MEDPAC | Medicare Payment Advisory Commission

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August 27, 2026

Mehmet Oz, M.B.A., M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
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Attention: CMS-1850-P

Dear Dr. Oz:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "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," *Federal Register* 91, no. 128 , pp. 41734-42032 (July 7, 2026). We appreciate CMS's ongoing efforts to administer and improve Medicare's payment systems for hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), particularly given the many competing demands on the agency's staff.

Our comments focus on CMS's proposals to:

- expand site-neutral payments for imaging without contrast services under the outpatient prospective payment system (OPPS),
- extend use of the hospital market basket to update ASC payment rates,
- continue phasing out the inpatient-only list and corresponding additions to the OPPS and ASC covered-procedures list (CPL),
- reduce OPPS payment rates for 340B-acquired drugs to ASP minus 33.4 percent,
- expand the scope of separate payment for domestic procurement of personal protective equipment (PPE) and essential medicines,

- implement an interim OPPS payment policy for software as a medical service (SaMS) in calendar year (CY) 2027, and
- repeal the alternative pathway for OPPS pass-through payments.

Proposed expansion of site-neutral payments for imaging without contrast services under the OPPS

CMS states that there is evidence of continued growth of HOPD services driven by site-of-service payment differentials between the Medicare physician fee schedule (PFS) and the OPPS. This growth increases both Medicare spending and beneficiaries' cost-sharing liabilities. In the CY 2019 final rule, CMS adopted a method to control growth in the volume of clinic visit services furnished in off-campus provider-based departments (PBDs) excepted from the site-neutral payments, previously established in Section 603 of the Bipartisan Budget Act of 2015.[1] In the CY 2026 final rule, CMS asserted that the effect of hospital–physician vertical integration and increased volume of outpatient services extend beyond clinic visits. As such, CMS finalized expansion of site-neutral payments to drug administration services provided in excepted off-campus PBDs, beginning in 2026.

For CY 2027, CMS proposes to address additional site-of-service payment differentials by expanding site-neutral payments to services for imaging without contrast provided at excepted off-campus PBDs. These services include ambulatory payment classifications (APCs) 5521–5524, 8004, 8005, and 8007, which comprise 337 Healthcare Common Procedure Coding System (HCPCS) codes. This proposal is not budget neutral, which means that reductions in payments for those services would not be offset by increases in payments for other services.

Comment

The Commission supports expanding site-neutral payments for imaging without contrast services that are provided in excepted off-campus PBDs.

In our June 2023 report to the Congress, we recommended closely aligning payment rates across ambulatory settings for selected services that are safe and appropriate to provide in all ambulatory settings when doing so does not pose a risk to access.[2] The Commission included an illustrative framework that could be helpful in identifying services for which it might be safe and appropriate to align payment rates, and encouraged CMS to consult with clinicians and other stakeholders when making decisions about which services to choose. At the same time, the Commission emphasized the importance of ensuring beneficiary access to care and that our recommendation to align payments would not adversely affect the

[1] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare program: Changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. *Federal Register* 83, no. 225 (November 21): 58818–59179.
[2] Medicare Payment Advisory Commission. 2023. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

ability of hospitals—especially safety-net and rural hospitals—to provide 24/7 emergency care. The Commission also discussed the importance of maintaining the packaging of ancillary items in the OPPS under a site-neutral payment policy.

In its 2023 report to the Congress, the Commission recommended applying site-neutral payment rates to selected services provided across ambulatory care settings, including *on-campus* HOPDs. The result would be that the payment rate for these selected services provided in both off-campus and on-campus HOPDs would more closely match the rate paid under the Medicare PFS.

Though we acknowledge that there are different approaches to implementing site-neutral payments across ambulatory settings, in our June 2023 report to the Congress we noted the benefits of making budget-neutral adjustments for some OPPS services in conjunction with site-neutral payments.[3] For example, applying a budget-neutral payment adjustment with a site-neutral policy would increase OPPS payment rates for other services including emergency department visits, which would support hospitals' emergency care and standby capacity.

