VIZIENT OFFICE OF PUBLIC POLICY AND GOVERNMENT RELATIONS

CY 2027 OPPS Proposed Rule Summary

MEDICARE PROGRAM: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS; AND QUALITY REPORTING PROGRAMS; INCLUDING THE HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM AND AMBULATORY SURGICAL CENTER QUALITY PROGRAM; REQUEST FOR INFORMATION ON STRENGTHENING THE STANDARDIZATION AND COMPARABILITY OF HOSPITAL PRICE TRANSPARENCY (HPT) DATA; PRIOR AUTHORIZATION; ACCREDITING ORGANIZATION (AO) DEEMING FOR EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA); AND NOTICES OF CLOSURE OF TEACHING HOSPITALS AND OPPORTUNITIES TO APPLY FOR AVAILABLE SLOTS

July 21, 2026

BACKGROUND & SUMMARY

On July 2, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Calendar Year (CY) 2027 Medicare payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS) (Proposed Rule) (Fact Sheet available here). The Proposed Rule includes changes to payment policies, payment rates and quality provisions for Medicare patients who receive care at hospital outpatient departments (OPDs) or receive care at ambulatory surgical centers (ASCs). This summary focuses primarily on policies related to hospital OPDs.

The Proposed Rule also refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and adjusts the previously established 340B remedy offset rate from -0.5% to -3%. Additionally, the agency proposes to reduce reimbursement for 340B acquired drugs, seeks information regarding incentive payments to providers for certain essential medicines and personal protective equipment (PPE), and advances site neutral payment policy for imaging services without contrast. CMS also proposes to continue a phased elimination of the inpatient only (IPO) list and to significantly expand the ambulatory surgical center covered procedures list (ASC-CPL).

Comments are due **August 31, 2026**, and the final rule is expected to be released by early November. Most provisions will go into effect January 1, 2027. Vizient looks forward to working with our provider clients to help inform our letter to the agency.

OPPS PAYMENT UPDATE

For CY 2027, CMS proposes to apply an OPD fee schedule increase factor of 2.4%, except for those hospitals not meeting certain quality reporting requirements, which would be subject to a 2% reduction resulting in a fee schedule increase factor of 0.4%. The proposed increase is based on the proposed hospital inpatient market basket percentage increase of 3.2% for inpatient services paid under the hospital Inpatient Prospective Payment System (IPPS), minus the proposed productivity adjustment of 0.8 percentage points. CMS estimates that total payments to OPPS providers for CY 2027 will be approximately $110.9 billion, which is an increase of approximately $9.5 billion compared to estimated CY 2026 OPPS payments.

As done in prior years, CMS proposes to use the OPD fee schedule increase factor and other budget neutrality adjustments to calculate the CY 2027 OPPS conversion factor. As a result, all budget neutrality changes combined with the market basket update are reflected in Column 5 of Table 1 below. Also, Column 7 shows the impact of all CY 2027 proposed changes and Column 8 shows the impact of adjustments for providers subject to the proposed -3.0% 340B remedy offset rate.

CMS estimates that based on changes for budget neutrality, both urban and rural hospitals would experience an increase (approximately 1.3% for urban hospitals and 5.9% for rural hospitals). When classifying hospitals by teaching status, CMS estimates non-teaching hospitals would experience an increase of 6.0%, minor teaching hospitals would experience an increase of 3.3% and major teaching hospitals would experience a decrease of -3.1%.

CMS estimates that, for CY 2027, the cumulative effect of all proposed changes will increase payments by 1.9% for all providers and 1.8% for all hospitals. Also, CMS proposes a CY 2027 conversion factor (CF) of $102.004 for hospitals that meet the Hospital Outpatient Quality Reporting (OQR) Program requirements.

Table 1. Estimated Impact of the Proposed CY 2027 Changes for the Hospital OPPS

	Number of Hospitals (1)	Proposed Ambulatory Payment Classification Recalibration Changes (2)	New Wage Index and Provider Adjustments (3)	340B Adjustment (4)	All Budget Neutral Changes (5)	Payment Adjustment for Imaging w/o Contrast at Off-campus Providers (6)	All CY 2027 Proposed Changes (7)	Impact of Adjustment for Providers Subject to 340B Remedy Offset (8)
All providers*	3471	0.0	0.1	0.0	2.5	-0.4	1.9	-2.9
All hospitals	3362	0.1	0.0	-0.1	2.4	-0.4	1.8	-2.9
Urban hospitals	2693	0.1	0.0	-0.5	1.9	-0.4	1.3	-2.9
Rural hospitals	669	-0.1	0.5	3.5	6.4	-0.1	5.9	-3.0
Non-teaching status hospitals	1993	0.3	0.1	3.5	6.4	-0.3	6.0	-2.9
Minor teaching status hospitals	905	0.3	0.1	1.1	3.9	-0.4	3.2	-3.0
Major teaching status hospitals	464	-0.3	-0.1	-4.3	-2.4	-0.5	-3.1	-2.9

*CMS estimates that 3,217 providers would be subject to the reduction to payments that result from the 340B remedy offset.

CY 2027 PROSPECTIVE ADJUSTMENT TO PAYMENTS FOR NON-DRUG ITEMS AND SERVICES TO OFFSET THE INCREASED PAYMENTS FOR NON-DRUG ITEMS AND SERVICES MADE IN CY 2018 THROUGH CY 2022 AS A RESULT OF THE 340B PAYMENT POLICY

Background

In the CY 2018 OPPS Final Rule, CMS finalized a policy to reimburse drugs acquired through the 340B Drug Pricing Program at the Average Sales Price (ASP) minus 22.5% instead of ASP plus 6% (hereinafter, "340B Payment Policy"). In addition, CMS provided a budget neutrality adjustment which increased the reimbursement for non-drug services and items under OPPS. In 2022, the Supreme Court held that because a survey of hospitals' acquisition costs was not conducted, that CMS could not vary the payment rates for outpatient prescription drugs by hospital group. As such, CMS was required to repay the amount of drug reimbursement that was lost.

As a result, in the CY 2023 OPPS Final Rule, CMS finalized policy reversing the 340B Payment Policy. Through additional rulemaking, CMS finalized that beginning in CY 2026, the agency would reduce the conversion factor for non-drug items and services to all OPPS providers, except any hospital that enrolled in Medicare after January 1, 2018, by 0.5% each year until the

offset was reached.[1] As currently implemented, this 0.5% reduction remains in effect until the estimated payment reduction reaches $7.8 billion, which CMS estimated will occur in CY 2041.

In the Proposed Rule, consistent with concerns the agency expressed in the CY 2026 OPPS Final Rule,[2] CMS reiterates that each hospital's utilization of non-drug items and services will likely diverge from what the hospital's utilization of non-drug items and services was when the 340B Payment Policy was in place. CMS also expresses concern that the $7.8 billion dollar figure does not account for inflation and does not contain interest.

New Proposed Remedy Offset

Due to the concerns described above, effective January 1, 2027, CMS proposes to increase certain providers' annual reduction to the OPPS conversion factor from 0.5% to 3%. CMS indicates this 3% reduction will continue until the estimated payment reductions for all applicable hospital outpatient items and service reaches $7.769 billion. Under this revised rate, CMS anticipates reaching this total by the end of CY 2029. **CMS also notes that it considered an alternative 2% reduction and invites stakeholder comments on both options.**

PROPOSED OPPS PAYMENT FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

Medicare OPPS Drug Acquisition Cost Survey

The Social Security Act[3] requires the Secretary of the Department of Health and Human Services (the Secretary) to set payment rates for specified covered outpatient drugs (SCODs) at the amount the Secretary determines to be the average acquisition cost for the drug for that year, at least when certain hospital acquisition cost survey data is available. The law provides a different approach to set payment rates when acquisition cost survey data is not available, and this rate is generally average sales price (ASP) plus 6%. In the CY 2018 OPPS Final Rule, CMS initially attempted to modify reimbursement of drugs acquired through the 340B Drug Pricing Program, but the Supreme Court found the agency acted unlawfully since the appropriate survey data was not utilized.[4]

In the CY 2026 OPPS Proposed Rule, CMS announced that the agency would conduct a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, with the eventual intent of proposing differential payment rates. Hospitals reported acquisition costs for 340B and non-340B-acquired drugs. In the Proposed Rule (pg. 327-378), CMS provides an overview of the OPPS Drug Acquisition Cost Survey (ODACS) design, implementation, data analysis, methodology and key proposals.

Survey Results and Proposed Payment Rates

CMS indicates that approximately 34.9% of non-340B hospitals and approximately 23.1% of 340B hospitals responded to the survey and reported that they had acquisition costs for the survey-eligible drugs. CMS considered different factors to refine the hospital population as part of the agency's analysis to more precisely reflect those entities with meaningful outpatient acquisition volume for drugs included in the survey. Table 51 of the Proposed Rule (pgs. 343-344) provides a comparison of hospital respondents versus non-respondents for the refined population. CMS also indicates that an additional summary of the agency's analysis of the survey results will be available in a technical report that will be posted on the ODACS website. CMS also indicates that the agency may continue to validate the results of the survey on a periodic basis (e.g., as often as every 4 years).

Based on the survey response data, CMS found that for drugs acquired through the 340B Program, hospitals' reported acquisition costs were approximately 33.4% below both the mean and the median ASP.[5] As a result, CMS proposes to pay for drugs acquired under the 340B Program as ASP minus 33.4%.[6] Similarly, for CY 2027 and subsequent years, CMS also proposes the

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[1] As part of the remedy, CMS also provided a one-time lump sum payment to affected 340B covered entity hospitals, calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs from CY 2018 through September 27, 2022 and what they would have received for those drugs if the 340B adjustment had not been in place. These one-time lump sum payments were issued in early 2024.

