

**Vizient Office of Public Policy and Government Relations**

**Regulatory Update: CMS Proposed Rule – Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model**

**August 7, 2018**

**Background & Summary**

On Wednesday, July 25, the Centers for Medicare & Medicaid Services (CMS) issued the [annual proposed rule](#) to update the calendar year (CY) 2019 Medicare payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). The OPPS is updated annually to include changes to payment policies, payment rates, and quality provisions for those Medicare patients who receive care at hospital outpatient departments (HOPDs) or receive care at ambulatory surgical centers (ASCs). This proposed rule also updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

The proposed rule makes significant changes to payment rates for provider-based hospital outpatient departments (OPDs), and expands the number of facilities that will be subject to Medicare payment reductions for prescription drugs acquired through the 340B Drug Pricing Program. Additionally, this proposed rule includes three Requests for Information (RFIs) on the following: 1) promoting interoperability and electronic health care information exchange through possible revisions to the CMS patient health and safety requirements for hospitals and other Medicare-participating and Medicaid-participating providers and suppliers; 2) improving beneficiary access to provider and supplier charge information; and 3) leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center model.

Comments are due September 24, 2018 and Vizient looks forward to working with members to help inform our letter to the Agency.

**OPPS Payment Update**

After accounting for inflation and other adjustments required by law, the proposed rule would increase outpatient operating payment rates by 1.25 percent in calendar year (CY) 2019. The table below details factors CMS includes in their estimate.

**Proposed OPPS Payment Rate Update for CY 2018**

<b>Proposed Policy</b>	<b>Average Impact on Payments (Rate)</b>
Estimated market-basket update for IPPS	2.8%
Multifactor productivity adjustment (MFP)	- 0.8%
ACA market-basket cut	- 0.75%
<b>Estimated payment rate update compared to CY 2018</b>	<b>1.25%</b>

The proposed increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.8 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.8 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act (ACA). For CY 2019, CMS estimates that the total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in

enrollment, utilization, and case-mix) would be “approximately \$74.6 billion, an increase of approximately \$4.9 billion compared to estimated CY 2018 OPSS payments.” **However, in considering all of the additional policies in this proposed rule, CMS estimated that the total OPSS payments would decrease by 0.1 percent in CY 2019 (compared to CY 2018).** Hospitals that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program reporting requirements are subject to an additional reduction of 2.0 percentage points. This statutorily required 2.0 percentage point reduction will be implemented by applying a proposed reporting factor of 0.980 to the OPSS payments and copayments for all applicable services.

### **Proposed Comprehensive APCs (C-APCs) for CY 2019**

CMS uses complexity adjustments to administer an increased payment for particular comprehensive services. The agency packages payment for add-on codes into the comprehensive Ambulatory Payment Classification (C-APC) payment rate. CMS designates a service described by a Healthcare Common Procedure Coding System (HCPCS) code assigned to a C-APC as the primary service when the service is identified by OPSS status indicator “J1”. CMS lists the complexity adjustments proposed for “J1” and add-on code combinations for CY 2019 – along with other proposed complexity adjustments and cost statistics – in Addendum J of the proposed rule (available on the [CMS website](#)). CMS notes that the information contained in Addendum J allows “stakeholders the opportunity to better assess the impact associated with the proposed reassignment of claims with each of the paired code combinations eligible for a complexity adjustment.”

In the CY 2018 OPSS/ASC final rule, CMS did not change the total number of C-APCs from 62. CMS reviews the services and the APC assignments under the OPSS annually. For CY 2019, CMS is proposing to add three C-APCs under the existing payment policy: 1) proposed C-APC 5163 (Level 3 ENT Procedures); 2) proposed C-APC 5183 (Level 3 Vascular Procedures); and 3) proposed C-APC 5184 (Level 4 Vascular Procedures).

### **Proposed OPSS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals**

Current statute provides for temporary additional payments – “transitional pass-through payments” – for certain drugs and biologicals. Under the OPSS, the average sales price (ASP) methodology uses several sources of data as a basis for payment – including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP).

CMS is proposing that the pass-through payment status of 23 drugs and biologicals would expire on Dec. 31, 2018 (listed in Table 19 of the [proposed rule](#), pgs. 258-259). With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status, CMS’s standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product’s estimated per day cost, and compare it with the OPSS drug packaging threshold for that calendar year. For CY 2019, CMS is proposing a packaging threshold of \$125.

CMS is also proposing that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPSS drug packaging threshold, the agency would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPSS drug packaging threshold, CMS is proposing to provide separate payment at the applicable relative ASP-based payment amount – which for CY 2019, is proposed at ASP plus 6 percent. The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this proposed rule (available on the [CMS website](#)).

The 49 drugs and biologicals that CMS is proposing to continue pass-through payment status for CY 2019, or have been granted pass-through payment status as of July 2018 are listed in Table 20 of the [proposed rule](#) (pgs. 263-265). For CY 2019, CMS is proposing to continue to pay for pass-through drugs and biologicals at ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician’s office setting in CY 2019. Additionally for CY 2019, CMS is proposing that for policy-packaged drugs, their pass-through payment amount would be equal to ASP plus 6 percent, minus a payment offset for any predecessor drug products contributing to the pass-through payment. CMS notes that they are making this proposal because, “if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.”

