Hot Topics in Reimbursement 2024

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- Final Fee Schedule Rule for 2024
- QPP for 2024
- Final Hospital Outpatient Rule 2024
- Final Rule for 340B Repayment
- CPT 2024 Oncology

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Physician Fee Schedule Rule for 2024

Medicare Physician Payment Basics

Payments are based on RVUs for each code (WRVUs+PERVUs+MalRVUs)

RVUs are multiplied times GPCIs for your geographical location (W*WGPCI+PE*PEGPCI+Mal*MalGPCI)

The Medicare conversion factor determines the overall level of Medicare payments (W*WGPCI+PE*PEGPCI+Mal*MalGPCI) times CF = $Your Total Allowable for your area, which will be inflated, deflated, or neutralized by your QPP performance

W = Work; PE = Practice Expense; MAL = Expense of Malpractice; RVUs = relative value units

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Sequestration

- Medicare 2% across the board started on April 1, 2013
- The 2% comes out of the Medicare portion (80%)
  - Drugs are paid at 104.304% ASP
  - All patient payments excluded
- Currently sequestration is back to -2% from 7/1/2022

Conversion Factor 2024—FINAL(?)

TABLE 116: Calculation of the CY 2024 PFS Conversion Factor

CY 2023 Conversion Factor		33.8872
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		33.0607
CY 2024 RVU Budget Neutrality Adjustment	-2.20 percent (0.9780)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**32.7375**

A Brief History of the Conversion Factor

Calendar Year	Conversion Factor	Actual Update %
2017	$35.8887	0.24
2018	$35.9996	0.31
2019	$36.0392	0.11
2020	$36.0896	0.14
2021	$34.8931	-3.32
2022	$34.6062	-0.82
2023	$33.8872	-2.08
2024	$32.7375	-3.39

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Specialty Impact

Be aware that this does not factor in the change in CF and the GPCI floor:

- Cardiology 1%
- Dermatology -1%
- Gastro 0%
- Hem-Onc +2%
- Neuro +1%
- Rad Onc -2%

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An Additional Wrinkle: GPCI Floor

- Section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs for the purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2024.
- Congress recently extended the 1.0 work GPCI floor only through December 31, 2023, in division CC, section 101 of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260, enacted December 27, 2020).
- Therefore, the CY 2024 work GPCIs and summarized GAFs do not reflect the 1.00 work floor.
- This has been reinstated many times—but not in the Final Rule

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Definitions of Telehealth Categories 2023

- Category 1: Services are similar to existing services, such as professional consultations, office visits, and office psychiatry services, which already are approved for telehealth delivery. In deciding whether to approve the new codes, similarities between the requested and existing telehealth services are examined, including interactions among the beneficiary and the practitioner at the distant site and, if necessary, the tele-presenter, and similarities in the technologies used to deliver the service.
- Category 2: Services not similar to Medicare-approved telehealth services. Reviews of these requests include an assessment of whether the service is accurately described by the corresponding CPT code when delivered via telehealth, and whether the use of technology to deliver the service produces a demonstrated clinical benefit to the patient.
- Category 3 — new in 2020: Services that are likely to provide clinical benefit via telehealth; yet lack sufficient clinical evidence to evaluate making them permanent under Category 1 or Category 2.These are to remain in effect until the end of the calendar year in which the COVID-19 public health crisis ends (not when the PHE ends).

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Changes to Telehealth Categories

- CMS will move all codes currently in Categories 1 and 2 to the "permanent" list.
- Any codes added on a "temporary Category 2" or a Category 3 basis would be placed on the "provisional" list. There is currently no specified timeframe to remove "provisional" codes from the list.
- CMS indicates in the proposal that it would not assign provisional status when it is improbable that the code would ever achieve permanent status, and that the agency would revisit provisional status through the regular annual rulemaking processes.

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Telehealth POS Codes

- In CY 2023, CMS stated that following the end of the calendar year in which the PHE ends, physicians and practitioners would no longer bill claims with the 95 modifier along with the POS code that would have applied had the service been furnished in person. Instead, in CY 2023, CMS finalized two POS codes for telehealth services:
  - *POS 02, redefined as Telehealth Provided Other than in Patient's Home (Descriptor: The location where health services and health related services are provided or received, through telecommunication technology. Patient is not located in their home when receiving health services or health related services through telecommunication technology.)*
  - *POS 10, Telehealth Provided in Patient's Home (Descriptor: The location where health services and health-related services are provided or received through telecommunication technology. Patient is located in their home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health-related services through telecommunication technology.)*
- CMS outlines that beginning in CY 2024, claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) would continue to be paid at the lower PFS facility rate. Claims billed with POS 10 (Telehealth Provided in Patient's Home) would be paid at the higher PFS non-facility rate.

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Virtual Supervision

- This change was temporary because CMS was concerned widespread direct supervision through virtual presence may not be safe for some clinical situations. CMS rejected requests to make virtual direct supervision a permanent feature in Medicare.
  - Virtual direct supervision will continue throughout 2024.
  - Physicians will NOT have to register their home addresses in PECOS.
- CMS is considering making this permanent for services that are ALWAYS 'incident to'.

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Other Telehealth Flexibilities 2024

- The following policies remain in place through January 1, 2025:
  - Delaying the in-person requirement for mental health telehealth, including services furnished at rural health clinics (RHCs) and federally qualified health centers (FQHCs) (i.e., the requirement for an in-person visit with the physician or practitioner within six months prior to the initial mental health telehealth service)
  - Expanding originating sites to include where the beneficiary is located at the time of the telehealth services, including an individual's home.
  - Expanding the list of eligible telehealth practitioners to include occupational therapists, speech language pathologists and qualified audiologists (the list is the same as finalized in the CY 2023 final rule)
  - Coverage of **audio-only services** for services on the Medicare Telehealth Service List. This includes 98966-98968.
- The CAA, 2023, also added MFTs and MHCs to the list of eligible practitioners. These professionals would be added permanently beginning January 1, 2024. Btw, they can also enroll in Medicare!