[2] In the CY 2026 OPPS Final Rule, the agency declined to finalize a proposal to increase the 340B remedy offset adjustment to -2%.

[3] Section 1833(t)(14)(A)(iii) of the Act.

[4] *American Hospital Ass'n v. Becerra*, 596 U.S. 724 (2022).

[5] Table 52 (pg. 346-347) of the Proposed Rule provides ODACS statistical data methodologies and results.

[6] Starting in CY 2027, CMS proposes that payment for 340B drugs when ASP is unavailable mirrors CMS's historic payment policies for drugs paid under OPPS. If ASP information is not available, payment is based on the WAC, with WAC minus 33.4%. If WAC information also is not available, we propose a payment rate of 59.69120% of AWP. For 340B drugs paid based on MUC, CMS proposes to continue to pay them at 100 % of MUC. Similarly, CMS proposes to continue to

same policy for products acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs. **CMS seeks comment on these proposals.**

As an alternative to establishing one aggregate discount amount based on survey data, CMS is also considering establishing one aggregate discount amount based on 340B ceiling prices from HRSA. Under the alternative, the acquisition cost margin is ASP minus 28% for 340B drugs. **CMS seeks comment on this alternative to set OPPS payment for 340B drugs at ASP minus 28%.**

Under the OPPS, Medicare pays separately payable drugs at rates that approximate their acquisition costs, such as at ASP or Wholesale Acquisition Cost (WAC). These drugs may also receive an add-on payment. However, CMS does not believe it is necessary to establish an add-on payment for overhead and handling of 340B-acquired drugs because the agency believes the amount proposed may already account for the costs of overhead and that hospitals will likely negotiate additional discounts that will render an additional add-on payment unnecessary. **CMS seeks comment on the proposal to not include an add-on payment.**

CMS indicates that as drug prices change, the agency will continue to update the calculated ASPs and then reduce payments by an appropriate percentage of ASPs to better align payment with the average cost of the drug. **CMS seeks comment on the proposal to apply a single discount factor to the ASP for 340B-acquired drugs in lieu of calculating individual acquisition cost amount for 340B-acquired drugs.**

For drugs acquired outside of the 340B Program, hospitals' survey-reported acquisition costs were approximately 2.7% above the mean ASP and 2.8% above the median ASP. However, CMS notes that the agency is still reviewing this data for future rulemaking.[7] Therefore, for CY 2027, for non-340B drugs, CMS proposes to maintain the current payment rate, which is generally ASP plus 6%.

Effectuating the 340B Payment Adjustment

To effectuate the payment adjustment for 340B-acquired drugs, CMS proposes that, beginning January 1, 2027, providers who are not exempted from the 340B payment adjustment would report modifier "JG" (Drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug was acquired under the 340B Program. Application of modifier "JG" would trigger a payment adjustment such that the 340B-acquired drug is paid at ASP minus 33.4%. CMS indicates that the phrase "acquired under the 340B Program" would include all drugs acquired under the 340B Program or Prime Vendor Program, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program would not be reported with the modifier "JG".

CMS also proposes that beginning January 1, 2027, all providers report a distinct modifier to identify drugs and biologicals that were not acquired under the 340B Program. Specifically, CMS is establishing a new modifier, "XX" (Drug or biological not acquired under the 340B Drug Pricing Program), which the agency proposes will be required for all separately payable drugs that were purchased outside of the 340B Program.[8] Table 56 (pg. 374) of the Proposed Rule includes drug claim modifiers for entities paid under the OPPS. **CMS seeks comment on the proposal to require all separately paid drug claims to be reported with a modifier of either "JG," "TB,"[9] or "XX".**

Coinsurance

Regarding beneficiary coinsurance, CMS estimates that the proposed policy to pay for separately paid drugs acquired under the 340B Program at ASP minus 33.4% will collectively reduce beneficiary copayments by an estimated $1.15 billion for CY 2027. In the Proposed Rule, CMS indicates that the Inflation Reduction Act Part B inflation rebate coinsurance adjustment

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pay for invoice priced 340B drugs at the invoice amount as the invoice price amount should already reflect the 340B discount. Also, CMS proposes for non-340B drugs acquired by 340B hospitals that the payment will not be adjusted. **CMS seeks comment on this proposal.**

[7] CMS notes that the results of the survey for non-340B drugs generally indicate lower acquisition costs than current payment. Since the discrepancy is not as clear and significant as with 340B drugs, the agency indicates it will continue to analyze the data from this survey, aligning those reported costs with hospital claims billing patterns, to see if any additional significant trends exist that merit further adjustments to OPPS payment policy in future years. CMS is also assessing billing patterns among those hospitals that did not respond. Lastly, CMS indicates that the agency collected and analyzed information on non-NDC-specific GPO discounts that hospitals receive and are still considering how these discounts could be factored into future analysis and policymaking. CMS indicates that it will consider these issues for future rulemaking.

[8] Note, "XX" is a placeholder modifier code that will be updated in the CY 2027 OPPS/ASC final rule with comment period, if this policy is finalized.

[9] In the Proposed Rule, CMS indicates providers exempted from the newly proposed reimbursement policy should report the informational modifier "TB" (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount.

amount would not apply to separately payable, non-pass-through 340B-acquired drugs under this proposal because those drugs would no longer be paid at the statutory amount (e.g., ASP plus 6%).

Exemptions

CMS proposes to exempt rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals from the proposed policy to adjust OPPS payments for drugs acquired under the 340B Program. These hospitals would generally be paid ASP plus 6%. CMS indicates it may reconsider these exemptions in future rulemaking. **CMS seeks comment on these exemptions.**

Budget Neutrality

To maintain budget neutrality within the OPPS, CMS estimated that OPPS payment for 340B acquired drugs will be reduced by approximately $4.85 billion in CY 2027; however, these payments will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under the OPPS. Specifically, the redistributed dollars will increase the conversion factor for OPPS non-drug items and services by 8.44% for CY 2027.

Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals and Radiopharmaceuticals

The law provides for temporary additional payments called “transitional pass-through payments” for certain drugs and biologicals.[10] For CY 2027, CMS proposes to continue assigning status indicator "G" to drugs and biologicals that remain eligible for transitional pass-through payment in CY 2027. The pass-through drugs and biologicals and their designated APCs assigned status indicator “G” are included in Addenda A and B in the Proposed Rule.

Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2026

CMS provides that there are 49 drugs and biologicals whose pass-through payment status will expire by December 31, 2026, as listed in Table 43 of the Proposed Rule (pgs. 272-275). Consistent with existing OPPS policy, CMS proposes to assign each drug and biological the appropriate payment status indicator after the pass-through status expires. Drugs and biologicals with costs above the packaging threshold would remain separately payable and generally receive status indicator K, while those with costs at or below the threshold generally receive status indicator N as packaged payments. **CMS is seeking comment on whether these proposed post-pass-through status indicator assignments are appropriate.**

Drugs, Biologicals and Radiopharmaceuticals with Pass-Through Payment Expiring in CY 2027

For CY 2027, CMS proposes to end pass-through payment status for 28 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2024 – January 1, 2025, are listed in Table 44 of the Proposed Rule (pgs. 278-279). For CY 2027, CMS proposes to continue to pay for pass-through drugs and biologics using the ASP methodology, which is generally at ASP plus 6%. This is equivalent to the rate these products would receive in the physician’s office setting in CY 2027.

Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing in CY 2027

CMS proposes to continue pass-through payment status in CY 2024 for 45 drugs and biologicals which had pass-through payment status begin between April 1, 2025 – April 1, 2026; these drugs and biologicals are listed in Table 45 of the Proposed Rule (pgs. 280-282).

Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

Since CY 2007, CMS has updated the threshold for establishing separate APCs for payment for drugs and biologicals, using a four-quarter moving average Producer Price Index (PPI) level for Pharmaceutical Preparations (Prescription) and rounding the resulting dollar amount to the nearest $5 increment. For CY 2027, CMS proposes a packaging threshold of $140.

For CY 2027, CMS proposes to continue using current methodology to determine whether drugs, biologicals, and radiopharmaceuticals are packaged into OPPS procedure payments or paid separately. As noted above, CMS proposes to package payment for drugs, biologicals, and therapeutic radiopharmaceuticals with a per-day cost of $140 or less, while products with a

[10] The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), established transitional pass-through payments under the OPPS to provide additional reimbursement for certain drugs, biologicals, radiopharmaceuticals, and brachytherapy sources. These payments apply to eligible existing products and certain new drugs and biologicals whose costs are significant relative to the associated OPPS payment.

per-day cost above $140 would generally receive separate payment unless they are subject to a policy requiring packaging. For diagnostic radiopharmaceuticals, CMS proposes a higher packaging threshold of $665 per day, with products exceeding that threshold receiving separate payment.

