CMS to Reprocess 2019 Clinic Visit Payments in Excepted Off-campus Provider-based Departments due to Court Ruling

AHA Special Bulletin
January 15, 2021

The Centers for Medicare & Medicaid Services (CMS) yesterday announced (https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2021-01-14-mlncff_Toc61416138) that, as a result of a July 17, 2020 U.S. Court of Appeals ruling in its favor, it will begin reprocessing claims for outpatient clinic visits furnished in calendar year (CY) 2019 from excepted off-campus provider-based departments (PBDs) to reduce payment for clinic visits from 100% to 70% of the full outpatient prospective payment system (OPPS) rates.

AHA Take:

AHA is disappointed by CMS' decision to begin to reprocess these CY 2019 claims. We continue to believe that the payment cut for hospital outpatient clinic visits in excepted off-campus PBDs threatens to impede access to care, especially in rural and other vulnerable communities and that CMS' policy undermines clear congressional intent and exceeds its legal authority. While the full U.S. Court of Appeals for the District of Columbia Circuit recently denied our request for a re-hearing of the July 31 decision overturning a lower court's ruling in favor of AHA and hospitals, we will ask the U.S. Supreme Court to review the appeals court decision.

Highlights of CMS' announcement follow.

HIGHLIGHTS OF CMS ANNOUNCEMENT TO REPROCESS CERTAIN 2019 CLAIMS

CMS yesterday announced that by July 1, 2021, it will begin reprocessing CY 2019 claims for outpatient clinic visit services furnished in excepted off-campus PBDs so they are paid at 70% of the OPPS rate, the same rate that non-excepted off-campus PBDs were paid for those services in 2019.

Background: In the CY 2019 OPPS final rule, CMS established a policy to pay for outpatient clinic visits furnished in excepted off-campus PBDs at 40% of the OPPS payment rate, the same rate that these services are paid in non-excepted off-campus PBDs. The agency phased-in the policy over two years, reducing payment to 70% of the OPPS rate in 2019 and 40% of the OPPS rate in 2020.

In December 2018, the AHA, joined by the Association of American Medical Colleges and several member hospitals, filed a lawsuit against the Department of Health and Human Services challenging these payment reductions as violating the Administrative Procedure Act and as exceeding the agency's statutory authority. A federal district court judge in September 2019 sided with AHA and other hospital organizations that challenged the cut, ruling that CMS exceeded its statutory authority when it reduced payments for hospital outpatient clinic visit services provided in off-campus PBDs excepted under the Social Security Act. As a result, CMS reprocessed the 2019 claims to pay them at 100% of the full OPPS rate. However, in July 2020, the appeals court reversed the district court ruling, upholding CMS' clinic visit cuts. AHA will ask the U.S. Supreme Court to review the appeals court decision.

NEXT STEPS

As the reprocessing of claims will be conducted automatically, starting sometime before July 1, CMS notes that hospitals do not need to take any actions. However, hospitals with excepted off-campus PBDs that billed clinic visits in 2019 should be aware that they may owe Medicare money as result of this claims reprocessing.

If you have further questions, contact Roslyne Schulman, AHA director of policy, at rschulman@aha.org (mailto:rschulman@aha.org).

KEY TAKEAWAYS

- Due to a U.S. Court of Appeals decision, CMS has announced it will reprocess 2019 claims furnished in excepted off-campus PBDs to reduce payment for clinic visits from 100% to 70% of the full OPPS rate.
- The reduction will be automatic – hospitals do not need to do anything.
- Hospitals should be aware that they may owe Medicare money as result of this claims reprocessing.
- AHA will ask the U.S. Supreme Court to review of the appeals court decision.

Key Resources

CMS to Reprocess 2019 Clinic Visit Payments in Excepted Off-campus Provider-based Departments due to Court Ruling

Related Resources

FACT SHEETS

Report: Examining the Real Factors Driving Physician Practice Acquisition (/fact-sheets/2023-06-07-fact-sheet-examining-real-factors-driving-physician-practice-acquisition)

INFOGRAPHICS

Site-neutral Payment Policies Threaten Access to Hospital-level Care Infographic (/infographics/2023-06-06-site-neutral-payment-policies-threaten-access-hospital-level-care-infographic)

SPECIAL BULLETIN

Join AHA to Discuss Site-neutral Payment Policies Impact on Hospitals and Health Systems (/special-bulletin/2023-05-30-join-aha-discuss-site-neutral-payment-policies-impact-hospitals-and-health-systems)

TESTIMONY

AHA Statement Opposing House Energy & Commerce Committee Bill Markup (/testimony/2023-05-24-aha-statement-opposing-house-energy-commerce-committee-bill-markup)

ACTION ALERT

ACTION NEEDED: New Analysis Shows Site-neutral Proposals Would Reduce Medicare Payments to Hospitals by Billions (/action-alert/2023-05-23-action-needed-new-analysis-shows-site-neutral-proposals-would-reduce-medicare-payments-

LETTER/COMMENT

AHA, Other National Hospital Groups Oppose Site-Neutral Legislation (/lettercomment/2023-05-23-aha-other-national-hospital-groups-oppose-site-neutral-legislation)

RELATED TOPICS: Outpatient PPS (/topics/outpatient-pps)

STRATEGIC HEALTH CARE

August 26, 2019

To: IHCC Members

From: David Introcaso, Ph.D., VP, Regulatory Policy
Paul Lee, Senior Partner

Re: Addressing CMS' Site Neutral Payment Policy Initiatives

Summary
First, CMS has exceeded the Congress's intent in regulatorily implementing Section 603 of the 2015 Balanced Budget Act. Second, site neutral works in abstraction but not in application. As applied or in practice, site neutral payments enjoy little or no supportive evidence. Site neutral payments do not account for non-comparable patient populations thereby creating an unlevel playing field. Third, CMS has moved beyond HOPD in its zeal to impose site neutral policy more broadly, for example, in CMMI demonstrations. Moreover, site neutral payments do not move past MedPAC's long-standing criticism that CMS needs to move beyond "just blindly paying FFS [Fee for Service] rates" or more towards recognizing and rewarding value or spending efficiency.

Background
Based in part on a March 2014 MedPAC recommendation that the Congress eliminate the differences in payment rates between hospital Out Patient Physician Departments or HOPDs (CMS terms these Provider Based Departments or PBDs) and freestanding physician offices, the Congress in its November 2, 2015 Balanced Budget Act included Section 603 that made payments to certain HOPDs site neutral. MedPAC's recommendation was based in part on a previous 2012 MedPAC recommendation that called for aligning HOPD Evaluation and Management (E&M) reimbursement with that of freestanding physician offices. "On campus," or those within 250 yards of a hospital or a remote location of a hospital, were exempted from this policy as were dedicated off campus emergency departments and Critical Access Hospitals.

More specifically, HOPDs that were not billing as of November 2, 2015 or those not defined as excepted or grandfathered, would, effective January 1, 2017, no longer be reimbursed under the Out-Patient Prospective Payment System (OPPS). Instead, the Congress determined non-excepted or grandfathered HOPDs were to be paid under an "applicable payment system" under Medicare Part B. The 2017 final OPPS rule established the Medicare Physician Fee Schedule (PFS) as the ''applicable payment system."

MedPAC's 2014 site neutral recommendation was based on its finding that HOPD reimbursement under the OPPS could be more than two times that of the PFS for the same service. Site neutral payment would therefore reduce HOPD spending, MedPAC estimated, by 2.7% and overall Medicare spending by 0.6%. Site neutral payment would also, MedPAC

argued, reduce beneficiary cost sharing and presumably drive care to the most efficient delivery site.

Overview of Regulatory Implementation
Here is an overview of Section 603's implementation to date:

2017 Policies

- The site neutral payment rate would generally be 50% of the OPPS rate.
- Reduced payments would not apply to exempted HOPDs that expand services.
- Relocating an existing HOPD would result in the HOPD losing its exempted status.
- Change of ownership would not cause an HOPD to lose its exempted status if the new owner accepted the existing Medicare provider agreement from the prior owner.

2018 Policies

- Payment for items and services furnished by nonexcepted HOPDs would generally be reimbursed at a rate of 40% of the applicable OPPS rate for 2018.
- CMS also adopted a related HOPD excepted or grandfathered policy regarding separately payable, nonpass-through drugs and biologicals (other than vaccines) purchased via the 340B Program. CMS would pay excepted HOPD providers the average sales price (ASP) minus 22.5% rather than ASP plus 6%. Rural Sole Community Hospitals, PPS-exempt Cancer Hospitals, and Children's Hospitals would be excepted from this policy.

2019 Policies

- CMS expanded site neutral payments to include "clinic visits" (HCPCS Code G0463) in excepted or grandfathered off campus HOPDs. Code G0463 represents approximately 50% of all services furnished in HOPDs annually. The policy would be implemented over two years and in a non-budget neutral manner.
- CMS extended its 2018 HOPD excepted 340B-acquired drugs and biologicals payment policy to non-excepted HOPDs meaning both would now be reimbursed Average Sales Price (ASP) minus 22.5% for 340B drugs.
- CMS added a new HCPCS modifier "ER" for HOPD furnished services in off campus emergency departments (ED) such that CMS can track these services if the agency chose to lower OPPS payment rates for emergency department services in the future.
- As in 2016 CMS again proposed, but did not finalize, paying excepted HOPDs the OPPS rate for services only if these services were in the same clinical family of services that a specific HOPD location had provided and billed prior to November 2, 2015.

2020 Proposed Policies

- CMS is proposing to implement the second year of its payment modification for "clinic visits" (HCPCS Code G0463) in excepted off campus HOPDs – again in a non-budget neutral manner.

Budgetary Impact
As context:

- CMS scored Section 603 of the 2015 BBA as saving $9.3 billion over the 10-year budget window.

- Hospitals are reimbursed approximately $75 billion annually for outpatient services.
- In 2017, total Medicare benefit payments totaled $702 billion.
- Fee for Service and Medicare Advantage spending for Part A was $293 billion, for Part B $309 billion and for Part D $100 billion.
- MA spending alone for Part A and B in 2017 was $210 billion.