### **Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status**

To determine the proposed CY 2019 packaging status for all non pass-through drugs and biologicals that are not policy-packaged (i.e., “threshold packaged” drugs), CMS calculated, on a HCPCS code-specific basis, the per day cost of all drugs that had a HCPCS code in CY 2017 and were paid (via packaged or separate payment) under the OPSS. To calculate the CY 2019 proposed per day costs for each drug and biological HCPCS code, CMS used an estimated payment rate of ASP plus 6 percent. CMS is proposing to “package items with a per day cost less than or equal to \$125, and identify items with a per day cost greater than \$125 as separately payable unless they are policy-packaged.” To calculate per day costs of HCPCS codes for drugs and biologicals, CMS is proposing to use ASP data from the fourth quarter of CY 2017 along with updated hospital claims data from CY 2017. Payment rates for HCPCS codes for separately payable drugs and biologicals – to be included in Addenda A and B for the final rule with comment period – will be based on ASP data from the third quarter of CY 2018. These payment rates are updated in the January 2019 OPSS update, based on the most recent ASP data to be used for physician’s office and OPSS payment as of Jan. 1, 2019. For items that do not currently have an ASP-based payment rate, CMS is proposing to “recalculate their mean unit cost from all of the CY 2017 claims data and updated cost report information available for the CY 2019 final rule with comment period to determine their final per day cost.”

Additionally, for CY 2019, CMS is proposing to continue their policy to make packaging determinations on a drug-specific basis (rather than a HCPCS code-specific basis) for HCPCS codes that describe the same drug or biological, but different dosages. The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2019 is displayed in Table 24 of the [proposed rule](#) (pg. 290).

### **CY 2019 Proposed OPSS Payment Methodology for 340B Purchased Drugs**

Last year, CMS finalized its proposal to pay for separately payable, non pass-through drugs and biologicals (other than vaccines) purchased through the 340B Drug Pricing Program at the average sales price (ASP) minus 22.5 percent, rather than the current rate of ASP plus 6 percent, effective January 1, 2018. Excluded from this payment adjustment in CY 2018 are rural sole community hospitals (SCHs), children’s hospitals, and PPS-exempt cancer hospitals. Critical Access Hospitals (CAHs) are not reimbursed under OPSS, so this policy does not apply to them. Additionally, this policy change did not apply to drugs on pass-through payment status, which are required to be based on the ASP methodology – or vaccines, which are excluded from the 340B Program.

In this proposed rule, CMS states that there “has been confusion” as to whether drugs that do not have average sales price (ASP) pricing, but instead receive wholesale acquisition cost (WAC) or average wholesale price (AWP) pricing are subject to the 340B payment adjustment. CMS is clarifying “that the 340B payment adjustment does apply to drugs that are priced using either WAC or AWP, and it has been [their] policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted.” CMS notes that less than 10 percent of all separately payable Medicare Part B drugs receiving WAC or AWP pricing are affected by the 340B payment adjustment (as of April 2018).

CMS cites limitations in their ability to identify and precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare OPSS claims data. Therefore, the agency established two modifiers to identify whether a drug billed under the OPSS was purchased under the 340B Program – one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction, but which do acquire drugs under the 340B Program. CMS implemented the modifiers such that they are required for drugs that were acquired under the 340B Program (rather than requiring its use on drugs that were not acquired under the 340B Program, as was originally proposed). Effective Jan. 1, 2018, CMS implemented modifier “JG” for the payment adjustment for 340B-acquired drugs. Hospitals paid under the OPSS (besides those excluded from this policy) are required to report modifier “JG” on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural SCHs, children’s hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment; they are required to report informational modifier “TB” for 340B-acquired drugs, and continue to be paid ASP plus 6 percent. For CY 2019, CMS is proposing to continue all of the 340B Program policies that were implemented in CY 2018.

However, for CY 2019, CMS is proposing to “pay non pass-through biosimilars acquired under the 340B program at ASP minus 22.5 percent of the biosimilar’s own ASP, rather than ASP minus 22.5 percent of the reference product’s ASP. CMS is making this proposal based on feedback received from stakeholders that the “current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program.” Additionally, CMS is proposing that Medicare would “continue to pay for drugs or biologicals that were not purchased with a 340B discount at ASP plus 6 percent.”

## Proposal to Pay an Adjusted Amount for 340B-Acquired Drugs and Biologicals Furnished in Nonexcepted Off-Campus PBDs in CY 2019 and Subsequent Years

Section 603 of the Bipartisan Budget Act (BBA) of 2015<sup>1</sup> requires that certain items and services – with the exception of dedicated emergency department services – furnished in off-campus provider-based departments (PBDs) that began billing under the Outpatient Prospective Payment System (OPPS) on or after November 2, 2015 are no longer to be paid under the OPPS, but under another “applicable payment system”. In the CY 2017 OPPS/ASC final rule with comment period<sup>2</sup>, CMS finalized the PFS as the “applicable payment system” for most nonexcepted items and services furnished by off-campus PBDs on or after January 1, 2017. On December 13, 2016, the 21st Century Cures Act was enacted into law, amending Section 603 of the BBA, and providing additional criteria about which off-campus PBDs will be “excepted” from this reduced payment under the law.