Biosimilar Biological Products

In the CY 2024 OPPS Final Rule, CMS finalized a policy that exempts biosimilars from the OPPS drug packaging threshold when their reference biologic is separately payable.[11] Under this policy, a biosimilar may continue to receive separate payment even if its per-day cost falls below the packaging threshold, so long as the corresponding reference product is paid separately. CMS proposes to continue this policy for CY 2027.[12]

The Inflation Reduction Act (IRA), which was signed into law in August 2022, provides enhanced Medicare payment for qualifying biosimilars by increasing the add-on payment from ASP plus 6% to ASP plus 8% of the reference biological's ASP during the applicable 5-year period.[13] Biosimilars that first receive ASP-based payment between October 1, 2022, and December 31, 2027 are eligible for this enhanced payment, with the five-year period beginning on the first day of the calendar quarter in which ASP-based payment starts. Although December 31, 2027, is the last date a biosimilar can first qualify for the enhanced payment, any biosimilar that qualifies by that date remains eligible for the full five-year payment adjustment, even if that period extends beyond 2027.

Proposed Payment Rates for Skin Substitute APCs

To address growth related to skin substitutes, CMS finalized, starting January 1, 2026, assigning sheet-form skin substitute products to one of three clinical ambulatory payment calculations (APCs) the agency created based on FDA regulatory categories: APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products). CMS also finalized a single payment rate of $127.14/cm^2 for all three APCs for CY 2026.[14] For CY 2027, CMS proposes to maintain the current skin substitute category payment rates, stating that there is not sufficient claims and utilization data from the new payment methodology to support recalculating the rates for the three APCs.

Non-Opioid Treatments for Pain Relief

CMS notes that the Consolidated Appropriations Act of 2023 (CAA, 2023) provides temporary additional payments for non-opioid treatments for pain relief. Specifically, non-opioid treatments furnished from January 1, 2025, and before January 1, 2028, for pain relief are not to be packaged and CMS is required to make an additional payment. Consistent with prior rulemaking, for CY 2027, CMS proposes to continue to exclude non-opioid treatment for pain relief from the packaged C-APC payment since those items are separately paid. **CMS is also seeking public comments on the proposed qualifying products for CY 2027, which can be found in Table 71 in the Proposed Rule (pgs. 522-524).**

PROPOSED WAGE INDEX

By law, CMS must determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions. For CY 2027, CMS proposes to continue setting the OPPS labor-related share at 60% of the national OPPS payment, meaning that for hospitals, approximately 60% of the costs of services paid under the OPPS are attributable to wage costs. Additionally, for CY 2027, CMS proposes to continue implementing various provisions affecting the wage index, such as reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment) and the permanent 5% cap on any decrease to a hospital's wage index from its wage index in a prior fiscal year (FY).

For CY 2027, CMS is also proposing to continue temporary payment protections for hospitals that were negatively affected by the elimination of the low wage index hospital policy.

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[11] https://www.govinfo.gov/content/pkg/FR-2023-11-22/pdf/2023-24293.pdf

[12] In the Proposed Rule, CMS explains this approach was adopted to eliminate financial incentives to use higher-cost reference biologics and to encourage the use of lower-cost biosimilars by ensuring they receive comparable payment treatment.

[13] Section 11403 of the IRA makes changes to the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years.

[14] Under this policy, payment rates are intended to be updated annually using the most recent available pricing data, including ASP data, hospital mean unit cost (MUC) data, and, when necessary, WAC or AWP-based pricing.

PROPOSED UPDATES AFFECTING OPPS PAYMENTS

Proposed Hospital Outpatient Outlier Payments

OPPS provides outlier payments (added to the APC amount) to help mitigate financial risks associated with high-cost and complex procedures that could present a hospital with significant financial loss. For CY 2027, CMS proposes to continue its current OPPS outlier payment policy keeping total outlier payments at approximately 1% of overall OPPS spending.[15] Under this policy, hospitals would qualify for outlier payments when the cost of providing a service exceeds both 1.75 times the APC payment rate and a fixed-dollar threshold. For CY 2027, CMS estimates that a proposed fixed dollar-threshold of $7,100 combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0% of aggregated total OPPS payments to outlier payments.

PROPOSED OPPS AMBULATORY PAYMENT CLASSIFICATION (APC) GROUP POLICIES

Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services and items are generally based on medical billing codes, specifically HCPCS codes, that are reported on hospital OPD claims. HCPCS codes are used to report surgical procedures, medical services, items and supplies under the hospital OPPS and are updated and changed throughout the year. In the April 2026 OPPS update, CMS established 61 new HCPCS codes effective April 1, 2026, and introduced 98 new HCPCS codes effective July 1, 2026. A full list of the updated April codes can be found in the Proposed Rule in Table 9 (pgs. 117-119), and the updated July codes are listed in Table 10 (pgs. 120-124). Furthermore, the codes for these updates are designated with comment indicator "NP" in Addendum B. **CMS seeks comments on these proposed APC and status indicator assignments**.

Application of the 2 Times Rule

CMS notes that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to resource use if the highest cost for an item or service in the group is more than two times greater than the lowest cost for an item or service within the same groups (known as the "2 Times Rule"). However, CMS may provide exceptions to the 2 Times Rule in unusual cases (e.g., low-volume items and services). For CY 2027, CMS proposes to grant exceptions to 27 APCs that exceed the limits of the 2 Times Rule. Table 12 of the Proposed Rule (pg. 133) lists the proposed exception codes.

Proposed New Technology APCs

In prior rulemaking, CMS established criteria for assigning a complete or comprehensive service to a New Technology APC (e.g., the service must be new; not eligible for transitional pass-through payments; and the service must be considered reasonable and necessary and fall within the scope of Medicare benefits under section 1832(a) of the Social Security Act. For CY 2027, CMS included the proposed payment rates for New Technology APCs 1491-1599 and 1901-1908 in Addendum A. In the Proposed Rule (pgs. 140-165), CMS proposes to retain various services within the New Technology APC groups until the agency obtains sufficient claims data to justify reassignment of the service to an appropriate clinical APC.

Proposed OPPS Payments for Software as a Medical Service (SaMS)

Terminology and Payment for Software as a Medical Service

Historically, CMS has referred to artificial intelligence (AI) and algorithm-based clinical decision-making technologies as Software as a Service (SaaS) when they assist providers with clinical assessments or diagnoses. CMS explains that in other industries, SaaS is used to describe general cloud-based computing service models outside of a health care context. To clarify this distinction, CMS proposes to change the terminology from SaaS to Software as a Medical Service (SaMS) to refer to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. **CMS welcomes comments on the proposed change in terminology.**

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[15] CMS sets the projected target for aggregate outlier payments at 1.0% of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2026, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times the APC payment amount (the multiplier threshold) and exceeded the APC payment amount plus $6,225 (the fixed dollar amount threshold) (90 FR 53502 through 53504). If the hospital's cost of furnishing a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50% of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount.

In addition, for CY 2027, CMS proposes an interim SaMS payment policy as the agency works to develop a permanent standardized payment framework for SaMS. Specifically, CMS proposes to designate 36 HCPCS codes as SaMS and reassign the designated SaMS that are currently paid separately (status indicator "S") under clinical APCs, to new technology APCs that closely align with current CY 2026 payment rates.[16] CMS is advancing these changes because the agency believes the current OPPS payment approach using clinical APCs is not well-suited to software-based technologies.

CMS also proposes creating a new OPPS status indicator, "O1," to identify and separately classify SaMS technologies from other services assigned to new technology APCs that are not software-based medical technologies. Under the proposal, each service assigned to status indicator O1 would receive separate payment, similar to services assigned to status indicator "S." Table 61 in the Proposed Rule (pgs. 453-457) provides the list of HCPCS codes and proposed new technology APC and status indicator assignments for CY 2027.[17] **CMS asks for comment on this proposal and also on whether a status indicator with the same payment specifications as status indicator "T"[18] would provide a more appropriate payment for these services. In addition, CMS seeks comment on its proposed list of SaMS-designated HCPCS codes, the codes proposed for reassignment to new technology APCs, and whether additional HCPCS codes should be included as SaMS technologies.**

SaMS Analyses Performed on Laboratory Tests

Currently, certain SaMS analyses are treated as clinical diagnostic laboratory tests (CDLTs) and paid under the Clinical Laboratory Fee Schedule (CLFS). CMS proposes that software algorithms that analyze previously generated laboratory data will be paid as SaMS or as other diagnostic tests rather than as laboratory tests under the CLFS.[19] Table 62 of the Proposed Rule (pg. 462) lists the currently payable SaMS analyses performed on laboratory tests under the CLFS with proposed new technology APC assignments under the OPPS for CY 2027. **CMS seeks comment on the proposed list of HCPCS codes and whether additional codes should be designated as SaMS and transitioned from the CLFS to the OPPS.**

PROPOSED OPPS PASS-THROUGH PAYMENT FOR DEVICES

Transitional device pass-through payment facilitates access for beneficiaries to new and innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate. Under the OPPS, a category of devices may be eligible for transitional pass-through payments for a minimum of two years, but not to exceed three years. Currently, 21 device categories are eligible for pass-through payment. Table 29 in the Proposed Rule (pgs. 194-196) lists these device categories along with the corresponding expiration dates for pass-through payment status. CMS received 13 complete applications by the March 3, 2026 deadline: 10 under the alternative pathway and 3 under the traditional pathway. More information regarding the applications is available in the Proposed Rule (pgs. 201-255). Also, CMS provides the full listing of proposed CY 2027 device-intensive procedures in Addendum P.[20] **CMS welcomes comment on these applications.**

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[16] CMS believes new technology APCs are a better temporary payment option for SaMS because they have traditionally been used to provide consistent payment for new services when there are not enough claims, clinical, or cost data to determine the most appropriate clinical APC assignment.

