Outpatient Prospective Payment System, Physician Fee Schedule & 340B Remedy CY 2024 Proposed Rules

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What are OPPS and PFS?

- The OPPS rule sets the reimbursement rate for Medicare **Outpatient** payments, including Ambulatory Surgical Center (ASC) procedures.
- The PFS rule sets the reimbursement rate for Medicare **Physician** payments.
- Rules become effective January 1, 2024.

OPPS Key Highlights

Price Transparency

- Use of a standard template for the machine-readable file.
- Strengthen enforcement actions.

New Outpatient Benefit

- New Intensive Outpatient Program (IOP) for behavioral health.

Changes to Inpatient Only List (IPO) and ASC Covered List

- Nine services added to IPO list.
- 26 dental procedures added to ASC covered list.

340B Remedy

- Pay Average Sales Price (ASP) plus 6% for 340B-acquired drugs.
- Make hospitals “whole” by providing lump sum.
- Budget neutral adjustment; phased cuts to OPPS conversion factor starting in CY 2025.

Payment for Medicine Buffer Stock

- Future potential payment for maintaining a 3-month medicine buffer stock.

PFS Key Highlights

Overall Payment Changes

- Decrease the conversion factor by 3.34%.
- Implement add-on code (G2211) for chronic care management in CY 2024.
- Maintain current split billing rules.
- Maintain the in-home additional payment for COVID-19 vaccine administration (HCPCS code M0201) *and* extend the payment to pneumococcal, influenza and hepatitis B vaccines.

Access to Behavioral Health

- Allow Marriage Therapists, Family Therapists (MFTs) and Mental Health Counselors (MHCs) to enroll in Medicare.
- Increase the work values for the psychotherapy codes by 19.1%.
- Allow Health Behavior Assessment and Intervention services to be billed by clinical social workers, MFTs and MHCs.

New Payments for Care Navigation and SDOH Screening

Separate payments for:

- Community Health Integration Services.
- Social Determinants of Health (SDOH) Risk Assessment.
- Principal Illness Navigation (PIN) Services.
- Caregiver Training Services.

Telehealth Coverage

- Extend current payment of telehealth services provided in the patient's home (POS 10) until end of CY 2024.
- Change the structure of telehealth lists.
- Extend additional flexibilities until end of CY 2024.

Outpatient Prospective Payment System (OPPS) Proposed Rule

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OPPS Overview

- Payment Update
- Hospital Price Transparency
- Quality Measures
- Behavioral Health
- 340B Program
- Cancer Hospital Payment Adjustment
- Biosimilar Biological Products
- Dental Care
- Inpatient Only List
- Outpatient Rehabilitation Services
- RFI: Drug Supply Chain Shortages

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Outpatient and ASC Payments

Contributing Factor	Outpatient	ASC
Net Update	+ **2.8%** ($6 billion compared to CY 2023)	**+2.8%** ($170 million compared to CY 2023)

CMS will resume using the most updated cost reports and claims data available for rate-setting.

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Hospital Price Transparency

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Hospital Price Transparency

Machine Readable Files (MRF)

Standardization:

- Require hospitals to display standardized data using a template provided by CMS.

Accessibility:

- Require hospitals to place a footer at the bottom of the hospital's homepage that links to the webpage that includes the MRF.
- Hospitals must ensure that a .txt file is included in the root folder of the publicly available website chosen by the hospital for posting the MRF.

Enforcement:

- Require hospitals to attest to the completeness and accuracy of their MRF.
- Require hospitals to submit an acknowledgment of any of the agency's warning notices for hospital noncompliance with the regulations.
- Enable CMS to publicize their assessment of hospital noncompliance, any actions taken against the hospital, and the outcome of such action, while also allowing CMS to publish notifications sent to hospital leadership.

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Hospital Price Transparency

Requests for Information

Machine Readable File (MRF):

CMS seeks comment on:

- How to improve access to MRFs.
- Benefits or challenges CMS should alternatively consider.
- Challenges which may become apparent by using automated tools to find MRFs.
- If the proposed footer requirements are duplicative of or contradictory to other regulations.

Legislative Alignment

CMS is seeking comment on additional considerations for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives, specifically, *Transparency in Coverage* (TIC) and *No Surprises Act* (NSA).

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Outpatient and ASC Quality Reporting Programs

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Quality Reporting Programs

The Outpatient Quality Reporting (OQR) Program is a pay-for-performance program in both the ASC and hospital outpatient departments. Hospitals must meet quality requirements or receive a reduction of 2.0 percentage points in their annual payment updates.