Extended use of the hospital market basket to update ASC payment rates

Before CY 2019, CMS annually updated the ASC payment rate using the Consumer Price Index for All Urban Consumers (CPI–U). Beginning in CY 2019, CMS has updated payment rates in the ASC payment system using the hospital market basket minus an adjustment for productivity, the same mechanism used to update the conversion factor under the OPPS. When the agency first implemented this policy, it did so for a five-year period (CY 2019 through CY 2023), with the intent of encouraging the migration of services from HOPDs to the ASC setting while the agency assessed the feasibility of collecting ASC cost data in a minimally burdensome manner.[4] However, CMS has not reported on the findings of its feasibility study, and in the CY 2024 final rule, the agency extended the use of the hospital market basket to update ASC payment rates for two additional years (through CY 2025).[5] In the CY 2026 final rule, the agency extended the use of the hospital market basket to update ASC payment rates once again.[6]

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[3] Medicare Payment Advisory Commission. 2023. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.
[4] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare program: Changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. *Federal Register* 83, no. 225 (November 21): 58818–59179.
[5] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2023. Medicare program: Hospital outpatient prospective payment and ambulatory surgical center payment systems; quality reporting programs; payment for intensive outpatient services in hospital outpatient departments, community mental health centers, rural health clinics, federally qualified health centers, and opioid treatment programs; hospital price transparency; changes to community mental health centers conditions of participation; changes to the inpatient prospective payment system Medicare code editor; rural emergency hospital conditions of participation technical correction. *Federal Register* 88, no. 224 (November 22): 81540–82185.
[6] Centers for Medicare and Medicaid Services, Department of Health and Human Services. 2025. Medicare program: Hospital outpatient prospective payment and ambulatory surgical center payment systems; quality reporting programs; overall hospital quality star rating; hospital price transparency; and notice of closure of a teaching hospital and opportunity to apply for available slots. *Federal Register* 90, no. 128 (November 25): 53448–54088.

For CY 2027, CMS proposes extending the use of the hospital market basket for an additional year (through CY 2027).

Comment

In the Commission's comments on the CY 2019, 2024, and 2026 OPPS/ASC proposed rules,[7] we expressed opposition to using the hospital market basket as an interim method for updating the ASC payment rates. While the use of the hospital market basket is an improvement over the CPI–U, we continue to urge CMS to instead move to using data reflective of ASCs' costs. Evidence indicates that the hospital market basket index does not accurately reflect the costs of ASCs: In the CY 2019 proposed rule, CMS acknowledged that ASCs' cost structure likely differs from that of hospitals, in part because ASCs tend to be single specialty, for profit, and are not required to comply with the Emergency Medical Treatment and Labor Act (EMTALA). In addition, relative to hospitals, ASCs are more urban, serve a different mix of patients demographically and by payer type, have a much higher share of expenses related to medical supplies and drugs, and have a smaller share of employee compensation costs.

As we noted in the Commission's comments on the CY 2024 and CY 2026 proposed rules,[8] analysis of ASC and HOPD service volume indicated that selected surgical procedures were already migrating from HOPDs to ASCs before CMS implemented the use of the hospital market basket in CY 2019. Therefore, we conclude that increasing the ASC payment rates by updating them with the hospital market basket was not necessary to encourage surgical procedures to migrate from HOPDs to ASCs, nor is it necessary for CMS to collect additional data on the effects of using the market basket update on ASC volume.

Instead, CMS should collect targeted cost data from ASCs and use it to construct an ASC-specific market basket, as the Commission recommended from 2010 to 2022 and recently discussed in our March 2026 report to the Congress.[9] There is precedent for this approach, evidenced by the Pennsylvania Health Care Cost Containment Council's collection of total operating costs and total operating revenue from ASCs in Pennsylvania.[10] The state of Pennsylvania has required ASCs to submit these data since at least 2005, and that has not appeared to be a barrier to the entry of additional ASCs in the state. From 2005 to 2018, the