2017: In the 2017 final rule CMS estimated Part B spending would be reduced by roughly $50 million in 2017. CMS initially estimated savings at $330 million, however, the agency lowered its estimate after reviewing OPPS claims data for the first six months of CY 2016. In addition, the proposed estimate included lower Medicare Advantage (MA) payments. In the final CMS deleted estimated MA-related savings because the 2017 Medicare Advantage payment rates were set before Section 603 could be implemented. If CMS had finalized the proposed rule policy using this revised assumption, the agency would have estimated reduced Medicare Part B expenditures at $70 million in 2017.

2018: CMS estimated the change in 340B reimbursement at $1.6 billion or $700 million over the proposed rule estimate. CMS recognized calculating an estimate was difficult in part because OPPS claims did not indicate the drub being provided was purchased with a 340B discount and outpatient drugs covered under 340B were not publicly available. CMS noted the agency would implement the policy in a budget neutral manner, i.e., the agency would redistribute an equal dollar amount for non-drug items and services across the OPPS.

2019: Regarding the agency's HCPCS G0463-related policy, CMS estimated a decrease in OPPS payments at $300 million plus another $80 million in beneficiary copayments. Had CMS fully implemented the policy change in 2019, total Medicare and beneficiary copayments would have decreased by $750 million.

2020: In the proposed 2020 OPPS rule, CMS estimated the second-year phase in of the HCPCS G0463-related policy would save $810 million in 2020. Fully implemented, CMS estimates the policy will reduce OPPS payments by 1.2% or more.

Support for Site Neutral Payments

Section 603 enjoys considerable bi-partisan support. For example, in a March 1 American Enterprise Institute (AEI) - Brookings joint letter to HELP Committee Chairman, Lamar Alexander, recommending policies "to slow the rate of increase of health care costs, AEI and Brookings recommended site neutral payments apply to "all services delivered in HOPDs – both off and on-campus." AEI and Brookings also recommended the Congress eliminate Section 603's excepted or grandfathered HOPDs. In a 2018 publication Brookings argued site neutral also be expanded to include currently-exempt ambulatory surgical centers. The HELP Committee in later June passed Chairman Alexander's bill, titled the Lower Health Care Costs Act of 2019 (S. 1895). It is expected to pass the full Senate this fall.

Beyond providing savings to the Medicare program and its beneficiaries, MedPAC, AEI, Brookings, and, among others, the Center for American Progress, argue eliminating current payment differentials may contribute to market consolidation eroding provider competition and weakening an insurer's ability to have patients seek lower cost care. Eliminating the excepted or

grandfathered off-campus provision and the standalone emergency department exemption would also reduce the incentive for hospitals to add clinicians to their excepted outpatient departments and the incentive to build more emergency capacity. In its 2019 budget the Trump administration proposed removing these exceptions and estimated savings at $34 billion over ten years. CBO estimated the savings at $14 billion. Concerning on-campus outpatient departments, if they too received site neutral payments, per a 2017 MedPAC estimate, combined savings would equal $2 billion annually.

With bipartisan support it is not surprising in CMS' July 10 press release announcing a radiation oncology payment demonstration, the agency noted the mandatory episode-based payment demo involving physician group practices, HOPDs and freestanding radiation therapy centers would be site neutral. Less than two weeks later in July 22 speech CMS Administrator Seema Verma lamented the fact that "Medicare actually pays more for many services when they're performed in the hospital." This has led, she argued, to "surplus [hospital] beds," causing hospital spending to be "the largest driver of healthcare costs" and "what's worse," she stated, "is government [payment differential] policies are leading to the creation of monopolies, further thwarting competitive forces, resulting in an upward trend in provider consolidation."

Challenging Site Neutrality

The regulatory implementation of Section 603 exceeds the Congress's intent.

The 2019 Final Rule Is Illegal

The American Hospital Association (AHA), the Association of American Medical Colleges and others filed suit against Secretary Azar this past December challenging CMS' 2019 final OPPS rule that reduced excepted HOPD reimbursements for clinic visits or for HCPCS Code G0463 visits. The AHA and others argue the Medicare statute prohibits CMS from "selectively slashing the payment rates for specific types of services," i.e., year-over-year payment adjustments must be budget neutral. The plaintiffs also argue reducing excepted HOPD reimbursements violates the Congress's deliberate intent to create excepted and non-excepted (or grandfathered and non-grandfathered) HOPDs. That is excepted and non-excepted PBDs be treated differently. Concerning the Department's defense that it has the authority under Subsection (t)(2)(F) of the Social Security Act or that it is controlling for "unnecessary increases in volume for a specific service," the plaintiffs argue the comparative disparity in visits does not, per se, make them unnecessary in part since HOPD patients on average tend to be higher acuity and for this reason visits to HOPDs and freestanding physician offices are not (altogether) interchangeable.

For these reasons there is nascent support in the Congress. The Protecting Local Access to Care for Everyone Act of 2019 (HR 2552), would for payment years 2019 and 2020 restore OPPS clinic visit (HCPCS Code G0463) reimbursement rates for excepted HOPDs.

In Practice Site Neutrality Is Unsupported by the Evidence, Fails to Recognize Non-Comparable Patient Characteristics and Fails to Recognize and Reward Value

There is Little Evidence To Support Section 603

CMS, MedPAC and others provide no evidence payment differentials alone are causing unnecessary or excessive utilization, market consolidation, etc. For example, there is evidence, (published in the Journal of Health Economics in 2016) that hospital ownership of physician practices increases the probability physician patients will choose the owning hospital for follow up care. Whether or not increased probability translates to excessive utilization or comparatively worse outcomes is unknown. In addition, as Brookings noted in its 2018 paper, "site-of-service payment differentials are not the only factor driving hospitals to acquire physician practices." For example, it is highly likely if not in fact the case hospitals are simply responding to the migration of medical technology to the outpatient setting. For example, in the currently proposed OPPS rule, CMS is seeking comment on moving total hip arthroplasty (THA) for appropriately selected patients off the Inpatient Only List (IPO) and into the outpatient setting.

Section 603 Fails to Recognize or Account for Non-Comparable Characteristics

In making its March 2014 recommendation MedPAC admitted three problems with HOPD site neutral payments:

1. HOPDs comparatively care for higher acuity patients
2. they incur standby emergency capacity, and
3. incur higher overhead costs.

MedPAC however failed to address these concerns.

Concerning higher acuity patients, in April the American Hospital Association (AHA) released findings by KNG Health Consulting that found when compared to Ambulatory Surgical Centers ASCs), HOPD patients were more likely to be minorities, dual eligible, from lower income areas, suffer higher acuity or burdened with more severe chronic conditions and more likely to be previously hospitalized.

CMS has recognized and rewards providers with comparatively higher acuity patients. For example, in 2017 CMS initiated an effort to make MA's Star Ratings rewards program more equitable for MA plans providers who care for a comparatively greater number of Dual Eligible, Low Income Subsidy (LIS) and disabled beneficiaries. CMS implemented a Categorical Adjustment Index (CAI) that would add or subtract from a MA contract's Overall and/or Summary Star Rating to adjust for the average within-contract proportion of Dual Eligible, LIS and disabled beneficiaries.

Concerning higher overhead costs, MedPAC cannot reasonably argue higher fixed cost organizations be reimbursed the same as lower fixed costs organizations nor can CMS expect the former to remain in business under the latter's reimbursement.

Section 603 Ignores Spending Efficiency

In its March 2014 report MedPAC appropriately recognized site neutral payments do not differentiate or discriminate between high and low spending efficient providers. More recently, MedPAC stated in its March 2019 report, "Medicare's goal should be to obtain the greatest possible value [or spending efficient] for the program's expenditures." "Managing payment

rates," MedPAC wrote," alone will not address the Medicare FFS system's key challenge . . . [that providers] are usually not held accountable for outcomes." "The Congress and the Secretary . . . [must] move the Medicare program beyond just blindly paying FFS rates."

Site neutral payments epitomize "blindly paying FFS rates."

The Medicare program, in sum, neither measures nor rewards for value or again spending efficiency - defined as outcomes achieved relative to spending. For example, the Medicare Access and CHIP Reauthorization Act's (MACRA's) Merit-Based Incentive Payment System (MIPS) program measures for quality and cost separately, not simultaneously. The Medicare Shared Savings Program, CMS' flagship Alternative Payment Model (APM), also does not measure quality and spending simultaneously or attempt to correlate quality or outcomes achieved relative to spending. Neither do Part A's four incentive payment programs, including the Hospital Value Based Purchasing Program (VBP), nor the MA program.

Failure to do so has led to perverse effects. Currently, CMS financially rewards hospitals and physician practice groups that are spending efficient but achieve comparatively worse quality performance while financially punish providers with superior quality that are comparatively less spending efficient. Failure to account for spending efficiency also produces a reverse Robin Hood effect where CMS financially rewards providers at the expense of financially penalizing others with comparatively higher acuity patients.

As it relates to HOPDS, in early 2015 this, then potential, problem was identified by researchers in a study published by the Healthcare Financial Management Association. Titled, "Why Medicare Should Recognize the Value of Provider-Based Clinics," researchers identified high, mid and low-impact (read: spending efficient) on-campus and off-campus outpatient hospital care by using E&M claims data and readmission ratios for Acute Myocardial Infarction (AMI), pneumonia and heart failure. Using MedPAC's 2012 model estimating equalizing or site neutral payments, researchers concluded 186 high-impact hospitals, or 10% of 1,863 hospitals identified in the study, would bear 56%t of total payment reductions. Beyond accruing a disproportionate percent of the reduce payments, the researchers found the high impact hospitals also disproportionately treated indigent or underserved patients. The researchers concluded, "if the outpatient payment equalization policy [as modeled by MedPAC] were enacted, hospitals with a high percentage of uncompensated care would be disproportionately affected to could be forced to change their business model. Loss or shrinkage of hospital-based clinical networks could force patients back to safety-net inpatient care and emergency departments." That is, the policy would not only lead to disproportionately distributing payment cuts but also lead to a reverse Robin Hood effect.

