician or practitioner under the MPFS, the physician or practitioner furnishing such services in the off-campus PBD would bill under the MPFS at the nonfacility rate. As discussed earlier in this section, we do not believe that, under current systems, an off-campus PBD could be paid for its facility services under the MPFS, but are actively exploring options that would allow for this beginning in CY 2018. Alternatively, an off-campus PBD would have the option to enroll as a freestanding facility or supplier in order to bill for the nonexcepted items and services it furnishes (which is different from billing only for reassigned physicians' services) under the MPFS.

At this time, we are not proposing a change in payment policy under the MPFS regarding these nonexcepted items and services. However, in the CY 2017 MPFS proposed rule, we are proposing to amend our regulations and subregulatory guidance to specify that physicians and nonphysician practitioners furnishing professional services would be paid the MPFS nonfacility rate when billing for such services because there will be no accompanying Medicare facility payment for nonexcepted items and services furnished in that setting. The MPFS nonfacility rate is calculated based on the full costs of furnishing a service, including, but not limited, to space, overhead, equipment, and supplies. Under the MPFS, there are many services that include both a professional component and a technical component. Similarly, there are some services that are defined as either a ''professional-only'' or ''technical-only'' service. The professional component is based on the relative resource costs of the physician's work involved in furnishing the service and is generally paid at a single rate under the MPFS, regardless of where the service is performed. The technical component portion of the service is based on the relative resource costs of the nonphysician clinical staff who perform the test, medical equipment, medical supplies, and overhead expenses. When the service is furnished in a setting where Medicare makes a separate payment to the facility under an institutional payment system, the technical component is not paid under the MPFS because the practitioner/supplier did not incur the cost of furnishing the technical component. Rather, it would be paid to the facility under the applicable institutional payment system.

If an off-campus PBD that furnishes nonexcepted items and services wishes to bill Medicare for those services, it could choose to meet the requirements to bill and receive payment under a payment system other than the OPPS by enrolling the off-campus PBD as another provider/supplier type. For example, an off-campus PBD could enroll in Medicare as an appropriate alternative provider or supplier type (such as an ASC or physician group practice). The enrolled provider/supplier would then be able to bill and be paid under the payment system for that type of Medicare enrolled entity. For example, if an off-campus PBD were to enroll as a group practice, it would bill on the professional claim and be paid under the MPFS at the nonfacility rate in accordance with laws and regulations that apply under the MPFS.

We recognize that our proposal to pay under the MPFS for all nonexcepted items and services furnished to beneficiaries may result in hospitals establishing business arrangements with the physicians or nonphysician practitioners who bill under the MPFS. We are interested in public comments regarding the impact of other billing and claims submission rules, the fraud and abuse laws, and other statutory and regulatory provisions on our proposals. Specifically, we are interested in public comments regarding the limitations of section 1815(c) of the Act and 42 CFR 424.73 (the reassignment rules); the limitations of section 1842(n) of the Act and 42 CFR 414.50 (the anti-markup prohibition); the application of section 1877 of the Act and 42 CFR 411.350 through 411.389 (the physician self-referral provisions) to any compensation arrangements that may arise; and the application of section 1128B(b) of the Act (the Federal anti-kickback statute) to arrangements between hospitals and the physicians and other nonphysician

practitioners who refer to them. We will consider these laws and regulations as well, and look forward to reviewing public comments on the anticipated impact of these provisions on our proposed policy and any possible future proposals.

We note that there are some services that off-campus departments may furnish that are not billed or paid under the OPPS. For example, although laboratory tests are generally packaged under the OPPS, there are some circumstances in which hospitals are permitted to bill for certain laboratory tests and receive separate payment under the CLFS. These circumstances include:

- Outpatient laboratory tests are the only services provided. If the hospital provides outpatient laboratory tests only and no other hospital outpatient services are reported on the same claim.
- Unrelated outpatient laboratory tests. If the hospital provides an outpatient laboratory test on the same claim as other hospital outpatient services that is clinically unrelated to the other hospital outpatient services (that is, the laboratory test is ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services and for a different diagnosis than the other hospital outpatient services). We note that this exception is being proposed for deletion for CY 2017. We refer readers to section II.B.3.b.(2) of this proposed rule for a discussion of this policy.
- Molecular pathology laboratory tests and advanced diagnostic laboratory tests (ADLTs) (proposed for CY 2017 in section II.B.3.b.(3) of this proposed rule).
- Laboratory tests that are preventive services.