[17] Of these codes, 21 HCPCS codes currently assigned to clinical APCs would be reassigned to new technology APCs with payment rates that generally align with CY 2026 levels and assigned the new "O1" status indicator. SaMS technologies already assigned to new technology APCs would remain in those APCs for CY 2027, but their status indicator would be changed to O1 to formally identify them as SaMS technologies.

[18] Status Indicator "T" is defined as a "Procedure or Service, Multiple Procedure Reduction Applies" the OPPS payment status is "Paid under OPPS; separate APC payment." This is paid separately under OPPS and not packaged into another APC payment and is also subject to multiple procedure discounting when more than one T-status procedure is performed during the same ient encounter. Multiple procedure discounting is where payment is reduced for additional procedures performed during the same outpatient visit. If multiple procedures are billed on the same claim, the highest-paid procedure is generally paid in full, while payment for additional procedures may be reduced.

[19] CMS notes that laboratory testing has increasingly incorporated algorithms to interpret laboratory data and generate clinically meaningful results. Historically, these technologies were reflected in CPT codes for Multi-Analyte Assays with Algorithmic Analysis (MAAA), which combine laboratory analyses (such as genomic sequencing or immunoassays) with computer-based algorithms. More recently, however, CMS has observed the emergence of standalone algorithmic analysis technologies that generate clinical information independently of laboratory testing. For example, when the genomic sequencing of an individual is performed, this sequencing will likely only need to be performed once. However, once the genomic sequence has been generated, the subsequent algorithmic analyses of that sequence data can be performed an infinite number of times to produce a wide range of results and/or diagnostic or risk-related information. These secondary analyses of original genomic sequences can be proprietary and unique to a single laboratory, but could also be conducted at a range of settings.

[20] Prior to CY 2017, CMS determined device-intensive status at the APC level, meaning an APC was considered device-intensive if the average device cost for procedures within that APC exceeded 40% of the total procedure cost. Beginning in CY 2017, CMS shifted to determining device-intensive status at the individual HCPCS code level rather than the APC level. Under the current approach, a specific procedure can qualify as device-intensive regardless of the APC to which it is assigned, allowing CMS to more accurately account for the costs of devices used in individual procedures.

METHOD TO CONTROL UNNECESSARY INCREASES IN THE VOLUME OF OUTPATIENT SERVICES FURNISHED IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS (PBDS): IMAGING WITHOUT CONTRAST APCS[21]

In the CY 2019 OPPS Final Rule, to control unnecessary increases in outpatient service volume, CMS finalized a site-neutral payment policy for clinic visit services (HCPCS code G 0463) furnished in excepted off-campus provider-based departments (PBDs), reducing payment from the full OPPS rate to a Physician Fee Schedule (PFS) relativity adjuster of 40% of the OPPS payment amount. CMS has expanded upon this policy, most recently in the CY 2026 OPPS Final Rule, where the agency finalized site neutral policy for drug administration services APCs, when provided at an excepted off-campus PBD.

Further, in the CY 2026 OPPS Final Rule, CMS expressed concern that higher OPPS payment rates for imaging without contrast services, compared to PFS rates, have created financial incentives that have led to unnecessary growth in OPD utilization. CMS notes that utilization of these services increased by more than 38% between 2016 and 2025 even with the introduction of the PFS equivalent rate for PBDs subject to section 603 of the Bipartisan Budget Act of 2015 starting in 2017. Therefore, for CY 2027, CMS proposes to apply a PFS relativity adjuster of 40% to imaging without contrast APCs when provided at excepted off-campus PBDs. CMS proposes to implement this policy in a non-budget neutral manner.[22] For CY 2027, CMS estimates this provision will reduce OPPS spending by $260 million, with $190 million of the savings accruing to Medicare, and $70 million saved by Medicare beneficiaries in the form of reduced beneficiary coinsurance. **CMS requests comments on additional outpatient services or alternative approaches to address unnecessary increases in hospital OPD service volume.**

Exemptions

CMS also proposes continuing the agency's exemption of rural SCHs as the agency has not found strong evidence that these services are being utilized at an unnecessary volume at excepted off-campus PBDs of rural SCHs. **CMS invites comments on the proposed exemption for rural SCHs. Additionally, CMS also seeks comment on whether additional hospital types should be exempt from the existing site neutral payment policies and whether the current exemptions for rural SCHs should be maintained for clinic visits and drug administration services.**

Extension of Site Neutral Policy to Multiple Imaging Composite APCs

Under a policy established in the CY 2009 OPPS Final Rule, CMS adopted a multiple imaging composite APC policy where hospitals receive a single composite payment when multiple imaging procedures from the same imaging family are performed during the same encounter.[23,24] For CY 2027, CMS proposes to apply the site neutral payment adjustment to composite APCs when the individual imaging procedures that comprise a composite APC payment would be subject to site neutral payment if billed separately. CMS explains that the composite APCs are composed of the same imaging-without-contrast HCPCS codes assigned to the imaging without contrast APCs and would therefore be subject to the proposed volume control methodology if billed separately.[25]

PROPOSED MODIFICATIONS TO IMPLEMENT THE PROVISIONS OF SECTION 6225 OF THE 2026 CONSOLIDATED APPROPRIATIONS ACT (CAA) AFFECTING OFF-CAMPUS HOSPITAL OPDS

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[21] The APCs for imaging without contrast service are 5521 (Level 1 Imaging Without Contrast), 5522 (Level 2 Imaging Without Contrast), 5523 (Level 3 Imaging Without Contrast), and (Level 4 Imaging Without Contrast) 5524. For 2026, 337 Healthcare Common Procedure Coding System (HCPCS) codes make up the four levels of the imaging without contrast APCs. Imaging without contrast services are diagnostic imaging procedures that do not require the administration of contrast agents and instead rely on standard imaging modalities such as X-ray, ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), and dual-energy X-ray absorptiometry scans (DXA) to produce clinically meaningful images. CMS states these services are generally low- to moderate-complexity and are routinely used to evaluate a wide range of conditions, including musculoskeletal injuries, organ structure, and disease screening

[22] CMS states this is consistent with how the agency previously implemented site-neutral payment policies for clinic visits in CY 2019 and drug administration services in CY 2026. CMS argues that its authority under section 1833(t)(2)(F) of the Social Security Act to develop methods for controlling unnecessary increases in outpatient service volume is distinct from other OPPS payment adjustments that are subject to budget-neutrality requirements.

[23] https://www.govinfo.gov/content/pkg/FR-2009-01-26/pdf/E9-1519.pdf

[24] CMS utilizes three imaging families based on imaging modality: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3 of the Proposed Rule (pg. 55-59).

[25] CMS states in the Proposed Rule that excluding these composite APCs from the policy would result in different payment treatment for the same imaging services based solely on whether they were billed individually or as part of a composite payment, creating inconsistent payment incentives.

Section 6225 of the CAA[26] requires off-campus hospital OPDs to meet certain new conditions for OPPS payment beginning January 1, 2028. Specifically, to receive payment for items and services furnished on or after January 1, 2028, an off-campus OPD will have to obtain and bill under its own separate National Provider Identifier (NPI) rather than the hospital's main NPI, file an initial provider-based status attestation demonstrating that the off-campus OPD is compliant with the provider-based requirements,[27] and submit updated attestations and documentation requirements within timeframes specified by CMS. In the Proposed Rule, CMS provides regulations to implement this section of the law.

Attestation Requirement Timeline

CMS proposes that all off-campus OPDs already furnishing services on or before January 1, 2028, submit an initial provider-based attestation during a two-year window from January 1, 2026, through December 31, 2027.[28] For departments that begin providing services after January 1, 2028, the attestation must be submitted within the two years before the billed services are delivered. CMS proposes that subsequent attestations would be required on a schedule established by CMS, but no less frequently than every 5 years. **CMS anticipates addressing the subsequent attestation requirement in the 2028 rulemaking cycle but requests comments on the proposed 5-year subsequent attestation timeframe.**

CMS is also considering requiring provider departments that received a provider-based determination before January 1, 2026, to submit an attestation letter from an authorized official, along with documentation of the prior CMS determination, affirming the department's continued compliance with the determination of provider-based status regulations. CMS also proposes to exempt Indian Health Service and Tribal facilities and certain federally qualified health centers (FQHCs) from the proposed attestation requirements. **CMS seeks comments on these proposals.**

Proposed Attestation Form

CMS proposes to create a standardized national attestation form and a centralized electronic submission system for provider-based determinations, replacing the current Medicare Administrative Contractor (MAC)-specific attestation templates. The standardized form would require identifying information for both the main provider[29] and provider-based department, along with a certification by an authorized official of the main provider, attesting that the department complies with the applicable provider-based requirements. Until the new attestation system is implemented, CMS will allow providers to continue submitting attestations through their MAC under existing procedures.

CMS proposes to allow contractors, including MACs, to conduct standardized review and validation activities and issue provider-based determinations on CMS's behalf, rather than requiring separate CMS review of each attestation.[30] Determinations issued through this process would constitute CMS's initial determinations and are subject to applicable Medicare appeals. CMS and the agency's contractors would use standardized review, validation, and risk-based screening processes to assess attestations for completeness, consistency with provider enrollment records, and compliance with the provider-based requirements.[31]

Proposed Attestation Documentation Requirements

To maintain consistency with Section 6225 of CAA, CMS proposes that attestations submitted through the proposed standardized attestation process must include documentation that demonstrates compliance with the applicable provisions of provider-based regulations. CMS anticipates that not all proposed documentation would be required at the time of initial attestation submission. Rather, CMS proposes that the agency and its contractors, including MACs, use risk-based screening and targeted documentation review processes to identify whether additional documentation is warranted. CMS outlines the categories of documentation that providers may be required to submit in connection with their attestations in the Proposed Rule (pgs. 601-603). **CMS invites comment on the appropriate scope of documentation requirements, including whether any of the categories described should be modified, consolidated, or eliminated to reduce provider burden.**

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[26] https://www.congress.gov/bill/119th-congress/house-bill/7148/text

[27] In in 42 C.F.R. § 413.65, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-413/subpart-E/section-413.65

[28] CMS clarifies that providers that submit an attestation before January 1, 2028, would satisfy the statutory attestation requirement even if CMS has not yet completed its review and issued a formal provider-based determination.

