Hot Topics in Reimbursement 2023-2024

Bobbi Buell, MBA
WINTER, 2023
650-255-7520
bbuell@onpointoncology.com
Bobbibuell1@yahoo.com
NEWSLETTER: www.onpointoncology.com

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Agenda

- Proposed Fee Schedule Rule for 2024
- QPP Proposals for 2024
- Proposed Hospital Outpatient Rule 2024
- Proposed Rule for 340B Repayment
- 505(b)(2) and HCPCS Michigoss

Proposed 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

Web Sites for the Proposed Regulations 2024

- This presentation is based on published rules. Fact sheets are available at these

  Physician Rule: https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-proposed-rule

  Hospital Outpatient Rule: https://www.cms.gov/newsroom/fact-sheets/cy-2024-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center

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—PROPOSED

TABLE 102: 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	-2.17 percent (0.9783)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**32.7476**

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 (proposed)	$32.3476	-3.36

Specialty Impact

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

- Cardiology 0%
- Dermatology -1%
- Family Practice +3%
- Gastro 0%
- Hem-Onc +2%
- Neuro +1%
- Rad Onc -2%

An Additional Wrinkle

- 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—watch the Final Rule.

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 proposed 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).

Changes to Telehealth Categories

- CMS proposes to 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.

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 proposes 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.

Virtual Supervision

- This change was temporary because CMS was concerned widespread direct supervision through virtual presence may not be safe for some clinical situations. In its proposed PFS rule, CMS rejected requests to make virtual direct supervision a permanent feature in Medicare. CMS is considering whether or not it should make virtual direct supervision a permanent feature of Medicare at some point in the future. Interested stakeholders with data are invited to submit comments and information to CMS on this topic.
- Virtual direct supervision will continue throughout 2024.

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.
- 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!

Other Telehealth Flexibilities 2024

- CMS proposes to 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.

RPM/RTM

- CMS discusses potential 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.
  - 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.

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. And will be paid at about $16.00.
- 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.
  - CMS also revised its assumption for how often G2211 would be billed alongside an O/O E/M visit code. CMS received significant feedback on this assumption, with some arguing that many practitioners deliver care in settings designed to address acute conditions that do not require the type of care coordination and follow-up that G2211 is intended to capture.
  - 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.

G2211 Descriptor

- G2211 (O/O E/M visit complexity) that can be reported in conjunction with O/O E/M visits to better account for additional resources associated with primary care, or similarly ongoing medical care related to a patient's single, serious condition, or complex condition (84 FR 62854 through 62856, 85 FR 84571). (CMS will refer to this code as the O/O E/M visit complexity add-on).

“Split Visits” in Facilities

- So what should you do for 2024 in terms of billing for Split Visits. You can use >50% of the time OR
  - “We also are clarifying that when one of the three key components is used as the substantive portion in 2022, the practitioner who bills the visit must perform that component in its entirety in order to bill. For example, if history is used as the substantive portion and both practitioners take part of the history, the billing practitioner must perform the level of history required to select the visit level billed. If physical exam is used as the substantive portion and both practitioners examine the patient, the billing practitioner must perform the level of exam required to select the visit level billed. If MDM is used as the substantive portion, each practitioner could perform certain aspects of MDM, but the billing practitioner must perform all portions or aspects of MDM that are required to select the visit level billed.” CMS Final Rule
  - Modifier –FS is necessary

Proposals for New Health Equity Codes

CMS proposes 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 and PIN Proposals 2024

GXXX1-GXXX2: CMS is also proposing separate coding and payment for community health integration services, which would include person-centered planning, health system coordination, promoting patient self-advocacy, and facilitating access to community-based resources to address unmet social needs that interfere with the practitioner's diagnosis and treatment of the patient. These are the first Physician Fee Schedule services designed to include care involving community health workers, who link underserved communities with critical health care and social services in the community and expand equitable access to care, improving outcomes for the Medicare population.

GXXX3-GXXX4: In alignment with the goal of the Biden-Harris Administration's Cancer Moonshot for everyone with cancer to have access to covered patient navigation services, CMS is proposing payment for Principal Illness Navigation services to help patients navigate cancer treatment and treatment for other serious illnesses. These services are also designed to include care involving other peer support specialists, such as peer recovery coaches for individuals with substance use disorder.