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OQR Proposals

- **Modify three measures:**
  - COVID-19 Vaccination Coverage Among Healthcare Personnel (aligns with updated CDC measure specs).
  - Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (standardize data collection and reduce administrative burden).
  - Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (align with updated clinical guidelines).

- **Adopt three measures:**
  - The Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty measure
  - The Hospital Outpatient /ASC Facility Volume Data on Selected Outpatient Surgical Procedures measures
  - To adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults electronic clinical quality measure (eCQM).

- **Remove one measure:**
  - Left Without Being Seen (LWBS) Measure.

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OQR Proposals

- **Amend regulatory language to:**
  - Replace references to “QualityNet” with “CMS-Designated Information System” or “CMS Website.”
  - To make other confirming technical edits to accommodate recent and future systems requirements and mitigate confusion for program participants.

- **RFI on potential future topics:**
  - Quality measurement gaps in the HOPD setting.
  - Changes in outpatient care (such as shifts in volume, technology, case complexity).
  - Concerns around workforce and patient safety.
  - Digital transformation.

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Behavioral Health

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Behavioral Health

Establishment of the Intensive Outpatient Program (IOP)

- **Scope of Benefits:**
  - Based on the per diem costs of items and services that are covered by other programs.

- **Physician Certification:**
  - Requires Physician certification of need and re-determination no less than every other month.

- **Opioid Treatment Settings:**
  - Medicare would cover IOP services provided by OTPs if each service is medically reasonable and necessary, and not duplicative of any service paid for under any bundled payments billed for an episode of care in a given week.

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Behavioral Health

Payment Rates:

CMS is proposing to establish two IOP Ambulatory Payment Classifications (APCs) for each provider type:

- One for days with three services per day.
- One for days with four or more services per day.

The APCs covered and the data on which payment rates are calculated differ on provider setting:

- **Hospital Outpatient Departments & Community Mental Health Centers:** for three services per day and four or more services per day based on cost per day using a broader set of OPPS data.
- **Rural Health Clinics:** for three IOP services per day based on the hospital outpatient department rate.

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340B Drug Program

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340B Drug Program: Proposed Remedy

CMS will make a one-time lump sum payment to providers affected by the payment cuts that occurred between CYs 2018 and 2022.

- Proposes to include within the lump sum the **additional amount hospitals would have received** in beneficiary cost sharing.
- **Excludes providers** that enrolled in Medicare **after Jan. 1, 2018**, from the prospective rate reduction.

Would be conducted in a budget-neutral manner:

- CMS would **reduce the OPPS conversion factor by 0.5% every year**, beginning in CY 2025.
- This would end in approximately **16 years** or when the previous budget neutrality adjustment of $7.8 billion is reached.

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Payment Adjustment: Cancer Hospitals

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Cancer Hospital Payments

The 21st Century Cures Act requires that cancer hospitals' payment-to-cost ratios be reduced by 1.0 percentage point every CY, until the cancer hospital's PCR after the additional payments equals the average for other OPPS hospitals.

- During the COVID-19 PHE, the Agency maintained the target 2021 PCR of 0.89.
- Paid at cost report settlement.

For the full proposal on Cancer Hospital Payments, click here.

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Cancer Hospital Payments

CMS proposes to resume decreasing the target PCF by 0.01 per calendar year.

- For CY 2024, CMS would use a target PCR of 0.88 to determine the CY 2024 cancer hospital payment adjustment for additional payments.

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Biosimilar Biological Products

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Biosimilar Biological Products

CMS proposes to except biosimilars from the OPPS threshold packaging policy when their reference biologicals are separately paid.

- If a reference product's per-day cost falls below the threshold packaging policy, all biosimilars related to the reference product would be similarly packaged.

"Medicare Part B spending for biologicals and biosimilars has **significantly outpaced** spending for non-biologic drugs."

- *CMS, CY '24 NPRM*

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Dental Care

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Dental Care

Ambulatory Payment Classification

- To assign 229 codes describing dental services to various clinical APCs to align with Medicare payment provisions regarding dental services in the CY 2023 PFS final rule.

ASC Covered Procedures List

- The addition of 26 dental surgical procedures to the ASC covered procedures list (CPL).

Packaged Payments

- To package payments for dental services when they are performed with another covered dental or medical service to promote clinical resource efficiencies.