Concerning resultant business model changes, in a recent Health Affairs essay, Mike Chernew and Richard Frank warned Medicare policymakers that they should carefully "titrate provider payment rates as their responses [to changes in payment policy] become more apparent." The authors supported this conclusion by noting data that showed increases in one-year AMI mortality after measurable changes in reimbursement. Previous cuts in Medicare reimbursement have shown, for example, that every $1,000 predicted loss in Medicare revenue per discharge was associated with a 2% increase in one-year mortality.

MedPAC has also argued for well over a decade that the Medicare program should reimburse providers based on beneficiary characteristics such as comorbidities, age and reason to treat. The Congress and CMS have been incrementally working toward this goal. For example, this was Congress's intent in passing in 2014 the bipartisan Improving Medicare Post-Acute Care Transformation (IMPACT) Act. IMPACT creates standardized assessments for care across the spectrum of four post-acute care providers (specifically home health, inpatient rehabilitation facilities long term care hospitals and skilled nursing facilities) that ensures patient care is delivered based on beneficiary characteristics and eliminates the current non-comparative, silo focused approach to quality performance benchmarking and reimbursement.

Similarly, the Senate HELP Committee's Lower Health Care Costs Act of 2019 (noted above) is designed, in part, to make transparent commercial payer-achieved care outcomes. Section 303 of the bill calls for a non-government, non-profit entity to publicly report commercial health care data concerning care delivery cost, quality and value or spending efficiency. Concerning CMS, in its just-published proposed Physician Fee Schedule rule the agency contemplates creating MIPS Value Pathways (MVPs) to "reward high value care." CMS states specifically in the proposed, "we define "value" as a measurement of quality as related to cost." Similarly, in the proposed OPPS rule's discussion of price transparency, CMS notes the agency's intent to "pair" quality of care and outcome data with price information "to allow patients to make informed decisions about where they could receive their care and to help ensure that consumers do not assume that the high cost of services necessarily equates to higher quality of care."

Conclusion

In implementing Section 603 CMS is effectively discriminating against excepted HOPDs thereby creating an unlevel playing field between them and freestanding physician offices. More substantively, differences in patient populations (that are recognized in other Medicare silos), differences in fixed or overhead costs, the failure to account for value or spending efficiency and the potential for unintended negative consequences, policy makers should reconsider or at least refine Section 603 to include rewarding value in provider payment policies. For example, since it appears HOPDs will be paid increasingly under the Physician Fee Schedule and since it is CMS' policy to incent providers to participate in APMs, HOPDs should be explicitly allowed to compete for MACRA's 5% Advanced APM bonus.

STRATEGIC HEALTH CARE

Summary of Site Neutral, 340B and Price Transparency Policies Contained in the CMS Proposed 2020 OPPS Rule

July 30, 2019

On July 29, 2019, CMS released the agency's 2020 Outpatient Prospective Payment System (OPPS) proposed rule. Click here for the CMS fact sheet and here for the 819-page rule. Below are summaries of the changes proposed for site neutral payments, 340B drug rates, and price transparency policies.

Price Transparency – This will impact CAHs

(CMS would require hospitals to post payer-specific negotiated charges)

CMS makes several proposals to implement President's Executive Order on Improving Price and Quality Transparency. First, CMS clarifies that the existing requirements that hospitals make standard charges available in a machine-readable format means that hospitals must make public gross charges and payer-specific negotiated charges for all items or services. Additionally, CMS proposes that hospitals make public standard charge data available for at least 300 "shoppable services," which are services that can be scheduled in advance.

CMS proposes to require hospitals to make public a list of their payer-specific negotiated charges for as many of the 70 shoppable services that are provided by the hospital, and as many additional shoppable services selected by the hospital as is necessary for a combined total of at least 300 shoppable services. More specifically, CMS is proposing definition changes to "hospital," a hospital's "items and services," types of "standard charges" or gross charges and payer-specific negotiated charges in connection with an inpatient admission and an outpatient department visit that hospitals would be required to make public and proposing different reporting requirements that would apply to certain hospitals. CMS also proposes requirements to make public a machine-readable file that contains a hospital's gross charges and payer-specific negotiated charges for all items and services provided by the hospital, requirements for making public payer-specific negotiated charges for select hospital-provided items and services that are "shoppable" and that are displayed in a consumer-friendly manner.

See moreover pages 568, ff. CMS lists at page 627 Table 37 that provides the proposed list of 70 CMC-specified shoppable services. There is no list of "300 shoppable services" provided by CMS. It appears CMS will require a significant increase in the initial 300 services to be added to the disclosed pricing list each year. CMS believes it is reasonable to require a portion (i.e. the 70 listed) of the 300 shoppable services to be CMS-selected in order to ensure standardization that would provide consumers with the ability to compare prices across hospital settings. CMS believes it would be prudent to permit hospitals to select a portion of the shoppable services themselves, recognizing that some hospitals may specialize in certain services or may serve populations that utilize other shoppable services with more frequency or are more relevant than the ones we have identified for purposes of the CMS-selected services.

Concerning how CMS is proposing to monitor price transparency regulations see the discussion beginning at page 638, titled "Proposed Monitoring and Enforcement of Requirements for Making Standard Charges Public." Concerning civil monetary penalties, at page 644 CMS states, "We are proposing that we may impose a CMP upon a hospital for a violation of each requirement of proposed 45 CFR part 180. The maximum daily dollar amount for a CMP to which a hospital may be subject would be $300. We are proposing that even if a hospital is in violation of multiple discrete requirements, the maximum total sum that a single hospital may be assessed per day is $300."

Site Neutral Payments – No Changes Impacting CAHs

(CMS' proposed rule fully implements HOPD payment cuts that started in January 2019)

In 2019, CMS expanded site neutral payment policy provisions under Section 603 of the 2015 Balanced Budget Act (BBA) to include clinic visits (HCPCS code G0463) for excepted - or grandfathered - off-campus Hospital Outpatient Physician Departments (HOPDs), or as CMS terms Physician Based Departments (PBDs). Because six percent of hospitals would have shouldered 73% of the proposed payment reduction in 2019, CMS chose to phase-in the reimbursement reduction over two years with visits being paid at 70 percent of the outpatient PPS rate for CY 2019 and transitioning to the full physician fee schedule rate for CY 2020.

In the proposed 2020 rule, CMS states it will continue with the agency's two-year implementation of payment modification to excepted off campus HOPDs/PBDs. CMS estimates the proposal will save the Medicare program $810 million in 2020. (See pages 426, ff.)

340B Payment Policy – No Changes Impacting CAHs

(Despite a federal court ruling against the rule, CMS continues the 340B payment cuts)

In 2018, CMS decreased payment for separately payable Part B drugs (excluding vaccines and drugs on pass-through payment status), acquired through the 340B program from average sales price (ASP) +6% to ASP - 22.5%. In the CY 2019 CMS expanded this provision to non-excepted, off-campus HOPDs/PBDs as well as finalized a policy to pay non-pass-through biosimilars acquired under the 340B program at ASP -22.5% of the biosimilar's own ASP rather than ASP -22.5% of the reference product's ASP. CMS proposes to continue this policy for CY 2020. (See pages 327, ff.)

In response to litigation filed by the AHA and others, CMS states in the proposed rule that, should the agency ultimately lose in court, it is seeking comments on whether reimbursing qualifying 340B claims at a rate of ASP +3% would be an acceptable remedy for 2020 as well as an "appropriate" retrospective remedy for 2018 and 2019. CMS is also seeking comments on whether the agency should over-pay in future payments for a set period of time to account for under-payments during the two previous years. If it does ultimately lose in court, CMS states it would in its proposed 2021 rule identify specific remedies for 2018, 2019 and possibly 2020 underpayments. (See page 20 and page 342, ff for more on the litigation and remedy.)

Contact David Introcaso, Ph.D., Vice President at david.introcaso@shcare.net or 202-266-2600

Final Rule OPPS FY 2019

TABLE 49.—CHANGES TO THE INPATIENT ONLY LIST FOR CY 2019

CY 2019 CPT Code	CY 2019 Long Descriptor	Action	CY 2019 OPPS APC Assignment	CY 2019 OPPS Status Indicator
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	Removed from IPO list	5153	J1
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty	Removed from IPO list	N/A	N
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed).	Removed from IPO list	5463	J1
00670	Anesthesia for extensive spine and spinal cord procedures (eg, spinal instrumentation or vascular procedures)	Removed from the IPO	N/A	N
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	Added to IPO list	N/A	C

BILLING CODE 4120–01–C

X. Nonrecurring Policy Changes

A. Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

The June 2017 Report to Congress[63] by the Medicare Payment Advisory Commission (MedPAC) states that, in recent years, there has been significant growth in the number of health care facilities located apart from hospitals that are devoted primarily to emergency department services. This includes both off-campus provider-based emergency departments that are eligible for payment under the OPPS and independent freestanding emergency departments not affiliated with a hospital that are not eligible for payment under the OPPS. Since 2010, we have observed a noticeable increase in the number of hospital outpatient emergency department visits furnished under the OPPS. MedPAC and other entities have expressed concern that services may be shifting to the higher acuity and higher cost emergency department setting due to: (1) Higher payment rates for services performed in off-campus provider-based emergency departments compared to similar services provided in other settings (that is, physician offices or urgent care clinics); and (2) the exemption for services provided in an emergency department included under section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–25), whereby all items and services (emergency and nonemergency) furnished in an emergency department are excepted from the payment implications of section 603, as long as the department maintains its status as an emergency department under the regulation at 42 CFR 489.24(b).

MedPAC and other entities are concerned that these payment incentives may be a key factor contributing to the growth in the number of emergency departments located off-campus from a hospital. MedPAC recommended in its March 2017[64] and June 2017 Reports to Congress that CMS require hospitals to append a modifier to claims for all services furnished in off-campus

[63] Available at: *http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.*

[64] Available at: *http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf.*

provider-based emergency departments, so that CMS can track the growth of OPPS services provided in this setting.