Code Descriptors: CHI and PIN

GXXX1--Community health integration services performed by certified or trained auxiliary personnel, which may include 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

GXXX2--Community health integration services, each additional 30 minutes per calendar month

GXXX3--Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, which may include a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities

GXXX4--Principal Illness Navigation services, additional 30 minutes per calendar month

GXXX5: 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.
- **GXXX5:** Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes

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.
- Codes include: 96202, 96203, 9X015, 9X016, 9X017 (Placeholders)
- 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.

Payment for New Services (Proposed)

Code (short descriptor)	Non-Fac	Fac
7X005 (N-invas est c ffr sw aly cta)	$34.06	$34.06
926X1 (Dx aly aud oi snd prcsr 1st)	$77.61	$64.19
926X2 (Dx aly aud oi snd prcsr each)	$19.98	$17.03
96202 (Mlt fam grp bhv train 1st 60)[B]	$23.25	$21.69
96203 (Mlt fam grp bhv train ea add)[B]	$5.57	$6.10
9X000 (Vngrph chd anom/persist svc)	N/A	$56.65
9X002 (Vngrph chd azygs/hemi-azygs)	N/A	$53.38
9X003 (Vngrph chd coronary sinus)	N/A	$67.46
9X004 (Vngrph chd vnvn cltrl at/abv)	N/A	$90.38
9X005 (Vngrph chd vnvn cltrl below)	N/A	$95.95
9X015 (Caregiver traing 1st 30 min)	$52.07	$44.54
9X016 (Caregiver traing ea addl 15)	$25.87	$23.91
9X017 (Group caregiver training)	$21.94	$10.48
9X036 (Pelvic examination)	$22.27	N/A
9X045 (Therapy activation ipnss)	$97.92	$41.26
9X046 (Interrog&prgrmg ipnss)	$85.47	$38.97
9X047 (Interrog&prgrmg ipnss polysm)	$155.88	$90.38
9X048 (Interrog w/o prgrmg ipnss)	$50.76	$20.96
9X070 (Perq trluml coronry lithotrp)	N/A	$139.83
GPFC1 (Psych for crisis, 1st 60 mins)	$208.60	$182.73
GPFC2 (Psych for crisis, ea add 30 mins)	$103.48	$91.69
GXXX1 (Comm health int, 1st 60 min/mo)	$78.92	$48.79
GXXX2 (Comm health int, add 30 mins)	$49.45	$34.06
GXXX3 (Principal ill nav, 1st 60 mins/mo)	$78.92	$48.79
GXXX4 (Principal ill nav, add 30 min/mo)	$49.45	$34.06
GXXX5 (SDOH risk assessment 5-15 mins)	$18.67	$8.84
B – Bundled service		

Drug Wastage Implementation

- Applicability--CMS will include in the Refund Program all separately payable drugs using the JW modifier, including such drugs that have been granted pass-through status in the hospital outpatient setting.
- Modifier Use--CMS asserts that the JW modifier is not used by providers in all cases where a portion of a drug is discarded. Based on this stated concern, Providers be required to report JZ modifier when the full amount is administered, to “attest” that there were no discarded amounts.
  - Required on every claim AFTER 7/1/2023
  - Not edited until 10/1/2023

Proposed Updates to Drug Wastage Rules

- **Key Takeaway: CMS proposes quarterly discarded drug refund reports begin in 2024 alongside additional implementation policies.**
  - CMS proposes 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. CMS stated that there may be a preliminary report with 2 quarters by 12/31/2023.
  - 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 proposes that refunds be apportioned by proportion of billing unit sales.
  - CMS also proposes 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 be established alongside this policy

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 goes 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

Proposed Behavioral Health Changes

CMS proposes to implement 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 proposes to allow addiction counselors that meet all the applicable requirements to be an MHC to enroll in Medicare as MHCs.
- CMS proposes to 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.