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Other Telehealth Flexibilities 2024

- CMS will continue other flexibilities on a temporary basis. The agency would continue to evaluate these through CY 2024 and reassess in subsequent rulemaking. These flexibilities include the following:
    - Removal of frequency limitations. CMS proposes to continue its suspension of frequency limitations for certain subsequent inpatient visits, subsequent NF visits and critical care consultations furnished via Medicare telehealth.
    - Supervision of residents in teaching settings. CMS proposes to continue to allow the teaching physician to have a virtual presence in all teaching settings only in clinical instances when the service is furnished virtually (for example, a three-way telehealth visit, with all parties in separate locations). This would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought through audio/video real time communications technology for all residency training locations.

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RPM/RTM

- CMS gave clarifications on the following topics:
  - Requirement that RPM services are only furnished to established (as opposed to new) patients.
  - Requirement that following the conclusion of the COVID-19 PHE, the 16-day data collection requirement (as opposed to the two-day data collection requirement) is reinstated. HOWEVER, management codes (98980-98981 AND 99457-99458) will not require the 16-day monitoring—only technical codes
  - Services with which RPM or RTM services can be furnished, such as care management. But, RTM and RPM cannot be billed by the same provider in the same month.
  - Scenarios where RPM or RTM may be separately reimbursable during the global period. CMS proposes that this is true when monitoring is for a separate problem.

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Caregiver Training Codes

For CY 2024, CMS is proposing to make payment when practitioners train and involve caregivers to support patients with certain diseases or illnesses (e.g., dementia) in carrying out a treatment plan.

- CMS proposes to pay for these services when furnished by a physician or a non-physician practitioner (nurse practitioners, clinical nurse specialists, certified nurse-midwives, physician assistants, and clinical psychologists) or therapist (physical therapist, occupational therapist, or speech language pathologist) under an individualized treatment plan or therapy plan of care.
- Requires consent.
- Codes include: 96202, 96203, 97550, 97551, 97552
- Conditions (but not limited to) include: stroke, traumatic brain injury (TBI), various forms of dementia, autism spectrum disorders, individuals with other intellectual or cognitive disabilities, physical mobility limitations, or necessary use of assisted devices or mobility aids.

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Caregiver Training Codes (Cont'd)

- After considering the public comments, CMS is finalizing a revised definition of caregiver to be "an adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation" and "a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition".
- To bill for CTS, practitioners should select the appropriate group code (CPT code 96202, 96203, or 97552) if more than one caregiver is trained at the same time, or individual code (CPT code 97550, 97551) if one individual caregiver is trained. If caregivers are trained in a group, practitioners would not bill individually for each caregiver. More than one caregiver trained at the same time must be billed under the group code, as the treating practitioner's time and effort should not be counted multiple times.

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New Health Equity Codes

- CMS FINALIZES new codes and payment for
  - Community Health Integration (CHI) services,
  - Principal Illness Navigation (PIN) services provided by social workers, community health workers and other auxiliary
  - Social Determinants of health (SDoH) risk assessment and (PIN) personnel.

CHI 2024 (G0019 & G0022)

- Must have an initiating O/O visit or Annual Wellness Visit.
- For offices, this is an ‘incident to’ service under ‘general’ supervision.
- Need for these services must be documented and part of the treatment plan.
- Consent must be documented.
- There are no frequency limits on these as yet.
- Personnel performing this should be trained and be authorized to perform under State Law.

CHI G0019 & G0022 Descriptors

G0019 Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:

• Person-centered assessment, performed to better understand the individualized context of the intersection between the SDOH need(s) and the problem(s) addressed in the initiating E/M visit.

++ Conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors.

++ Facilitating patient-driven goal-setting and establishing an action plan.

++ Providing tailored support to the patient as needed to accomplish the practitioner's treatment plan.

• Practitioner, Home-, and Community-Based Care Coordination

++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable).

++ Communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. 318

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the SDOH need(s).

• Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the SDOH need(s), and educating the patient on how to best participate in medical decision-making.

• Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing the SDOH need(s), in ways that are more likely to promote personalized and effective diagnosis or treatment.

• Health care access / health system navigation

++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care and helping secure appointments with them.

• Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.

• Facilitating and providing social and emotional support to help the patient cope with the problem(s) addressed in the initiating visit, the SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.

• Leveraging lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

G0022 Each additional 30 minutes per Calendar Month

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PIN 2024 (G141 & G146)

- This is for a disease that is supposed to last 3 months or more.
- This is not necessarily related to SDOH.
- Cannot be initiated for ED or inpatient.
- “Incident to” under General Supervision.
- Must have an initiating visit once per year.
- Personnel must be trained or certified and are qualified under State Law.
- Consent verbal or written is required.
- Only one HCP can bill per condition per month.

PIN 2024 (G0140 & G0146)

“Documentation of the PIN services furnished in relation to the serious, high-risk condition in the medical record is required to track a patient’s progress through the diagnosis and treatment of their principal illness, describe the interventions and PIN service elements performed, and to describe the medical necessity of PIN services to the principal illness.

Documentation is also required to describe the ongoing need or changes to the treatment plan that allow for the cessation of PIN services; we appreciate that CBOs may not have access to the electronic health record in which the furnishing practitioner is documenting the patient’s care in the medical record. To reduce administrative burden, we are not requiring that all auxiliary personnel performing PIN services must document the services in the medical record themselves. Rather, the billing practitioner is responsible for ensuring appropriate documentation of the PIN services provided to the patient is included in the medical record..”

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PIN 2024 (G0140-G0146)

G0140 – Principal Illness Navigation – Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following activities:

• Person-centered interview, performed to better understand the individual context of the serious, high-risk condition.

++ Conducting a person-centered interview to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors, and including unmet SDOH needs (that are not billed separately).

++ Facilitating patient-driven goal setting and establishing an action plan.

++ Providing tailored support as needed to accomplish the person-centered goals in the practitioner's treatment plan.

• Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.

• Practitioner, Home, and Community-Based Care Communication

++ Assist the patient in communicating with their practitioners, home-, and community based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, goals, preferences, and desired outcomes, including cultural and linguistic factors.

++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

• Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making. 386

• Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.

• Developing and proposing strategies to help meet person-centered treatment goals and supporting the patient in using chosen strategies to reach person-centered treatment goals.

• Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet person-centered diagnosis and treatment goals.

• Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

G0146 – Principal Illness Navigation – Peer Support, additional 30 minutes per calendar month (List separately in addition to G0140).