Under our proposal, if a laboratory test furnished by a nonexcepted off-campus PBD is eligible for separate payment under the CLFS, the hospital may continue to bill for it and receive payment under the CLFS. In addition, a bill may be submitted under the MPFS by the practitioner (or hospital for physicians who have reassigned their benefit), provided that the practitioner meets all the MPFS requirements. Consistent with cost reporting guidance and Medicare Program Reimbursement Manual, Part 1, Chapter 23, Section 2302.8, hospitals should report these laboratory services on a reimbursable cost center on the hospital cost report.

In addition, with respect to partial hospitalization programs (PHP) (intensive outpatient psychiatric day treatment programs furnished to patients as an alternative to inpatient psychiatric hospitalization or as a stepdown to shorten an inpatient stay and transition a patient to a less intensive level of care), section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital, to its outpatients, or by a CMHC. Because CMHCs also furnish PHP services and are ineligible to be provider-based to a hospital, we note that a nonexcepted off-campus PBD is eligible for PHP payment if the entity enrolls and bills as a CMHC for payment under the OPPS. A hospital may choose to enroll a nonexcepted off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation.

(3) Comment Solicitation on Allowing Direct Billing and Payment for Nonexcepted Items and Services in CY 2018

For nonexcepted items and services furnished in an off-campus PBD, we are soliciting public comments which we intend to consider in developing a new billing and payment policy proposal for CY 2018. Specifically, we are interested in comments regarding whether an off-campus PBD should be allowed to bill nonexcepted items and services on the professional (not institutional) claim and receive payment under the MPFS, provided the PBD meets all the applicable MPFS requirements. Under this proposal, we envision that the PBD would still be considered to be part of the hospital and that the hospital as a whole would continue to be required to meet all applicable conditions of participations and regulations governing its provider-based status, but, for payment purposes, the off-campus PBD would be considered a nonhospital setting that is similar to a freestanding physician office or clinic and that is paid the same rate that is paid to freestanding offices or clinics under the MPFS. We note that there are other nonpractitioner entities that bill these kinds of services under the MPFS (for example, Independent Diagnostic Testing Facilities, Radiation Treatment Centers), and we are seeking public comments on whether or not there are administrative impediments for hospitals billing for such services. We are seeking public comments on whether making the necessary administrative changes that would allow the hospital to bill for these kinds of services under the MPFS would provide any practical benefit to the hospitals relative to the current requirements for billing under the MPFS. We also are seeking public comments on other implications or considerations for allowing the hospital to do this, such as how the cost associated with furnishing such services might be reflected on the hospital cost report.

4. Beneficiary Cost-Sharing

Under our proposed policy, payment for most nonexcepted items and services under section 1833(t)(21)(C) of the Act would be made under the MPFS to the physician at the nonfacility rate. As a result, we expect that the beneficiary cost-sharing for such nonexcepted items and services would generally be equal to the beneficiary cost-sharing if the service was provided at a freestanding facility.

5. Summary of Proposals

Under our proposed policy, all excepted off-campus PBDs would be permitted to continue to bill for excepted items and services under the OPPS. These excepted items and services include those furnished in an ED, in an on-campus PBD, or within the distance from a remote location of a hospital facility. In addition, excepted items and services include those furnished by an off-campus PBD that was billing Medicare for covered OPD services furnished prior to November 2, 2015 for all services within a clinical family of services, provided that those services continue to be furnished at the same physical address of the PBD as of November 2, 2015. Items and services furnished in a new off-campus PBD (that is, not billing under the OPPS for covered OPD services furnished prior to November 2, 2015) or new lines of service furnished in an excepted off-campus PBD would not be excepted items and services. An excepted off-campus PBD would lose its status as excepted (that is, the off-campus PBD would be considered a new nonexcepted off-campus PBD) if the excepted off-campus PBD changes location or changes ownership; if the new owners also acquire the main hospital and adopt the existing Medicare provider agreement, the excepted off-campus PBD may maintain its excepted status under the other rules outlined in this proposed rule.

For CY 2017, we are proposing that the MPFS will be the ''applicable payment system'' for the majority of nonexcepted items and services furnished in an off-campus PBD. Physicians furnishing services in these departments would be paid based on the professional claim and would be paid at the nonfacility rate for services for which they are permitted to bill. Provided it can meet all Federal and other requirements, a hospital continues to have the option of enrolling the nonexcepted off-campus PBD as the

type of provider/supplier for which it wishes to bill in order to meet the requirements of that payment system (such as an ASC or group practice).