Nonexcepted off-campus PBDs are not subject to the payment changes that apply to hospitals and PBDs paid under the OPPS. Because the “separately payable drugs and biologicals acquired under the 340B Program and furnished in nonexcepted off-campus PBDs are no longer covered outpatient department services, these drugs and biologicals are currently paid in the same way Medicare Part B drugs are paid in the physician office and other nonhospital settings – typically at ASP plus 6 percent – regardless of whether they are acquired under the 340B Program.” CMS believes that the difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments – excepted off-campus PBDs versus nonexcepted off-campus PBDs – creates an incentive for hospitals to move drug administration services for these drugs (i.e., to nonexcepted off-campus PBDs to receive a higher payment amount). Thus, for CY 2019, CMS is proposing “changes to the Medicare Part B drug payment methodology for drugs and biologicals furnished and billed by nonexcepted off-campus departments of a hospital that were acquired under the 340B Program.” **CMS is proposing to pay for separately payable, non pass-through drugs and biologicals (other than vaccines) purchased through the 340B Drug Pricing Program – when they are furnished by nonexcepted off-campus PBDs of a hospital – at the average sales price (ASP) minus 22.5 percent, rather than the current rate of ASP plus 6 percent, effective January 1, 2019.** Excluded from this payment adjustment in CY 2019 are rural sole community hospitals (SCHs), children’s hospitals, and PPS-exempt cancer hospitals.

### Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

Payments for separately payable drugs and biologicals furnished by providers and suppliers include an add-on of 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition cost (WAC) for the drug or biological (the “6 percent add-on”). Consistent with a similar policy in the CY 2019 Physician Fee Schedule (PFS) proposal, CMS is proposing that effective January 1, 2019, in the case of a drug or biological during an initial sales period in which data on the prices for sales (ASP) is not yet available from the manufacturer, WAC-based payments for Part B drugs will utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. CMS usually has sufficient data to calculate and reimburse an ASP for new drugs and biologicals beginning in the third quarter (6 months after launch). Additionally, CMS is proposing to apply this policy to specified covered outpatient drugs (known as SCODs). If WAC data are not available for a drug or biological product, CMS is proposing to continue current policy to pay separately payable drugs and biological products at 95 percent of the average wholesale price (AWP). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 percent, or 69.46 percent of AWP) would continue to apply.

CMS notes that the separately payable drug and biological payment rates are listed in Addenda A and B to this proposed rule (available on the [CMS website](#)), which illustrate the CY 2019 payment of ASP plus 6 percent for separately payable non pass-through drugs and biologicals, and ASP plus 6 percent for pass-through drugs and biologicals. These rates reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician’s office setting effective April 1, 2018, or WAC, AWP, or mean unit cost from CY 2017 claims data and updated cost report information available for this proposed rule. However, the proposed payment rates listed are not for January 2019 payment purposes, and

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<sup>1</sup> Bipartisan Budget Act of 2015, Pub. L. No. 114-74.

<sup>2</sup> 81 Fed. Reg. 79713, 79720 through 79729 (Nov. 14, 2016).



are only illustrative of the proposed CY 2019 OPPTS payment methodology using the most recently available information at the time of this proposal's release.

**Proposed OPPTS Payment for Hospital Outpatient Visits and Critical Care Services**

For CY 2019, CMS is proposing to continue with current clinic and emergency department (ED) hospital outpatient visits and critical care services payment policies. Additionally, CMS is seeking comment on “any changes to these codes that [they] should consider for future rulemaking.” CMS continues to “encourage commenters to provide the data and analysis necessary to justify any suggested changes.”

**Proposed Procedures That Would Be Paid Only as Inpatient Procedures**

For CY 2019, CMS is proposing to remove two procedures from the IPO list, and to add one procedure. Procedures proposed to be removed from the IPO list for CY 2019 and subsequent years – including the HCPCS code, long descriptors, and the proposed CY 2019 payment indicators – are displayed in the table below.

CY 2019 CPT Code	CY 2019 Long Descriptor	Proposed Action	Proposed CY 2019 OPPTS APC Assignment	Proposed CY 2019 OPPTS Status Indicator
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	Remove from IPO list	5153	J1
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty	Remove from IPO list	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	Add to IPO list	N/A	C

CMS is proposing to add to the IPO list for CY 2019 the procedure described by HCPCS code C9606. CMS believes that the procedure should be added to the IPO list because this procedure is performed during acute myocardial infarction (AMI), and is similar to the procedure described by CPT code 92941 – which was added to the IPO list for CY 2018. CMS is seeking comment on these proposals. The complete proposed list of codes that would be paid by Medicare in CY 2019 as inpatient only procedures (the proposed IPO list) is included as [Addendum E to the proposed rule](#).

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

CMS states that since 2010, the agency has “observed a noticeable increase in the number of hospital outpatient emergency department visits furnished under the OPPTS.” Additionally, the Medicare Payment Advisory Commission (MedPAC) has stated that services may be shifting higher acuity and higher cost emergency department settings, and are concerned that “payment incentives may be a key contributing factor to the growth in the number of emergency departments located off-campus from a hospital.”

MedPAC made recommendations in its [March 2017](#) and [June 2017](#) Reports to Congress that “CMS require hospitals to append a modifier to claims for all services furnished in off-campus provider-based emergency departments, so that CMS can track the growth of OPPTS services provided in this setting.” CMS states that they agree with this recommendation, and believes they “need to develop data to assess the extent to which OPPTS services are shifting to off-campus provider-based emergency departments.” In this proposed rule, CMS is announcing that they will be implementing – through the subregulatory HCPCS modifier process – a new modifier for this purpose effective beginning January 1, 2019. CMS 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. The modifier would be reported on the UB–04 form (CMS Form 1450) for hospital outpatient services. Critical access hospitals (CAHs) would not be required to report this modifier.”

**Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services**

CMS continues to be concerned with the rate of increase in program expenditures under the OPPTS. Furthermore, CMS is “concerned that the rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, may be affecting site-of-service decision-making.” If there are lower-cost sites-of-service available, CMS believes 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.”

Section 4011 of the 21<sup>st</sup> Century Cures Act established new requirements to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgery center. Beginning in 2018 (and in each subsequent year), the HHS Secretary is required to make information available to the public via a searchable website on: 1) the estimated Medicare payment amounts for the items and services provided under both the hospital OPPTS fee schedule and the ASC payment system; and 2) the estimated amount of beneficiary liability for each item or service<sup>3</sup>. CMS notes that, “although resources such as this website will help beneficiaries and physicians select a site of service, [they] do not believe this information alone is enough to control unnecessary volume increases.” Furthermore, CMS believes “that the higher payment that is made under the OPPTS, as compared to payment under the PFS, is likely to be incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting.” CMS considers shifts in the sites of services as “unnecessary” if the beneficiary can safely receive the same services in a lower cost setting, but instead receives care in a higher cost setting.

CMS states that “capping the OPPTS 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.” **Therefore, for CY 2019, CMS is proposing 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 (departments that bill the modifier “PO” on claim lines).** CMS cites they are making this proposal “given the unnecessary increases in the volume of clinic visits in hospital outpatient departments.” In other words, CMS is proposing to pay for clinic visit (i.e., evaluation and management (E/M)) services in excepted off-campus PBDs at the same rate they are paid in nonexcepted off-campus PBDs – which is 40 percent of the OPPTS payment rate (the “PFS equivalent” payment rate).

In CY 2019, for an individual Medicare beneficiary, the standard unadjusted Medicare OPPTS proposed payment for the clinic visit is approximately \$116. The proposed CY 2019 “PFS equivalent” rate for Medicare payment to excepted off-campus PBDs for a clinic visit would be approximately \$46. The table below displays the overall impact of this proposed policy:

**Estimated Impact of the Proposed CY 2019 Changes to Off-Campus PBD Visits for the Hospital OPPTS**

	Number of Hospitals	Proposed Off-Campus PBD Visits Policy	All Proposed Changes
All facilities	3,806	-1.2	-0.1
All hospitals	3,695	-1.2	-0.1

Under CMS’s proposal, an excepted off-campus PBD would continue to bill HCPCS code G0463 with the “PO” modifier in CY 2019. However, the payment rate for services described by HCPCS code G0463 when billed with the “PO” modifier would be equivalent to the payment rate for services described by HCPCS code

<sup>3</sup> Pub. L. 114-255, 2016

G0463 when billed with modifier “PN”. In other words, the PFS relativity adjuster “will now be used to pay for all outpatient clinic visits provided at all off-campus PBDs.”

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 OPSS”, CMS believes that this method must be adopted in a non-budget neutral manner. While CMS develops a method to “systematically control for unnecessary increases in the volume of other hospital outpatient department services, [they] continue to recognize the importance of not impeding development or beneficiary access to new innovations.” Thus, CMS is seeking comment on “how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services.”

Additionally, CMS is seeking comments on how to “expand the application of the Secretary’s statutory authority [...] to additional items and services paid under the OPSS that may represent unnecessary increases in OPD utilization.” The agency is seeking comment on a list of specific questions regarding their proposals, including other methods to control unnecessary increases in the volume of outpatient services, accounting for providers that serve beneficiaries in provider shortage areas or rural areas, the impact on beneficiaries and the health care market, and additional proposals for exceptions (on pages 374-375 of the [proposed rule](#)).

### **Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider**

Section 603 of the Bipartisan Budget Act (BBA) of 2015<sup>4</sup> requires that certain items and services – with the exception of dedicated emergency department services – furnished in off-campus provider-based departments (PBDs) that began billing under the Outpatient Prospective Payment System (OPSS) on or after November 2, 2015 are no longer to be paid under the OPSS, but under another “applicable payment system”. In the CY 2017 OPSS/ASC final rule with comment period<sup>5</sup>, CMS finalized the PFS as the “applicable payment system” for most nonexcepted items and services furnished by off-campus PBDs on or after January 1, 2017. On December 13, 2016, the 21st Century Cures Act was enacted into law, amending Section 603 of the BBA, and providing additional criteria about which off-campus PBDs will be “excepted” from this reduced payment under the law.

In previous rulemaking, CMS indicated concerns regarding excepted off-campus PBDs expanding the types of services provided, while continuing to be paid OPSS rates for these new types of services. CMS believed that this enabled hospitals to purchase additional physician practices, and expand the services furnished by existing excepted off-campus PBDs. In this proposed rule, CMS notes ongoing concerns that excepted off-campus PBDs are allowed to furnish new types of services that were not provided prior to the date of enactment of the Bipartisan Budget Act of 2015 (Nov. 2, 2015). CMS notes that “while there is no congressional record available for section 603 of the Bipartisan Budget Act of 2015, [they] do not believe that Congress intended to allow for new service lines to be paid OPSS rates because providing for such payment would allow for excepted off-campus PBDs to be paid higher rates for types of services they were not performing prior to enactment of the [law] that would be paid at lower rates if performed in a nonexcepted PBD.” CMS believes that the growth of service lines in currently excepted off-campus PBDs may be an unintended consequence of the agency’s current policy – which allows for full OPSS payment for any services furnished by excepted off-campus PBDs, including services in new service lines.