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G0136: Health Risk Assessment of SDoH

- This rule also proposes coding and payment for social determinants of health risk assessments, which could be furnished as an add-on to an annual wellness visit or in conjunction with an evaluation and management visit.
  - If this code is used with the AWV, no patient portion will be assessed.
- **G0136:** Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes

G0136: Health Risk Assessment of SDoH

- Must be a standardized test--possible evidence-based tools include the CMS Accountable Health Communities (AHC) 24 tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) 25 tool, and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.
- Cannot be billed more than every six months.
- Code with Z-codes if SDOH are found.
- Follow up referrals are expected.
- Can be associated with E/M, AWV, TCM.

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G0136: Health Risk Assessment of SDoH

G0136--Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months. SDOH risk assessment refers to a review of the individual’s SDOH or identified social risk factors that influence the diagnosis and treatment of medical conditions.

Oh No! Look at What’s Back…

- In this year’s rule, CMS reaffirms that G2211 will go into effect as expected on January 1, 2024. CMS proposes to institute several policy refinements to G2211 that would result in a less significant negative budget neutrality adjustment.
  - First, CMS would clarify that G2211 cannot be billed when the O/O E/M visit code is reported with payment modifier -25, which denotes a separately billable E/M service by the same practitioner furnished on the same day of a procedure or other service.
  - Further, CMS does not believe that G2211 should be reported if care is delivered by a provider that does not have an ongoing relationship with the patient. The provider must have a longitudinal relationship with the patient.

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G2211 Descriptor

- G2211 (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)) (85 FR 84571) We also estimated that the O/O E/M visit complexity add-on service would be reported by specialties that rely on office/outpatient E/M visits to report the majority of their services and would be billed in addition to those E/M visits.

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"Split Visits" in Facilities--BIG NEWS!!

- CMS implementing this definition of substantive portion at all, with many requests that we also recognize MDM as the substantive portion of the visit. In consideration of the changes made by the CPT Editorial Panel, we are revising our definition of "substantive portion" of a split (or shared) visit to reflect the revisions to the CPT E/M guidelines. Specifically, for CY 2024, for purposes of Medicare billing for split (or shared) services, the definition of "substantive portion" means more than half of the total time spent by the physician and NPP performing the split (or shared) visit, or a substantive part of the medical decision making as defined by CPT.
    - Modifier –FS is necessary

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Dental Services 2024

- Medicare Parts A and B pay for dental services in a limited number of circumstances, specifically when that service is an integral part of specific treatment of a beneficiary's primary medical condition.
- For CY 2024, CMS will codify previously finalized payment policies for dental services prior to or during head and neck cancer treatments, whether primary or metastatic.
- CMS will permit payment for certain dental services prior to therapy (2-3 weeks). Services must be inextricably linked to other covered services used to treat cancer, including
  - chemotherapy,
  - CAR T cell therapy and
  - antiresorptive therapy (IV).

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Drug Wastage Implementation

- Modifier Use--CMS asserts that the JW modifier is not used by providers in all cases where a portion of a drug is discarded. It must be used! Providers are also required to report JZ modifier when the full amount is administered, to “attest” that there were no discarded amounts.
    - Required on every claim ON or AFTER 7/1/2023
    - Edited ON OR AFTER 10/1/2023
    - We are seeing lots of denials

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Drugs and Biologicals Rules Under the IRA Codified

- Drugs and Biologicals Rules Under the IRA Codified--This proposal which formalizes a lot of things that were in The Inflation Reduction Act and contains several provisions that affect payment **allowables:**
  - Section 11403 makes changes to the payment limit for certain biosimilars when they are new. So, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003 (!!!), or (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price negotiation period, 106 percent of the maximum fair price (2028?) of the reference biological. If finalized, this went into effect on July 1, 2024.
  - Section 11101 requires that beneficiary coinsurance for a Part B rebated drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, We have already seen how this works.
  - Section 11407 provides that for insulin furnished through an item of DME on or after July 1, 2023, the deductible is waived and coinsurance is limited to $35 for a month's supply of insulin furnished through a covered item of DME

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Updates to Drug Wastage Rules

- **Key Takeaway: CMS will issue quarterly discarded drug refund reports begin in 2024 alongside additional implementation policies.**
  - .
  - CMS outlines that the initial discarded drug refund report to manufacturers would be issued no later than December 31, 2024, and subsequent reports would be issued quarterly.
  - Annual reports would include lagged claims data from two years (8 quarters) prior, which would be used to revise the manufacturer refund amount.
  - When there are multiple manufacturers for a generic or 505(b)(2) drug, CMS outlines that refunds be apportioned by proportion of billing unit sales for ASP pricing.
  - CMS also states that drugs with low volume doses and rarely administered orphan drugs receive increased applicable percentages, which lowers the refund amount owed by manufacturers.
  - CMS proposes that a formal application process for manufacturers seeking increased applicable percentages is established alongside this policy

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Wastage Reporting Schedule

TABLE 20: Timing of Refund Reports and Which Calendar Quarters are Included in Each Report

Timing of Report	New Refund Quarters Included	Updated Refund Quarters Included
Not later than December 31, 2024 (Initial Refund Report)	Calendar quarters in 2023	None
Not later than September 30, 2025	Calendar quarters in 2024	Calendar quarters in 2023
Not later than September 30, 2026	Calendar quarters in 2025	Calendar quarters in 2024
Not later than September 30, 2027	Calendar quarters in 2026	Calendar quarters in 2025
Not later than September 30, XXXX	Calendar quarters in the year prior to XXXX	Calendar quarters in the year 2 years prior to XXXX

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Behavioral Health Changes

CMS implements several provisions of the CAA, 2023, with the intent of encouraging and expanding access to behavioral health services. This includes

- Provide Medicare Part B coverage and payment for the services of Marriage and Family Therapists (MFTs) and
- Mental Health Counselors (MHCs).
- CMS will allow addiction counselors that meet all the applicable requirements to be an MHC to enroll in Medicare as MHCs.
- CMS will allow the Health Behavior Assessment and Intervention services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167 and 96168 (and any successor codes), to be billed by clinical social workers, MFTs and MHCs, in addition to clinical psychologists.
- Crisis services will be paid at 150% of the Fee Schedule, while MFTs and MHCs will be paid at the lesser of 80% of billed charges or 75% of the MFS.