[29] CMS refers to main providers as a single entity that owns and operates multiple facilities that were treated as part of the main provider for purposes of payment, certification, coverage, and/or billing.

[30] Under the current attestation process, providers submit their attestations and supporting documentation to their MAC, which performs a preliminary review and forwards its recommendation to CMS for the initial determination.

[31] These reviews could include automated validation, data analysis, targeted documentation reviews, and other contractor review procedures designed to promote national consistency and program integrity.

Separately, CMS proposes to revise documentation requirements by allowing providers to initially submit a standardized attestation form without supporting documentation, while requiring providers to maintain supporting documentation compliance records. CMS, or the agency's contractors, could later request documentation as part of validation, audit, review, or oversight activities. CMS also proposes to establish future uniform review criteria, validation protocols, and documentation standards through operational guidance and plans to maintain ongoing quality review and oversight of attestation determinations and related attestation review activities. CMS anticipates giving providers a reasonable period, generally not to exceed 60 days, to furnish requested supporting documentation. **For providers that submit attestations for more than one off-campus outpatient department, CMS is considering streamlined supporting documentation requirements, including reducing duplicative submissions by allowing supporting documentation that applies to multiple locations to be submitted once, and seeks input on how best to minimize burden**.

Proposed Attestation Compliance Requirements

CMS proposes that if an attestation demonstrates compliance with the provider-based requirements, CMS, the agency's contractors, would issue an approval determination. If an attestation fails to demonstrate compliance, a provider fails to furnish requested documentation, or the provider does not attest to all applicable requirements, CMS or its contractors, could issue a denial with applicable appeal rights. CMS also proposes that the agency or contractors may request supporting documentation at any stage of the review, validation, audit, or oversight process to evaluate compliance with provider-based requirements. In addition, CMS proposes using a layered, risk-based oversight approach that would include automated validation and screening of all attestations to assess accuracy and completeness.[32] CMS proposes to establish review criteria through operational guidance and plans to focus oversight resources on providers and departments presenting the highest risk of noncompliance. Failure to submit requested documentation within CMS-established timeframes could result in a determination of noncompliance and recovery of payments.

Proposed Definition of "Off-Campus Outpatient Department of a Provider"

CMS proposes to add a definition of "off-campus outpatient department of a provider," a term that is not currently defined in the provider-based regulations.[33] Consistent with Section 6225 of the CAA, CMS proposes to define an off-campus outpatient department of a provider as a department that is not located on the campus of the main provider or within 250 yards of a remote location of a hospital. CMS also proposes revisions to the provider-based regulations to align with the statutory distinction between off-campus provider-based departments and facilities located near a remote hospital location.[34] Accordingly, departments located within 250 yards of a remote hospital location would be excluded from the proposed off-campus provider-based attestation requirements.[35]

PROPOSED SERVICES THAT WILL BE PAID ONLY AS INPATIENT SERVICES

In the CY 2026 OPPS Final Rule, CMS finalized eliminating the Inpatient Only (IPO) list through a 3-year transition, completing the elimination by January 1, 2029, to allow providers time to prepare to furnish newly removed procedures on an outpatient basis, update their billing systems and gain experience with newly removed procedures eligible to be paid under either the IPPS or OPPS. CMS notes that when a procedure is removed from the IPO list, the procedure becomes eligible for payment in either the inpatient or outpatient hospital setting. When assigning payment to these newly eligible outpatient procedures, CMS evaluates the service's clinical characteristics and resource costs, compares it with similar procedures already paid under the OPPS, and considers the corresponding inpatient payment under the IPPS. CMS finalized beginning the elimination of the IPO list by removing 285 mostly musculoskeletal procedures in CY 2026.

For CY 2027, CMS proposes to remove an additional 638 "less complex" services from the following clinical families: auditory, digestive, endocrine, hemic and lymphatic systems, integumentary, male and female genital, maternity care and delivery, mediastinum and diaphragm, respiratory, and urinary. CMS specifies that the remaining 801 procedures, which are more clin-

[32] Attestations identified as incomplete, inconsistent, or higher risk could be subject to targeted documentation review, while selected providers may undergo more extensive compliance reviews, including remote audits, site visits, investigations, additional documentation requests, and reviews conducted by Medicare program integrity contractors.

[33] The closest definition in current regulation is "department of a provider" which is defined as a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-413/subpart-E/section-413.65

[34] While current provider-based requirements generally apply to all off-campus outpatient departments, CMS notes that Section 603 of the Bipartisan Budget Act of 2015 and Section 6225 of the CAA distinguish between departments located within 250 yards of a remote hospital location and other off-campus provider-based departments https://www.congress.gov/114/plaws/publ74/PLAW-114publ74.pdf

[35] CMS also clarifies that regulatory references to facilities located on the main provider's campus also include facilities located within 250 yards of a remote hospital location.

ically complex in nature, would be removed from the IPO list during the third and final phase of the elimination in CY 2028.[36] The services proposed for removal from the IPO list for CY 2027 and the proposed status indicators and APC assignments are included in Addendum B and the complete list of codes that describe services that are proposed to be paid in CY 2027 as IPO services is included as Addendum E to this Proposed Rule.

PROPOSED CHANGES TO THE AMBULATORY SURGICAL CENTER (ASC)-COVERED PROCEDURES LIST (CPL)

For CY 2027, CMS proposes to update the ASC CPL by adding 618 procedures that are proposed to be removed from the IPO list as procedures CMS believes can be safely performed in an ASC. This list includes four procedures that were recommended by interested parties for addition to the ASC CPL.[37] These procedures are listed in the public use file titled "Proposed Additions to the List of ASC Covered Procedures for CY 2027," available on the CMS website. CMS previously expanded the criteria for adding procedures to the ASC-CPL beginning January 1, 2026, when a procedure may be added to the list if it is separately payable under the OPPS; is not designated as an inpatient-only procedure; is not reported solely through an unlisted CPT surgical code; and is not otherwise excluded from Medicare coverage.[38]

ADJUSTMENT FOR COST-OF-LIVING IN ALASKA AND HAWAII

In the Proposed Rule, CMS acknowledges stakeholder concerns that hospitals in Alaska and Hawaii face significantly higher operating costs than hospitals in other states due to geographic challenges, including reliance on shipped supplies, remote locations, and transportation difficulties.[39] CMS already provides a special cost-of-living adjustment (COLA) for hospitals in Alaska and Hawaii under IPPS that increases payment for non-labor costs to address similar concerns. For CY 2027, CMS proposes to adjust non-labor related costs for hospitals located in Alaska and Hawaii, using the Overseas Cost-of-Living Allowance (OCOLA) data published by the Department of Defense (DOD). Beginning with the FY 2027 payment year, CMS also proposes to eliminate the 25% limit on IPPS COLA factors.

PROVISION OF CARDIAC REHABILITATION (CR), INTENSIVE CARDIAC REHABILITATION (ICR) AND PULMONARY REHABILITATION (PR) SERVICES TO HOSPITAL OUTPATIENTS IN THEIR HOMES VIA AUDIO AND VIDEO REAL-TIME COMMUNICATIONS TECHNOLOGY

CMS proposes to implement Section 6211(a) of the CAA, 2026 that extended flexibility for cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR), and pulmonary rehabilitation (PR) services.[40] Specifically, through December 31, 2027, hospitals may furnish these rehabilitation services to hospital outpatients in their homes using two-way audio and video communications technology (excluding audio-only services). The statute authorized CMS to implement this policy through sub-regulatory guidance, which CMS released in April 2026.[41]

EXPANSION OF BOTULINUM TOXIN INJECTION CODES FOR HOSPITAL OUTPATIENT DEPARTMENT (OPD) PRIOR AUTHORIZATION PROCESS

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[36] For example, some of the remaining procedures for removal in CY 2028 would be from the neurological family, cardiovascular family, solid organ, intestinal, and islet cell transplants and related services. CMS believes these services require additional considerations due to their complex clinical nature and resources required.

[37] CPT code 49596 (Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated), 49616 (Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated), 40617 (Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible), and 40618 (Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated).

[38] CMS also relaxed several longstanding ASC eligibility restrictions. Factors that previously served as exclusion criteria, such as procedures involving extensive blood loss, major body cavity invasion, major blood vessels, or overnight monitoring, are now treated as nonbinding physician considerations rather than automatic barriers to ASC eligibility.

[39] CMS notes that cost report data show some hospitals in these states have relatively low payment-to-cost ratios and higher-than-average costs compared with other OPPS hospitals.