In order to participate in Medicare as a hospital, the facility must meet the statutory definition of a hospital at section 1861(e) of the Act, which requires a facility to be primarily engaged in providing care and services to inpatients. In addition, 42 CFR 482.55 requires hospital emergency department services (to include off-campus provider-based emergency departments) to be fully integrated with departments and services of the hospital. The integration must be such that the hospital can immediately make available the full extent of its patient care resources to assess and furnish appropriate care for an emergency patient. Such services would include, but are not limited to, surgical services, laboratory services, and radiology services, among others. The emergency department must also be integrated with inpatient services, which means the hospital must have a sufficient number of inpatient beds and nursing units to support the volume of emergency department patients that could require inpatient services. The provision of services, equipment, personnel and resources of other hospital departments and services to emergency department patients must be within timeframes that protect the health and safety of patients and is within acceptable standards of practice.

We agree with MedPAC's recommendation and believe we need to develop data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments. Therefore, we announced in the CY 2019 OPPS/ASC proposed rule (83 FR 37138) that we are implementing through the subregulatory HCPCS modifier process a new modifier for this purpose, effective beginning January 1, 2019.

We stated in the proposed rule that we will create a HCPCS modifier (''ER''—Items and services furnished by a provider-based off-campus emergency department) that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department. We specified in the proposed rule that the modifier would be reported on the UB–04 form (CMS Form 1450) for hospital outpatient services. We stated that critical access hospitals (CAHs) would not be required to report this modifier.

In response to our announcement of the creation of HCPCS modifier ''ER'' (Items and services furnished by a provider-based off-campus emergency department), we received the following feedback from commenters in response to the CY 2019 OPPS/ASC proposed rule: Some commenters, including MedPAC, supported the creation of HCPCS modifier ''ER'', citing the opportunity to facilitate the collection of data on services furnished in off-campus emergency departments. Other commenters were opposed to the creation of the HCPCS modifier ''ER'' because they believed it would be an undue and unnecessary administrative burden on hospitals. Another commenter expressed a desire to have a better understanding of the reasoning for the creation of the modifier.

While we note that the creation of the HCPCS modifier ''ER'' was included in the CY 2019 OPPS/ASC proposed rule as an announcement, as opposed to a proposal, and therefore was not subject to public comment, we nonetheless appreciate the feedback provided by interested stakeholders, and will consider such feedback in potential future policy development.

B. Method To Control for Unnecessary Increases in the Volume of Outpatient Services

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), when the Medicare program was first implemented, payment for hospital services (inpatient and outpatient) was based on hospital-specific reasonable costs attributable to furnishing services to Medicare beneficiaries. Although payment for most Medicare hospital inpatient services became subject to a prospective payment system (PPS) under section 1886(d) of the Act in 1983, Medicare hospital outpatient services continued to be paid based on hospital-specific costs. This methodology for payment provided little incentive for hospitals to furnish such outpatient services efficiently and in a cost effective manner. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the hospital inpatient setting to the hospital outpatient setting.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99–509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the Healthcare Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The codes under the HCPCS enabled us to determine which specific procedures and services were billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital outpatients were reported on hospital bills and captured in the hospital outpatient data that were used to develop an outpatient PPS.

The brisk increase in hospital outpatient services further led to an interest in creating payment incentives to promote more efficient delivery of hospital outpatient services through a Medicare outpatient PPS. Section 9343(f) of OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) required that we develop a proposal to replace the existing hospital outpatient payment system with a PPS and submit a report to the Congress on a new proposed system. The statutory framework for the Outpatient Prospective Payment System (OPPS) was established by section 4523 of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33), which amended section 1833 of the Act by adding subsection (t), which establishes a PPS for hospital outpatient department services, and by section 201 of the Balanced Budget Reconciliation Act (BBRA) of 1999 (Pub. L. 106–113), which amended section 1833(t) of the Act to require outlier and transitional pass-through payments. At the outset of the OPPS, there was significant concern over observed increases in the volume of outpatient services and corresponding rapidly growing beneficiary coinsurance. Accordingly, most of the focus was on finding ways to address those issues.

When section 4523 of the BBA of 1997 established the OPPS, it included specific authority under section 1833(t)(2)(F) of the Act that requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered outpatient department (OPD) services.[65] In the initial rule that proposed to implement the OPPS (63 FR 47585 through 47587), we discussed several possible approaches for controlling the volume of covered outpatient department services furnished in subsequent years, solicited comments on those options, and stated that the agency would propose an appropriate ''volume control'' mechanism for services furnished in CY 2001 and beyond after completing further analysis. For the CY

[65] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

2000 OPPS, we proposed to implement a method that was similar to the one used under the Medicare Physician Fee Schedule (PFS) (known as the sustainable growth rate or "SGR"), which would be triggered when expenditure targets, based on such factors as volume, intensity, and beneficiary enrollment, were exceeded (63 FR 47586 through 47587). However, as we discussed in the CY 2001 OPPS final rule (65 FR 18503) and the CY 2002 OPPS final rule (66 FR 59908), we delayed the implementation of the proposed volume control method as suggested by the "President's Plan to Modernize and Strengthen Medicare for the 21st Century" to give hospitals time to adjust to the OPPS and CMS time to continue to examine methods to control unnecessary increases in the volume of covered OPD services.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66612), we noted that we had significant concerns about the growth in program expenditures for hospital outpatient services, and that while the OPPS was developed in order to address some of those concerns, its implementation had not generally slowed that growth in expenditures. To address some of those concerns, we established a set of packaging policies beginning in CY 2008 that would explicitly encourage efficiency in the provision of services in the hospital outpatient setting and potentially control future growth in the volume of OPPS services (72 FR 66612). Specifically, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), we adopted a policy to package seven categories of items and services into the payment for the primary diagnostic or therapeutic modality to which we believe these items are typically ancillary or supportive.

Similarly, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925 through 74948), we expanded our packaging policies to include more categories of packaged items and services as part of a broader initiative to make the OPPS more like a prospective payment system and less like a per service fee schedule. Packaging can encourage hospitals to furnish services efficiently while also enabling hospitals to manage their resources with the maximum flexibility, thereby encouraging long-term cost containment, which is an essential component of a prospective payment system. While most of the packaging policies established in the CY 2014 OPPS focused on ancillary services that were part of a primary procedure, we also introduced the concept of comprehensive APCs (C–APCs) (78 FR 74861 through 74910), which were implemented beginning in the CY 2015 OPPS (79 FR 66798 through 66810). Comprehensive APCs package payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level.

While we have developed many payment policies with these goals in mind, growth in program expenditures for hospital outpatient services paid under the OPPS continues. As illustrated in Table 30 in the CY 2019 OPPS/ASC proposed rule (83 FR 37139), total spending has been growing at a rate of roughly 8 percent per year under the OPPS, and total spending under the OPPS is projected to further increase by more than $5 billion from approximately $70 billion in CY 2018 through CY 2019 to nearly $75 billion. This is approximately twice the total estimated spending in CY 2008, a decade ago. We continue to be concerned with this rate of increase in program expenditures under the OPPS for several reasons. The OPPS was originally designed to manage Medicare spending growth. What was once a cost-based system was mandated by law to become a prospective payment system, which arguably should have slowed the increases in program spending. To the contrary, the OPPS has been the fastest growing sector of Medicare payments out of all payment systems under Medicare Parts A and B. Furthermore, we are concerned that the rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, are affecting site-of-service decision-making. This site-of-service selection has an impact on not only the Medicare program, but also on Medicare beneficiary out-of-pocket spending. Therefore, to the extent that there are lower-cost sites-of-service available, we believe that beneficiaries and the physicians treating them should have that choice and not be encouraged to receive or provide care in higher paid settings solely for financial reasons. For example, to provide for easier comparisons between hospital outpatient departments and ASCs, as previously discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59389), we stated in the CY 2019 OPPS/ASC proposed rule that we also will make available a website that provides comparison information between the OPPS and ASC payment and copayment rates, as required under section 4011 of the 21st Century Cures Act (Pub. L. 114–255). Making this information available can help beneficiaries and their physicians determine the cost and appropriateness of receiving care at different sites-of-service. Although resources such as this website will help beneficiaries and physicians select a site-of-service, we do not believe this information alone is enough to control unnecessary volume increases. The growth in OPPS expenditures and the increase in the volume and intensity of hospital outpatient services were illustrated in Tables 30 and 31, respectively, of the CY 2019 OPPS/ASC proposed rule (83 FR 37139 through 37140). These tables, which include updated information, are presented below.

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TABLE 50.—GROWTH IN EXPENDITURES UNDER OPPS FROM CY 2010 THROUGH CY 2019* (in millions)

Calendar Year (CY)	Incurred Cost	Percent Increase
CY 2010	$36,774	-
CY 2011	$39,781	8.2%
CY 2012	$43,154	8.5%
CY 2013	$46,462	7.7%
CY 2014	$52,429	12.8%
CY 2015	$56,275	7.3%
CY 2016	$59,869	6.4%
CY 2017	$64,050	7.0%
CY 2018	$68,264	6.6%
CY 2019 (Estimated)	$74,468	9.1%

*Includes Medicare Part B Drug Expenditures.

TABLE 51.—PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES*

Calendar Year (CY)	Percentage Increase
CY 2011	3.7%
CY 2012	5.1%
CY 2013	5.5%
CY 2014	8.1%
CY 2015	3.4%
CY 2016	6.4%
CY 2017	5.4%
CY 2018	6.4%
CY 2019 (Estimated)	5.4%

*Includes Medicare Part B Drug Expenditures.

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As noted in its March 2018 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) found that, from 2011 through 2016, combined program spending and beneficiary cost-sharing on services covered under the OPPS increased by 51 percent, from $39.8 billion to $60.0 billion, an average of 8.6 percent per year.[66] In its 2018 report, MedPAC also noted that "A large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs".[67] We consider these shifts in the sites of service unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting.