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Vaccines 2024

- For CY 2024, CMS proposes to maintain the in-home additional payment for COVID-19 vaccine administration under the Part B preventive vaccine benefit and
  - CMS will extend the additional payment ($38.51) to the home administration of the other three preventive vaccines included in the Part B preventive vaccine benefit (pneumococcal, influenza and hepatitis B vaccines) effective January 1, 2024.
  - CMS limits the additional payment to one payment per home visit, even if multiple vaccines are administered at the same visit.
  - This additional payment amount would be annually updated using the percentage increase in the MEI and adjusted to reflect geographic cost variations .

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Vaccines 2024

TABLE 47: CY 2024 Part B Payments for Preventive Vaccine Administration if the EUA Declaration for Drugs and Biologicals with Respect to COVID-19 Continues into CY 2024

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$32.57	MEI	GAF
COVID-19 Vaccine[2,4]	$43.43	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)	$38.55	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis) [3,4,5]			
Infusion: Health Care Setting	TBD	N/A	GAF
Infusion: Home	TBD	N/A	GAF
Intravenous Injection: Health Care Setting	TBD	N/A	GAF
Intravenous Injection: Home	TBD	N/A	GAF
Injection: Health Care Setting	TBD	N/A	GAF
Injection: Home	TBD	N/A	GAF
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4,5]			
Injection: Health Care Setting	TBD	N/A	GAF
Injection: Home	TBD	N/A	GAF

TABLE 48: Part B Payments for Preventive Vaccine Administration Beginning January 1, 2024, if the EUA Declaration for Drugs and Biologicals with Respect to COVID 19 is Terminated on or Before December 31, 2023

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[7]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B[1,4]	$32.57	MEI	GAF
COVID-19[2,4]	$32.57	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)	$38.55	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3,5]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	TBD [5,6]	N/A	GAF

E-Prescribing Controlled Substances

- The SUPPORT ACT established January 1, 2022 as a compliance date for this requirement.
- In 2023, warning letters will be sent but no monetary penalties will be levied. This will continue as the penalty in 2024.
- CMS also says that for prescribers to be considered compliant, they must prescribe at least 70% of their Part D controlled substance prescriptions electronically per calendar year.
- The exception of the above parameter was when the pharmacy and provider were the same entity. That has been rescinded

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Appropriate Use Criteria Timeline

Paused Until Further Notice!!!

Summary of QPP Rule 2024

MIPS 2024

- Increased threshold for 2024 WAS proposed
  - To avoid a negative adjustment and be eligible for a positive payment adjustment, a provider's MIPS total score must reach a performance threshold.
  - CMS proposed to increase the 2023 MIPS performance threshold of **75 points to 82 points** for the 2024 performance period, creating a more challenging program for participants. In the end, this was rescinded and**, in 2024, the total points for a neutral adjustment is 75 points.**
- **78.76% of EPs got a positive payment 2022 reporting.**

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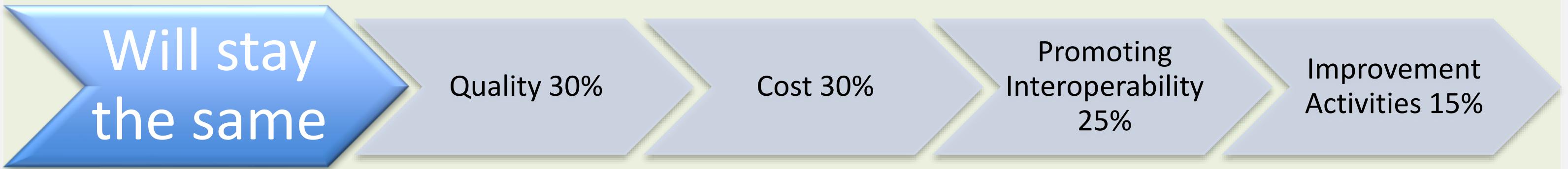
Components for 2024



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MVP Timeline

- For 2023, 2024, and 2025 performance years, CMS will allow individuals, single specialty groups, multispecialty groups, APM entities, and SUBGROUPS to report MVPs.
- From 2026 on, CMS will allow individuals, single specialty groups, APM entities to report MVPs. Multispecialty groups will be required to form SUBGROUPS for reporting. Subgroups will have additional reporting and scoring requirements.
- There is now no definitive date for the sunsetting of MIPS.

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New MVPs for 2024 Reporting

- Women's Health
- Infectious Disease Including HIV and Hepatitis C
- Mental Health and Substance Abuse Disorder
- Quality Care for Ear, Nose, and Throat
- Rehab Support for Musculoskeletal Disease
- Consolidation of Promoting Wellness and Managing Chronic Conditions

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Quality (30%) Component

- Specific measures are outlined in more detail in the QPP fact sheet and include
  - the addition of 14 measures,
  - removal of 12 quality measures (see Appendix C),
  - partial removal of three quality measures from the MIPS quality measure inventory (proposed for removal for traditional MIPS and retained for MVP use only) and
  - substantive changes to 59 existing quality measures.
- CMS will maintain the data completeness criteria threshold of at least 75%

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Cost (30%) 2024

- CMS will add five new episode-based measures to the cost performance category beginning with the CY 2024 performance period. The measures are related to
  - depression,
  - emergency medicine,
  - heart failure,
  - low back pain, and
  - psychoses and related conditions.
  - Proposes to remove the Simple Pneumonia with Hospitalization episode-based measure

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Improvement Activities (15%) 2024

CMS intends to add five, modify one and remove three improvement activities from the improvement activities inventory. These include an MVP-specific improvement activity titled

Practice-Wide Quality Improvement in MIPS Value Pathways that would allow clinicians to receive full credit in this performance category.

Promoting Interoperability(15%) 2024

CMS will do the following:

- Lengthening the performance period for this category from 90 days to 180 days.
- Modifying one of the exclusions for the Query of Prescription Drug Monitoring Program measure.
- Providing a technical update to the e-Prescribing measure.
- Modifying the Safety Assurance Factors for Electronic Health Record Resilience (SAFER)) Guide measure to require MIPS eligible clinicians to affirmatively attest to completion of the self-assessment of their implementation of safety practices.
- Continuing to reweight this performance category at 0% for clinical social workers for the CY 2024 performance period/2026 MIPS payment year.