[40] https://www.congress.gov/bill/119th-congress/house-bill/7148/text/ih

[41] https://www.cms.gov/files/document/virtual-cardiac-rehabilitation-cr-intensive-cardiac-rehabilitation-icr-pulmonary-rehabilitation-pr.pdf

CMS proposes to expand the Hospital OPD Prior Authorization (PA) Program by adding eight additional Botulinum Toxin Injection HCPCS codes (Table 76 in the Proposed Rule (pg. 588)) to the existing list of services subject to PA when furnished on or after July 1, 2027. **CMS is seeking comment on this proposal, including any potential unintended consequences of expanding PA to these additional codes and the potential impacts on providers and beneficiaries.**

QUALITY PROGRAM UPDATES

PROPOSED REMOVAL OF THE APPROPRIATE FOLLOW-UP INTERVAL FOR NORMAL COLONOSCOPY IN AVERAGE RISK PATIENTS MEASURE IN THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) AND THE AMBULATORY SURGERY CENTER (ASC) QUALITY REPORTING PROGRAMS

CMS proposes to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure from the Hospital OQR and the ASC Quality Reporting Programs, beginning with the CY 2027 reporting period/CY 2029 payment determination.[42] CMS proposes removal of the Colonoscopy Follow-Up Interval measure because the OQR and ASC Quality Reporting Programs already include the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure[43] which is more directly tied to meaningful patient outcomes. **CMS requests comment on this proposal.**

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

The Hospital OQR Program is a pay-for-reporting program intended to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency and ensure accountability of hospital OPDs. Certain hospitals that do not submit data required for measures selected each year will incur a 2.0 percentage point reduction to their annual OPD fee schedule increase factor.[44] In this Proposed Rule, CMS did not propose changes to the OQR measure set.

Request for Information on the Advance Care Planning Electronic Clinical Quality Measure (eCQM)

In the Proposed Rule, CMS is seeking feedback on the potential adoption of an Advance Care Planning (ACP) eCQM for the Hospital OQR Program, as well as suggestions for future measure development, measure refinement, and other opportunities to address advance care planning in the OPD setting. CMS notes that OPDs increasingly care for patients with serious and complex medical conditions and as the agency phases out the IPO list, additional complex procedures are expected to shift to the outpatient setting. **CMS is seeking feedback on whether the Advance Care Planning eCQM would be appropriate for use in the hospital OPD, either as currently designed or with modifications. CMS is also requesting suggestions for additional quality measures related to ACP that may be suitable for hospital OPDs.**

Proposed Updates to the Validation of Hospital Outpatient Quality Reporting Program Data

To ensure the accuracy of Hospital OQR Program data and the ability of interested parties to rely on such data using the provider comparison tool on Medicare.gov, CMS proposes to incorporate the validation of eCQM data into the Hospital OQR Program's existing validation processes and to streamline certain validation processes. **CMS requests comment on the proposals outlined below.**

Proposed Electronic Clinical Quality Measure Data Validation

To incorporate validation of eCQMs into the existing Hospital OQR Program data validation process, CMS proposes that validation will begin with each eCQM when there is a full year of data available. Under the proposal, an eCQM would become subject to validation after hospitals have completed one full year of mandatory reporting.[45] Any future eCQMs adopted into the measure set would become eligible for validation after mandatory reporting of a full year of data is in effect, and information regarding the measures to be validated would be obtained from the CMS-designated websites.

Proposed Changes to Selection Process for Hospital Outpatient Quality Reporting Program Validation

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[42] This measure assesses the percentage of patients aged 45 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. https://p4qm.org/measures/0658

[43] This measure assesses the incidence of hospital returns within 7 days of a colonoscopy, including emergency department visits, observation stays, and unplanned readmissions https://p4qm.org/measures/2539

[44] Subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act)

[45] For example, hospitals are required to submit all four quarters of data for the Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) eCQM beginning with data from the CY 2027 reporting period; therefore, validation for the STEMI eCQM would begin with data from the CY 2027 reporting period.

CMS proposes modifying the validation process by reducing the number of hospitals selected randomly for validation and increasing the number of hospitals selected using targeted criteria. Beginning with hospital selections for validation affecting the CY 2030 payment determination, up to 200 hospitals would be selected at random and up to 200 hospitals would be selected using targeted criteria.[46]

CMS also proposes, beginning with validation for the CY 2030 payment determination, that any hospital selected for Hospital OQR Program validation, through either random selection or targeted criteria, must submit both chart-abstracted measure data and eCQM data for validation.[47] Hospitals selected for validation affecting the CY 2029 payment determination would continue to be subject only to chart-abstracted measure validation because eCQMs are not yet eligible for validation.

Case Selection for Validation

CMS proposes to revise case selection for the validation process beginning with CY 2027 data affecting the CY 2030 payment determination. Under the proposal, CMS would validate up to 32 randomly selected patient cases for each measure, replacing the current approach that validates up to 48 cases in total across all measures. For chart-abstracted measures, hospitals would submit up to 8 cases per quarter, while for eCQMs, hospitals would submit up to 32 cases annually, allowing CMS to review up to 8 cases from each quarter. Further, under this proposal, CMS would add one annual eCQM validation request, bringing the total to five requests for hospitals selected for validation.

Timing and Electronic File Submission for Medical Records Requests

CMS proposes to apply the same electronic file submission requirements used for chart-abstracted measure validation to eCQM validation. Under the proposal, hospitals selected for validation would be required to submit PDF copies of supporting medical records through a CMS-approved secure electronic file transfer process when requested by CMS or its contractor. Hospitals would have 30 days from the date of the request to submit the documentation and would continue to receive $3 per chart in reimbursement for electronically submitted records.

Submission Quarters

CMS proposes to align the timing of chart-abstracted measure validation and eCQM validation by moving to a 3-year validation cycle for both processes.[48] To transition to the new approach, validation for the CY 2029 payment determination would continue to use CY 2027 chart-abstracted data under the existing 2-year cycle. The CY 2030 payment determination would serve as a transition year, during which CMS would validate both CY 2027 chart-abstracted data and CY 2027 eCQM data. As a result, CY 2027 chart-abstracted data would be used for both the CY 2029 and CY 2030 payment determinations. To reduce provider burden, CMS proposes a one-time modification to its hospital selection process so that hospitals selected for validation based on CY 2027 data for the CY 2029 payment determination would not be selected again, either randomly or through targeted criteria, for validation of the same data affecting the CY 2030 payment determination. Table 74 in the Proposed Rule (pgs. 555-556) illustrates the proposed changes, including a transition year, to align the validation for chart-abstracted and eCQM data.

Beginning with CY 2028 reporting period data/CY 2031 payment determination, CMS will implement the new 3-year validation cycle for both chart-abstracted measures and eCQMs, under which validation results would affect payment determinations three years after the reporting period. For example, validation of CY 2028 chart-abstracted and eCQM data would affect the CY 2031 payment determination.

Scoring Method

CMS proposes to apply the same scoring standards used for chart-abstracted quality measures to eCQMs beginning with CY 2027 data affecting the CY 2030 payment determination. Beginning with the CY 2030 payment determination, hospitals se-

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[46] In 2012, CMS finalized an annual process for the Hospital Outpatient Quality Reporting Program of selecting a random sample of 450 hospitals for validation purposes and an additional 50 hospitals based on specific targeting criteria. CMS explains that since the total number of hospitals required to participate in validation each year would be fewer, this proposed change would also reduce overall burden for hospitals. Rebalancing the number of randomly selected hospitals compared to the number of hospitals selected by targeting criteria would also more effectively and efficiently direct validation program resources to ensure data accuracy. This proposal would reduce the total number of hospitals selected for validation each year from 500 to up to 400 hospitals

[47] CMS explains the agency has found that hospitals randomly selected for validation generally have high accuracy rates for chart-abstracted measures and believe the number of hospitals randomly selected for validation could be reduced without impacting the ability to assess the accuracy of hospital data. CMS also explains that increasing the number of hospitals selected for validation based on specific targeting criteria will help to ensure data accuracy by allowing a greater number of hospitals meeting specific targeting criteria to have their data submissions reviewed for accuracy.

[48] Currently, hospitals selected for chart-abstracted validation are required to submit data from 2 years prior to the applicable CY payment determination year, consisting of validation quarter 1 (January 1 through March 31), validation quarter 2 (April 1 through June 30), validation quarter 3 (July 1 through September 30), and validation quarter 4 (October 1 through December 31).

lected for validation would receive separate validation scores for chart-abstracted measures and eCQMs, and failure to meet the 75% accuracy threshold for either validation type would result in the hospital not receiving the full annual OPPS payment update.

Educational Review Process

CMS proposes that the results of educational reviews for all four quarters of chart-abstracted measure validation can be incorporated into a hospital's final validation score beginning with the CY 2030 payment determination. Under current policy, educational reviews for the fourth quarter are not completed in time to affect validation results, requiring hospitals to pursue the reconsideration process instead.[49] CMS also proposes to extend the existing educational review process for chart-abstracted measures to eCQM validation beginning with validation of CY 2027 data for the CY 2030 payment determination. CMS would review the submitted information and provide a written determination through its secure file transfer process.

Proposed Updates to the Hospital Outpatient Quality Reporting Program Validation Reconsiderations and Appeals Procedures

CMS proposes, beginning with CY 2026 reporting period data affecting the CY 2028 payment determination, to revise regulations so hospitals would no longer be required to resubmit medical records or other materials already submitted to CMS as part of a validation reconsideration request, unless CMS specifically requests this information.[50] Hospitals may continue to submit revised medical records, but would no longer need to resubmit records that have already been submitted.

ACCREDITING ORGANIZATION (AO) DEEMING AUTHORITY FOR THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)

CMS proposes to amend accreditation regulations to require CMS-approved accrediting organizations (AOs) to evaluate hospitals' compliance with certain EMTALA administrative requirements during initial accreditation and reaccreditation surveys. Specifically, AOs would review compliance requirements including posting EMTALA signage, maintaining a central emergency department log, retaining transfer records for five years, and maintaining an on-call physician list.