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[7] Medicare Payment Advisory Commission. 2018. Comment letter on CMS's 2019 proposed rule for the hospital outpatient and ambulatory surgical center payment systems, September 21.
Medicare Payment Advisory Commission. 2023. Comment letter on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2024, September 11.
Medicare Payment Advisory Commission. 2025. Comment letter on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2026. September 12.
[8] Medicare Payment Advisory Commission. 2023. Comment letter on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2024, September 11.
Medicare Payment Advisory Commission. 2025. Comment letter on CMS's proposed rule on the payment systems for hospital outpatient departments and ambulatory surgical centers for 2026. September 12.
[9] Medicare Payment Advisory Commission. 2026. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
[10] Pennsylvania Health Care Cost Containment Council. 2025. *Financial analysis 2024. Volume two, ambulatory surgery centers.* Harrisburg, PA: PHC4.

number of ASCs in Pennsylvania rose from 153 to 242 (an average increase of 3.6 percent per year). As of 2024, there were 240 ASCs.

Proposed continued phase-out of the inpatient-only list and corresponding additions to the OPPS and ASC covered-procedures list

The inpatient-only (IPO) list is a list of HCPCS codes that are typically provided in an inpatient setting and cannot be paid under the OPPS. The IPO list currently comprises 1,438 HCPCS codes. In the CY 2026 final rule, CMS finalized the phase-out of the IPO list over a three-year period beginning January 1, 2026, and ending January 1, 2029. This included the removal of 269 HCPCS codes for musculoskeletal services and 16 HCPCS codes for non-musculoskeletal services from the IPO list, beginning January 1, 2026.

CMS asserted that the IPO list was no longer needed to distinguish the services that require inpatient care from those that can be provided safely in the outpatient setting. Physicians should use their clinical knowledge and judgment, together with the patient's specific needs, to determine the appropriate site of service. CMS also argued that there have been significant developments in the practice of medicine that have allowed numerous services to be safely and effectively provided in the outpatient setting. Finally, CMS argued that the combination of physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of patients in both the inpatient and outpatient settings, even in the absence of the IPO list. CMS also revised their regulatory criteria to evaluate potential additions to the ASC covered-procedures list (CPL).

For CY 2027, CMS proposes to remove 637 HCPCS codes from the IPO list, include all 637 as separately payable services under the OPPS, and add 618 of those codes to the ASC CPL.

Comment

The Commission understands CMS's motivation to continue the phase-out of the IPO list but suggests that CMS should proceed cautiously. In the absence of the IPO list, clinicians generally will use their knowledge and judgment to provide patient care in the most appropriate setting. However, factors other than clinical knowledge and judgment, such as financial considerations, can affect these decisions. Therefore, the Commission urges CMS to monitor the effects of last year's removal of 285 codes from the IPO list on patient outcomes and provide information about the effects on patient safety and outcomes thus far (if any).

With respect to the proposed additions to the ASC CPL, we understand the motivation here as well and urge similar caution. The Commission generally supports giving providers more autonomy in decisions about the appropriate clinical setting for providing surgical procedures. We urge CMS to proceed carefully and strengthen monitoring of patient safety and quality outcomes to ensure that the migration of procedures to ASCs does not adversely affect beneficiaries.

Reduce OPPS payment rates for 340B-acquired drugs to ASP minus 33.4 percent

From January 1, 2018, through September 27, 2022, CMS set OPPS payments for separately payable non-pass-through drugs that hospitals acquired through the 340B Drug Purchasing Program at a rate of ASP − 22.5 percent, which was lower than the rate of ASP + 6 percent that preceded it. CMS cited work from the Commission's May 2015 report to the Congress to support the ASP − 22.5 percent payment rate.[11] However, the United States Supreme Court held in 2022 that because CMS had not conducted a survey of hospitals' acquisition costs, it could not vary the payment rates for outpatient prescription drugs by hospital group.[12]

In the 2026 OPPS/ASC proposed rule, CMS announced that the agency would conduct a survey of the acquisition cost of specified covered outpatient drugs (SCODs) and other drugs and biologics that are separately payable under the OPPS and that CMS has historically treated as SCODs.[13] In this proposed rule, CMS presents results from this survey, which captured hospitals' acquisition cost data for drugs purchased over a one-year period from July 1, 2024, through June 30, 2025. The survey collected acquisition cost data for drugs separately payable under the OPPS at the 11-digit National Drug Code (NDC) level for 1,843 NDCs, which corresponded to 519 drug HCPCS codes. CMS collected data from hospitals that had reported drug acquisition costs or had outpatient billing volume for HCPCS codes corresponding to NDCs included in the survey during the specified period.