Dental Services Proposal 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 proposes to codify previously finalized payment policies for dental services prior to or during head and neck cancer treatments, whether primary or metastatic.
- CMS also proposes to permit payment for certain dental services inextricably linked to other covered services used to treat cancer, including
  - chemotherapy,
  - CAR T cell therapy and
  - antiresorptive therapy.

Vaccine Proposal 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 proposes to 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 proposes to limit 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 .

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, if the proposal is enacted.

Appropriate Use Criteria Timeline

Paused Until Further Notice!!!

Proposal's Impact on A Few Codes

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CPT				STATUS	MCA	MCA	$	%
HCPCS	MOD	Help	DESCRIPTION	CODE	2023 Final	2024 Final	Difference	Difference
99211		99211	Off/op est may x req phy/qhp	A	$23.38	$22.92	($0.46)	-2.0%
99212		99212	Office o/p est sf 10-19 min	A	$56.93	$55.67	($1.26)	-2.2%
99213		99213	Office o/p est low 20-29 min	A	$90.82	$89.40	($1.42)	-1.6%
99214		99214	Office o/p est mod 30-39 min	A	$128.43	$126.08	($2.35)	-1.8%
99215		99215	Office o/p est hi 40-54 min	A	$179.94	$177.49	($2.45)	-1.4%

Thank you, Jordan

BRIDGE ONCOLOGY

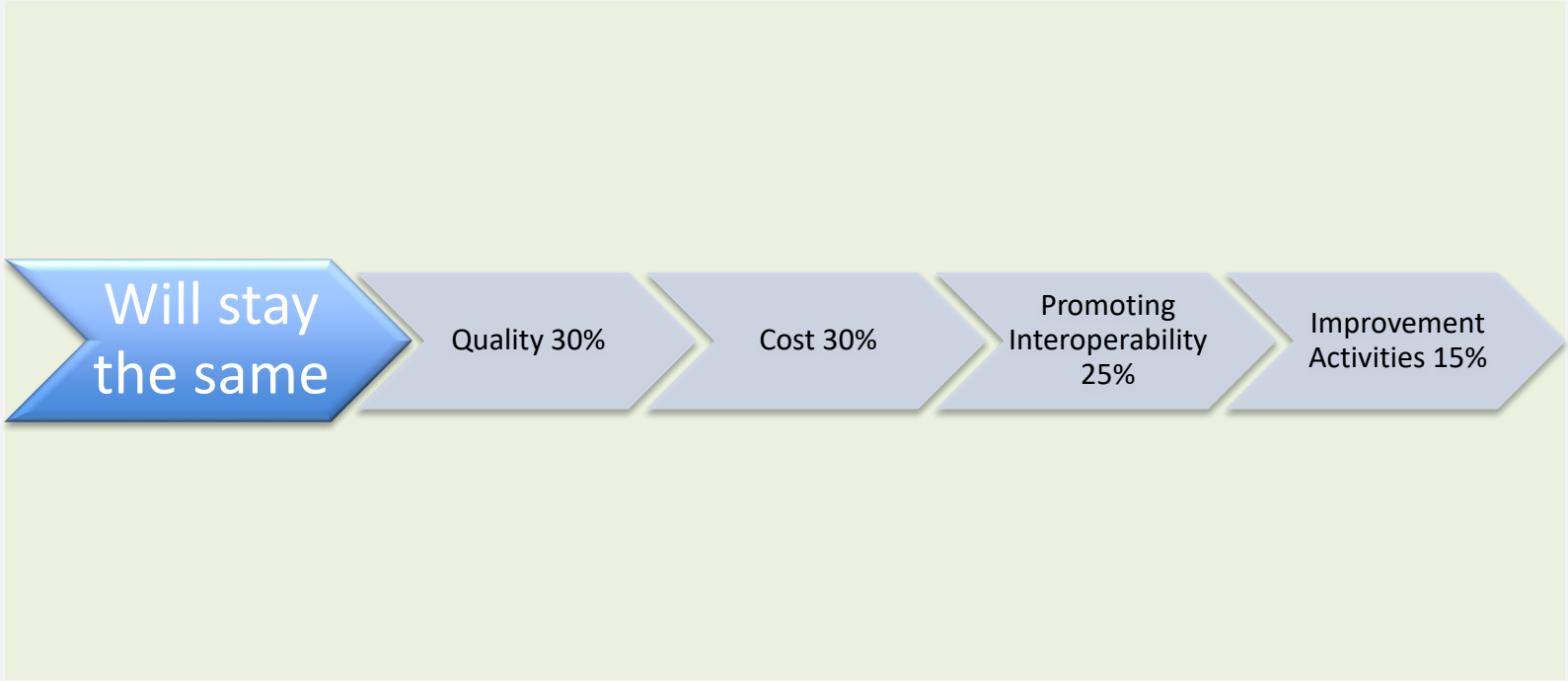
CPT			STATUS	MCA	MCA	$	%
HCPCS	MOD	DESCRIPTION	CODE	2023 Final	2024 Final	Difference	Difference
96365		Ther/proph/diag iv inf init	A	$64.72	$61.57	($3.16)	-4.9%
96366		Ther/proph/diag iv inf addon	A	$20.67	$19.98	($0.70)	-3.4%
96367		Tx/proph/dg addl seq iv inf	A	$29.14	$27.84	($1.31)	-4.5%
96372		Ther/proph/diag inj sc/im	A	$14.23	$14.08	($0.15)	-1.1%
96401		Chemo anti-neopl sq/im	A	$73.54	$70.41	($3.13)	-4.3%
96411		Chemo iv push addl drug	A	$55.91	$53.38	($2.54)	-4.5%
96413		Chemo iv infusion 1 hr	A	$132.16	$127.06	($5.10)	-3.9%
96415		Chemo iv infusion addl hr	A	$28.47	$27.18	($1.28)	-4.5%
96416		Chemo prolong infuse w/pump	A	$129.79	$125.10	($4.69)	-3.6%
96417		Chemo iv infus each addl seq	A	$65.06	$62.55	($2.52)	-3.9%