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Performance Threshold 2024

1716 **TABLE 60: Illustration of Point System and Associated Adjustments Comparison between the CY 2023 Performance Period/2025 MIPS Payment Year and the CY 2024 Performance Period/2026 MIPS Payment Year**

2023 Performance Period		2024 Performance Period	
Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment
0.0-18.75	Negative 9%	0.0-18.75	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.00	0% adjustment	75.00	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 86.00 to 100.00 This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

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Advanced APM 2024

- In performance year 2024/payment year 2026, MACRA also provides for two different CFs depending on advanced APM participation:
    - Eligible clinicians who are qualifying participants in Advanced APMs will receive a differentially higher 0.75% update to the CF compared to the 0.25% update to the general CF each year.
    - This is not great seeing as the CF is reduced each year.
- In December 2022, Congress extended availability of the advanced APM incentive payment for one year, allowing eligible clinicians to receive a 3.5% (down from the 5%) incentive payment in the 2023 performance year/2025 payment year.

Some Advanced APM Additions 2024

- QP Thresholds for full participation
  - Qualifying APM Participants: CMS proposed to make QP determinations at the individual eligible clinician-level only and no longer the APM Entity-level. This did not happen.
  - Medicare APM Thresholds. Under current statute, the QP threshold percentages will increase beginning with the 2024 performance year/2026 payment year as follows on the next page..

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QP Thresholds Change in 2024

TABLE 61: QP Threshold Score Updates

Medicare Option - Payment Amount Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Payment Amount Threshold	50		50		50		75	
Partial QP Payment Amount Threshold	40		40		40		50	
Medicare Option - Patient Count Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	35		35		35		50	
Partial QP Patient Count Threshold	25		25		25		35	
All-Payer Combination Option - Payment Amount Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	50	25	50	25	50	25	75	25
Partial QP Patient Count Threshold	40	20	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum
All-Payer Combination Option - Patient Count Method								
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

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Medicare Hospital Outpatient Final Rule 2024

OPPS Payment Update

- For CY 2024, CMS increased payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the ASC Payment System by a productivity-adjusted market basket factor of 3.1%.
- Hospitals and ASCs that fail to meet their respective quality reporting program requirements will be subject to a 2% reduction in the CY 2024 fee schedule increase factor.

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2024 Drug/Biologic Payments

For “K” status drugs, some will be bundled into the APC. This was proposed for non-pass-through drugs whose cost is $140 or less per encounter, a $5 increase. Will stay at $135.

For CY 2024, CMS plans to except biosimilars from the OPPS threshold packaging policy when their reference products are separately paid. However, they are not finalizing that all the biosimilars related to the reference product would be similarly packaged if a reference product’s per-day cost falls below the threshold packaging policy.

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Drug and Biologic Modifiers

- CMS will continue to pay the statutory default rate, ASP plus 6%, for 340B-acquired drugs and biologicals.

- CMS also finalized its proposal to use a single modifier to identify drugs and biologicals acquired through the 340B program. All 340B covered entity hospitals paid under the OPPS are required to report the TB modifier effective January 1, 2025.

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Changes to Hospital Transparency

- CMS finalized its proposal to require hospitals to display standard charge information using a machine-readable file template similar to those it made available for voluntary use in 2022. CMS will require hospitals to link to this information from their website homepage.

- CMS also finalized a requirement that each hospital make a good-faith effort to ensure that the information in its machine-readable file is true, accurate and complete. The file must include an affirmation that the hospital, to the best of its knowledge and belief, has included all required standard charge information.

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Changes to Hospital Transparency

- Additions and modifications to enforcement regulations are also finalized in this rule, including the following:
  - An authorized hospital official must certify the accuracy and completeness of hospital price transparency data.
  - Hospitals are required to acknowledge receipt of warning notices.
  - CMS may notify a health system's leadership of noncompliance by one of its hospitals.
  - CMS may publicize information related to its assessment of a hospital's compliance, compliance actions taken against a hospital (including the status and outcome of those actions) and notifications sent to health system leadership.

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Current Enforcement Actions To Date

Enforcement Actions

Below is a list of civil monetary penalty (CMP) notices issued by CMS.

Date Action Taken	Hospital Name	CMP Amount	Effective Date
2022-06-07	Northside Hospital Atlanta	$883,180.00	2021-09-02
2022-06-07	Northside Hospital Cherokee	$214,320.00	2021-09-09
2023-04-19	Frisbie Memorial Hospital	$102,660.00	2022-10-24
2023-04-19	Kell West Regional Hospital *Under Review **	$117,260.00	2022-07-08

*45 CFR §180.90(e)(2)(i)

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Intensive Outpatient Services

- Medicare will provide coverage for intensive outpatient services beginning in CY 2024. Intensive outpatient services are furnished under IOPs, which are distinct and organized outpatient programs for psychiatric services provided to individuals who have an acute mental illness, including depression, schizophrenia and substance use disorders.
- CMS finalized its proposal that IOP services may be furnished in hospital outpatient departments, community mental health centers, federally qualified health centers and rural health clinics.
- In this rule, CMS finalized the payment and program requirements for the new IOP benefit. The final rule includes
  - the scope of benefits,
  - physician certification requirements,
  - coding and billing guidelines, and
  - payment rates under the IOP benefit.

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The Inpatient Only List

- CMS finalized proposals to add nine services to, and remove none from, the inpatient only (IPO) list.
- Historically, CMS has identified services that it believes are safely provided only in an inpatient setting and thus will not be paid by Medicare under the OPPS. These services are designated to the IPO list.
- While CMS received requests to remove procedures from the list, the agency found that none of the proposed services met the criteria for removal. CMS finalized its proposal to add to the IPO list nine services that were newly defined by the American Medical Association CPT Editorial Panel for CY 2024.

C-APCs 2024

- Under the OPPS, CMS assigns items, services and procedures to APCs that are used to set payment rates. The APCs are organized such that each group is intended to be homogeneous both clinically and in terms of resource use. Starting in 2015, CMS began implementing comprehensive APCs (C-APCs) that include a primary service and all adjunctive services provided to support the delivery system of the primary service.
- For CY 2024, CMS finalized a proposal to create two new C-APCs:
  - Splitting the existing Level 2 Intraocular C-APC 5492 into Level 2 and Level 3 Intraocular C-APC 5493, which requires renaming the previously existing Levels 3, 4 and 5 Intraocular APCs (5493, 5494, 5495) to Levels 4, 5 and 6, respectively (APCs 5494, 5495, 5496)
  - Creating C-APC 5342 for Level 2 Abdominal/Peritoneal/Biliary and Related Procedures to improve the clinical and resource homogeneity in the Level 1 Abdominal/Peritoneal/Biliary and Related Procedures APC (5341).