Because the 340B Program allows some hospitals and other health care providers (covered entities) to purchase "covered outpatient drugs" at discounted prices from drug manufacturers, it was important for the survey to distinguish between drugs purchased under the 340B Program and those purchased outside the 340B program. The CMS survey therefore instructed hospitals to report four pieces of data for each NDC purchased during the one-year survey period:

- total units for drugs purchased outside the 340B Program,
- total acquisition cost for drugs purchased outside the 340B Program,
- total units for drugs purchased under the 340B Program, and
- total acquisition cost for drugs purchased under the 340B Program.

Using the collected data, CMS found that hospitals' acquisition costs for 340B-acquired drugs averaged 33.4 percent below average sales price, while hospitals' acquisition costs for non-340B drugs averaged 2.7 percent more than ASP.

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[11] Medicare Payment Advisory Commission. 2015. *Report to the Congress: Overview of the 340B Drug Pricing Program.* Washington, DC: MedPAC.
[12] 20-1114 American Hospital Assn. v. Becerra (06/15/2022)
[13] Section 1833(t)(14)(B) of the Social Security Act defines a SCOD as a drug that is a radiopharmaceutical or that had pass-through status under the OPPS before January 1, 2003.

Based on these findings, CMS proposes for CY 2027:

- To set the OPPS payment rate for 340B-acquired separately payable drugs at ASP – 33.4 percent.[14] This proposed policy would not apply to drugs with pass-through status, which statute requires to be paid at ASP + 6 percent. PPS-exempt cancer hospitals, children's hospitals, and rural sole-community hospitals would be exempted from this policy.
- To continue to set OPPS payments for drugs purchased outside the 340B Program at their current payment rate of ASP + 6 percent.
- To set the OPPS payment rate for 340B-acquired separately payable drugs furnished in nonexcepted off-campus PBDs at ASP – 33.4 percent.[15] (Drugs furnished in the nonexcepted off-campus PBDs are usually paid at the same rate as in physician offices, ASP + 6 percent.) CMS has proposed this payment adjustment to offset incentives for hospitals to shift the provision of 340B-acquired drugs to nonexcepted off-campus PBDs.

Because of OPPS budget-neutrality requirements, CMS states that the reduction in payment rates for 340B-acquired Part B drugs would be offset by an 8.44 percent increase in OPPS payment rates for nondrug services.

Comment

The Commission has expressed concern over the level of OPPS payments for 340B-acquired drugs, and in March 2016, we recommended an approach that would better target support to safety-net hospitals while sharing savings from the 340B Program with Medicare beneficiaries. While we appreciate CMS's attention to this issue, we note important differences between CMS's proposal for CY 2027 and our recommended approach.

In our March 2016 report, the Commission concluded that it was appropriate for beneficiaries to share in the savings from 340B-acquired drugs while permitting hospitals to continue to receive support via the 340B Program and better targeting resources toward safety-net providers.[16] Therefore, we recommended that payment rates for all separately payable drugs acquired under the 340B Program be reduced by 10 percent of the ASP, with the beneficiaries' portion of savings retained by beneficiaries and the program's portion of savings redirected to safety-net providers.[17]

Under CMS's proposal, because of OPPS budget-neutrality requirements, reducing payments for 340B-acquired drugs to ASP – 33.4 percent would result in an 8.44 percent

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[14] When a drug does not have ASP data available, CMS proposes to set the payment rate equal to wholesale acquisition cost (WAC) minus 33.4 percent. If both ASP and WAC data are not available, CMS proposes to set the payment rate equal to 59.69 percent of average wholesale price (AWP). If a drug does not have ASP, WAC, or AWP available, CMS would set the payment rate equal to the drug's mean unit cost, which CMS derives from claims data.