If an AO identifies noncompliance with these administrative requirements, the AO will address the deficiency through its normal accreditation processes, including corrective action plans, monitoring compliance, and reporting findings to CMS as appropriate. CMS clarifies this proposal would not authorize AOs to determine or enforce compliance with the EMTALA requirements. CMS and the Office of the Inspector General (OIG) would retain EMTALA enforcement authority, including requirements related to medical screening examinations, stabilizing treatment, appropriate transfers, receiving hospital responsibilities, and imposing civil monetary penalties.

REQUESTS FOR INFORMATION AND COMMENT ON STRENGTHENING THE STANDARDIZATION AND COMPARABILITY OF HOSPITAL PRICE TRANSPARENCY DATA

The Proposed Rule includes a request for information (RFI) seeking suggestions to further standardize machine-readable files (MRFs), including the reporting of complex contract provisions and payer information. The Proposed Rule also contains a request for comment (RFC) requesting feedback on methods to improve the comparability of the consumer-friendly display data as outlined below.

Machine Readable File RFI

CMS requests information on how to strengthen the transparency and usability of the MRFs.

CMS notes that hospitals currently report certain contract terms in free-text fields within MRFs, but stakeholders have reported these descriptions are difficult to interpret, compare, and analyze across hospitals. Further, CMS has received stakeholder feedback regarding the need for greater standardization of common contract provisions, such as outlier payments, stop-loss provisions, rate-tiering arrangements, and carve-outs, that can affect how negotiated rates are applied. **CMS is seeking input on how these provisions should be reported and standardized to improve transparency and usability.**

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[49] Because CMS is proposing to move from a 2-year to a 3-year validation cycle, the agency believes there will be sufficient time to complete educational reviews for all four quarters before final validation scores are calculated. As a result, any corrections identified through educational reviews would be reflected in the final confidence interval and validation score used for payment purposes.

[50] Currently, hospitals requesting reconsideration of a validation determination must resubmit all materials previously provided to CMS, including medical records used for validation. Because hospitals now submit validation records electronically and CMS already has access to those records, CMS believes this requirement is duplicative and unnecessary.

CMS is also seeking feedback on methods to standardize payer and health plan names across MRFs, such as using standardized naming conventions, unique payer identifiers, or additional plan information, to make comparisons across hospitals easier. Specific questions for this RFI can be found in the Proposed Rule (pgs. 638-640).

Consumer-Friendly Display RFC

In the CY 2020 Hospital Price Transparency Final Rule, CMS required hospitals to display pricing information for 300 shoppable items, and services, 70 of which CMS specified, in a consumer-friendly manner, while allowing hospitals flexibility to do so through either a shoppable services file or using a price estimator tool.[51] Through recent stakeholder engagements on the effectiveness of consumer-friendly display options, CMS identified a need for greater standardization and comparability of data in consumer-friendly displays to help consumers more easily compare prices and access cost information in advance of scheduled care.[52] Stakeholders noted challenges with navigating different hospital consumer-friendly display formats to find meaningful price comparisons, and the need for a consistent set of requirements across the shoppable services file and the price estimator tool. **Among other issues, CMS is seeking feedback on the following issues:**

- **Whether hospitals should continue to be deemed compliant with consumer-friendly price transparency requirements solely using a price estimator tool, given concerns that widely varying tool formats make it difficult for consumers to compare prices across hospitals.**
- **Discrepancies between hospitals' consumer-friendly displays and MRFs, including instances where the same services are reported with different prices, and how these inconsistencies affect the accuracy and usefulness of price transparency information.**
- **Situations if hospitals provide discounted cash prices through price estimator tools but this information is not reflected in their MRFs.**

As such, the agency is seeking information on how to enhance the comparability of the consumer-friendly display data to inform future rulemaking. The questions for this RFC can be found in the Proposed Rule (pg. 642-643).

CONSIDERATION OF POTENTIAL APPROACHES FOR SEPARATE IPPS PAYMENT FOR DOMESTIC PROCUREMENT OF PERSONAL PROTECTIVE EQUIPMENT AND ESSENTIAL MEDICINES

In the Proposed Rule, CMS outlines a recent request for information where the agency sought feedback regarding potential approaches to support a more resilient supply chain for American-made personal protective equipment (PPE) and essential medicines. Specifically, CMS requested input on a possible new "Secure American Medical Supplies" friendly designation that could be earned by hospitals that demonstrate their commitment to domestic procurement. In addition, the agency sought input on potential ways such a designation could facilitate the creation of new, streamlined payment policies to support hospitals in their efforts. CMS also sought input on a potential new structural quality measure as part of the Hospital Inpatient Quality Reporting (IQR) Program that could promote hospital commitments to invest in domestic procurement. However, CMS indicated that after public feedback, the agency is no longer exploring, at this time, a new "Secure American Medical Supplies" friendly designation or a new structural quality measure as part of the Hospital IQR Program.

In the Proposed Rule, as further detailed below, **CMS seeks comment on potential policy approaches for a payment adjustment, a methodology to calculate the price differential between domestic and non-domestic PPE and essential medicines, information sources of those price differentials, a definition of domestic essential medicine and PPE, and a process for verifying that a given essential medicine or PPE is "domestic."** CMS is particularly interested in expanding the existing voluntary payment policy where hospitals are reimbursed for the additional resource costs that hospitals face in pro-

[51] At that time, CMS provided limited specifications about the data requirements, allowing hospitals flexibility in the format used to display this information. https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf

[52] Stakeholders reported that differences in hospitals' consumer-friendly display formats make it difficult to compare prices across hospitals and called for more standardized requirements across shoppable services files and price estimator tools. Some stakeholders recommended that CMS no longer allow hospitals to satisfy the consumer-friendly display requirement solely through the use of a price estimator tool, noting significant variation in the design, functionality, and information presented by these tools. Stakeholders also emphasized the need for additional context to help consumers understand the actual cost of care, including whether displayed prices include facility and professional fees, which services are included or excluded from the price, and what ancillary services may generate additional charges. In addition, stakeholders suggested requiring more comprehensive service package information and updating the list of 70 CMS-specified shoppable services, arguing that some currently required services are outdated, may not be relevant to consumers, or are not furnished by all hospitals.

curing domestic National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 filtering facepiece respirators (FFRs). CMS indicates they are considering expanding this payment policy under IPPS to include other forms of domestic PPE and certain essential medicines.

Expanded Scope of PPE and Domestic Definition

For PPE, CMS is considering expanding the existing PPE policy to include all domestic NIOSH-approved filtering face piece respirators that demonstrate compliance with the American Society for Testing and Materials (ASTM) Respirator Fit Capability Standard; domestic medical gloves in compliance with FDA requirements and conforming to ASTM standards; and domestic gowns in compliance with FDA requirements and conforming to Association for the Advancement of Medical Instrumentation (AAMI) standards. CMS indicates the agency is not considering including other PPE products such as face shields, protective eyewear, surgical masks, and head and foot coverings at this time.

Currently, CMS relies on the Berry Amendment for purposes of the domestic definition. However, CMS indicates that it is considering defining the term "domestic" using the contract terms listed in the Make PPE In America Act[53], which identifies American-made PPE as domestically-made from domestic materials and components that are "grown, reprocessed, reused, or produced in the United States". CMS notes that the Make PPE in America Act definition of domestic is similar to the Berry Amendment but broader in the scope of PPE products it covers.

CMS indicates that given the lack of available domestic nitrile butadiene rubber (NBR), the agency is considering an exception for nitrile gloves which are made in the U.S. with foreign rubber.

Also, CMS clarifies that annual attestations from PPE manufacturers would have to demonstrate that the product was in compliance with the "Make PPE in America" standards for domestic procurement, with the exception of NBR.

Potentially Eligible Essential Medicines and Domestic Definition

For essential medicines, CMS developed a potential subset of essential medicines by prioritizing non-substitutable sterile injectables and generic antibiotics. Table 80 in the Proposed Rule (pg. 621-622) includes the priority matrix for essential medicine drug selection. **In addition, CMS seeks comments on expanding the PPE policy to include this subset of FDA-approved medicines, so long as they also have existing U.S. finished dosage form (FDF) production and do not contain API from countries listed as "foreign adversaries."[54]**

For these essential medicines, an essential medicine would be domestic if the country of origin is the U.S. CMS clarifies that "country of origin" is defined through incorporation by reference as "substantial transformation" of the final dosage form (or the Active Pharmaceutical Ingredient) via 19 CFR 134.1(b).[55] This is identical to the standard used by U.S. Customs and Border Protection, and thus represents a familiar definition for the pharmaceutical industry. **CMS requests comment as to whether an essential medicine should be defined as domestic when the county of origin is outside of the United States, but where "substantial transformation" of the final dosage form occurs within the United States.[56]**

In addition, CMS requests feedback regarding whether alternatives to "country of origin" would be more appropriate for determining eligibility for domestic essential medicines, such as identifying the specific FDA-registered facilities responsible for producing the FDF and API.

Domestic and Non-domestic Cost Differential

CMS is considering whether the methodology for determining a payment adjustment amount should be based on the use of standardized cost differentials for eligible domestic PPE and essential medicines, which would be updated on an annual basis.