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Dental Services in OPPS

- In 2023, CMS began allowing payment for dental services that are inextricably linked to, and substantially related and integral to, the clinical success of other covered medical services. This policy change allows payment for certain dental services performed in outpatient settings when OPPS coverage and payment conditions are met.
- To ensure that CMS can pay for dental services under OPPS, the agency proposed to assign 229 additional dental codes to clinical APCs. After consideration of public comments, CMS decided to finalize its proposal to add those 229 dental codes to clinical APCs and to include an additional 14 dental codes identified by commenters. FR Table 111 identifies the 243 dental codes assigned to clinical APCs for 2024.

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Unbundle Certain Radiopharmaceuticals???

- In the CY 2024 proposed rule, CMS invited comments on potential modifications to its packaging policy for diagnostic radiopharmaceuticals. CMS requested information on specific cost-prohibitive diagnostic radiopharmaceuticals that commenters believe are superior to alternative diagnostic modalities. CMS is interested to learn about specific clinical scenarios where only the more expensive diagnostic radiopharmaceutical is clinically appropriate, rather than a lower cost alternative, as well as clinical scenarios in which the only diagnostic modality is a high-cost radiopharmaceutical.

- CMS sought comments on the following payment alternatives:
  - Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140
  - Establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold
  - Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals
  - Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials
  - Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

- CMS ultimately chose not change its policy for this upcoming year. While stakeholders were supportive of changes to the existing policy, there was no clear consensus on the best payment alternative. Given the issue's complexity, CMS determined that it would not finalize any changes this year and instead will consider stakeholder feedback in future rulemaking

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Final Rule Regarding 340B Repayment

Repayment Finalized

- In the proposed rule, HHS estimates that the reimbursement cut to 340B providers from January 2018 to September 2022 was approximately $10.5 billion.
- CMS estimates that from CY 2018 through September 27, 2022, affected hospitals received $10.6 billion less in 340B drug payments than they otherwise would have received. However, CMS also estimates that hospitals have already been paid $1.6 billion as the result of claims reprocessing to the full OPPS payment rate and associated beneficiary cost sharing that has already occurred for certain claims with dates of service in CY 2022. This $1.6 billion is accounted for in the agency’s calculation of remedy payments and excluded from the lump sum payments that will be repaid as a result of this policy change.
- Of note, CMS updated these dollar figures in the final rule to reflect passing time

Repayment

- CMS requires that MACs issue the one-time lump sum payments to affected 340B hospitals within 60 calendar days of receiving the payment instruction from CMS.
  - CMS will likely make the lump sum payments at the beginning of CY 2024, after the MAC instructions for each affected 340B covered entity hospital have been issued.
  - The final rule updates the Addendum AAA with new hospital-specific payment amounts and accounts for all payment activity that has occurred since the proposed rule was issued.
  - An affected 340B covered entity hospital can alert CMS to potential errors in the calculation of its lump sum payment amount in Addendum AAA by emailing CMS at outpatientpps340b@cms.hhs.gov no later than 11:59 PM EST on November 30, 2023. Submissions must include the following:
    - A description of the nature of the error
    - A designated contact person for the purposes of addressing the error Relevant supporting documentation, such as claim numbers, total units, payment amount received and date of payment.

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Budget Neutrality

- Beginning in CY 2026, CMS will reduce all payments for non-drug items and services to all OPPS providers (except new providers) by 0.5% each year until the $7.8 billion is offset. (This is a one-year delay compared to the proposed rule, which proposed to begin the adjustment in CY 2025.)
- CMS estimates that this recoupment will take approximately 16 years. CMS notes that it could have opted for more aggressive adjustments that would have offset these payments faster and at higher increments.
- Nonetheless, a 0.5% annual reduction will still meaningfully reduce future OPPS payments to all hospitals. CMS will finalize the methodology, then calculate and publish the payment rates derived from this policy in the CY 2026 OPPS/ASC proposed rule.

Beneficiary Cost Sharing

- Rather than subject Medicare beneficiaries to additional cost-sharing obligations associated with the previously dispensed 340B drugs, CMS incorporated the value of these cost-sharing amounts into the $9 billion lump sum. According to CMS, this should make 340B hospitals whole for the amount they lost from January 1, 2018, through September 27, 2022.
- CMS estimates that $1.8 billion of the total $9 billion is funding 340B hospitals is directly from lost collection of cost sharing from beneficiaries for these 340Bacquired drugs. As a result, CMS prohibits covered entity 340B hospitals from collecting any additional beneficiary cost sharing on drugs subject to the prior payment cuts.

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Medicare Advantage & Repayment

- In the final rule, CMS states that such comments are outside the scope of the final remedy rule. CMS refers commenters to its prior guidance on applying Medicare payment methodologies to out-of-network hospitals and the statutory provision that prohibits CMS from interfering in contractual pricing structures negotiated between hospitals and Medicare Advantage plans.
- CMS states in the final rule that "CMS may not require MAOs (Medicare Advantage Organization) to contract with a particular healthcare provider or use particular pricing structures with their contracted providers. Therefore, MAOs that contract with a provider or facility eligible for 340B drugs can negotiate the terms and conditions of payment directly with the provider or facility and CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities."