[15] Nonexcepted off-campus PBDs are those that were not excepted from site-neutral payments established under Section 603 of the Bipartisan Budget Act of 2015.

[16] Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

[17] This recommendation would result in a payment rate for 340B acquired drugs of ASP – 4 percent.

increase in payment rates for nondrug OPPS services. While beneficiaries receiving 340B-acquired drugs would experience lower cost sharing, beneficiary cost sharing for other OPPS services would increase because payment rates for those services would rise, contributing to greater differences in Medicare's payment rates for those services delivered in both the hospital and office settings.

A key aspect of our March 2016 recommendation was exempting the reduction in payment rates for 340B-acquired drugs from OPPS budget-neutrality requirements. Under the Commission's approach, beneficiaries would experience lower cost sharing for 340B-acquired drugs while cost sharing for nondrug services would remain unchanged. Medicare program savings from reduced payments for 340B-acquired drugs would be redirected to hospitals that provide the most uncompensated care. This approach would better target these funds to safety-net hospitals that disproportionately treat low-income patients.

In summary, the benefits of our March 2016 recommendation are therefore threefold:

- It allows beneficiaries to share in the savings from the 340B Program through lower cost sharing without increasing beneficiary cost sharing for nondrug services.
- It better targets resources to safety-net hospitals.
- Hospitals would still be paid for 340B-acquired drugs at rates that exceed acquisition cost.

If CMS believes that legislation would be needed to implement our recommendation (such as authority to direct program savings from reduced payments for 340B-acquired drugs to safety-net hospitals), we encourage the agency to consider seeking the statutory authority needed to support implementation.

Proposed expanded scope of separate payment for domestic procurement of PPE and essential medicines

The proposed rule states that CMS continues to believe that hospitals' procurement preferences directly influence upstream intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for domestically manufactured goods. In addition, because hospitals are the primary purchasers and users of essential medicines and medical PPE, CMS believes a voluntary payment adjustment that reflects the additional marginal costs that hospitals face in procuring these products may help to sustain their domestic production and availability and thereby help to safeguard personnel and beneficiary safety over the long term. Effective in 2023, CMS finalized a voluntary payment policy under the inpatient prospective payment systems (IPPS) and OPPS for the additional resource costs that hospitals face in procuring domestic National Institute for Occupational Safety and Health (NIOSH)–approved surgical N95 filtering facepiece respirators (FFRs). Effective in 2025, CMS finalized a separate payment under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a six-month buffer stock of one or more essential medicines.

For CY 2027, CMS proposes expanding the scope of the current separate IPPS payments for domestic procurement of personal protective equipment and essential medicines. Specifically, CMS proposes expanding the scope of PPE and domestic definition 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 Food and Drug Administration (FDA) requirements and conforming to ASTM standards (with an exception for nitrile gloves made in the U.S. with foreign rubber), and
- domestic gowns in compliance with FDA requirements and conforming to Association for the Advancement of Medical Instrumentation (AAMI) standards.

CMS also proposes expanding the scope of the essential medicines to include certain FDA-approved medicines that have existing U.S. finished dosage form (FDF) production and do not contain active pharmaceutical ingredients (API) from countries listed on the "foreign adversaries" list.

CMS also proposes several related policies and seeks feedback on potential approaches.

Regarding the current payment adjustment under the OPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 FFRs, CMS notes that because of the current statutory authority, CMS is not considering expanding and revising the current OPPS N95 policy. Instead, CMS is considering sunsetting the existing surgical N95 FFRs policy and simultaneously prospectively removing the associated OPPS budget-neutrality adjustment while CMS explores alternative outpatient approaches for the future.

Comment

We agree with CMS that ensuring a robust supply chain for PPE and sufficient inventory of essential medicines is vitally important for the nation's public health and security. However, we oppose the proposed expansions of separate IPPS payments because Medicare payment policy is neither a sufficient, nor the best suited, mechanism to support adequate supplies of PPE or essential medicines for all patients (whether or not they are covered by Medicare). Ensuring that hospitals have a robust domestic supply of PPE and sufficient inventory of essential medicines for all their patients likely involves solutions beyond the Medicare program, such as direct purchases and stockpiling by the federal government.