In response to the agency’s concerns regarding expansion of services in excepted off-campus PBDs, for CY 2019 and subsequent years, **CMS is proposing that if an excepted off-campus PBD furnishes services from any of the 19 clinical family of services – defined in Table 32 of this proposed rule – from which it did not furnish and bill under the OPSS for an item or service during a baseline period from Nov. 1, 2014 through Nov. 1, 2015, items and services from these new clinical families of services would no longer be excepted items and services and, thus, would not be covered Outpatient Department (OPD) services. Instead, these items and services will be non-excepted and paid under the PFS at 40 percent of the OPSS amount.** Furthermore, CMS proposes to limit the definition of “excepted items and services”. Generally, “excepted items and services are items or services that are furnished on or after January 1, 2017 by an excepted off-campus PBD that has not impermissibly relocated or changed ownership.” CMS proposes that beginning on Jan. 1, 2019, excepted items and services would be items or

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<sup>4</sup> Bipartisan Budget Act of 2015, Pub. L. No. 114-74.

<sup>5</sup> 81 Fed. Reg. 79713, 79720 through 79729 (Nov. 14, 2016).

services that are furnished and billed by an excepted off-campus PBD only from the clinical families of services for which the excepted off-campus PBD furnished and billed under the OPSS for at least one item or service from Nov. 1, 2014 through Nov. 1, 2015.

CMS is proposing that if an excepted off-campus PBD furnished any of the new items or service from a clinical family of services listed in Table 32 from Nov. 1, 2014 through Nov. 1, 2015, these items and service would continue to be paid under the OPSS. CMS notes that this is “because items and services from within a clinical family of services for which the nonexcepted off-campus PBD furnished an item or service during the baseline period would not be considered a “service expansion.”

For purposes of OPSS payment eligibility, excepted off-campus PBDs will be required to “ascertain the clinical families from which they furnished services from Nov. 1, 2014 through Nov. 1, 2015 (that were subsequently billed under the OPSS).” Additionally, items and services furnished by an excepted off campus PBD not identified in Table 32 must be reported with modifier “PN”. If an excepted off-campus PBD did not furnish services under the OPSS until after Nov. 1, 2014, CMS is proposing that the 1-year baseline period begins on the first date the off-campus PBD furnished covered OPD services prior to Nov. 2, 2015. For providers that met the mid-build requirement (as defined by statute), CMS is proposing to establish a 1-year baseline period that begins on the first date the off-campus PBDs furnished a service billed under the OPSS.

**Table 32: Proposed Clinical Families of Services for Purposes of Section 603 Implementation**

Clinical Families	APCs
Airway Endoscopy	5151-5155
Blood Product Exchange	5241-5244
Cardiac/Pulmonary Rehabilitation	5771; 5791
Diagnostic/Screening Test and Related Procedures	5721-5724; 5731-5735; 5741-5743
Drug Administration and Clinical Oncology	5691-5694
Ear, Nose, Throat (ENT)	5161-5694
General Surgery and Related Procedures	5051-5055; 5061; 5071-5073; 5091-5094; 5361-5362
Gastrointestinal (GI)	5301-5303; 5311-5313; 5331; 5341
Gynecology	5411-5416
Major Imaging	5523-5525; 5571-5573; 5593-5594
Minor Imaging	5521-5522; 5591-5592
Musculoskeletal Surgery	5111-5116; 5101-5102
Nervous System Procedures	5431-5432; 5441-5443; 5461-5464; 5471
Ophthalmology	5481; 5491-5495; 5501-5504
Pathology	5671-5674
Radiation Oncology	5611-5613; 5621-5627; 5661
Urology	5371-5377
Vascular/Endovascular/Cardiovascular	5181-5184; 5191-5194; 5200; 5211-5213; 5211-5244; 5231-5232
Visits and Related Services	5012; 5021-5025; 5031-5035; 5041; 5045; 5821-5823



CMS is “aware of past stakeholder concern regarding limiting service line expansion for excepted off-campus PBDs using the 19 clinical families identified in Table 32.” However, CMS believes that the proposed clinical families recognize all clinically distinct service lines for which a PBD might bill under the OPPS, while simultaneously allowing for new services within a clinical family of services to be considered for designation as “excepted items and services”, where the types of services within a clinical family expand due to new technology or innovation<sup>6</sup>.

CMS notes that “requiring excepted off-campus PBDs to limit their services to the exact same services they furnished during the proposed baseline period would be too restrictive and administratively burdensome.” CMS is seeking comment on the proposed clinical families, whether any specific groups of hospitals should be excluded from their proposal to limit the expansion of excepted services (e.g., rural SCHs). CMS specifically notes the consideration of excluding rural SCHs “in light of” recent reports of hospital closures in rural areas.