For CY 2018, we are soliciting public comments on regulatory and operational changes that we could make to allow an off-campus PBD to bill and be paid for its services under an applicable payment system. We will take these comments into consideration in developing a new payment policy proposal for CY 2018.

As we and our contractors conduct audits of hospital billing, we and our contractors will examine whether off-campus PBDs are billing under the proper billing system. We expect hospitals to maintain proper documentation showing what lines of service were provided at each off-campus PBD prior to November 2, 2015, and to make this documentation available to us and our contractors upon request.

6. Proposed Changes to Regulations

To implement the provisions of section 1833(t) of the Act, as amended by section 603 of Public Law 114–74, we are proposing to amend the Medicare regulations by (a) adding a new paragraph (v) to § 419.22 to specify that, effective January 1, 2017, for cost reporting periods beginning January 1, 2017, excluded from payment under the OPPS are items and services that are provided by an off-campus provider-based department of a hospital that do not meet the definition of excepted items and services; and (b) adding a new § 419.48 that sets forth the definition of excepted items and services.

B. Changes for Payment for Film X-Ray

Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1833(t)(16) of the Act by adding new subparagraph (F). New section 1833(t)(16)(F)(i) of the Act provides that, effective for services furnished during 2017 or any subsequent year, the payment under the OPPS for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) that would otherwise be made under the OPPS (without application of subparagraph (F)(i) and before application of any other adjustment) shall be reduced by 20 percent. New section 1833(t)(16)(F)(ii) of the Act provides that payments for imaging services that are X-rays taken using computed radiography (including the X-ray component of a packaged service) furnished during CY 2018, 2019, 2020, 2021, or 2022, that would otherwise be made under the OPPS (without application of subparagraph (F)(ii) and before application of any other adjustment), be reduced by 7 percent, and similarly, if such X-ray services are furnished during CY 2023 or a subsequent year, by 10 percent. New section 1833(t)(16)(F)(iii) of the Act provides that the reductions made under section 1833(t)(16)(F) shall not be considered an adjustment under section 1833(t)(2)(E) of the Act, and shall not be implemented in a budget neutral manner. New section 1833(t)(16)(F)(iv) of the Act instructs the implementation of the reductions in payment set forth in subparagraph (F) through appropriate mechanisms which may include use of modifiers. Below we discuss the proposed implementation of the reduction in payment for imaging services that are X-rays taken using film provided for in section 1833(t)(16)(F)(i) of the Act. We will address the reductions in OPPS payment for imaging services that are X-rays taken using computed radiography technology (including the imaging portion of a service) in future rulemaking.

To implement the provisions of sections 1833(t)(16)(F)(i) of the Act relating to the payment reduction for imaging services that are X-rays taken using film that are furnished during CY 2017 or a subsequent year, in this proposed rule, we are proposing to establish a new modifier to be used on claims, as allowed under the provisions of new section 1833(t)(16)(F)(iv) of the Act. The applicable HCPCS codes describing imaging services that are X-rays taken using film can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). We are proposing that, beginning January 1, 2017, hospitals would be required to use this modifier on claims imaging services that are X-rays taken using film. The use of this proposed modifier would result in a 20-percent payment reduction for an imaging service that is an X-ray service taken using film, as specified under section 1833(t)(16)(F)(i) of the Act, of the determined OPPS payment amount (without application of subparagraph (F)(i) and before any other adjustments under section 1833(t) of the Act). For further discussion regarding the budget neutrality of the payment reductions under section 1833(t)(16)(F) of the Act, we refer readers to section XX.A.3. of this proposed rule.

C. Changes to Certain Scope-of-Service Elements for Chronic Care Management (CCM) Services

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70450 through 70453), we finalized the CCM scope of service elements (as described in the CY 2015 MPFS final rule with comment period (79 FR 67721)) required in order for hospitals to bill and receive OPPS payment for furnishing CCM services. These scope-of-service elements are the same as those required for CCM under the MPFS. In the CY 2017 MPFS proposed rule, we are proposing some minor changes to certain CCM scope of service elements. We are proposing that these proposed changes also would apply to CCM services furnished to hospital outpatients under the OPPS. All of the fundamental scope-of-service requirements are remaining intact. An example of these proposed minor changes are that the electronic sharing of care plan information would need to be timely but not necessarily on a 24 hour a day/7 days week basis, as is currently required. We refer readers to the CY 2017 MPFS proposed rule for a detailed discussion of the proposed changes to the scope of service elements for CCM.

D. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access of Medicare Act of 2014 (PAMA, Pub. L. 113–93) amended section 1834 of the Act by adding paragraph (q) which directs the Secretary to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 MPFS final rule with comment period (80 FR 71102 through 71116) addressed the initial component of the Medicare AUC program, including specifying applicable AUC and establishing CMS authority to identify clinical priority areas for making outlier determinations. The regulations governing the Medicare AUC program are codified at 42 CFR 414.94. The program's criteria and requirements were established and are being updated as appropriate through the MPFS rulemaking process. While the MPFS is the most appropriate vehicle for this practitioner-based program, we note that ordering practitioners will be required to consult AUC at the time of ordering advanced diagnostic imaging, and imaging suppliers will be required to report information related to such consultations on claims, for all applicable advanced diagnostic imaging services paid under the MPFS, the OPPS, and the ASC payment system. The CY 2017 MPFS proposed rule includes proposed requirements and processes for the second component of the Medicare AUC program, which is the specification of qualified clinical

i. Effects of Proposed Requirements for the Hospital VBP Program

In section XIX. of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to remove the HCAHPS Pain Management dimension in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain.

As required under section 1886(o)(2)(A) of the Act, the HCAHPS Survey is included the Hospital IQR Program. Therefore, its inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program. The proposed removal of the HCAHPS Pain Management dimension from the Hospital VBP Program also would not result in any additional reporting burden.

j. Effects of Proposed Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating To Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider

In section X.A. of this proposed rule, we discuss the proposed implementation of section 603 of the Bipartisan Budget Act of 2015 relating to payments for certain items and services furnished by certain off-campus departments of a provider. Section 603 does not impact OPPS payment rates or payments to OPPS-eligible providers. The impact tables displayed in section XXIII.A.3. of this proposed rule do not factor in changes in volume or service-mix in OPPS payments. As a result, the impact tables displayed in section XXIII.A.3. of this proposed rule do not reflect changes in the volume of OPPS services due to the implementation of section 603.

We estimate that implementation of section 603 will reduce net OPPS payments by $500 million in CY 2017, relative to a baseline where section 603 was not implemented in CY 2017. We estimate that section 603 would increase payments to physicians under the MPFS by $170 million in CY 2017, resulting in a net Medicare Part B impact from the provision of reducing CY 2017 Part B expenditures by $330 million. These estimates include both the FFS impact of the provision and the Medicare Advantage impact of the provision. These estimates also reflect that the reduced spending from implementation of section 603 results in a lower Part B premium; the reduced Part B spending is slightly offset by lower aggregate Part B premium collections.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards*.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule would increase payments to small rural hospitals by less than 3 percent; therefore, it should not have a significant impact on approximately 634 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $146 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2017. Table 31 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.6 percent increase in payments for all services paid under the OPPS in CY 2017, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed wage index changes, including the proposed frontier State wage index adjustment, proposed estimated payment for outliers, and proposed changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2017.

The proposed updates to the ASC payment system for CY 2017 would affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 32 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI–U update factor of 1.2 percent for CY 2017.

XXV. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 30 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 1.6 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government

ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs—health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

■ 1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 416.171 is amended by revising paragraph (b)(2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(b) * * *

(2) The device portion of device-intensive procedures, which are procedures with a HCPCS code-level device offset of greater than 40 percent when calculated according to the standard OPPS APC ratesetting methodology.

* * * * *

■ 3. Section 416.310 is amended by revising paragraphs (c)(1)(ii) and (d)(1) and adding paragraph (e) to read as follows:

§ 416.310. Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(ii) *Data collection requirements.* The data collection time period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Beginning with the CY 2017 payment determination year, data collected must be submitted during the time period of January 1 to May 15 in the year prior to the payment determination year.

* * * * *

(d) * * *

(1) Upon request of the ASC. ASCs may request an extension or exemption within 90 days of the date that the extraordinary circumstance occurred. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site; or

* * * * *

(e) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Ambulatory surgical centers must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS survey as a vendor on behalf of one or more ambulatory surgical centers when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS Web site, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Web site.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 4. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 5. Section 419.22 is amended by adding paragraph (v) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(v) Effective January 1, 2017, for cost reporting periods beginning on or after January 1, 2017, items and services that are provided by an off-campus provider-based department (as defined at § 419.48(b)) that do not meet the definition of excepted items and services under § 419.48(a).

■ 6. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(8) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*8*) For calendar year 2017, a multiproductivity adjustment (as determined by CMS) and 0.75 percentage point.