As noted in MedPAC's March 2017 Report to Congress, "from 2014 to 2015, the use of outpatient services increased by 2.2 percent per Medicare FFS beneficiary. Over the decade ending in 2015, volume per beneficiary grew by 47 percent. One-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of evaluation and management (E&M) visits billed as outpatient services. This growth in part reflects hospitals purchasing freestanding physician practices and converting the billing from the Physician Fee Schedule to higher paying hospital outpatient department (HOPD) visits. These conversions shift market share from freestanding physician offices to HOPDs. From 2012 to 2015, hospital-based E&M visits per beneficiary grew by 22 percent, compared with a 1-percent decline in physician office-based visits."[68]

MedPAC has documented how the billing for these services has shifted from physician offices to higher-cost outpatient sites of care for several years. At the same time, MedPAC has repeated its recommendation that the difference in payment rates between hospital outpatient departments and physician offices should be reduced or eliminated. It specifically recommended in its 2012

[66] Available at: *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.*

[67] Ibid.

[68] Available at: *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch3.pdf?sfvrsn=0.*

Report to Congress that the payment rates for E&M visits provided in hospital outpatient departments be reduced so that total payment rates for these visits are the same, whether the service is provided in a hospital outpatient department or a physician office. In its 2014 Report to Congress, MedPAC recommended that Congress direct the Secretary to reduce or eliminate differences in payment rates between hospital outpatient departments and physician offices for selected APCs. Both of these recommendations were reiterated in MedPAC's March 2017 Report to Congress.

As previously noted, in addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we also are concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in freestanding physician offices. For example, MedPAC estimates that "the Medicare program spent $1.0 billion more in 2009, $1.3 billion more in 2014, and $1.6 billion more in 2015 than it would have if payment rates for E&M office visits in HOPDs were the same as freestanding office rates. Relatedly, beneficiaries' cost-sharing was $260 million higher in 2009, $325 million higher in 2014, and $400 million higher in 2015 than it would have been because of the higher rates paid in HOPD settings."[69] We believe that this volume growth and the resulting increase in beneficiary cost-sharing is unnecessary because it appears to have been incentivized by the difference in payment for each setting rather than patient acuity. If there was not a difference in payment rates, we believe that we would not have seen the increase in beneficiaries' cost-sharing and the shift in site-of-service.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41013), we stated that we continued to seek a better understanding of how the growing trend toward hospital acquisition of physicians' offices and subsequent treatment of those locations as off-campus provider-based departments (PBDs) of hospitals affects payments under the PFS and the OPPS, as well as beneficiary cost-sharing obligations. We noted that MedPAC continued to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and that MedPAC recommended that Medicare pay selected hospital outpatient services at PFS rates (MedPAC March 2012 and June 2013 Reports to Congress).

To understand how this trend was affecting Medicare, we explained that we needed information on the extent to which this shift was occurring. To that end, during the CY 2014 OPPS/ASC rulemaking cycle, we sought public comment regarding the best method for collecting information and data that would allow us to analyze the frequency, type, and payment for physicians' services and hospital outpatient services furnished in off-campus PBDs of hospitals (78 FR 75061 through 75062 and 78 FR 74427 through 74428). Based on our analysis of the public comments we received, we believed that the most efficient and equitable means of gathering this important information across two different payment systems would be to create a HCPCS modifier to be reported with every code for physicians' services and hospital outpatient services furnished in an off-campus PBD of a hospital on both the CMS–1500 claim form for physicians' services and the UB–04 form (CMS Form 1450 and OMB Control Number 0938–0997) for hospital outpatient services. We noted that a main provider may treat an off-campus facility as provider-based if certain requirements at 42 CFR 413.65 are satisfied, and we define a "campus" at 42 CFR 413.65(a)(2) to be the 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 2015, the Congress took steps to address the higher Medicare payments for services furnished by certain off-campus PBDs that may be associated with hospital acquisition of physicians' offices through section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015. In the CY 2017 OPPS/ASC proposed rule, we discussed section 603 of the Bipartisan Budget Act of 2015, which amended section 1833(t) of the Act. For the full discussion of our initial implementation of this provision, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (79720 through 79729).

Section 603 of the Bipartisan Budget Act of 2015 (Section 603) amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 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 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead 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.

Section 603 amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of "covered OPD services" applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of the section. Section 603 also added a new paragraph (21) to section 1833(t) of the Act, which defines the terms "applicable items and services" and "off-campus outpatient department of a provider," requires the Secretary to make payments for such applicable items and services furnished by an off-campus PBD under an applicable payment system (other than the OPPS), provides that hospitals shall report on information as needed for implementation of the provision, and establishes a limitation on administrative and judicial review of the Secretary's determinations of applicable items and services, applicable payment system, whether a department meets the definition of an off-campus outpatient department of a provider, and information hospitals are required to report. 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 Pub. L. 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) of the section, an off-campus PBD that was billing under section 1833(t) of the Act with respect to covered OPD services furnished prior

[69] Ibid.

to the date of enactment of the Bipartisan Budget Act of 2015, that is, November 2, 2015. We note that 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 continued to be paid under the OPPS.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79720), we established a number of policies to implement section 603 of the Bipartisan Budget Act of 2015. Broadly, we: (1) Defined 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 will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established 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, we finalized 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; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

As part of developing policies to implement the section 603 amendments to section 1833(t) of the Act, we solicited public comments on information collection requirements for implementing this provision in accordance with section 1833(t)(21)(D) of the Act (81 FR 45686; 81 FR 79709 through 79710). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79719 and 79725), we created modifier "PN" to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS rates for nonexcepted items and services.

While the changes required by the section 603 amendments to section 1833(t) of the Act address some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting, the majority of hospital off-campus departments continue to receive full OPPS payment (including off-campus emergency departments and excepted off-campus departments of a hospital), which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. Therefore, the current site-based payment creates an incentive for an unnecessary increase in the volume of this type of OPD service, which results in higher costs for the Medicare program, its beneficiaries, and taxpayers more generally. These differences in payment rates have unnecessarily shifted services away from the lower paying physician's office to the higher paying hospital outpatient department. We believe that the higher payment that is made under the OPPS, as compared to payment under the PFS, contributes to incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting. In 2012, Medicare was paying approximately 80 percent more for a 15-minute office visit in a hospital outpatient department than in a freestanding physician office.[70]

For example, under Medicare payment policy in effect for CY 2018, the Medicare program would pay more for a clinic visit (HCPCS code G0463) furnished under the OPPS than it would for the visit codes under the PFS. In the CY 2017 OPPS/ASC interim final rule, we noted that the most frequently billed service with the "PO" modifier was described by HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is paid under APC 5012 (Clinic Visits and Related Services); the total number of CY 2017 claim lines for this service was approximately 10.8 million lines with the "PO" modifier as of October 2018, out of a total 30.5 million lines in CY 2017. When services are furnished in the hospital outpatient setting, an additional payment for the professional services is generally made under the PFS using the "facility" rate. For example, in CY 2017, the OPPS payment rate for APC 5012, which is the APC to which the outpatient clinic visit code was assigned, was $106.56. The CY 2017 PFS "facility" payment rate for a Level 3 visit, a service that commonly corresponds to the OPPS clinic visit, was $77.88 for a new patient and $51.68 for an established patient.

However, when services are furnished in the physician office setting, only one payment is made—typically, the "nonfacility" rate under the PFS. The CY 2017 PFS nonfacility payment rates for a Level 3 visit, a commonly billed service under the PFS, was $109.46 for a new patient and $73.93 for an established patient. Therefore, the total Medicare Part B payment rate (for the hospital and professional service) for a new patient when the service was furnished in the hospital outpatient setting was $184.44 ($106.56 + $77.88) compared to $109.46 in the physician office setting (approximately $75 or 68 percent more per visit), or for an established patient, $158.24 ($106.56 + $51.68) in the hospital outpatient setting compared to $73.93 in the physician office setting (approximately $84 or 114 percent more per visit). Under these examples, the payment rate was approximately $75 to $84 more for the same service when furnished in the hospital outpatient setting instead of the physician office setting, 20 percent of which was the responsibility of the beneficiary. Taking into account that this payment discrepancy occurs across tens of millions of claims each year, this is a significant source of unnecessary spending by Medicare beneficiaries directly (in the form of unnecessarily high copayments) and on behalf of Medicare beneficiaries (in the form of unnecessarily high Medicare payments for services that could be performed in a different setting).

We understand that many off-campus departments converted from physicians' offices to hospital outpatient departments without a change in either the physical location or a change in the acuity of the patients seen. To the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another. We believe the difference in payment for these services is a significant factor in the shift in services from the physician's office to the hospital outpatient department, thus unnecessarily increasing hospital outpatient department volume and Medicare program and beneficiary expenditures.

We consider the shift of services from the physician office to the hospital outpatient department unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the

[70] Available at: *http://www.medpac.gov/docs/default-source/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf.*

higher paid setting due to payment incentives. We believe the increase in the volume of clinic visits is due to the payment incentive that exists to provide this service in the higher cost setting. Because these services could likely be safely provided in a lower cost setting, we believe that the growth in clinic visits paid under the OPPS is unnecessary. Further, we believe that capping the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed. In particular, we believe this method of capping payment will control unnecessary volume increases both in terms of numbers of covered outpatient department services furnished and costs of those services.

Therefore, given the unnecessary increases in the volume of clinic visits in hospital outpatient departments, in the CY 2019 OPPS/ASC proposed rule (83 FR 37142), for the CY 2019 OPPS, we proposed to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). Off-campus PBDs that are not excepted from section 603 (departments that bill the modifier "PN") already receive a PFS-equivalent payment rate for the clinic visit.

In CY 2019, for an individual Medicare beneficiary, the standard unadjusted Medicare OPPS proposed payment for the clinic visit was approximately $116, with approximately $23 being the average copayment. The proposed PFS equivalent rate for Medicare payment for a clinic visit was approximately $46, and the copayment would be approximately $9. Under this proposal, an excepted off-campus PBD would continue to bill HCPCS code G0463 with the "PO" modifier in CY 2019, but the payment rate for services described by HCPCS code G0463 when billed with modifier "PO" would now be equivalent to the payment rate for services described by HCPCS code G0463 when billed with modifier "PN". This would save beneficiaries an average of $14 per visit. For a discussion of the amount paid under the PFS for clinic visits furnished by nonexcepted off-campus PBDs, we referred readers to the CY 2018 PFS final rule (82 FR 53023 through 53024), as well as the CY 2019 PFS proposed rule and final rule.