Table 2 includes the potential eligible PPE items, per item differentials, and qualifying criteria under consideration. **CMS seeks comment on the potential base cost differential for eligible categories of PPE and the potential base cost differentials for eligible essential medicines.**

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[53] Section 70953 of Pub. L. 117-58

[54] 15 CFR 791.4 lists countries considered to be "foreign adversaries"

[55] 19 CFR 134.1(b) Country of origin. "Country of origin" means the country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the "country of origin" within the meaning of this part; however, for a good of a NAFTA or USMCA country, the marking rules set forth in part 102 of this chapter (hereinafter referred to as the part 102 Rules) will determine the country of origin.

[56] CMS references 19 CFR 134.1(b) regarding the definition of country of origin.

Table 3 includes the domestic essential medicines begin considered with base cost differentials and drug base dosages. CMS indicates that the agency expects to add additional drugs in the future until it eventually includes all non-scheduled generic drugs with domestic FDF production on the latest ARMI list. Also, CMS may account for the production location of pharmaceutical precursors or key starting materials in addition to API and FDF locations.

Table 2. Domestic PPE Items Considered for the Incentive Payment with Base Cost Differentials and Qualifying Criteria

Eligible PPE Item	Domestic Differential Per Single Item	Required Compliance
Filtering Facepiece Respirators	$0.38	• NIOSH-approved • ASTM Respirator Fit Capability Standards
Isolation Gowns	$0.82	• FDA Compliance • AAMI Standards
Nitrile Exam Gloves	$0.05	• FDA Compliance • ASTM Standards

Table 3. Domestic Essential Medicines Being Considered for the Incentive Payment with Base Cost Differentials and Drug Base Dosages[57]

Eligible Drug Molecule	Drug Base Dosage	Base Cost Domestic Differential: U.S. FDF + non-U.S. API	Base Cost Domestic Differential: U.S. FDF + U.S. API
ACYCLOVIR	500 MG	$1.50	$6.00
AMOXICILLIN	500 MG	$0.12	$0.25
AMPICILLIN	500 MG	$0.07	$0.62
ATROPINE SULFATE	1 MG	$0.95	$7.20
AZITHROMYCIN	500 MG	$0.95	$2.88
CEFEPIME	1000 MG	$0.25	$2.29
CEFTRIAXONE	1000 MG	$0.11	$0.96
DOXYCYCLINE	100 MG	$1.30	$8.20
EPINEPHRINE	1 MG	$0.35	$3.15
LEVOFLOXACIN	5 MG	$0.27	$2.85
LINEZOLID	1000 MG	$1.40	$10.07
MEROPENEM	1000 MG	$0.85	$1.94
METHYLPREDNISOLONE ACETATE	100 MG	$0.54	$5.70
METHYLPREDNISOLONE SODIUM SUCCINATE	1000 MG	$1.80	$7.42
PENICILLIN G	1000 MG; 1.67 million units	$0.29	$2.10
PIPERACILLIN / TAZOBACTAM	500 MG	$0.30	$1.20
VALGANCICLOVIR	100 MG	$0.30	$0.57
VANCOMYCIN HCL	500 MG	$2.75	$6.05

[57] In the Proposed Rule, CMS indicates the potential base cost differentials were "derived from economic analysis of wholesale acquisition costs and informed by public comments, consultations with pharmacists and government procurement specialists, and available literature to estimate costs of domestic production (including a 2022 study by ASPR that found domestic API is around 12 times more expensive than foreign API, and several studies identifying domestic generic costs as 35 to 50 percent higher than generics in India and China."

Under this potential policy, HHS would compile the information provided by manufacturers and create an annual file of eligible domestic products and domestic cost differential estimates, including the NDC or Unique Device Identifier (UDI) for the product, as applicable, manufacturer name, and part number. This public file would be intended to provide hospitals with a simple, reliable reference for identifying eligible domestic products and the estimated domestic cost differentials.

Manufacturer Attestation of Domestic Origin

CMS is considering potential policy under which a manufacturer should voluntarily be able to provide an attestation to HHS that its product meets the applicable domestic definition. CMS indicates that, to make it easier for hospitals to identify domestic products, the Department of Health and Human Services would compile these attestations annually and create a public file of eligible products by NDC or UDI, as applicable, based on the information provided by the manufacturers. Only products in this file would be eligible for separate payment.

Potential Payment Adjustment Approaches

Although included in the OPPS Proposed Rule, CMS is considering establishing a voluntary separate IPPS payment adjustment for the IPPS share of the additional resource costs incurred by hospitals in procuring eligible domestic PPE and essential medicines, as discussed in greater detail in this section. The voluntary separate payment would not be budget neutral.

CMS is considering two potential approaches that would be proposed in future rulemaking: (1) claims-based payment approach and (2) cost-report payment approach. Approach 1 and Approach 2 would operate similarly for domestic PPE as they would for domestic essential medicines.

Approach 1

For the essential medicines, the claims processing system would use the domestic cost differentials discussed above to automatically calculate and pay the separate IPPS payment adjustment. The IPPS payment adjustment would be based on the domestic NDCs and units of those NDCs for eligible domestic essential medicines furnished to an IPPS inpatient during an IPPS hospital stay that a hospital voluntarily bills on the IPPS claim for that IPPS stay.

For PPE, the claims processing system would use the domestic cost differentials discussed above to automatically calculate and pay the separate IPPS payment adjustment. The IPPS payment adjustment would be based on the amount of eligible domestic PPE used in furnishing services to an IPPS inpatient during an IPPS hospital stay that a hospital voluntarily bills on the stay's IPPS claim. To implement this approach, CMS would create three new billing codes for this purpose: a billing code for eligible domestic N95 FFRs, a billing code for eligible domestic gloves, and a billing code for eligible domestic gowns.

Approach 2

For the essential medicines, a hospital would voluntarily use that same information to calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing individually on its IPPS claims. The payment is the same under either approach, but the hospital would not need to submit the NDCs on the claim under Approach 2. As with the current N95 policy, hospitals could request interim biweekly payments under Approach 2 which would be reconciled at cost report settlement. Biweekly payment amounts would be determined by the Medicare Administrative Contractor, consistent with existing policies and procedures using an estimate of the annual reimbursable amount for the year divided into 26 equal payments.

Similarly, for PPE, a hospital would voluntarily calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing it individually on its IPPS claims. To the extent tracking domestic PPE use at the IPPS patient level may not be possible for a hospital, a reasonable allocation methodology would need to be used under Approach 2 to allocate the aggregate amount of domestic PPE purchased by the hospital to IPPS inpatients. In the Proposed Rule (pgs. 629-633), CMS discusses two potential options for an allocation methodology under Approach 2 that the agency may consider for future rulemaking. Under either potential allocation option, CMS clarifies that a hospital would report on its cost report the aggregate amount of eligible domestic FFRs purchased, the aggregate amount of eligible domestic gloves purchased, and the aggregate amount of eligible domestic gowns purchased.

Maximum Annual Amount of Aggregate Payments

CMS indicates that under any approach that may be considered, it would be prudent to establish an appropriate maximum annual aggregate separate payment (e.g., $500 million or $1 billion) across all IPPS hospitals. In addition, CMS provides that the agency could prospectively allocate shares of the aggregate amount to individual hospitals before the start of the fiscal year. CMS clarifies that under this approach, if the actual separate payment to a hospital for the fiscal year exceeds its allo-

cated maximum amount, the excess amount would be reconciled at cost report settlement, as the payment for that hospital's excess cost could be bundled into the MS-DRG payment and not separately payable.

To allocate the amount to the individual hospitals, CMS may utilize the Medicare inpatient days as reported on Worksheet S-3.[58] A hospital's share of the Medicare inpatient days aggregated across all hospitals would be multiplied by the maximum annual amount of aggregate separate payment in order to determine its allocated amount.[59]

Solicitation of Additional Options: Domestic PPE and Essential Medicines

In addition to the approaches described in the Proposed Rule, CMS seeks general input from the public on a range of topics (e.g., economic impacts, timing, potential statutory authorities, and a discussion of trade-offs with respect to such options). CMS also requests comment on the operational feasibility and differences of the two payment adjustment approaches, including different considerations for PPE versus essential medicines under each approach.

OPPS N95 Policy

CMS clarifies that due to certain budget neutrality requirements under OPPS, the agency is not considering expanding and revising the current OPPS N95 policy. Rather, CMS may sunset the existing N95 policy and remove the associated OPPS budget neutrality adjustment while exploring alternative outpatient approaches for the future.

WHAT'S NEXT?

The OPPS tables for this CY 2027 Proposed Rule are available on the CMS website. CMS is anticipated to publish the final OPPS regulation by early November, and the changes are effective at the beginning of the calendar year (January 1, 2027). The comment period closes on August 31, 2027.

Vizient's Office of Public Policy and Government Relations looks forward to hearing client 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. Please direct your feedback to Jenna Stern, Vice President, Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.

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[58] CMS clarifies that Worksheet S-3 data as, Worksheet S-3, Part I, column 6 (Title XVIII), or column 6.01 (if applicable), lines 1, 8 through 12, and subscripts as applicable.

[59] The example CMS provides is: "… if the maximum annual amount of aggregate separate payment under this potential policy were $1 billion in a given fiscal year and a hospital's share of aggregated Medicare inpatient days was 0.03 % based on historical cost reports, then the prospectively determined allocated maximum amount for that hospital for that fiscal year would be $300,000 (=$1 billion * 0.03 %)."

TO LEARN MORE, CONTACT:
Vizient's Office of Public Policy & Government Relations
at (202) 354-2600 or VizientGR@vizientinc.com