Summary of QPP Proposed Rule 2023

Biggest MIPS Proposal 2024

- Increased threshold for 2024 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 proposes 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.
  - Historically, CMS had increased the MIPS performance threshold, but during the COVID-19 PHE, the agency maintained a 75-point threshold for two consecutive years, allowing MIPS participants to avoid additional quality reporting challenges.

Component Proposal for 2024



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.

New MVPs Proposed 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

Quality (30%) Proposals

- CMS proposes changes that would result in a total of 200 quality measures in its quality inventory.
- 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) (See Appendix D) and
  - substantive changes to 59 existing quality measures.
- CMS proposes to maintain the data completeness criteria threshold of at least 75% for the CY 2026 performance period/2028 MIPS payment year and increase the data completeness incrementally after that.

Cost (30%) Proposals 2024

- CMS proposes to 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

Improvement Activities (15%) 2024 Proposal

CMS proposes to add five, modify one and remove three improvement activities from the improvement activities inventory (see Appendix E). These proposals 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 2024 Proposals

CMS proposes 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.

Some Advanced APM Proposals 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 Proposals 2024

- QP Thresholds for full participation
  - Qualifying APM Participants: CMS proposes to make QP determinations at the individual eligible clinician-level only and no longer the APM Entity-level.
  - Proposed Medicare APM Thresholds. Under current statute, the QP threshold percentages will increase beginning with the 2024 performance year/2026 payment year as follows:
    - Medicare Payments: QP threshold increasing from 50% to 75%; Partial QP threshold increasing from 40% to 50%
    - Medicare Patients: QP threshold increasing from 35% to 50%; Partial QP threshold increasing from 25% to 35%.

Medicare Hospital Outpatient Proposed Rule 2024

OPPS Payment Update

- For CY 2024, CMS proposes to increase payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the ASC Payment System by a factor of 2.8%. Hospitals and ASCs that fail to meet their respective quality reporting program requirements are subject to a 2.0% reduction in the CY 2024 fee schedule increase factor.

2024 Proposed Drug/Biologic Payments

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

CMS is proposing “to exempt biosimilars from the OPPS threshold packaging policy when their reference biologicals are separately paid, meaning we would pay separately for these biosimilars even if their per-day cost is below the threshold packaging policy.”