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CPT 2024 for Cancer Practices

CPT Split Visit Guidelines 2024

- "If code selection is based on total time on the date of the encounter, the service is reported by the professional who spent the majority of the face-to-face or non-face-to-face time performing the service.
- For the purpose of reporting E/M services within the context of team-based care, performance of a substantive part of the MDM requires that the physician(s) or other QHP(s) made or approved the management plan for the number and complexity of problems addressed at the encounter and takes responsibility for that plan with its inherent risk of complications and/or morbidity or mortality of patient management.
    - By doing so, a physician or other QHP has performed two of the three elements used in the selection of the code level based on MDM.
    - If the amount and/or complexity of data to be reviewed and analyzed is used by the physician or other QHP to determine the reported code level, assessing an independent historian's narrative and the ordering or review of tests or documents do not have to be personally performed by the physician or other QHP, because the relevant items would be considered in formulating the management plan.
    - Independent interpretation of tests and discussion of management plan or test interpretation must be personally performed by the physician or other QHP if these are used to determine the reported code level by the physician or other QHP"

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Time for Time

- CPT codes for E/M services will no longer specify time ranges from both new and established patient codes. Instead, these codes will include a single total time amount, which "must be met or exceeded," according to new wording in the code descriptors.
    - For instance, if an oncologist sees a new patient for a total time of 20 minutes, this service would be reported with 99202 (Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/ or examination and straightforward medical decision making...), which has a current time range of 15-29 minutes.
    - As of Jan. 1, this code descriptor will only specify "15 minutes must be met or exceeded." The next code in the series, 99203, will specify "30 minutes must be met or exceeded."

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Chemo Administration

- Two brand new add-on codes have been introduced for hyperthermic intraperitoneal chemotherapy (HIPEC) in patients who have cancerous tumors in the peritoneal cavity. The codes are:
    - +96547 (Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (List separately in addition to code for primary procedure))
    - +96548 (… each additional 30 minutes (List separately in addition to code for primary procedure)) Add-on codes cannot be reported on their own; they must accompany a primary procedure code, as they indicate that the physician performed an additional service during a single session or patient encounter.

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Chemo Administration

- Our old friend, Chemotherapy code 96446 is changing. Currently, the descriptor states “Chemotherapy administration into the peritoneal cavity via indwelling port or catheter.” When the new code set takes effect, this will change to “Chemotherapy administration into the peritoneal cavity via implanted port or catheter.” So, the change is that “indwelling” will become “implanted.

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Many Vaccine Changes

- Effective January 1, 2024, there will be several changes to the immunization vaccine codes in the CPT® code set. The changes include:
    - Addition of vaccine codes (90380, 90381, 90589, 90623, 90683)
    - Update to dosing guidance for Janssen COVID-19 vaccine code (91303)
    - Respiratory syncytial virus codes 90380 and 90831 are effective upon receiving Emergency Use Authorization or approval from the Food and Drug Administration (FDA)
    - Removal of FDA approval pending symbol for code 90678 Respiratory syncytial virus vaccine, preF, subunit, bivalent, for intramuscular use

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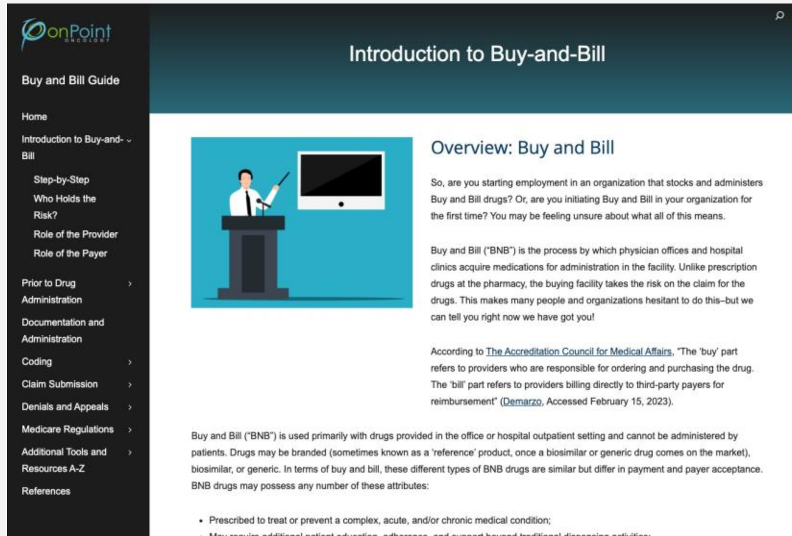

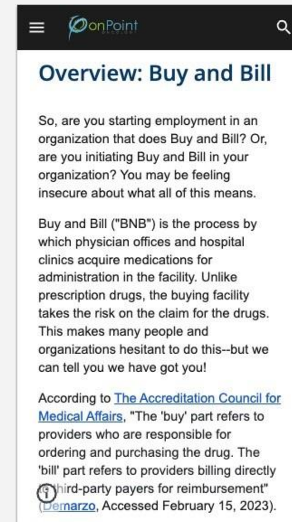

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Appendices

- References
- IRA Slides (Source: KFF)

References Regarding Final Rules

- Medicare Fact Sheets
  - https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-final-rule-medicare-shared-savings-program https
  - https://www.cms.gov/newsroom/fact-sheets/cy-2024-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0

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  - https://www.aamc.org/advocacy-policy/washington-highlights/cms-releases-cy-2024-opps-final-rule#:~:text=In%20the%20final%20rule%2C%20the,eligible%20for%20the%20full%20update.

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Prescription Drug Provisions in the Inflation Reduction Act

- For the first time, **requires the federal government to negotiate prices** for some top-selling drugs covered under Medicare
- Requires drug companies to pay **rebates if prices rise faster than inflation** for drugs used by Medicare beneficiaries
- **Eliminates 5% coinsurance** for catastrophic coverage in Medicare Part D in 2024, adds a **$2,000 cap on Part D out-of-pocket spending** in 2025, and limits annual increases in Part D premiums for 2024-2030
- Limits monthly cost sharing for **insulin products to $35** for people with Medicare
- **Expands eligibility** for **Medicare Part D Low-Income Subsidy** full benefits
- **Eliminates cost sharing for adult vaccines** covered under Medicare Part D and improves access to adult vaccines under Medicaid and CHIP
- Further **delays implementation** of the Trump Administration's **drug rebate rule**

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Overall Timeline

2023	2024	2025	2026	2027	2028	2029
Requires drug companies to pay rebates if drug prices rise faster than inflation	Eliminates 5% coinsurance for Part D catastrophic coverage	Adds $2,000 out-of-pocket cap in Part D and other drug benefit changes	**Implements negotiated prices for certain high-cost drugs:** • 10 Medicare Part D drugs	• 15 Medicare Part D drugs	• 15 Medicare Part B and Part D drugs	• 20 Medicare Part B and Part D drugs
Limits insulin copays to $35/month in Part D	Expands eligibility for Part D Low-Income Subsidy full benefits up to 150% FPL			Further delays implementation of the Trump Administration's drug rebate rule to 2032		
Reduces costs and improves coverage for adult vaccines in Medicare Part D, Medicaid & CHIP						

2024-2030: Limits Medicare Part D premium growth to no more than 6% per year

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Requires the Secretary of HHS to Negotiate Medicare Drug Prices

Modifies the current law “non-interference” clause to require the HHS Secretary to negotiate drug price with manufacturers for some drugs covered under Medicare Part B and Part D

Which drugs qualify for negotiation?