In addition, in the CY 2019 OPPS/ASC proposed rule (83 FR 37142), we proposed to implement this proposed method in a nonbudget neutral manner. Specifically, while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, we note that this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. In particular, section 1833(t)(9)(A) of the Act, titled "Periodic review," provides, in part, that the Secretary must annually review and revise the groups, the relative payment weights, and *the wage and other adjustments* described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors" (emphasis added). Section 1833(t)(9)(B) of the Act, titled "Budget neutrality adjustment" provides that if "the Secretary makes *adjustments* under subparagraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made" (emphasis added). However, section 1833(t)(2)(F) of the Act is not an "adjustment" under paragraph (2). Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a "method" for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those paragraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not. Therefore, the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased *beyond* amounts established through those methodologies, the Secretary *may* appropriately adjust the update to the conversion factor otherwise applicable in a *subsequent year*. We interpret this provision to mean that the Secretary will have implemented a volume control method under section 1833(t)(2)(F) of the Act in a nonbudget neutral manner in the year in which the method is implemented, and that the Secretary may then make further adjustments to the conversion factor in a subsequent year to account for volume increases that are *beyond* the amounts estimated by the Secretary under the volume control method.

We stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37143) that we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the movement of the volume within the OPPS system in the aggregate, a concern similar to the one we discussed in the CY 2008 OPPS final rule with comment period (72 FR 66613). This estimated payment impact was displayed in Column 5 of Table 42.— Estimated Impact of the Proposed Changes for the Hospital Outpatient Prospective Payment System in the CY 2019 OPPS/ASC proposed rule (83 FR 37228 through 37229). An estimate that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2019 President's Budget approximates the estimated savings at $760 million, with $610 million of the savings accruing to Medicare, and $150 million saved by Medicare beneficiaries in the form of reduced copayments. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply reallocate expenditures that are unnecessary within the OPPS, we believe that this method must be adopted in a nonbudget neutral manner. The impact associated with this proposal is further described in section XXI. of the CY 2019 OPPS/ASC proposed rule.

Comment: Numerous commenters, including organizations representing private health insurance plans, physician associations, specialty medical associations, and individual Medicare beneficiaries, supported the proposal. Some of these commenters commended CMS for its proposal, which they believed will help to control costs for both beneficiaries and the Medicare program, as well as foster greater competition in the physician services market. Commenters were

supportive of the immediate impact this policy would have in lowering Medicare beneficiaries' out-of-pocket costs. One commenter noted that there ''is no principled basis for treating excepted and nonexcepted PBDs differently with respect to payment for E&M services or for perpetuating the payment differential between off-campus PBDs and physician offices.'' Several commenters supported implementing this policy in a nonbudget neutral manner because they believed to do otherwise would be simply to redistribute expenditures for unnecessary services within the OPPS rather than eliminating those expenditures from the OPPS altogether. A number of commenters urged CMS to continue on a path to bring full parity in payment for outpatient services, regardless of the site-of-service, to lower beneficiary cost-sharing, reduce Medicare expenditures, and stem the tide of provider consolidation. Two commenters believed that several factors demonstrate to them that HOPDs drive up volume for several other common outpatient services, including:

- Patients receive more chemotherapy administration sessions, on average, when treated in the HOPD. Chemotherapy days per beneficiary were an estimated 9 to 12 percent higher in the hospital outpatient department than the physician office setting.[71]
- Differences in utilization of chemotherapy drugs and services between hospital outpatient departments and physicians' offices resulted in an estimated increase in Medicare payments and Medicare beneficiary copayments of $167 million. Over 93 percent of the additional payments were related to chemotherapy and other chemotherapy-related drugs.[72]
- Cardiac imaging procedures resulted in higher payments for a 3-day episode (217 percent) and 22-day episodes (80 percent) when performed in a HOPD compared to a physician's office.[73]
- For certain cardiology, orthopedic, and gastroenterology services, employed physicians were seven times more likely to perform services in a HOPD setting than independent physicians, resulting in additional costs of $2.7 billion to Medicare and $411 million in patient copayments over a 3-year period.[74]

One commenter believed that payment differentials between independent physician practices and hospital outpatient departments stem in part from inadequate Medicare physician payment rates and that any savings from site neutrality proposals derived from OPPS should be reinvested in increasing payment rates elsewhere in Part B, including payments to physicians. Some commenters urged HHS to work with Congress to expand site-neutral policies in the OPPS.

Response: We appreciate the commenters' support. As mentioned in the proposed rule (83 FR 37138 through 37143), we share the commenters' concern that the current payment incentives, rather than patient acuity or medical necessity, are affecting site-of-service decision-making. As we noted in the proposed rule (83 FR 37138 through 37143), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs''.[75] We continue to believe that these shifts in the sites of service are unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. In addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices.

We appreciate the comments supporting the implementation of this policy in a nonbudget neutral manner. As we stated in the proposed rule (83 FR 37138 through 37143), we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the volume of services within the OPPS system in the aggregate. As detailed later in this section, we are finalizing our proposal, with modifications, in response to public comments. We will continue to take information submitted by the commenters into consideration for future study.

With respect to the comment that it is inappropriate to establish a PFS-equivalent rate because PFS rates are inadequate and that any savings should be redistributed across Medicare Part B, we disagree that PFS rates as a whole are inadequate and note that the methodology to develop such rates was established by law and regulations and is updated each year through notice-and-comment rulemaking. We note that the overall amount of Medicare payments to physicians and other entities made under the PFS is determined by the PFS statute, and the rates for individual services are determined based on the resources involved in furnishing these services relative to other services paid under the PFS. To the extent the commenter believes that the PFS rate for a particular service is misvalued relative to other PFS services, we encourage the commenter to nominate the service for review as a potentially misvalued service under the PFS.

Comment: MedPAC supported the proposal to reduce the OPPS payment rate for clinic visits provided in an excepted off-campus PBD to a PFS-equivalent payment rate. MedPAC noted that the policy would be consistent with its past recommendations for site-neutral payments between HOPDs and freestanding physician offices. In its comments, MedPAC highlighted two key points from its March 2012 recommendation on site-neutral payments. While MedPAC recommended that OPPS payment rates for clinic visits be reduced so that Medicare payments for these services are the same whether they are provided in HOPDs or physician offices, it also recommended that this policy be phased in over 3 years to allow providers time to adjust to lower payment rates. During the phase-in, MedPAC recommended that payment reductions to hospitals with a disproportionate share (DSH) patient percentage at or above the median be limited to 2 percent of overall Medicare payments because these hospitals are often the primary source of care for low-income beneficiaries and limiting the reduction in revenue would help maintain access to care for these beneficiaries.

Response: We thank MedPAC for its comments and support of this policy. In its comments, MedPAC recommended this policy be phased in over 3 years to allow providers time to adjust to lower payment rates. As detailed later in this section, we will be implementing this policy with a 2-year phase-in. We believe that a 2-year phase-in allows us

[71] The Moran Company: Cost Differences in Cancer Care Across Settings; August 2013.

[72] BRG: Impact of Medicare Payments of Shift in Site of Care for Chemotherapy Administration; June 2014.

[73] Avalere: Medicare Payment Differentials Across Outpatient Settings of Care; February 2016.

[74] Avalere, PAI: Physician Practice Acquisition Study: National and Regional Employment Changes, October 2016.

[75] Available at: *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.*

to balance the immediate need to address the unnecessary increases in the volume of clinic visits with concerns like those articulated by MedPAC regarding providers' need for time to adjust to these payment changes. While we acknowledge and share MedPAC's concern about beneficiary access to care, we do not believe that a limit on the payment reduction to hospitals with a DSH patient percentage at or above the median is necessary because we believe the increase in the volume of clinic visits in excepted off-campus provider-based departments of hospitals with high DSH percentages is equally unnecessary as it is at other hospitals.

Many commenters challenged the statutory authority for various aspects of the proposal. These comments are summarized below.

Comment: Several commenters disagreed with CMS' interpretation of section 1833(t)(2)(F) of the Act. The commenters contended that section 1833(t)(2)(F) of the Act does not confer direct authority on CMS to modify OPPS payment rates for specific services. Rather, the commenters asserted that section 1833(t)(2)(F) of the Act only permits the agency to develop a "method," which the commenters interpreted to mean a "way of doing things" or a "plan." The commenters stated that utilizing the authority at section 1833(t)(2)(F) of the Act to reduce payments to excepted off-campus PBDs to rates that equal the lower payment amounts received by nonexcepted off-campus PBDs was improper. The commenters maintained that the Secretary can only control unnecessary increases in volume using authority conferred by other provisions of section 1833(t) of the Act, such as through the equitable adjustment authority at section 1833(t)(2)(E) of the Act. The commenters believed that the clinic visit proposal was arbitrary and capricious for this and other reasons. In particular, the commenters expressed concern that there was no data-driven basis to conclude that OPD services have increased unnecessarily. The commenters also claimed that the proposal is based on unsupported assertions and assumptions regarding increases in volume. The commenters were concerned that other factors, such as the shift from inpatient services to outpatient services or the 2-midnight policy, might be driving the increases in the volume of outpatient services. Other commenters asserted that CMS should consider the impact of severity of illness and patient demographics on outpatient volume prior to moving forward with any payment changes. One commenter stated that, relative to patients seen in physician offices, patients seen in HOPDs:

- Have more severe chronic conditions;
- Have higher prior utilization of hospitals and EDs;
- Are more likely to live in low-income areas;
- Are 1.8 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.4 times more likely to be nonwhite;
- Are 1.6 times more likely to be under age 65 and disabled; and
- Are 1.1 times more likely to be over 85 years old.

The commenters also noted that Medicare beneficiaries with cancer seen in HOPDs relative to those beneficiaries seen in physician offices have more severe chronic conditions, higher prior utilization of services in hospitals and emergency departments, and higher likelihood of residing in low-income areas. In addition, the commenters noted that these cancer patients were more likely to be dually eligible for Medicare and Medicaid and be nonwhite, under age 65, and disabled.

Response: After consideration of these comments, we continue to believe that section 1833(t)(2)(F) of the Act gives the Secretary broad authority to develop a method for controlling unnecessary increases in the volume of covered outpatient department (OPD) services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and as a result, is unnecessarily increasing service volume.[76] We continue to believe shifts in the sites of service described in the preceding paragraphs are inherently unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to the payment incentives created by the difference in payment amounts. While we did receive some data illustrating that HOPDs serve unique patient populations and provide services to medically complex beneficiaries, these data did not demonstrate the need for higher payment for all clinic visits provided in HOPDs. The fact that the commenters did not supply data supporting these assertions is suggestive that the payment differential may be the main driver for unnecessary volume increases in outpatient department services, particularly clinic visits.

In fact, the Government Accountability Office (GAO) found that "the percentage of E/M visits—as well as the number of E/M office visits per beneficiary—performed in HOPDs, rather than physician offices, was generally higher in counties with higher levels of vertical consolidation in 2007–2013."[77] Vertical consolidation is the practice of hospitals acquiring physician practices. We believe that higher payment rates for services furnished in HOPDs, which include clinic visits, have led hospitals to increasingly purchase physician practices. We believe there is a correlation among the increasing volume of HOPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits. The GAO discovered that "the median percentage of E/M office visits performed in HOPDs in counties with the lowest levels of vertical consolidation was 4.1 percent in 2013. In contrast, this rate was 14.1 percent for counties with the highest levels of consolidation." The GAO also found that, in 2013, the number of E/M office visits performed in HOPDs per 100 beneficiaries was 26 for the counties with low levels of vertical consolidation, whereas the number was substantially higher—82 services per 100 beneficiaries—in counties with the highest levels of vertical consolidation.[78] The GAO determined that the association between higher levels of vertical consolidation and high utilization of E/M office visits in HOPDs remained even after controlling for differences in county-level characteristics and other market factors that could affect the setting in which E/M office visits are performed. The GAO describes the model it ran as a "regression model that controlled for county characteristics that do not change over relatively short periods of time, such as whether a county is urban or rural, and county characteristics that could change over time, such as the level of competition among hospitals and physicians within counties." The GAO explained that its "regression model's results were similar to [its] initial results: the level of vertical consolidation in a county was significantly and positively associated with a higher number and percentage of E/M office visits performed in HOPDs—that is, as vertical consolidation increased in a given county, the number and percentage of E/M office visits

[76] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

[77] Available at: *https://www.gao.gov/assets/680/674347.pdf.*

[78] Ibid.

performed in HOPDs in that county also tended to be higher." [79]

The GAO findings align with our assertions in the proposed rule (83 FR 37138 through 37143). Paying substantially more for the same service when performed in an HOPD rather than a physician office provides an incentive to shift services that were once performed in physician offices to HOPDs after consolidation has occurred. The GAO findings suggest that providers responded to this financial incentive: E/M office visits were more frequently performed in HOPDs in counties with higher levels of vertical consolidation. The GAO found this association in both of its analyses of E/M office visit utilization in counties with varying levels of vertical consolidation and in its regression analyses.

We heard from many commenters that the higher payment rate was justified by the fact that HOPDs were treating sicker patient populations. The GAO's study did not support this conclusion. It examined counties that experienced large growth in the billing of clinic visits in HOPDs and was able to determine that: "Beneficiaries from counties with higher levels of vertical consolidation were not sicker, on average, than beneficiaries from counties with lower levels of consolidation. Specifically, beneficiaries from counties with higher levels of vertical consolidation tended to have either similar or slightly lower median risk scores, death rates, rates of end-stage renal disease, and rates of disability compared to those from counties with lower levels of consolidation. Further, counties with higher levels of consolidation had a lower percentage of beneficiaries dually eligible for Medicaid, who tend to be sicker and have higher Medicare spending than Medicare beneficiaries who are not dually eligible for Medicaid."

This suggests that areas with higher E/M office visit utilization in HOPDs are not composed of sicker-than-average beneficiaries. As we stated in the proposed rule (83 FR 37138 through 37143), paying more for the same service when performed in an HOPD rather than a physician's office provides an incentive to shift services that were once performed in physician offices to HOPDs. The GAO's findings suggest that providers responded to this financial incentive. As we noted in the proposed rule (83 FR 37138 through 37143), we have developed many payment policies, such as packaging policies and comprehensive APCs, to address the rapid growth of services in the OPPS. However, these policies have not been able to control for unnecessary increases in volume that are due to site-of-service payment differentials, which create an incentive to furnish a service in the OPD that could be furnished in a lower cost setting based solely on the higher payment amount available under the OPPS. Here, the clinic visit service furnished in excepted off-campus PBDs is the same as the clinic visit service furnished in nonexcepted off-campus PBDs. We believe that applying an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act is an appropriate method to control the unnecessary increase in the volume of outpatient services.

Comment: Several commenters expressed concern that CMS lacks the statutory authority to reduce OPPS payments for certain clinic visit services furnished at off-campus PBDs that are excepted from payment "under the applicable payment system" under section 1833(t)(21) of the Act. The commenters stated that Congress expressly chose in section 603 of the Bipartisan Budget Act of 2015 not to confer on CMS authority to pay excepted off-campus PBDs at the reduced rates paid to nonexcepted off-campus PBDs. The commenters asserted that CMS is ignoring the express and statutorily mandated grandfathering exception created by section 603.

Response: We believe the changes required by section 603 of the Bipartisan Budget Act of 2015 made in section 1833(t) of the Act address some of the concerns related to shifts in settings of care and overutilization of services in the hospital outpatient setting for new off-campus PBDs after November 1, 2015. However, the majority of hospital off-campus departments continue to receive full OPPS payment (including off-campus emergency departments and excepted off-campus departments of a hospital), which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. Therefore, the current site-based payment creates an incentive for an unnecessary increase in the volume of this type of OPD service, which results in higher costs for the Medicare program, beneficiaries, and taxpayers more generally. We interpret our authority under section 1833(t)(2)(F) of the Act to allow us to implement our proposed method of applying an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at off-campus PBDs, even those that are excepted from section 1833(t)(21) of the Act. We believe that this is an appropriate method because the clinic visit service is the same service furnished in excepted and nonexcepted off-campus PBDs.

When Congress passed the Bipartisan Budget Act of 2015, Medicare OPPS expenditures were $56 billion and growing at an annual rate of about 7.3 percent. In addition, the percentage increase in volume and intensity of outpatient services was increasing at 3.4 percent. For the upcoming 2019 calendar year, we estimate that, without this policy, OPPS expenditures would be $74.5 billion, growing at a rate of 9.1 percent, with the volume and intensity of outpatient services increasing at 5.4 percent, based on the Midsession Review for 2019. While it is clear that the action Congress took in 2015 to address certain off-campus PBDs helped stem the tide of these increases in the volume of OPD services, it is likewise clear that the more specific payment adjustment has not adequately addressed the overall increase in the volume of these types of OPD services because most off-campus PBDs continue to be paid the higher OPPS amount for these services. We would not be able to adequately address the unnecessary increases in the volume of clinic visits in HOPDs if we did not apply this policy to all off-campus HOPDs. We do not believe that the section 603 amendments to section 1833(t) of the Act, which exclude applicable items and services furnished by nonexcepted off-campus PBDs from payments under the OPPS, preclude us from exercising our authority in section 1833(t)(2)(F) of the Act to develop a method for controlling unnecessary increases in the volume of covered outpatient department services under the OPPS.

Comment: Several commenters believed that CMS does not have statutory authority to implement this policy in a nonbudget neutral manner. The commenters explained that, because CMS lacks the authority to reduce clinic visit payment rates as a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act, that provision cannot provide authority for the

[79] Available at: *https://www.gao.gov/assets/680/674347.pdf.*

payment reduction to be made in a nonbudget neutral way. The commenters also claimed that the only nonbudget neutral option available to the agency is to adjust the conversion factor in a subsequent year, as provided under section 1833(t)(9)(C) of the Act. The commenters argued that if Congress had intended to give CMS the authority to make a volume control method nonbudget neutral, it would have done so in clearer and more express terms. Other commenters stated that if this policy is finalized, it should be done so only in a budget neutral manner.

Response: We maintain that while section 1833(t)(9)(B) of the Act does require that certain changes made under the OPPS be made in a budget neutral manner, this provision does not apply to the volume control method under section 1833(t)(2)(F) of the Act as outlined through our proposal. As we noted in the proposed rule (83 FR 37138 through 37143), unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a "method" for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those paragraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not include such a requirement. Therefore, we maintain that the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in paragraph (2)(F) of section 1833(t) of the Act that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year. We continue to interpret this provision to mean that the Secretary will have implemented a volume control method under section 1833(t)(2)(F) of the Act in a nonbudget neutral manner in the year in which the method is implemented. Further, as we stated in the proposed rule (83 FR 37138 through 37143), we believe that implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the volume within the OPPS system in the aggregate.

Comment: Several commenters supported the recommendation from the HOP Panel not to implement this proposal and to instead study the matter to better understand the reasons for increased utilization.

Response: Section 1833(t)(9)(A) of the Act provides that the Secretary shall consult with the Panel on policies affecting the clinical integrity of the ambulatory payment classifications and their associated weights under the OPPS. The Panel met on August 20, 2018 and made recommendations on this proposed policy, and we consulted with the Panel on those recommendations. The HOP Panel's recommendations, along with public comments on provisions of the proposed rule, have been taken into consideration in the development of this final rule with comment period. While we are not accepting the HOP Panel's recommendation to not implement this proposal, we will continue to monitor and study the utilization of outpatient services as recommended by the Panel.

Comment: Several commenters expressed concern that this policy proposal would disproportionately affect safety net hospitals and rural providers. Numerous commenters representing providers and beneficiaries in the State of Washington expressed concerned about the impact this proposal would have on their area. Several commenters also requested that sole community hospitals (urban and rural), rural referral centers, and Medicare-dependent hospitals be exempted from this policy. A number of commenters, including many State hospital associations, expressed concern that the magnitude of the proposed payment reduction would have a drastic effect on their margins and endanger the investments many hospitals have made in their provider-based facilities. In addition, commenters suggested that the reduction in payment would ultimately lead to a reduction of services that would adversely affect vulnerable patient populations. One commenter conducted a trend analysis and found that 200 hospitals would shoulder 73 percent of the proposed payment reduction. According to this commenter's analysis, for the 200 hospitals most affected by this proposal, the average reduction would be 5.5 percent. For the remaining hospitals, the average reduction would be 0.5 percent.

Response: We share the commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. Medicare has long recognized the unique needs of rural communities and the financial challenges for rural providers. Across the various Medicare payment systems, CMS has implemented a number of special payment provisions for rural providers to maintain access and deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural sole community hospitals. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural sole community hospitals of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006. In the CY 2019 OPPS/ASC proposed rule (83 FR 37143), we sought public comment on how we might account in the future for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas. In addition, we sought public comment on whether there should be exceptions from this policy for rural providers, such as those providers that are at risk of hospital closure or those providers that are sole community hospitals. Taking into consideration the comments regarding rural hospitals, we believe that implementing this policy with a 2-year phase-in will help to mitigate the immediate impact on rural hospitals. We may revisit this policy to consider potential exemptions in the CY 2020 OPPS rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act

(departments that bill the modifier "PO" on claim lines). In addition, we are finalizing our proposal to implement this policy in a nonbudget neutral manner. We will continue to monitor the impacts of this policy as it is phased in to ensure that beneficiaries continue to have access to quality care.

In response to public comments we received, we will be phasing in the application of the reduction in payment for HCPCS code G0463 in this setting over 2 years. In CY 2019, the payment reduction will be transitioned by applying 50 percent of the total reduction in payment that would apply if these departments were paid the site-specific PFS rate for the clinic visit service. The final payment rates are available in Addendum B to this final rule with comment period (which is available via the internet on the CMS website). The PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40 percent of OPPS payment (that is, 60 percent less than the OPPS rate) for CY 2019. Based on a 2-year phase-in of this policy, half of the total 60-percent payment reduction, a 30-percent reduction, will apply in CY 2019. In other words, these departments will be paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30-percent payment reduction that applies in CY 2019) for the clinic visit service in CY 2019. In CY 2020, these departments will be paid the site-specific PFS rate for the clinic visit service. We note that by phasing in this policy over 2 years, the estimated savings associated with this policy will change. Considering the effects of estimated changes in enrollment, utilization, and case-mix, this policy results in an estimated CY 2019 savings of approximately $380 million, with approximately $300 million of the savings accruing to Medicare, and approximately $80 million saved by Medicare beneficiaries in the form of reduced copayments. We will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services.

While we are exploring developing a method to systematically control for unnecessary increases in the volume of other hospital outpatient department services that we may propose in future rulemaking, we continue to recognize the importance of not impeding development or beneficiary access to new innovations. In the CY 2019 OPPS/ASC proposed rule (83 FR 37143), we solicited public comments on how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services.

In addition, we solicited public comments on how to expand the application of the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in the utilization of OPD services. Therefore, we sought public comment on the following:

- How might Medicare define the terms "unnecessary" and "increase" for services (other than the clinic visit) that can be performed in multiple settings of care? Should the method to control for unnecessary increases in the volume of covered OPD services include consideration of factors such as enrollment, severity of illness, and patient demographics?
- While we proposed to pay the site-specific PFS payment rate for clinic visits beginning in CY 2019, we also were interested in other methods to control for unnecessary increases in the volume of outpatient services. Prior authorization is a requirement that a health care provider obtain approval from the insurer prior to providing a given service in order for the insurer to cover the service. Private health insurance plans often require prior authorization for certain services. Should prior authorization be considered as a method for controlling overutilization of services?
- For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?
- Several private health plans use utilization management as a cost-containment strategy. How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency? Could utilization management help reduce the overuse of inappropriate or unnecessary services?
- How should we account for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas? With respect to rural providers, should there be exceptions from this policy, such as for providers who are at risk of hospital closure or that are sole community hospitals?
- What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered OPD services have?
- What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made?

We received feedback on a variety of issues in response to the comment solicitation on additional future considerations. These comments are summarized below.

Comment: In response to the solicitation on how CMS might expand the application of the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in OPD volume, MedPAC suggested that CMS consider using the five criteria that MedPAC has developed for identifying services for which it is reasonable to have site-neutral payments between freestanding physician offices and HOPDs.[80]

In response to the solicitation on whether prior authorization should be considered as a method for controlling overutilization of services, most commenters believed that, while prior authorization may be a good method for controlling overutilization of services, it can also lead to increased administrative burden and inhibit patient access. One commenter suggested that CMS consider applying prior authorization for providers with service volumes that are statistical outliers or for those whose ordering rates are not in compliance with clinical guidelines.

In response to the comment solicitation on when it might be appropriate to pay a higher OPPS payment rate for a service that can be performed safely in a lower cost setting, several commenters believed that it would be appropriate to pay a higher OPPS rate for services that can be performed in a lower cost setting if providing this higher payment can improve patient experience, efficiency, and quality of care. Several commenters also mentioned that the comprehensive care management and coordination that accompanies receiving services at an off-campus PBD of a hospital might justify the higher OPPS payment rate. Commenters also asserted that the additional certifications required for services furnished in PBDs compared to services furnished in physician offices justify a higher payment rate.

In response to the comment solicitation on utilization management, several commenters were opposed to this concept and stated that utilization management would increase provider burden and delay patient access to care. One commenter supported the concept

[80] Medicare Payment Advisory Commission. 2013. Report to the Congress: Medicare and the health care delivery system. Washington, DC: MedPAC.

of utilization management, but believed that it must be based on clinical validity, support the continuity of patient care, be transparent and fair, provide timely access to care and administrative efficiency, and provide alternatives and exemptions to those clinicians with appropriate utilization rates. Other commenters supported appropriate use criteria and evidence-based clinical guidelines and pathways as effective clinical-decision support tools to assist clinicians and hospitals in the reduction of potentially harmful or rarely appropriate services.

Response: We thank commenters for their responses to our comment solicitation. We will consider these comments for future rulemaking.

C. Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

1. Historical Perspective

a. Section 603 of the Bipartisan Budget Act of 2015

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we discussed implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 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 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. We indicated 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, we refer to an "off-campus outpatient department of a provider," which is the term used in section 603 of the Bipartisan Budget Act of 2015, as an "off-campus outpatient provider-based department" or an "off-campus PBD." For a detailed discussion of the legislative history and statutory authority related to payments under section 603 of the Bipartisan Budget Act of 2015, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

b. Applicable Payment System

As we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37143 through 37144), to implement the amendments made by section 603 of Public Law 114–74, we issued an interim final rule with comment period (81 FR 79720) which accompanied the CY 2017 OPPS/ASC final rule with comment period to establish the Medicare PFS as the "applicable payment system" that applies in most cases, and we established payment rates under the PFS for those nonexcepted items and services furnished by nonexcepted off-campus PBDs. As we discussed in the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79718) and reiterated in the CY 2018 PFS final rule with comment period (82 FR 53028), payment for Medicare Part B drugs that would be separately payable under the OPPS (assigned a status indicator of "K"), but are not payable under the OPPS because they are furnished by nonexcepted off-campus PBDs, is made in accordance with section 1847A of the Act (generally, at a rate of ASP+6 percent), consistent with Part B drug payment policy for items or services furnished in the physician office (nonfacility) setting. We did not propose or make an adjustment to payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, but indicated we may consider doing so through future notice-and-comment rulemaking.

In the interim final rule with comment period that accompanied the CY 2017 OPPS/ASC final rule with comment period, we established payment policies under the Medicare PFS for nonexcepted items and services furnished by a nonexcepted off-campus PBD on or after January 1, 2017. In accordance with sections 1848(b) and (c) of the Act, Medicare PFS payment is based on the relative value of the resources involved in furnishing particular services (81 FR 79790). Resource-based relative values are established for each item and service (described by a HCPCS code(s)) based on the work (time and intensity), practice expense (such as clinical staff, supplies and equipment, office rent, and overhead), and malpractice expense required to furnish the typical case of the service. Because Medicare makes separate payment under institutional payment systems (such as the OPPS) for the facility costs associated with many of the same services that are valued under the PFS, we establish two different PFS payment rates for many of these services—one that applies when the service is furnished in a location where a facility bills and is paid for the service under a Medicare payment system other than the PFS (the facility rate), and another that applies when the billing practitioner or supplier furnishes and bills for the entire service (the nonfacility rate). Consistent with the long-established policy under the PFS to make payment to the billing practitioner at the facility rate when Medicare makes a corresponding payment to the facility (under the OPPS, for instance) for the same service, physicians and nonphysician practitioners furnishing services in nonexcepted PBDs continue to report their services on a professional claim form and are paid for their services at the PFS facility rate.

Similarly, there are many (mostly diagnostic) services paid under the PFS that have two distinct portions of the service: A technical component (TC) and a professional component (PC). These components can be furnished independently in time or by different suppliers, or they may be furnished and billed together as a "global" service (82 FR 52981). Payment for these services can also be made under a combination of payment systems; for example, under the PFS for the professional component and the OPPS for the facility portion. For instance, for a diagnostic CT scan, the technical component relates to the portion of the service during which the image is captured and might be furnished in an office or HOPD setting, and the professional component relates to the interpretation and report by a radiologist.

In the CY 2017 interim final rule with comment period, we stated that we continue to believe that it is operationally infeasible for nonexcepted off-campus PBDs to bill directly under the PFS for the subset of PFS services for which there is a separately valued technical component (81 FR 79721). In addition, we explained that we believe hospitals that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS. We stated that we therefore believe it is necessary to establish a new set of payment rates under the PFS that reflect the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS that is specific to one site of service (the off-campus PBD of a hospital) with the packaging (bundling) rules that are significantly different from current PFS rules (81 FR 79721).

In continuing to implement the requirements of sections 1833(t)(1)(B) and (t)(21) of the Act, we recognize that