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Inpatient Only List (IPO)

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Inpatient Only List

CMS proposes to reassign one code and add nine newly created codes the IPO list:

- **CPT X114T:** *Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed.*
- **CPT 2X002:** *Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments.*
- **CPT 2X003:** *Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments.*
- **CPT 2X004:** *Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed.*
- **CPT 619X1:** *Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s).*
- **CPT 7X000:** *Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic.*
- **CPT 7X001:** *Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report.*
- **CPT 7X002:** *placement, manipulation of transducer, and image acquisition only.*
- **CPT 7X003:** *interpretation and report only.*
- **CPT 0646T:** *Transcatheter tricuspid valve implantation (ttvi)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed.*

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Inpatient Only List

Request for Information

CMS is soliciting comments regarding whether these four services are appropriate to be removed from the IPO list:

- **CPT 43775**: *Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy).*
- **CPT 43644**: *Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less).*
- **CPT 43645**: *Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption.*
- **CPT 44204**: *Laparoscopy, surgical; colectomy, partial, with anastomosis.*

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Outpatient Rehabilitation Services

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Outpatient Rehabilitation Services

Supervision

CMS proposes two changes to the supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), and Pulmonary Rehabilitation (PR) services:

- Include nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) as supervisory practitioners.
- Extend the policy allowing the direct supervision of these services to be conducted through audio-visual technology through December 31, 2024.
    - This will also extend to the non-physician practitioners who would be eligible beginning in 2024.

Site-Neutral Payment

CMS proposes to pay for intensive cardiac rehabilitation services furnished by an off-campus, non-excepted provider-based department of a hospital at 100% of the OPPS rate, which is the amount paid for these services under the PFS.

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Request for Information: Reimbursement for Essential Drug Buffer-Stocks

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RFI: Essential Drug Buffer-Stocks

Background

In 2022, HHS published a supply chain resilience assessment identifying 86 medicines which are:

- Critical for minimum patient care in acute settings, or
- Important for acute care, with no comparable alternative available.

Proposal

Separate payment under the Inpatient Prospective Payment System (IPPS) to cover the costs of establishing and maintaining access to a 3-month buffer stock of one or more essential medicines.

Future Considerations

- The current RFI only considers the separate payment through the IPPS rule, CMS indicates it may apply this program to the OPPS rule in the future.
- CMS is also considering extending this program to include critical medical devices.

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RFI: Essential Drug Buffer-Stocks

Requested Feedback

CMS specifically requests comment on:

- The potential efficacy of the program to boost medicine supply chain resilience.
- The frequency with which the essential medicines list should be updated.
- The overhead costs incurred from maintaining medicine buffer stocks which should be covered by the proposed separate payment.
- The types of medical devices considered critical and how hospitals currently maintain buffer stocks for these devices.

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Physician Fee Schedule (PFS) Proposed Rule

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PFS Overview

- Conversion Factor Update
- Services Addressing Health–Related Social Needs
- Quality Payment Programs
- Medicare Shared Savings Program
- Remote Monitoring
- Telehealth
- Behavioral Health
- Evaluation and Management (E/M)
- Appropriate Use Criteria (AUC)

Conversion Factor Update

- **CMS proposes to decrease the conversion factor for CY 2024 by 3.34% (from $33.89 to $32.75)**
  - Congress negotiated only a partial increase to the Medicare conversion factor of 2.5% for 2023 and a 1.25% adjustment for 2024.
  - Budget neutrality results in an additional 2.17% reduction for 2024.

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Congress Seeks Physician Payment Reform

"MACRA was intended to support a health care system with greater value to both patients and providers, but it has become evident that further reforms are necessary…We seek your feedback on actions Congress could take to stabilize the Medicare payment system, without dramatic increases in Medicare spending."

Congressional Letter to Speaker McCarthy and Leader Jefferies.
To view letter, click here.