Proposed Changes to Hospital Transparency

- For CY 2024, CMS proposes to require hospitals to display standard charge information using a machine-readable file template like those it made available for voluntary use. CMS proposes to require hospitals to link to this information from their website homepage.
- CMS also seeks additions and modifications to its enforcement regulations, including requiring an authorized hospital official to certify
  - the accuracy and completeness of hospital price transparency data;
  - requiring hospitals to acknowledge receipt of warning notices;
  - allowing CMS to notify a health system's leadership of noncompliance by one of its hospitals; and allowing CMS to publicize information related non-compliance

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)

Proposal to Add Intensive Outpatient Services

- In this rule, CMS proposes the payment and program requirements for the new IOP benefit for mental illness and substance abuse. The proposed rule includes
  - the scope of benefits,
  - physician certification requirements,
  - coding and billing, and
  - payment rates under the IOP benefit.

- CMS proposes that IOP services may be furnished in hospital outpatient departments, community mental health centers, federally qualified health centers and rural health clinics.

Proposals for the Inpatient Only List

- Historically, CMS has identified services that are safely provided only in an inpatient setting and thus would not be paid by Medicare under the OPPS.
- For CY 2024, CMS proposes to remove no procedures from the IPO list. CMS proposes to add nine services that were newly defined by the American Medical Association CPT Editorial Panel for CY 2024 to the IPO list. These new services are described by the placeholder CPT codes X114T, 2X002, 2X003, 2X004, 619X1, 7X000, 7X001, 7X002 and 7X003. Table 47 in the proposed rule outlines the proposed changes to the IPO list for CY 2024.
- Other than new codes, there are no other additions.

Proposal for C-APCs 2024

- The APCs are arrayed so that each group is intended to be homogeneous clinically and in terms of resource use. Starting in 2015, CMS added comprehensive APCs (C-APCs) that include a primary service and all adjunctive services provided to support the delivery system of the primary service.
- For 2024, CMS proposes 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. This would require renaming the previously existing Levels 3, 4 and 5 Intraocular APCs (5493, 5494, 5495) to be 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).

Proposal for Dental Services

- The Physician Proposal applies to Part A as well.
- To ensure that CMS can pay for dental services under OPPS, the agency now proposes to assign 229 additional dental codes to clinical APCs..

Proposal to Unbundle Certain Radiopharmaceuticals

- CMS wants to learn about specific clinical scenarios for which it is only clinically appropriate and necessary to use the more expensive diagnostic radiopharmaceutical, rather than a lower cost one, as well as clinical scenarios in which the only diagnostic modality is a high-cost radiopharmaceutical.
- The proposal includes five (5) alternatives for possible unbundling:
  1. Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140 (proposed)
  2. Establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold
  3. Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals
  4. Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials
  5. Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

Proposed Rule Regarding 340B Repayment

Proposal for Repayment

- In the proposed rule, HHS estimates that the reimbursement cut to 340B providers from January 2018 to September 2022 was approximately $10.5 billion.
- HHS estimates that the reimbursement methodology change put in place by HHS starting September 27, 2022 has corrected $1.5 billion of that amount. Many of the 2022 claims have been re-processed.
- Thus, HHS is proposing lump sum payments to 340B providers totaling approximately $9 billion.

Proposed Repayment

- HHS is proposing to pay this shortfall by examining claims data for each and every 340B provider from January 1, 2018 to September 27, 2022 .
  - HHS will calculate these payments based on the full amount a 340B provider should have been reimbursed had the payment reductions not gone into effect, and
  - They will then subtract from that total what HHS has already compensated the 340B provider for the claims.
  - HHS states in the proposed rule that it does not believe it has the authority to account for interest on these claims, thus no interest calculation will be included in the lump sum payment.
  - This will take place at the end of this year and beginning of next year.