Additionally, CMS is seeking comments on “alternate methodologies to limit the expansion of excepted services in excepted off-campus PBDs for CY 2019.” Specifically, CMS is seeking comment on MedPAC’s recommended approach, whereby CMS would “establish a baseline service volume for each applicable off-campus PBD, cap excepted services (regardless of clinical family) at that limit, and when the hospital reaches the annual cap for that location, additional services furnished by that off-campus PBD would no longer be considered covered OPD services and would instead be paid under the PFS (the annual cap could be updated based on the annual updates to the OPPS payment rates).” Under this approach, hospitals would be required to report service volume for each off-campus PBD for the applicable period (e.g., Nov. 1, 2014 – Nov. 1, 2015), and would be subject to audit.

### **Hospital Outpatient Quality Reporting (OQR) Program Proposals**

CMS has implemented quality reporting programs for multiple care settings – including for hospital outpatient care – the Hospital Outpatient Quality Reporting (OQR) Program. CMS notes that the Hospital OQR Program is aligned with that of hospital inpatient services, the Hospital Inpatient Quality Reporting Program (IQR Program). As previously mentioned, hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor.

CMS has placed regulatory reform and reducing regulatory burden as top priorities. In October 2017, the agency launched the Meaningful Measures Initiative to reduce the regulatory burden on the health care industry. The goals of this initiative are to foster operational efficiencies and reduce costs while producing quality measures that are easier to collect and report and are more focused on meaningful outcomes. CMS has identified a list of measure priority areas, and is using them to review measures in its quality and value programs. CMS notes that the proposals for the OQR reflect efforts to improve the usefulness of the data that are publicly reported in the Hospital OQR Program. The agency’s goal is to improve the usefulness and usability of CMS quality program data by streamlining how facilities are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on the [Hospital Compare](#) website. Additionally, CMS makes proposals that are in line with proposed changes made earlier this year to the other quality reporting and value-based purchasing programs for CY 2018 and FY 2019.

In the FY 2018 and CY 2018 proposed rules for quality reporting and value-based purchasing programs for CMS’s quality reporting and value-based purchasing programs, the agency requested feedback on which social risk factors “provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or facility that would also allow for a comparison of those differences, or disparities, across facilities.” As a next step, CMS is “considering options to reduce health disparities among patient groups within and across health care settings by increasing the transparency of disparities as shown by quality measures.” Additionally, CMS is taking into consideration how this will apply to other CMS quality programs in the future. The agency indicates more details – including the potential stratification of certain Hospital IQR Program outcome measures – are discussed in the FY 2018 IPPS/LTCH final rule. The agency notes that they plan to continue working with stakeholders to look for policy solutions that will lead to health equity among all beneficiaries while

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<sup>6</sup> 42 CFR 419.48

minimizing unintended consequences, and that they will continue to look for options to address equity and disparities in their value-based purchasing programs.

**Proposed Removal of Quality Measures from the Hospital OQR Program Measure Set**

In this proposed rule, CMS is not proposing any new measures for the Hospital OQR Program. However, the agency is proposing to remove a total of 10 measures from the Hospital OQR Program measure set across the CY 2020 and CY 2021 payment determinations.

Beginning with the CY 2020 payment determination, CMS is proposing to remove the following measure:

- OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

Beginning with the CY 2021 payment determination, CMS is proposing to remove the following measures:

- OP-5: Median Time to ECG (NQF #0289);
- OP 31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536);
- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658);
- OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659);
- OP-9: Mammography Follow-up Rates (no NQF number);
- OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513);
- OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (NQF endorsement removed);
- OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT (no NQF number); and
- OP-17: Tracking Clinical Results between Visits (NQF endorsement removed).

Additionally, CMS is also proposing to extend the reporting period to 3 years from 1 year for the measure OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy – beginning with the CY 2020 payment determination (using claims data from Jan. 1, 2016 through Dec. 31, 2018) and for subsequent years. Tables in the [proposed rule](#) (pgs. 543-545) summarize the proposed Hospital OQR Program measure sets for the CY 2020 and 2021 payment determinations and subsequent years (including previously adopted measures and excluding measures proposed for removal in this proposed rule). CMS is seeking comment on future measure topics, and intends to propose new measures in future rulemaking. Specifically, CMS is seeking comment on outcome measures to add, as well as any process measures that should be eliminated.

**Hospital OQR Program Annual Payment Determinations**

In previous rulemaking, CMS finalized a proposal to shift the quarters for which the Hospital OQR Program payment determinations are based, beginning with the CY 2018 payment determination. The finalized deadlines for the CY 2020 payment determination and subsequent years are illustrated in the table below:

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2018 (April 1 – June 30)	11/1/2018
Q3 2018 (July 1 – September 30)	2/1/2019
Q4 2018 (October 1 – December 31)	5/1/2019
Q1 2019 (January 1 – March 31)	8/1/2019

**Proposal to Change Frequency of Hospital Outpatient Quality Reporting Specifications Manual Release Beginning with CY 2019 and for Subsequent Years**

Currently, CMS revises the Hospital Outpatient Quality Reporting Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. CMS notes that this provides “sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary.” Generally, CMS releases the Hospital Outpatient Quality Reporting Specifications Manual every 6 months and release addenda as necessary. This release schedule

provides at least 3 months of advance notice for non-substantive changes such as changes to ICD-10, Current Procedural Terminology (CPT), National Uniform Billing Committee (NUBC), and HCPCS codes, and at least 6 months of advance notice for changes to data elements that would require significant systems changes. However, CMS believes “that unnecessarily releasing two manuals a year has the potential to cause confusion for Hospital OQR Program participants.” Thus, CMS is proposing to update the frequency with which they release the Specifications Manuals. Beginning with CY 2019 and for subsequent years, instead of every 6 months, CMS would release the Specifications Manuals every 6 to 12 months. Under this proposal, CMS would release a Hospital Outpatient Quality Reporting Specifications Manual “one to two times per calendar year, depending on the need for an updated release and consideration of [their] policy to provide at least 6 months’ notice for substantive changes.”