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Impact by Specialty

Payment Impact		
Positive Impact	**+3%**	Family Practice
	+3%	Endocrinology
	+2%	Clinical Psychologist
Adverse Impact	**-2%**	Anesthesiologist
	-3%	Vascular Surgery
	-4%	Interventional Radiology

- See table 104 for more details.
- Percentages reflect overall impact on specific specialties, not the impact on individual providers

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Services Addressing Health-Related Social Needs

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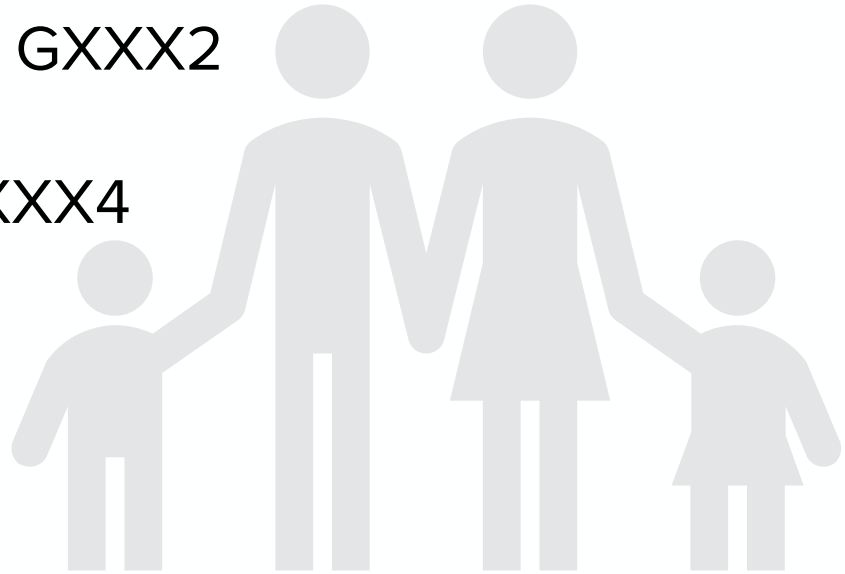
Services Addressing Health-Related Social Needs

CMS proposes new ”G-codes” for services aimed at addressing health-related social needs.

- SDOH Risk Assessment – GXXX5
- Community Health Integration (CHI) – GXXX1 & GXXX2
  30 and 60-minute intervals
- Principal Illness navigation (PIN) – GXXX3 & GXXX4
  30 and 60-minute intervals



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New HRSN G-Codes

SDOH – Gxxx5

- *Tools include CMS Accountable Health Communities tool, PRAPARE tool, instruments identified for MA special Needs Population Risk Assessment.*
- *ID'ed needs must be noted in the medical record but not required to use z-codes*
- *Must be furnished by billing practitioner on same day as E/M visit.*

CHI – Gxxx1/2

- *CHI Initiating visit – E/M Visit in which the billing practitioner Id's presence of SDOH needs that limit the ability to diagnose or treat the problems addressed in the visit (separate billing).*
- *CHI services performed by certified or trained auxiliary personnel under general supervision of billing practitioner*
- *Gxxx1 = 60 mins. Per calendar month & Gxxx2 = each additional 30 mins*

PIN – Gxxx3/4

- *Patients diagnosed with serious high-risk disease*
- *PIN Initiating Visits – E/M visit in which billing practitioner will identify the medical necessities for PIN services, establishes appropriate treatment plan and specifies how PIN services would help accomplish that plan*
- *Gxxx3 = 60 mins. Per calendar month & Gxxx4 = each additional 30 mins*

Quality Payment Program

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Overview

The Quality Payment Program (QPP) seeks to reward high-value care through the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs).

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QPP: Snapshot

- **Quality Measures**: Proposes the addition of 14 measures, removal of 12 measures, and substantive changes to 59 existing measures. If finalized, the quality measure inventory would contain 200 quality measures.
- **Data Completeness**: Maintain current data completeness threshold at 75 percent for 2024 and 2025. Proposes to establish data completeness thresholds for 2026 (75 percent) and 2027 (80 percent).
- **CAHPS**: Proposes to require vendor to administer the Spanish survey translation to Spanish-preferring patients.

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QPP:
Merit-based Incentive Payment System & MIPS Value Pathways (MVP)

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Overview

The Merit-based Incentive Payment System (MIPS) is one of three tracks housed within the QPP.

Its goal is to migrate Medicare Part B providers into a performance-based payment system.

Reminder! Performance Year 2022 was the last year participants were able to earn the exceptional performance bonus. Final payments will be made in 2024 based on PY2022 data.

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MIPS

CMS proposes to use the mean of final scores from the 2017-2019 MIPS performance periods (2019-2021 MIPS payment years) to set the MIPS performance threshold.

- **This would increase the performance threshold to 82 points,** rounded, for the 2024 MIPS performance period/2026 MIPS payment year.