Budget Neutrality Proposal

- In FY 2018, HHS increased OPPS payments to hospitals for NON-DRUG items and services by 3.19% when the cuts to drug acquisition costs for 340B hospitals were enacted. In the proposed rule,
  - HHS estimates that acute care hospitals received an estimated $7.8 billion in additional spending on the aforementioned non-drug items and services for Medicare beneficiaries.
  - For these (sort of) bonus payments, HHS is proposing a 0.5% reduction in the OPPS fee schedule for non-drug items and services for all hospitals (340B and non-340B) for each year until the $9 Billion in lump sum payments to 340B hospitals is fully repaid. HHS estimates the 0.5% reduction will take place for the next 16 fiscal years from 2025 to 2040.

505(b)(2) Drugs and the HCPCS Storm

What is Going On?

After 2020, the HCPCS climate changed with ongoing drug shortages and increased use of unlisted codes ("NOC" which are unspecified/miscellaneous codes, e.g., J9999 or J3490) due to the swell of provider-administered drug approvals, particularly of 505(b)(2) drugs. According to MMIT, 60% of approved NDAs were submitted via the 505(b)(2) pathway.

So, the Centers for Medicare & Medicaid Services (CMS) took steps in Fall 2022 to recognize the value of 505(b)(2) value-added medicines that are not therapeutically equivalent to their reference products by approving distinct HCPCS codes for them based upon FDA equivalence status. An important change to the approval process was that The Consolidated Appropriations Act of 2022 now requires CMS to review 505(b)(2) drugs for HCPCS designation within 180 days of launch. To date (July 2023), 60+ 505(b)(2) products have been assigned a unique code. https://www.mmitnetwork.com/thought-leadership/new-hcpcs-codes-for-generics-what-payers-and-manufacturers-should-know-to-ensure-accurate-reimbursement

What's the Problem? An Example

505(b)(2) Report

DRUG NAME	What Are They?	NDC	J-code
Bendamustine	BendaAPO	60505-6228-00	J9058
Bendamustine	BendaBAXTER	60505-6228-00	J9059
Vivamusta	Vivamusta	71225-0120-01	J9056
Belrapso	Belrapso	42367-0521-25, 42367-0520-25	J9036
Bendeka	Bendeka	63459-0348-04	J9034
Treanda	TreandaGen	63459-0391-20, 63459-0391-20	J9033
Bendamustine	BendaGenAPO	60505-6095-00, 60505-6096-00	J9033
Bendamustine	BendaGenMEI	71288-0102-10, 71288-0103-20	J9033
Bendamustine	BendaGenEUGIA	55150-0391-01, 55150-0392-01	J9033
Bendamustine	BendaGenBlueP	68001-0571-41, 68001-0572-41	J9033
Bendamustine	BendaGenACCORD	16729-0251-05, 16729-0250-03	J9033

What's the Problem?

- **Matching National Drug Codes to HCPCS can be tricky.** Currently over 68% of payers require NDC codes. Incorrect NDC codes have been a billing problem for the last several years. For any given chemical compound, there may be multiple unique HCPCS codes that correspond to certain NDCs. Some of these NDCs are generics and some 505(b)(2)s. It is hard to know which 11-digit NDC matches to a HCPCS when there are multiple choices, The HCPCS is never conveyed on the package or label. A mismatch can cause a claim to be denied and/or cause extra steps to payment.
- **Keeping up with the quarterly load of codes is hard on providers**. CMS issues codes each quarter; plus, manufacturers gain additional 505(b)(2)s approvals on an ongoing basis. Providers must constantly change their computerized charge documents to reflect these changes. The last thing stretched offices and clinics need is more administrative tasks. https://www.mmitnetwork.com/thought-leadership/new-hcpcs-codes-for-generics-what-payers-and-manufacturers-should-know-to-ensure-accurate-reimbursement/

What's the Problem?

- **505(b)(2) drug prices are a challenge for HCPs as they can fluctuate wildly from quarter to quarter**. Additionally, drug costs change as do discounts and rebates from distributors. Choosing the right drug for a practice or clinic may be a daunting task as the best price for 505(b)(2) may change again the very next quarter, while the Average Sales Price for Medicare reimbursement may also increase or decrease. Moreover, Alchemy Healthcare , a company that tracks pricing for drugs, has indicated there have been MAJOR errors in NDC alignments from all four pricing compendia.