As we noted in our prior comments when CMS initially proposed separate payments for domestically produced N95 masks and a buffer stock of essential medicines,[18] adding new

[18] Medicare Payment Advisory Commission. 2022. Comment letter on CMS's proposed rule for the hospital outpatient and ambulatory surgical center payment systems, September 12. https://www.medpac.gov/wp-content/uploads/2022/09/09122022_OPPS_FY2023_MedPAC_COMMENT_v2_SEC.pdf.

Medicare hospital payments for specific national public health goals creates a precedent, opening opportunities to establish separate cost-based payments for other supplies and other providers. Indeed, this proposal is one such expansion. In addition to moving further away from prospectively set payments, the proposed policy also would increase administrative costs for hospitals.

Interim OPPS payment system for software as a medical service (SaMS) in CY 2027

In this proposed rule, CMS states that it will work to gather additional data to better understand and more fully address the inherent payment challenges for SaMS items. While CMS gathers these data and examines payment approaches for SaMS items, the agency proposes an interim OPPS payment policy for CY 2027.

Under the OPPS, SaMS items currently fall into one of these categories:

- Separately payable in a clinical APC.
    - Separately payable means that each time that an OPPS hospital bills Medicare for the service, Medicare reimburses the hospital at a specified OPPS payment rate.
    - A clinical APC is a collection of HCPCS codes that represent services that are similar based on cost and clinical attributes. All HCPCS codes in the same clinical APC have the same OPPS payment rate. The clinical APCs in which the SaMS items reside include HCPCS codes for services that do not involve any SaMS items.
    - Twenty-one HCPCS codes that represent SaMS items currently are in this category.
- Separately payable in a new-technology APC.
    - New-technology APCs are for new services for which CMS does not yet have enough cost information to assign them to a clinical APC.
    - New-technology APCs are strictly dollar cost bands that reflect what CMS believes is a reasonable cost for the service.
    - Eleven HCPCS codes that represent SaMS items are currently in this category.
- Conditionally packaged items that are in clinical APCs.
    - Conditionally packaged means that the item is packaged into the payment for a separately payable service when the item is provided with that service.
    - The item is paid separately if there is no separately payable service provided with the item.
    - Five HCPCS codes that represent SaMS items are currently in this category.

Medicare Payment Advisory Commission. 2023. Comment letter on CMS's proposed rule for the hospital outpatient and ambulatory surgical center payment systems, September 11. https://www.medpac.gov/wp-content/uploads/2023/09/09112023_CY2024_OPPS_MedPAC_comment_v2_SEC.pdf.

- Never separately payable.
    - Never separately payable means CMS has determined that the item is always packaged into the payment rate of a separately payable service or that the item is not covered under the OPPS.
    - Ten HCPCS codes that represent SaMS items are in this category.

For CY 2027, CMS proposes the following interim OPPS payment policy for SaMS items while examining a range of approaches to payment for these items:

- Reassign the 21 HCPCS codes that are separately payable and in clinical APCs to new-technology APCs that have payment rates that closely align with their CY 2026 OPPS payment rates.
- Keep the 11 HCPCS codes in new-technology APCs in the same new-technology APCs.
- Keep the 5 HCPCS codes that are conditionally packaged in the same clinical APCs and maintain their conditionally packaged status.
- Maintain the same payment status for the 10 HCPCS codes that are either always packaged or are not covered under the OPPS.

CMS states that this proposed approach of assigning all of the separately payable SaMS items to the same APC series (that is, new-technology APCs) "would allow CMS to take the first step towards standardization and applying a consistent payment methodology across these services as we consider more comprehensive long-term approaches, including those that may better align payment with clinical outcomes."

CMS also addresses OPPS payment for stand-alone algorithmic analyses performed on laboratory tests that are separate from examinations of human material by a laboratory certified by the Clinical Laboratory Improvement Amendments (CLIA). These algorithmic analyses are currently treated as clinical diagnostic laboratory tests (CDLTs) and paid under the clinical laboratory fee schedule (CLFS). However, CMS does not view these analyses as CDLTs nor does CMS believe they should be paid under the CLFS because they do not require laboratory services and entities that are regulated by CLIA to perform them.