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QPP:
Alternative Payment Model (APM) Performance Pathways (APP)

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Advanced Alternative Payment Models (APMs)

- **Remove the numerical 75% threshold for the use of CEHRT** and specifying that the APM must require the use of CEHRT.
- Make Qualifying APM Participants (QP) determinations at the individual eligible clinician level only, instead of the APM entity level.
- Freeze the QP/partial QP threshold percentages for both the payment amount and patient count methods for PY 2023/2025.
- Affirm that QP threshold percentages will increase consistent with statute consistent with PY 2024/2026.
- Codify the transition to differential PFS payment updates for QPs versus non-QPs beginning in payment year 2026.

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Medicare Shared Savings Program

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Overview

The Medicare Shared Savings Program (MSSP) is a voluntary Alternative Payment Model (APM) that gives providers the opportunity to create an Accountable Care Organization (ACO) and earn bonuses through shared savings.

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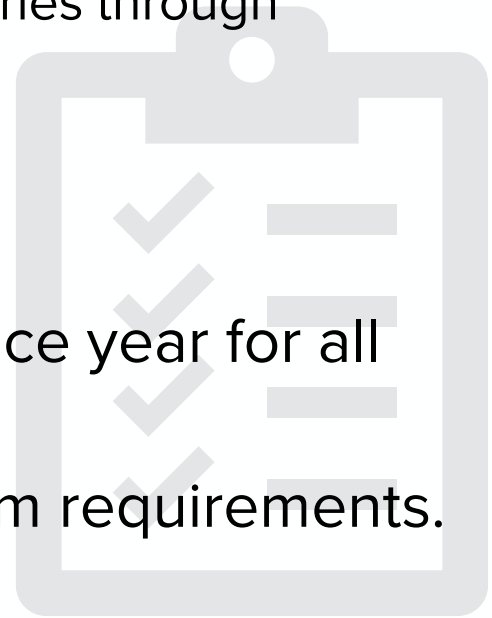
MSSP Proposed Changes

- Update the quality performance standard and reporting requirements under APM Performance Pathway (APP) by:
  - ACOs would be allowed to report on only their Medicare beneficiaries through Medicare CQMs.
- Expand window for beneficiary assignment.
- Update benchmarking methodology.
- Apply same HCC risk adjustment model used in performance year for all benchmark years.
- Make refinements to Advance Investment Payment program requirements.



Click here for the full proposal of changes to the Shared Savings program.

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MSSP: Quality Performance Standard

- Add a third step to the step-wise beneficiary assignment methodology that better reflects the role nurse practitioners, physician assistants and clinical nurse specialists plan in primary care delivery.
- Establish a new “Medicare CQMs” collection type beginning with PY 2024.
- Provide ACOs with a list of beneficiaries who are eligible for Medicare CQMs within the ACO.
  - The ACO must first request the data explicitly for purposes of population-based activities relating to improving health or reducing health care costs.

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ACO Risk Adjustment

Modify the calculation of the regional component of the blended benchmark update factor, for agreement periods beginning in 2024.

- This cap on regional risk score growth would be applied independent of the cap on an ACO's own prospective HCC risk score growth.
- The policy would result in an increase in the regional component of the update factor for ACOs located in regions with regional risk score growth above the cap.

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MSSP: Advance Investment Payments (AIPs)

- Allow ACOs to advance to two-sided risk within the BASIC track's glide path, beginning in PY 3 of the agreement period in which they receive AIPs.
- Modify the recoupment policy to recoup AIPs from shared savings of an ACO who renews early (instead of recouping payments directly from the ACO).

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MSSP: RFI

CMS seeks comments on:

- Future development of a higher risk track;
- How an ACO's prior savings are accounted for and potential modifications to positive regional adjustments;
- Refinements to the recently finalized Accountable Care Prospective Trend (ACPT) and the three-way blended benchmark factor
- Approaches to promote collaboration between ACOs and community-based organizations.

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Remote Monitoring

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Remote Monitoring

Remote Monitoring and Navigation

Include remote physiologic monitoring, remote therapeutic monitoring, Community Health Integration and Principal Illness Navigation services in the general care management code.

Beneficiary Consent

Before Chronic Care Management may begin, informed consent under general supervision of the billing practitioner must be obtained.