- **505(b)(2)s with unique HCPCS are also new for non-Medicare payers. Payers adopt new HCPCS in varying time frames**. The large payers, like United, CVS/Aetna, and CIGNA, usually adopt new codes quickly. Smaller payers and Medicaid do not—another issue for HCPs. But, even if the HCPCS is adopted, with all 505(b)(2)s, generics, biosimilars and branded drugs HCPCS, it is dubious that all payers have correctly adopted all changes for 60 codes since the beginning of 2023. This may be causing adjudication delays and unnecessary claim denials.

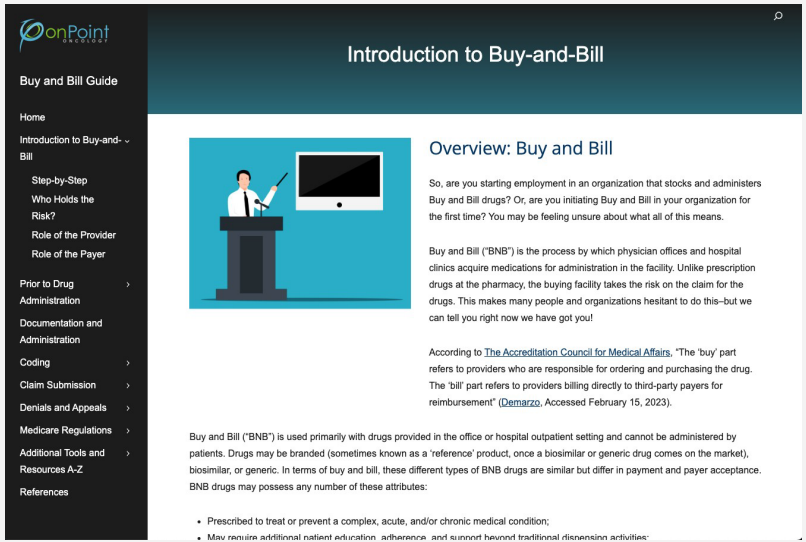
What Can You Do?

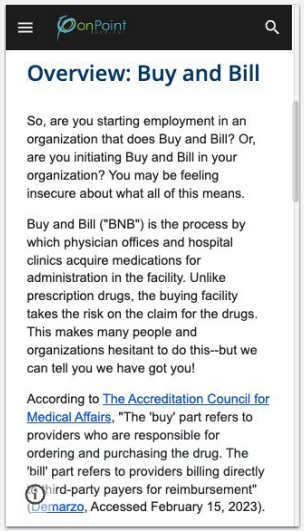
- Make sure you look at the Quarterly HCPCS and update charge documents for the drugs you use.
- Ensure that your pharmacy knows that the NDCs are quite important with these drugs and must be specified for each infusion.
- Compare prices for all drugs with the same active ingredient each quarter. Use *BuyandBill.com*.
- Bear in mind that your distributor may not have the most profitable product and, in fact, it might even be in shortage!

The People's Guide to Buy and Bill

Comprehensive BNB education via a convenient, simple-to-use, and password-protected site.

Current information at your fingertips (or your phone).





Available in web and mobile versions

Thank you for Your Attendance!!

Appendices

- References
- IRA Slides (Source: KFF)

References Regarding Proposals

- Medicare Fact Sheets
  - https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-proposed-rule-medicare-shared-savings-program
  - https://www.cms.gov/newsroom/fact-sheets/cy-2024-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center
- Legal Summaries
  - https://www.jdsupra.com/legalnews/policy-update-cms-releases-cy-2024-6554922/
  - https://www.jdsupra.com/legalnews/policy-update-cms-releases-cy-2024-2278743/
- Medical societies
  - ASCO https://old-prod.asco.org/news-initiatives/policy-news-analysis
  - AUA https://www.auanet.org/advocacy/get-involved/comment-letters-and-resources/physician-payment-and-coverage-issues/cy-2023-physician-fee-schedule-final-rule-summary

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**

Overall Timeline

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

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**

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

Which drugs are excluded from negotiation?

- 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

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

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

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