* * * * *

■ 7. Section 419.43 is amended by adding paragraph (d)(7) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(d) * * *

(7) *Community mental health center (CMHC) outlier payment cap.* Outlier payments made to CMHCs for services provided on or after January 1, 2017 are subject to a cap, applied at the individual CMHC level, so that each CMHC's total outlier payments for the calendar year do not exceed 8 percent of that CMHC's total per diem payments for the calendar year. Total per diem payments are total Medicare per diem payments plus the total beneficiary share of those per diem payments.

* * * * *

■ 8. Section 419.44 is amended by revising paragraph (b)(2) to read as follows:

§ 419.44 Payment reductions for procedures.

* * * * *

(b) * * *

(2) For all device-intensive procedures (defined as having a device offset of greater than 40 percent), the device offset portion of the device-intensive procedure payment is subtracted prior to determining the program payment and beneficiary copayment amounts identified in paragraph (b)(1)(ii) of this section.

■ 9. Section 419.46 is amended by adding paragraph (g) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(g) *Requirements for Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey.* OAS CAHPS is the Outpatient and Ambulatory Surgical Center Consumer Assessment of Healthcare Providers and Systems Survey that measures patient experience of care after a recent surgery or procedure at either a hospital outpatient department or an ambulatory surgical center. Hospital outpatient departments must use an approved OAS CAHPS survey vendor to administer and submit OAS CAHPS data to CMS.

(1) [Reserved]

(2) CMS approves an application for an entity to administer the OAS CAHPS Survey as a vendor on behalf of one or more hospital outpatient departments when the applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official OAS CAHPS Web site, and agrees to comply with the current survey administration protocols that can be found on the official OAS CAHPS Survey Web site. An entity must be an approved OAS CAHPS Survey vendor in order to administer and submit OAS CAHPS Survey data to CMS on behalf of one or more hospital outpatient departments.

■ 10. Section 419.48 is added to subpart D to read as follows:

§ 419.48 Definition of excepted items and services.

(a) Excepted items and services are items or services that are furnished on or after January 1, 2017—

(1) In a dedicated emergency department (as defined at § 489.24(b) of this chapter); or

(2) By an off-campus provider-based department that submitted a bill for a covered OPD service prior to November 2, 2015, are furnished at the same location that the department was furnishing such services as of November 1, 2015, and are in the same clinical family of services as the services that the department furnished prior to November 2, 2015.

(b) For the purpose of this section, ''off-campus provider-based department'' means a department of a provider (as defined at § 413.65(a)(2) of this chapter as in effect as of November 2, 2015) that is not located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a remote location of a hospital (as defined in § 413.65 of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter.

■ 11. Section 419.66 is amended by revising paragraph (g) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(g) *Limited period of payment for devices.* CMS limits the eligibility of a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment is made.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 12. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 13. Section 482.80 is amended by revising paragraph (c)(2)(ii)(C) to read as follows:

§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(C) The number of observed events divided by the number of expected events is greater than 1.85.

* * * * *

■ 14. Section 482.82 is amended by revising paragraph (c)(2)(ii)(C) to read as follows:

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(C) The number of observed events divided by the number of expected events is greater than 1.85.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 15. The authority citation for part 486 continues to read as follows:

Authority: 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

■ 16. Section 486.302 is amended by revising the definition of ''Eligible death'' to read as follows:

§ 486.302 Definitions.

* * * * *

Eligible death. An eligible death for organ donation means the death of a person—

(1) Who is 75 years old or younger;

(2) Who is legally declared dead by neurologic criteria in accordance with State or local law;

(3) Whose body weight is 5 kg or greater;

(4) Whose body mass Index (BMI) is 50 kg/m2 or less;

(5) Who had at least one kidney, liver, heart, or lung that is deemed to meet the eligible data definition as follows:

(i) The kidney would be initially deemed to meet the eligible data definition unless the donor meets one of the following:

(A) Is more than 70 years of age;

(B) Is age 50–69 years with history of Type 1 diabetes for more than 20 years;

(C) Has polycystic kidney disease;

(D) Has glomerulosclerosis equal to or more than 20 percent by kidney biopsy;

(E) Has terminal serum creatinine greater than 4/0 mg/dl;

(F) Has chronic renal failure; or

(G) Has no urine output for at least or more than 24 hours;

(ii) The liver would be initially deemed to meet the eligible data definition unless the donor has one of the following:

(A) Cirrhosis;

(B) Terminal total bilirubin equal to or more than 4 mg/dl;

(C) Portal hypertension;

(D) Macrosteatosis equal to or more than 50 percent or fibrosis equal to or more than stage II;