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Telehealth

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Telehealth: CAA, 2023 Alignment

Proposes to align policies with telehealth extensions in CAA by:

- Waiving geographic and location requirements.
- Delaying in-person requirement for tele-behavioral health services.
- Continuing FQHC and RHC reimbursement for telehealth services.
- Continuing coverage of certain audio-only telehealth services through 2024.
- Expanding the list of telehealth practitioners to include:
  - Marriage and Family Therapists
  - Mental Health Counselors
  - Occupational Therapists
  - Physical Therapists
  - Speech-Language Pathologists
  - Audiologists

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Telehealth: Service List

- Replace categories 1, 2 and 3 with new categories: “permanent” and “provisional.”
- Refine the process to evaluate eligibility for the new categories.
- Any services added to the “temporary Category 2”, or Category 3 lists would be moved to the provisional category.
- No stated timeframe for removing provisional codes from the telehealth services list.

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Telehealth: Other Changes

Reminder! Beginning in 2024, use POS-02 (telehealth provided other than in patient's home) or POS-10 (telehealth provided in patient's home).
- Discontinue use of 95 modifier + POS if service had been furnished in person.

- POS-02 to be paid at facility rate; POS-10 to be paid at non-facility rate.
- **Suspend frequency limitations** for subsequent inpatient visits, subsequent nursing facility visits, and critical care consultations
- Continue to **permit teaching physician to have virtual presence** when service furnished via telehealth (three-way telehealth visits)
- **Permanently eliminate in-person requirement for injection training** for Diabetes Self-Management Training (DSMT); expands list of eligible DSMT distant site providers
- Continue to **permit Opioid Treatment Programs to furnish periodic assessments via audio-only telecommunications** through end of 2024.

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Behavioral Health Services

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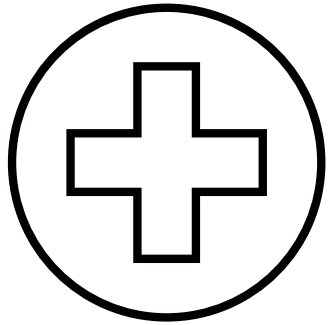
Behavioral Health Services

Coverage for Marriage and Family Therapists (MFT) and Mental Health Counselors (MHC):

- Provide Medicare Part B coverage for services provided by MHCs (including substance use disorders) and MFTs.
- Allow payment at 75% of the psychologist rate.
- Can enroll in the program after the final PFS rule is released.
- Added to the list of RHC and FQHC practitioners.



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Behavioral Health Services

- **Reimbursement for Psychotherapy for Crisis Services**:
  - Two new G-codes for psychotherapy for crisis services furnished in any non-facility POS other than physician office setting; payment at 150% of the rate for physician office setting.

- **Health and Behavior Assessment and Intervention Billing Expansion**:
  - Permit clinical social workers, MFTs and MHCs to bill CPT codes.

- **Adjustments to Payment for Timed Behavioral Health Services:**
  - Proposes to improve the accuracy of the valuation for timed psychotherapy services with an add on code for complexity.

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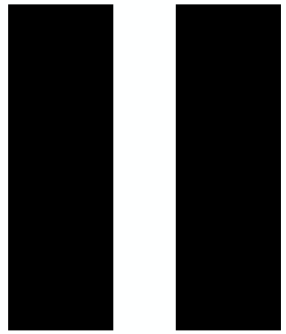
Split (or Shared) E/M Visits

CMS proposes to delay the implementation of its definition of the "substantive portion" through at least December 31st, 2024.

- For 2024, maintain the current definition of substantive portion that allows for use of either one of the three key components (history, exam, or MDM) or more than half of the total time spent to determine who bills the visit.



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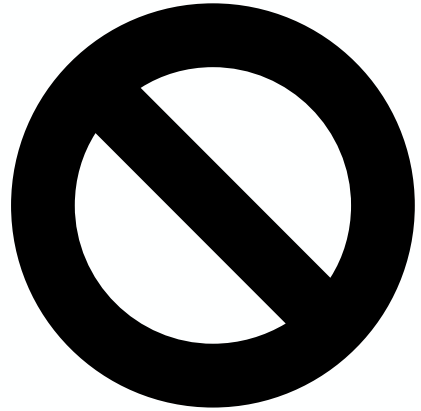
Appropriate Use Criteria (AUC) Program

- Mandated by Protecting Access to Medicare Act (PAMA) of 2014.
  - Practitioner ordering advanced diagnostic imaging service must consult clinical decision support mechanisms.

- **CMS proposes to pause implementation and rescind current AUC program regulations.**



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Questions?

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