CMS views these stand-alone algorithmic analyses as SaMS items because, like other SaMS items covered under the OPPS, they perform algorithmic analyses on previously generated data. Consequently, for payment purposes, these two types of SaMS items should be treated the same. For CY 2027, CMS proposes to assign the 10 HCPCS codes that describe the SaMS analyses performed on laboratory tests to new-technology APCs.

Comment

We support CMS's proposed interim OPPS payment policy for SaMS items in CY 2027. CMS typically assigns new services for which CMS does not yet have the data necessary for assigning an appropriate clinical APC and OPPS payment rate to new-technology APCs. Isolating payments for the separately payable SaMS items from payments for other non-SaMS services in clinical APCs should help CMS more clearly identify the differences in costs incurred by hospitals when they use SaMS items from the costs they incur when they provide other services.

In this proposed rule, CMS mentions aligning payment for SaMS items with clinical outcomes. This statement is consistent with the Commission's stance on Medicare payment for new technologies. In the Commission's June 2024 report to the Congress, we stated, "To ensure that the [SaMS items] improve health outcomes, Medicare could require that manufacturers of the [SaMS items] provide evidence that their products result in a clinically meaningful improvement compared with the current standard of care for Medicare beneficiaries."[19] In developing an approach to paying for SaMS items, CMS should consider the evidence of products and their effects on clinical outcomes.

Proposed repeal of the alternative pathway for OPPS pass-through payments

As in the FY 2027 IPPS proposed rule, CMS proposes to repeal the alternative pathway for OPPS device pass-through payment eligibility and require all applicants for OPPS device pass-through payments to demonstrate that they meet the same eligibility requirements to receive pass-through payments, including the substantial clinical improvement requirement.

Since the FY 2027 OPPS proposed rule was published, CMS has released the FY 2027 IPPS final rule. In that rule, CMS finalized the repeal of the alternative pathway for OPPS device pass-through eligibility for applications received after Oct 1, 2026, with a limited exception through CY 2029 for devices that received the FDA's Breakthrough Devices Program designation and FDA marketing authorization by September 30, 2026.[20]

Comment

We applaud the agency for finalizing this proposal as part of the FY 2027 IPPS final rule. The Commission supports CMS's decision to repeal the alternative pathway for OPPS pass-through payments and thus require that all technologies receiving these additional payments meet the substantial clinical improvement requirement, as we noted in our comment letter on the IPPS proposed rule for FY 2027 and consistent with our comment letter on the OPPS proposed rule for CY 2020 when the alternative pathway was first introduced.[21]

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[19] Medicare Payment Advisory Commission. 2024. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

[20] Centers for Medicare and Medicaid Services, Department of Health and Human Services. 2026. Medicare program; hospital inpatient prospective payment systems for acute care hospitals (IPPS) and the long-term care hospital prospective payment system and policy changes and fiscal year (FY) 2027 rates; requirements for quality programs; other policy changes; and adoption of updated versions of certain health information technology standards. *Federal Register* 91, no. 148 (August 4): 49570-50461.

[21] Medicare Payment Advisory Commission. 2026. Comment letter on CMS's proposed rule for the hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system, June 9. https://www.medpac.gov/wp-content/uploads/2026/06/06092026_MedPAC_IPPS_LTCH_PPS_FY2027_comment_v2_SEC.pdf. Medicare Payment Advisory Commission. 2019. Comment letter on CMS's proposed rule for the hospital outpatient and ambulatory surgical center payment systems, September 13. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/09132019_opps_asc_2020_medpac_comment_v2_sec.pdf.

The Commission recognizes the need to maintain financial rewards for innovation while preserving the incentives within OPPS for efficiency. Including the substantial clinical improvement requirement ensures that additional Medicare payments are used to support Medicare beneficiaries' access to innovations that are demonstrated to improve outcomes compared to the currently available treatment.

Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship. If you have any questions regarding our comments, please do not hesitate to contact Paul B. Masi, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

Amol S. Navathe, M.D., Ph.D.
Chair