### **Proposed Updates to the HCAHPS Survey Measure (NQF #0166) for the FY 2024 Payment Determination and Subsequent Years**

CMS, in partnership with the Agency for Healthcare Research and Quality (AHRQ), developed the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey (NQF #0166) (e.g., the HCAHPS Survey). The HCAHPS Survey is the first national, standardized, publicly reported survey of patients’ experience of hospital care and asks discharged patients 32 questions about their recent hospital stay. The HCAHPS Survey, which is not restricted to Medicare beneficiaries, is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and 6 weeks (42 calendar days) after discharge. Hospitals must survey patients throughout each month of the year.

In the FY 2018 IPPS/LTCH PPS final rule, CMS finalized a refinement to the HCAHPS Survey measure (as used in the Hospital IQR Program) by removing the previously adopted pain management questions and incorporating new ‘Communication About Pain’ questions, beginning with patients discharged in January 2018 (for FY 2020 payment determination and subsequent years). The three new survey questions address how providers communicate with patients about pain; CMS incorporated these changes “out of an abundance of caution” and “in the face of a nationwide epidemic of opioid overprescription.” Additionally, CMS finalized public reporting on the Communication About Pain questions – hospital performance data on the questions would be publicly reported on the [Hospital Compare website](#) beginning October 2020, using CY 2019 data. CMS stated that they would provide performance results based on CY 2018 data to hospitals in confidential preview reports as early as July 2019. CMS “believed implementing the Communication About Pain questions as soon as feasible was necessary to address any perceived conflict between appropriate management of opioid use and patient satisfaction by relieving any potential pressure physicians may feel to overprescribe opioids,”

Since finalization of the Communication About Pain questions, CMS has received feedback and concerns from some stakeholders that the questions still could potentially “impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey.” CMS notes that “some hospitals identified patient experience of care as a potential source of competitive advantage.” Further, CMS has heard “that some hospitals may be disaggregating their raw HCAHPS Survey data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. Some hospitals also may be using the HCAHPS Survey to assess their emergency and outpatient departments.” CMS clarifies that the “HCAHPS Survey was never designed or intended to be used in these ways.”

CMS is proposing to update the HCAHPS Survey by removing the Communication About Pain questions effective with January 2022 discharges (FY 2024 payment determination and subsequent years). This proposal reduces the overall length of the HCAHPS Survey from 32 to 29 questions, and the final four quarters of reported Communication About Pain data (comprising data from all four quarters in 2021) would be publicly reported on [Hospital Compare](#) in Oct. 2022, and then subsequently discontinued. In proposing removal of these questions, CMS does not propose to change how performance scores are calculated for the remaining questions on the HCAHPS Survey. CMS is seeking comment on this proposal, and whether the questions should be removed from the HCAHPS Survey and Hospital IQR Program. Of particular interest to the agency is feedback regarding any potential implications on patient care related to removing these questions.

### **ASC Payment Update**

The Secretary updates the ASC payment amounts annually, based on a previously adopted and codified policy to update the ASC conversion factor using the Consumer Price Index for All Urban Consumers (CPI-U) for CY 2010 and subsequent years. CMS notes a variety of differences which illustrate “why there is

reason to believe there is a measure of misalignment between the HOPD and ASC cost structure, and should be considered when assessing the suitability of using the hospital market basket as a better proxy for ASC costs than the CPI-U.” Furthermore, “the administration recognizes the value that ASCs may bring to the Medicare Program that results in the delivery of efficient, high-quality care to beneficiaries at a lower cost.”

There are several factors that contribute to the divergence in payment between the OPSS and ASC systems – including the different distribution of costs between hospitals and ASCs, and different ratesetting methodologies between the OPSS and the ASC. CMS believes “that an alternative update factor could stabilize the differential between the OPSS payment and the ASC payment, to the extent that the CPI-U has been lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.” Additionally, CMS notes that “there are many services that can safely be performed in either the hospital setting or the ASC setting and a common rate update factor recognizes that the two provider types often compete for the same patients though patient acuity is likely higher in hospitals.”

Therefore, for CY 2019, CMS is proposing to provide ASCs with the same rate update mechanism as hospitals “in order to encourage the migration of services from the hospital setting to the ASC setting and increase the presence of ASCs in health care markets or geographic areas where previously there were none or few.” CMS states that this will also promote better beneficiary access to care. CMS acknowledges that “because physicians have a financial interest in ASCs, higher payments could also lead to greater utilization of services.” Medicare does not currently collect cost data from ASCs, which makes assessing payment adequacy – the same way it is assessed for hospitals – difficult to assess. CMS is aware of additional concerns, including that they cannot validate alignment between ASC and hospital cost structure, or establish an ASC-specific market basket. Therefore, CMS is proposing to apply a hospital market basket update to ASCs for an interim period of 5 years (through CY 2023), but is seeking comments and evidence to assess “whether the hospital market basket is an appropriate proxy for ASC costs.” Additionally, CMS will “reassess whether application of the hospital market basket update to ASC rates has provided more patient choice to obtain services at a lower cost beginning with the CY 2024 rulemaking period, or sooner if appropriate.”