The Secretary selects drugs to be negotiated from the **50 “negotiation-eligible” drugs with the highest total Medicare Part D spending** and the **50 “negotiation-eligible” drugs with the highest total Medicare Part B spending**

Which drugs are excluded from negotiation?

“Negotiation eligible drugs” include **brand-name drugs or biologics** and exclude the following drugs:

- Drugs that have a generic or biosimilar available
- Drugs less than 9 years (for small-molecule drugs) or 13 years (for biological products) from their FDA-approval or licensure date
- Certain “small biotech drugs” (from 2026 to 2028)
- Drugs that account for Medicare spending of less than $200 million in 2021
- Drugs with an orphan designation as the only FDA-approved indication

How many drugs will be subject to negotiation?

The number of drugs subject to price negotiation will be **10 Part D** drugs for **2026**, **15 Part D** drugs for **2027**, **15 Part D and Part B** drugs for **2028**, and **20 Part D and Part B** drugs for **2029 and later years**

The number of drugs with negotiated prices available will **accumulate over time**

Establishing the Negotiated "Maximum Fair Price" for Medicare

The upper limit for the negotiated price of a drug (the "maximum fair price") is equal to *the lower of*:

- The drug's enrollment-weighted negotiated price (net of all price concessions) for a Part D drug;
- The average sales price for a Part B drug; or
- A percentage of the non-federal average manufacturer price (i.e., the average price wholesalers pay manufacturers for drugs distributed to non-federal purchasers), depending on FDA approval date:
  - **75%** for small-molecule drugs more than 9 years but less than 12 years beyond FDA approval;
  - **65%** for drugs between 12 and 16 years beyond FDA approval; and
  - **40%** for drugs more than 16 years beyond FDA approval

Financial penalties would be imposed on drug manufacturers for non-compliance

- An excise tax would be imposed on prior year sales of a given drug for manufacturers that do not negotiate with the Secretary, starting at 65%, increasing by 10% every quarter up to 95%
  - *The excise tax would be suspended if manufacturers choose to have their drugs no longer covered by Medicare or Medicaid*
- A civil monetary penalty would be imposed on drug manufactures for not offering the agreed-upon maximum fair price of up to 10x difference between price charged and negotiated price

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Requires Drug Manufacturers to Pay Rebates For Drug Price Increases Above Inflation

- Requires drug manufacturers to pay a rebate if drug prices increase faster than the rate of inflation (CPI-U) for:
- Single-source drugs and biologicals covered under Medicare Part B
- All covered drugs under Medicare Part D except those where average annual cost is <$100
- 2021 is the base year for measuring cumulative price changes relative to inflation
- The rebate amount is based on units sold in Medicare multiplied by the amount that a drug's price in a given year exceeds the inflation-adjusted price
- Price changes are measured based on the average sales price (for Part B drugs) or the average manufacturer price (for Part D); these measures include prices charged in the commercial market
- Rebates paid by manufacturers would be deposited in the Medicare Supplementary Medical Insurance (SMI) trust fund
- Manufacturers that do not pay the required rebate would face a penalty of at least 125% of the original rebate amount

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Capping Medicare Part D Out-of-Pocket Spending and Other Part D Benefit Changes

Changes would lower beneficiary spending, reduce Medicare's liability for high drug costs, and increase Part D plan and manufacturer liability for high drug costs

Beneficiaries

- Eliminates 5% coinsurance for catastrophic coverage in 2024
- Caps out-of-pocket drug spending at $2,000 beginning in 2025
- Allows spreading out of out-of-pocket costs over the year
- Limits premium growth to no more than 6% per year for 2024-2030

Medicare

- Lowers share of costs above the out-of-pocket spending cap ("reinsurance")

Part D Plans

- Increases share of costs above the out-of-pocket spending cap
- Modifies share of costs below the out-of-pocket spending cap

Drug Companies

- Requires a price discount on brand-name drugs above the out-of-pocket spending cap
- Modifies the price discount on brands below the out-of-pocket spending cap

Limits Monthly Copayments for Insulin in Medicare

- Beginning in 2023, **limits copayments to $35 per month** per prescription for **covered insulin** products in **Medicare Part D** plans and for insulin furnished through durable medical equipment under **Medicare Part B**, **with no deductible**
- For 2026 and beyond, limits monthly Part D copayments for insulin to the lesser of:
  - $35
  - 25% of the maximum fair price (in cases where the insulin product has been selected for negotiation)
  - 25% of the negotiated price in Part D plans

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Expands Eligibility for Full Benefits Under the Medicare Part D Low-Income Subsidy Program

The Part D Low-Income Subsidy (LIS) Program helps beneficiaries with their Part D premiums, deductibles, and cost sharing. Beneficiaries qualify for full or partial benefits depending on their income and resources.

- **Current law**:
  - Beneficiaries qualify for **full LIS benefits** if they have **income up to 135% of poverty and lower resources** (up to $9,900 individual, $15,600 couple in 2022*)
  - Beneficiaries qualify for **partial LIS benefits** if they have **income between 135-150% of poverty and higher resources** (up to $15,510 individual, $30,950 couple in 2022*)
- **Inflation Reduction Act:**
  - Expands eligibility for full LIS benefits to individuals with **incomes between 135% and 150% of poverty** and **higher resources** (at or below the limits for partial LIS benefits), and eliminates the partial LIS benefit

NOTE: *Includes a $1,500 per person allowance for funeral/burial expenses.

Eliminates Cost Sharing for Adult Vaccines in Medicare Part D and Improves Access to Adult Vaccines in Medicaid & CHIP

Medicare Part D

- Eliminates cost sharing for adult vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP), such as for shingles

Medicaid and CHIP

- Requires state Medicaid and CHIP programs to cover all approved vaccines recommended by ACIP and vaccine administration, without cost sharing