The hospital market basket update would be derived using the same hospital inpatient market basket percentage increase CMS proposes to use to derive the OPD fee increase factor, and adjusted for multifactor productivity. CMS is proposing this payment update methodology for a 5-year period, during which they would assess “whether there is a migration of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences.” The agency provides examples of potential “unintended consequences”, which could include “an unnecessary increase in the overall volume of services or beneficiaries’ out-of-pocket costs”. CMS is also seeking comment on implementing the hospital market basket update for a different number of years.

**Proposed ASC Payment Rate Update for CY 2019**

<b>Proposed Policy</b>	<b>Average Impact on Payments (Rate)</b>
Estimated market-basket update for IPPS	2.8%
Multifactor productivity adjustment (MFP)	- 0.8%
<b>Estimated payment rate update compared to CY 2018</b>	<b>2.0%</b>

ASCs that fail to meet the ASC Quality Reporting (ASCQR) Program reporting requirements are subject to an additional reduction of 2.0 percentage points to the update factor. CMS is proposing to implement this 2.0 percentage points for ASCs that do not meet quality reporting requirements by utilizing the hospital market basket update of 2.8 percent, and then subtracting the 0.8 percentage point MFP adjustment. Thus, CMS would apply a 0.0 percent MFP-adjusted hospital market basket update factor for ASCs not meeting the quality reporting requirements.

Addenda AA and BB to this proposed rule (available on the [CMS website](#)) display the proposed updated ASC payment rates for CY 2019 for covered surgical procedures and covered ancillary services, respectively. The proposed payment rates in these addenda do not reflect the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.



## Ambulatory Surgical Center Quality Reporting (ASCQR) Program Proposals

As previously noted, CMS has implemented quality reporting programs for multiple care settings – to measure the quality of Ambulatory Surgical Center (ASC) services, the agency has implemented the ASC Quality Reporting (ASCQR) Program. Consistent with the agency’s Meaningful Measures Initiative, CMS is proposing a number of new policies for the Program. CMS is making efforts to fully align the ASCQR Program with the Hospital OQR Program measure removal factors to provide consistency across both outpatient setting quality reporting programs. Therefore, CMS is proposing to remove Factor 2, “availability of alternative measures with a stronger relationship to patient outcomes,” beginning Jan 1, 2019. CMS is proposing to add the one factor not currently in the ASCQR Program, “performance or improvement on a measure does not result in better patient outcomes” to replace the removed Factor 2.

### **Proposed Removal of Quality Measures from the ASCQR Program Measure Set**

In this proposed rule, CMS is not proposing any new measures for the ASCQR Program. However, the agency is proposing to remove a total of seven measures from the ASCQR Program measure set across the CY 2020 and CY 2021 payment determinations.

Beginning with the CY 2020 payment determination, CMS is proposing to remove the following measure:

- ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

Beginning with the CY 2021 payment determination, CMS is proposing to remove the following measures:

- ASC-1: Patient Burn (NQF #0263);
- ASC-2: Patient Fall (NQF #0266);
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267);
- ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265);
- ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658);
- ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659); and
- ASC-11: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

Additionally, CMS is also proposing to extend the reporting period to 3 years from 1 year for the measure ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy – beginning with the CY 2020 payment determination (using claims data from Jan. 1, 2016 through Dec. 31, 2018) and for subsequent years. Tables in the [proposed rule](#) (pgs. 604-606) summarize the proposed ASCQR Program measure sets for the CY 2020, 2021, and 2022 payment determinations and subsequent years (including previously adopted measures and excluding measures proposed for removal in this proposed rule). CMS is seeking comment on possible future validation of ASCQR Program measure data, and believes the Hospital OQR Program validation policy could be a good model for the ASCQR Program. Thus, CMS is seeking comment on the methodology, as well as identifying one measure with which to start. The agency states that it would be beneficial to start with validation of just one measure – specifically, ASC-13: Normothermia Outcome, before expanding to more measures. Additionally, CMS notes that ASCs “may benefit from the opportunity to better understand their data and examine potential discrepancies.”

### Requests for Information (RFIs)

This proposed rule includes three Requests for Information (RFIs) on 1) promoting interoperability and electronic health care information exchange through possible revisions to the CMS patient health and safety requirements for hospitals and other Medicare-participating and Medicaid-participating providers and suppliers; and 2) improving beneficiary access to provider and supplier charge information. These RFIs were also included in the FY 2019 IPPS and CY 2019 PFS/QPP proposed rules, which were detailed in Vizient summaries, [here](#) and [here](#). Additionally, CMS included an RFI on leveraging the agency’s authority for a Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a possible CMS Innovation Center model in the future (which can be found on pgs. 642-655 of the [proposed rule](#)).

### What’s Next?

CMS publishes the final OPPI/ASC regulation around November 1, and the changes are effective at the beginning of the calendar year (Jan. 1, 2019). The 60-day comment period closes on September 24, 2018. Vizient’s Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to



policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern.

It is possible there will be substantial shifts between the proposed and final rule based on public comments and further analysis by CMS. Look for more information from our office when the final rule is released in November.

### **Additional Resources**

[Chelsea Arnone](#), Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring this rule and other regulatory developments. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues.