Hot Topics in Reimbursement 2023

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- The information described herein is subject to change as many of the details herein are subject to interpretation. This is our first review of the regulations and more information may be available after this presentation.
- This presentation is a look at the Final Regulations. Conclusions are subject to change.
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Agenda

- Final Fee Schedule Rule for 2023
- Final Hospital Outpatient Rule 2023
- E/M 2023
- Inflation Reduction Act

A Few Items To Review…

Status of the Public Health Emergency

All applicable waivers remain in place.

Xavier Becerra, the Secretary of the U.S. Department of Health and Human Services (HHS), has renewed the COVID-19 public health emergency (PHE), extending the many waivers that are in place until approximately January 11, 2023. HHS has HINTED that there will be one more extension.
https://aspr.hhs.gov/legal/PHE/Pages/COVID19-12Apr2022.aspx

Omnibus CAA Act of 2022

- The Consolidated Appropriations Act, 2022 (the Act), was passed by the U.S. House and Senate on March 9th and 10th, 2022, and signed into law by the President on March 15, 2022. The Act extends certain telehealth flexibilities for Medicare patients for 151 days after the official end of the federal public health emergency (PHE). Currently, the PHE will end in mid-July unless further extended.
- Telehealth stakeholders will have a brief 5-month (151 days) glide path for certain telehealth flexibilities instituted during the PHE. Legislation is essential because without Congressional action, CMS does not have the authority to allow most of the flexibilities to continue once the PHE ends.

CAA 2022 (Cont'd)

1. **Medicare Will Pay for Telehealth Provided at Home**
    a) Perhaps the biggest change provided by the Act is the new definition of "originating site" to mean "any site in the United States at which the eligible telehealth individual is located at the time the service is furnished…including the home of an individual." Before the PHE, the statute restricted Medicare coverage to services delivered to patients located at hospitals and other provider facilities (i.e., not the patient's home).
    b) The PHE flexibilities waived the originating site requirement for telehealth services, allowing providers to receive Medicare payment for delivering telehealth services to patients at home. The new law continues this flexibility for 151 days past the end of the PHE.
2. **Expands List of Telehealth Practitioners**
    a) Prior to COVID-19, only physicians, nurse practitioners, physician assistants, and other specified providers could deliver Medicare covered telehealth services. Under the new law, the list of telehealth practitioners will continue to be expanded to include qualified occupational therapists, physical therapists, speech language pathologists, and audiologists for 151 days past the end of the PHE

CAA 2022 (Cont'd)

3. **Payment for Audio-Only Telehealth Continues**
   - Currently, Medicare covers audio-only telehealth under temporary waivers that will expire when the PHE ends. In the new legislation, Medicare coverage of audio-only telehealth services remains for 151 days after the PHE ends. Without this extension, once the PHE concludes, the emergency waiver authority ends, and so would have audio-only telehealth.
4. **Delayed In-Person Requirement for Mental Health Services via Telehealth**
   - In December 2020, Congress imposed new conditions on telemental health coverage under Medicare, creating an in-person exam requirement alongside coverage of telemental health services at a patient's home that was intended to go into effect when the PHE ends. The law included a requirement for an in-person visit within six months of the first telehealth service and subsequent in-person visits every 12 months thereafter. Now, this in-person requirement for mental health services furnished through telehealth is delayed until the 152nd day after the PHE sunsets.

Drug Waste (Part of Infrastructure)

- First, the legislation requires manufacturers of single-dose container or single-use package drugs payable under Medicare Part B to provide a rebate to the government for any discarded portion of that drug. HHS Secretary to calculate the total cost of the discarded medications, based off the Average Sales Price (or Wholesale Acquisition Cost if not available);
- HHS Secretary to notify the drug's manufacturer that they are required to provide a rebate to HHS for 100 percent of the amount of discarded medication that was recorded above a 10% low-volume threshold. This rebate would be deposited to the Medicare Trust Fund (failure by a manufacturer to provide a timely rebate would incur civil monetary penalties).
- The rebates will be charged each quarter, beginning with the first quarter of 2023, and must be paid in regular intervals, as determined appropriate by the Secretary of the U.S. Department of Health and Human Services ("HHS"). The legislation provides that, in order to enforce this provision, HHS will conduct periodic audits of both drug manufacturers and providers who submit claims. For violations of this provision, HHS will impose Civil Monetary Penalties in amounts equal to the sum of the amount that the manufacturer would have paid and twenty-five percent of such amount.
- The legislation provides exclusions for: (1) radiopharmaceuticals or imaging agents; (2) Food and Drug Administration ("FDA")-approved drugs that require filtration prior to administration; and (3) new drugs approved by the FDA on or after the date of enactment and have been paid by Medicare for less than 18 months.
- Separate Rulemaking will be released regarding this provision.

All of These Are Important to PFS Understanding!

The Final Physician Fee Schedule for 2023

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 Final Regulations 2023

This presentation is based on published rules

- Physician Rule: https://www.cms.gov/newsroom/press-releases/hhs-finalizes-physician-payment-rule-strengthening-access-behavioral-health-services-and-whole

- Hospital Outpatient Rule: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS

Sequestration

- Medicare 2% across the board started on April 1, 2013
- Impacts everything including drugs
- 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

For more information visit this website:
https://www.nejm.org/doi/full/10.1056/NEJMp1303266?query=TOC&goback=.gde_917937_member_224781137&page=-33&sort=oldest

Conversion Factor 2023

TABLE 146: Calculation of the CY 2023 PFS Conversion Factor

CY 2022 Conversion Factor		34.6062
Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		33.5983
Statutory Update Factor	0.00 percent (1.0000)	
CY 2023 RVU Budget Neutrality Adjustment	-1.60 percent (0.9840)	
CY 2023 Conversion Factor		**33.0607**

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	$33.0607	-4.47

Specialty Impact of the CF for 2023

- Cardiology= -1%
- Dermatology = 1%
- Family practice = 0%
- Gastro = -1%
- Hem-Onc = -1%
- Radiation = -1%

- But, the impact of the RVU changes and CF changes is an estimated range of -3% to +7% per Table 148 of the Final Rule

Definitions of Telehealth Categories

- 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).

The Biggest Concepts to Know Right Now

There are two types of temporary Telehealth services

- Those that will expire 151 days after the expiration of the Public Health Emergency (Estimate: Mid-April)
- Those that are Category 3 that MAY become permanent or expire at the end of 2023.

Category 1: Additions 2023

TABLE 13: Services Finalized for Permanent Addition to the Medicare Telehealth Services List on a Category 1 Basis

HCPCS	Short Descriptor
G0316	Prolonged inpatient or observation services by physician or other QHP
G0317	Prolonged nursing facility services by physician or other QHP
G0318	Prolonged home or residence services by physician or other QHP
G3002	Chronic pain tx monthly b
G3003	Addition 15m pain mang

Category 3 Codes: End 12/31/2023

CMS' Category 3 list contains services that likely have a clinical benefit when furnished via telehealth, but lack sufficient evidence to justify permanent coverage. CMS proposed adding 54 codes to that Category 3 list. The services fall into nine categories: (1) therapy; (2) electronic analysis of implanted neurostimulator pulse generator/transmitter; (3) adaptive behavior treatment and behavior identification assessment; (4) behavioral health; (5) ophthalmologic; (6) cognition; (7) ventilator management; (8) speech therapy; and (9) audiologic. The complete list can be found at this link.

Keep in mind, these codes will expire December 31, 2023. In this year's proposed rule, CMS declined any further extension, so all Category 3 codes will expire at the end of 2023. In the event the PHE extends well into 2023, CMS said it will consider a further extension of the Category 3 codes at that time.

Category 3 Codes

TABLE 12: Services Finalized for Addition to the Medicare Telehealth Services List on a Category 3 Basis Through the End of CY 2023

HCPCS	Short Descriptor
90875	Psychophysiological therapy
90901	Biofeedback train any meth
92012	Eye exam estab pat
92014	Eye exam & tx estab pt 1/>vst
92507	Speech/hearing therapy
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
94005	Home vent mgmt supervision
95970	Alys npgt w/o prgrmg
95983	Alys brn npgt prgrmg 15 min
95984	Alys brn npgt prgrmg addl 15
96105	Assessment of aphasia
96110	Developmental screen w/score
96112	Devel tst phys/qhp 1st hr
96113	Devel tst phys/qhp ea addl
96127	Brief emotional/behav assmt
96170	Hlth bhv ivntj fam wo pt 1st
96171	Hlth bhv ivntj fam w/o pt ea
97129	Ther ivntj 1st 15 min
97130	Ther ivntj ea addl 15 min
97150	Group therapeutic procedures
97151	Bhv id assmt by phys/qhp
97152	Bhv id supvt assmt by 1 tech
97153	Adaptive behavior tx by tech
97154	Grp adapt bhv tx by tech
97155	Adapt behavior tx phys/qhp
97156	Fam adapt bhv tx gdn phy/qhp
97157	Mult fam adapt bhv tx gdn
97158	Grp adapt bhv tx by phy/qhp
97530	Therapeutic activities
97537	Community/work reintegration
97542	Wheelchair mngment training
97763	Orthc/prostc mgmt sbsq enc
98960	Self-mgmt educ & train 1 pt
98961	Self-mgmt educ/train 2-4 pt
98962	Self-mgmt educ/train 5-8 pt
99473	Self-meas bp pt educaj/train
0362T	Bhv id supvt assmt ea 15 min
0373T	Adapt bhv tx ea 15 min

What Expires 151 Days Post-PHE

- Audio Only Telehealth Services
  - With the exception of certain telemental health services, CMS stated two-way interactive audio-video telecommunications technology will continue to be the Medicare requirement for telehealth services following the PHE. This is because Section 1834(m)(2)(A) of the Social Security Act requires telehealth services be analogous to in-person care by being capable of serving as a substitute for the face-to-face encounter.
  - CMS wants providers to add modifier 93, which indicates an audio-only service, effective January 1, 2023. CMS intends to adopt the telehealth waiver extension that Congress passed in Consolidated Appropriations Act of 2022. The extension locks in a wide range of telehealth waivers for 151 days after the PHE expires, including the audio-only exceptions that have been so popular with providers.

What Expires 151 Days Post-PHE

- Postpone the Effective Date of the Telemental Health Six-Month Rule Until 151 Days After PHE Ends
  - In 2020, Congress imposed new conditions on telemental health coverage under Medicare, creating an in-person exam requirement alongside coverage of telemental health services when the patient is located at home. Under the rule, Medicare will cover a telehealth service delivered while the patient is located at home if the following conditions are met:
    1. The practitioner conducts an in-person exam of the patient within the six months before the initial telehealth service;
    2. The telehealth service is furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder (other than for treatment of a diagnosed substance use disorder (SUD) or co-occurring mental health disorder); and
    3. The practitioner conducts at least one in-person service every 12 months of each follow-up telehealth service.
  - For a full understanding of the rule, read the frequently asked questions and what it means for practitioners at Medicare Telehealth Mental Health FAQs.

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 expire at the end of the calendar year in which the PHE ends…so, the supervision waiver will end December 31, 2023.

We Will Review 2023 CPT E/M Later

2022 Final Rule for Split Visits…Let's Step Back

There are three ways to bill for APP Visits

1. Incident to (In-Office)
2. Under the APP number (Anywhere)
3. Split Visits (Out of Office)

“Split Visits

- So what should you do for 2023..
  - “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

Another Place CMS Differs from the AMA

- CMS will have 3 separate codes (CPT has two), as follows:
  - **G0316** (Prolonged hospital inpatient or observation care evaluation and management service[s] beyond the total time for the primary service [when the primary service has been selected using time on the date of the primary service]; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact [list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services]. [Do not report G0316 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0, 99415, 99416]. [Do not report G0316 for any time unit less than 15 minutes]).
  - **G0317** (Prolonged nursing facility evaluation and management service[s] beyond the total time for the primary services [when the primary service has been selected using time on the date of the primary service]; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact [list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management service[s]. [Do no report G0317 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0]. [Do not report G0317 for any time unit less than 15 minutes]).
  - **G0318** (Prolonged home or residence evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99345, 99350 for home or residence evaluation and management services). (Do not report G0318 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99417). (Do not report G0318 for any time unit less than 15 minutes))

CMS E/M Thresholds: Prolonged Services

TABLE 24: Required Time Thresholds to Report Other E/M Prolonged Services

Primary E/M Service	Prolonged Code*	Time Threshold to Report Prolonged	Count physician/NPP time spent within this time period (surveyed timeframe)
Initial IP/Obs. Visit (99223)	G0316	105 minutes	Date of visit
Subsequent IP/Obs. Visit (99233)	G0316	80 minutes	Date of visit
IP/Obs. Same-Day Admission/Discharge (99236)	G0316	125 minutes	Date of visit to 3 days after
IP/Obs. Discharge Day Management (99238-9)	n/a	n/a	n/a
Emergency Department Visits	n/a	n/a	n/a
Initial NF Visit (99306)	G0317	95 minutes	1 day before visit + date of visit +3 days after
Subsequent NF Visit (99310)	G0317	85 minutes	1 day before visit + date of visit +3 days after
NF Discharge Day Management	n/a	n/a	n/a
Home/Residence Visit New Pt (99345)	G0318	140 minutes	3 days before visit + date of visit + 7 days after
Home/Residence Visit Estab. Pt (99350)	G0318	110 minutes	3 days before visit + date of visit + 7 days after
Cognitive Assessment and Care Planning (99483)	G2212	100 minutes	3 days before visit + date of visit + 7 days after
Consults	n/a	n/a	n/a

* Time must be used to select visit level. Prolonged service time can be reported when furnished on any date within the primary visit's surveyed timeframe, and includes time with or without direct patient contact by the physician or NPP. Consistent with CPT's approach, we do not assign a frequency limitation.

CMS will change the payment status for CPT codes 99358 and 99359 to "I" (Not valid for Medicare purposes. Medicare uses another code for reporting of, and payment for, these services).

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 a new JZ modifier when the full amount is administered, to “attest” that there were no discarded amounts.

Drug Wastage Implementation

- This definition includes single-dose or single-use “kits.” CMS further proposes that for a drug to meet this definition, all National Drug Codes (NDCs) assigned to the drug’s billing and payment code must be single-dose containers or single-use packages.
  - Exclusions: Consistent with the statutory text, CMS reinforced that the following drugs would be excluded from this definition: bundled drugs, radiopharmaceuticals and imaging agents, drugs requiring filtration, and drugs for which payment under Medicare Part B has been made for fewer than 18 months.
    - The 18-month period runs from the date of first sale as reported to CMS for the drug to the first day of the sixth calendar quarter thereafter. This 18-month exclusion would apply only once for a drug. If additional NDCs in the same billing and payment code were subsequently approved under the same FDA-approved application, a new 18-month period would not apply.
    - This period starts 11/15/2021.

Drug Wastage Implementation

- The Infrastructure Act specifies that absent “unique circumstances,” the refund is the amount equal to the estimated amount by which
  - 10% of the estimated total allowed charges for a drug during a quarter exceeds the product of
  - the total number of units of the billing and payment code for such drug that were discarded during such quarter and
  - the payment limit amount for the refundable single-dose container or single-use package drug
- Reports of what is owed will be potentially coordinate with other rebate reports and will be released by 12/31/2022.

Drug Wastage: Drugs Cited by CMS

HCPCS Code	Brand Name	CY 2020 Total Allowed Amount	Percent Units Discarded	Percent Discarded Units - 10%	Estimated Annual Refund	Estimated Quarterly Refund
J9041	Velcade	$ 400,736,898.62	26.67%	16.67%	$ 66,802,841.00	$ 16,700,710.25
J9043	Jevtana	$ 135,486,070.48	28.14%	18.14%	$ 24,577,173.19	$ 6,144,293.30
J2796	Nplate	$ 240,489,959.82	16.83%	6.83%	$ 16,425,464.26	$ 4,106,366.06
J9264	Abraxane	$ 352,102,440.73	14.46%	4.46%	$ 15,703,768.86	$ 3,925,942.21
J0775	Xiaflex	$ 55,922,761.61	20.18%	10.18%	$ 5,692,937.13	$ 1,423,234.28
J9309	Polivy	$ 49,591,437.88	15.79%	5.79%	$ 2,871,344.25	$ 717,836.06
J9042	Adcetris	$ 167,324,055.19	11.41%	1.41%	$ 2,359,269.18	$ 589,817.29
J9179	Halaven	$ 45,528,228.20	12.60%	2.60%	$ 1,183,733.93	$ 295,933.48
J2997	Activase	$ 71,164,289.22	11.34%	1.34%	$ 953,601.48	$ 238,400.37
J0485	Nulojix	$ 65,351,086.26	11.43%	1.43%	$ 934,520.53	$ 233,630.13
Q4195	PuraPly	$ 6,233,097.24	20.47%	10.47%	$ 652,605.28	$ 163,151.32
J9229	Besponsa	$ 25,178,218.24	12.06%	2.06%	$ 518,671.30	$ 129,667.82
J2562	Mozobil	$ 17,986,116.53	12.41%	2.41%	$ 433,465.41	$ 108,366.35
J0223	Givlaari	$ 3,953,268.84	20.80%	10.80%	$ 426,953.03	$ 106,738.26
J9153	Doxil, Vyxeos	$ 8,651,250.34	14.63%	4.63%	$ 400,552.89	$ 100,138.22
J1640	Hemin	$ 7,204,322.44	14.87%	4.87%	$ 350,850.50	$ 87,712.63
J9205	Onyvide	$ 54,328,144.16	10.50%	0.50%	$ 271,640.72	$ 67,910.18
J0565	Zinplava	$ 2,724,776.12	19.55%	9.55%	$ 260,216.12	$ 65,054.03
J9228	Yervoy	$ 375,059,594.99	10.06%	0.06%	$ 225,035.76	$ 56,258.94
J3300	Triescense	$ 8,454,347.46	11.44%	1.44%	$ 121,742.60	$ 30,435.65
Q4106	Dermagraft	$ 2,098,353.95	15.07%	5.07%	$ 106,386.55	$ 26,596.64
J9352	Yondelis	$ 9,562,087.18	10.95%	0.95%	$ 90,839.83	$ 22,709.96
J9307	Folotyn	$ 22,242,951.07	10.27%	0.27%	$ 60,055.97	$ 15,013.99
Q4101	Apligraf	$ 2,701,473.78	12.11%	2.11%	$ 57,001.10	$ 14,250.27
J9262	Synribo	$ 342,668.12	19.96%	9.96%	$ 34,129.74	$ 8,532.44
J0291	Zemdri	$ 264,734.03	10.80%	0.80%	$ 2,117.87	$ 529.47
				Total	$ 141,516,918.47	$35,379,229.62

Coverage for Colorectal Cancer 2023

- Colorectal Screening: For CY 2023, CMS proposes two updates to expand Medicare coverage policies for colorectal cancer screening.

1. First, CMS will expand Medicare coverage for certain colorectal cancer screening tests by reducing the minimum age payment limitation to 45 years.
2. Second, CMS will expand the regulatory definition of colorectal cancer screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. There will be no patient cost with these tests.

Behavioral Health New Code for 2023

CMS addresses the shortage of behavioral health services in these ways:

1. creates a new G-code, G0323 (Work RVU 0.61), to allow clinical psychologists (“CPs”) and clinical social workers (“CSWs”) to bill for general behavioral health integration (“GBHI”); and
2. amends the direct supervision requirement under CMS’ “incident to” regulation at 42 CFR § 410.26 to allow behavioral health services to be furnished by clinical staff under the general supervision of a physician or non-physician practitioner (“NPP”), so long as CMS’ “incident to” requirements and state licensure requirements are met.
3. Allows psych visit code, 90791, to be used for initiating BH services.

Pain Management 2023 for Medicare Patients

Code	Description
G3002	Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and/or maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, for example, physical therapy and occupational therapy, complementary and integrative approaches, and community-based care, as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using HCPCS code G3002, 30 minutes must be met or exceeded)
G3003	Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month

Vaccine Pricing 2023

- CMS asked for comments on the costs involved in furnishing preventive vaccines, like pneumonia, flu and hepatitis B. CMS got comments on the following:
  - The fact that non-COVID vaccine are tied to 96372 rather than 36000 has annoyed many stakeholders. CMS will pay $30 per dose for administration.
  - How the PHE may have impacted admin costs, including whether those costs will continue beyond the PHE. COVID vaccine will stay at $40 per dose for administration.
- This year vaccine administration allowables were updated for more parity with COVID vaccine. Geographical adjustment factors (GAFs) and Medicare Economic Index (MEI) will be added to vaccine administration to make administration of vaccines more cost-effective for providers.

E-Prescribing Controlled Substances

- The SUPPORT ACT established January 1, 2022 as a compliance date for this requirement.
- CMS will extend the compliance date for ECPS requirements until January 1, 2023. In 2023, warning letters will be sent but no monetary penalties will be levied. This was reinforced in the Final Rule.
- CMS will extend the compliance date for Part D controlled substance prescriptions written for beneficiaries in long-term care facilities until January 1, 2025
- 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.

EPCS Exceptions

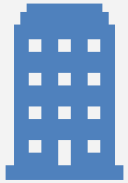
- Exceptions to the aforementioned requirements *would be for prescriptions issued where the prescriber and dispensing pharmacy are the same entity.*
- Other exceptions:
  - prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year,
  - prescribers who are prescribing during a recognized emergency (like a natural disaster or pandemic), and
  - prescribers who request and receive a waiver from CMS due to extraordinary circumstances would be also exempt from the 70% rule.

Appropriate Use Criteria Timeline

Penalties Postponed Until Further Notice!!!

Summary of QPP Final Rule 2023

MVPs (MIPS VALUE PATHWAYS): The Big Concept



An option to motivate providers to move away from self-selected activities and options

An aligned set of measures designed to be more meaningful for improved patient care

MIPS is expensive and time consuming

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. It had been 2027.

How Are MVPs Scored

- First and foremost, you must REGISTER to be in MVPs as an individual, a group, or a subgroup.
- Quality Reporting
  - MVP Participants will select 4 quality measures. One must be an outcome measure (or a high-priority measure if an outcome isn't available or applicable). This can include an outcome measure calculated by CMS through administrative claims, if available in the MVP.
- Improvement Activities
  - MVP Participants will select 2 medium-weighted improvement activities OR one high-weighted improvement activity OR IA_PCMH (participation in a patient-centered medical home).

How Are MVPs Scored

- Cost Performance Category
  - MVP Participants will be scored on the cost measures included in the selected MVP.
- Foundational Layer (MVP Agnostic)
  - Population Health Measures
    - MVP Participants will select, at the time of MVP Participant registration, one population health measure to be calculated on. The results will be added to the quality score.
  - For the 2023 performance period, CMS anticipates there will be 2 population health measures available for selection.
    - Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups (finalized in CY 2021 PFS Final Rule).
    - Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (finalized in CY 2022 PFS Final Rule)

How Are MVPs Scored

- Promoting Interoperability
  - MVP Participants will report on the same Promoting Interoperability measures required under traditional MIPS, unless they qualify for reweighting of the Promoting Interoperability performance category due to clinician type, special status, or an approved Promoting Interoperability Hardship Exception Application.
- For an Example of an MVP, see https://www.asco.org/news-initiatives/policy-news-analysis/more-4-conversion-factor-decrease-2023-medicare-physician#:~:text=CMS%20has%20proposed%20a%20Calendar,Congress%20funded%20for%20CY%202022.

New MVPs for 2023

- Advancing Cancer Care
- Optimal Care for Kidney Health
- Supportive Care for Neurodegenerative Conditions
- Optimal Care for Patients with Episodic Neurological Conditions
- Promoting Wellness

MVPs 2023--ALL

2023 MVPs

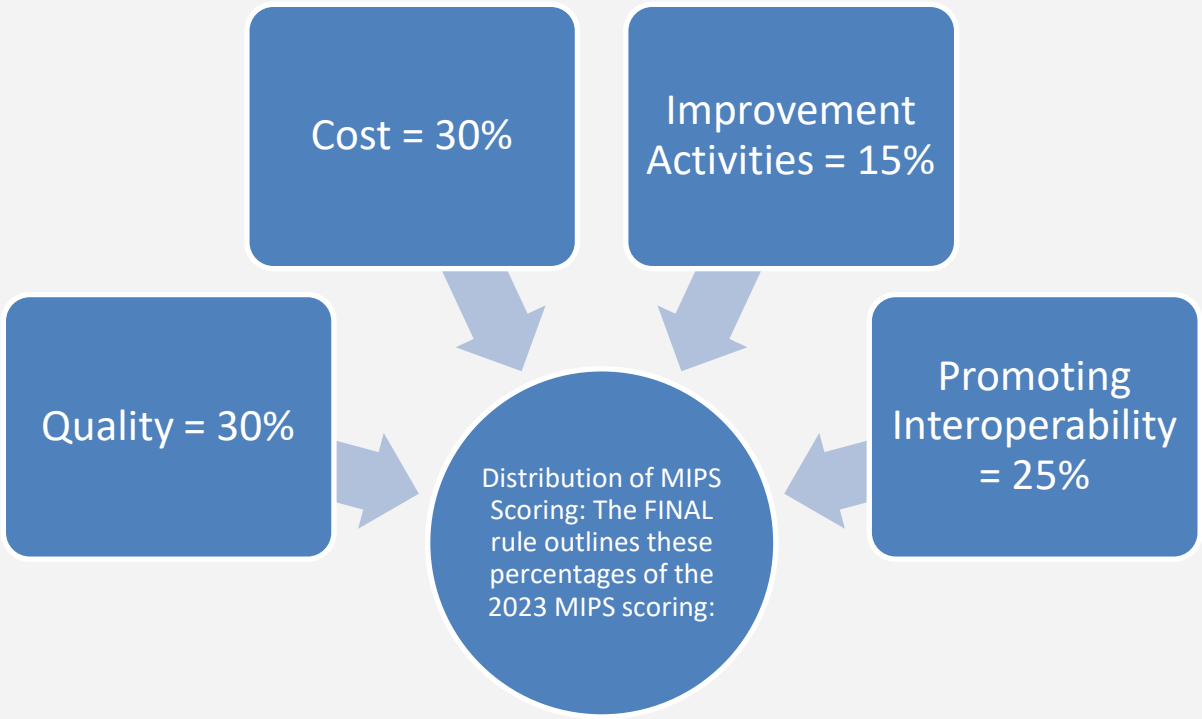
- Anesthesia
- Chronic Disease Management
- Emergency Medicine
- Heart Disease
- Lower Extremity Joint Repair
- Rheumatology
- Stroke Care and Prevention

UPDATED

The Calendar Year (CY) 2023 Physician Fee Schedule (PFS) Proposed Rule includes proposals for 5 new MVPs and revisions to the 7 previously finalized MVPs listed on this webpage. The proposed new MVPs are the following:

- Advancing Cancer Care
- Optimal Care for Kidney Health
- Optimal Care for Neurological Conditions
- Supportive Care for Cognitive-Based Neurological Disorders
- Promoting Wellness

MIPS 2023: Final (And the Same)



MIPS 2023

Must report at least 6 measures including at least one outcome measure

Data completeness standard will be 75% for 2024 and 2025, up from 70% for 2023

Improvement Activities and Promoting Interoperability will be 90-days again.

APMs

- CMS finalized several policies to reduce burden and facilitate participation in Advanced APMs.
  - However, CMS recognizes the incentive for participating in an Advanced APM will diminish significantly over the next couple of years. CMS is therefore seeking comment about what's coming.
  - There was a five percent lump bonus for participating in Advanced APMs between payment years 2019 and 2024 (performance years 2017 to 2022), but
  - there is no bonus in payment year 2025 (performance year 2023), and only a small 0.75% Conversion Factor update available in payment years 2026 onward (performance year 2024 onward). This will have to be legislated some time this year as it is the law per MACRA

Shared Savings Program

- Medicare Shared Savings Program (MSSP) Revisions: CMS finalized several changes to the MSSP to increase participation and advance health equity, including longer glide paths to downside risk for accountable care organizations (ACOs). For example, any MSSP ACO presently participating in BASIC Track Level A or B can elect to eschew downside risk for the balance of its current agreement period.
  - Beginning in 2024, CMS will offer new ACOs (meeting certain criteria) the opportunity to receive advanced shared savings payments of $250,000 to fund infrastructure development.
  - CMS also made changes to benchmark calculations intended to grow and sustain long-term program participation.
  - Finally, CMS implemented several changes to reduce the "administrative burden".

Medicare Hospital Outpatient Final Rule 2023

OPPS Payment Update

- MS finalizes an update to OPPS rates of 3.8% for CY 2023 — higher than the 2.7% it had proposed.
  - This update is based on a market basket percentage increase of 4.1%, reduced by 0.3 percentage points for productivity. These payment adjustments, in addition to other changes in the rule, are estimated to result in an overall increase in OPPS payments of 4.5% compared to CY 2022 payments.
  - For hospitals that do not publicly report quality measure data, CMS will continue to impose the statutory 2.0 percentage point additional reduction in payment, resulting in a 1.8% OPPS update. CMS estimates that total payments to hospitals (including beneficiary cost-sharing) will increase by approximately $3.0 billion in CY 2023 compared to CY 2022.

2023 Drug Payments

All will be bundled into the APC. This is for non-pass-through drugs whose cost is $135 or less per encounter,, a $5 increase.

Pay non-pass-through drugs acquired under the 340B program at ASP plus 6%, not ASP – 22.5%

340B Will Change....

- CMS has withdrawn payment cuts for drugs acquired through the 340B program in 2023. Recently, the Supremes ruled that CMS improperly assessed and reduced reimbursements for 340B drugs when it changed payment policy in 2018.
- A Judge ordered CMS to adjust drug allowables ASAP. CMS has changed prices for 340B hospitals. Modifiers will still be used, however.
- CMS also asked for comments on how to remedy the reductions implemented between 2018 and 2022. This will be the subject of future rule-making.

Hospital Telehealth 2023

- CMS finalized its proposal to designate remote mental health services furnished by clinical staff to a beneficiary's home as a covered outpatient service under OPPS. The clinical staff must be physically located in the hospital when providing the mental health services.
- Consistent with other related Medicare payment policies, a beneficiary must undergo an in-person visit within six months of starting telehealth visits under OPPS and within 12 months of each mental health visit furnished.
- Clinical staff must be able. to provide two-way, audio/visual services but may use audio-only to accommodate a beneficiary's technological limitations, abilities and preferences.
- The requirement for an in-person visit is waived for beneficiaries who began receiving mental health telehealth services in their homes during the 151-day period after the end of the PHE.

Specific Codes for Hospital Telemental Health

HCPCS	Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service)

PPE Compensation

- The agency also outlines a potential pay increase to pay hospitals for the extra cost of buying domestically produced N95 respirators. Payments would be made bi weekly and reconciled in cost reports.

Supervision in Hospital Outpatient

- CMS will allow nonphysician practitioners (NPPs) – nurse practitioners, clinical nurse specialists, physician assistants, certified registered nurse anesthetists and certified nurse midwives – can provide general, direct and personal supervision of selected outpatient diagnostic services to the extent that they are authorized to do so under their scope of practice and applicable state law.

Site Neutral Payments

- For CY 2023, CMS will continue the policy of paying the PFS-equivalent rate of 40% of the OPPS payment rate for hospital outpatient clinic visits coded under HCPCS G0463 when delivered by a previously excepted off-campus provider-based department.
- However, in a welcome development for many rural providers, CMS finalized its policy to exempt services furnished by excepted off-campus provider-based departments **of rural sole community hospitals**.
- The agency noted that exempting rural sole community hospitals from the site-neutral payment policy will help maintain access to care in rural areas. Stakeholders urged CMS to extend this exemption to other rural hospitals, but CMS declined to do so at this time.

Rural Emergency Hospitals

- The Conditions of participation for REHs announced in that rule generally track the CoPs for CAHs and would allow for REHs to be staffed with a registered nurse, clinical nurse specialist or licensed practical nurse when the REH is providing emergency or observation services, with higher-level staffing (e.g., physician or non-physician practitioner) only required to be available to respond when needed.
- CMS also proposed to allow REHs to provide a wide range of outpatient services, subject to a community needs assessment.
- Although REHs are prohibited by statute from providing inpatient service, they are not allowed to keep patients more than 24 hours.
- REHs will be paid 105% of the OPPS for covered services, but patients will not pay the +5%.

Other Reimbursement Rules 2023

- The agency will remove 10 procedures from the inpatient-only list, so that they can be paid for when performed at outpatient facilities and will 8 new CPT codes to the list.
- CMS will add a new prior authorization category for outpatient hospitals, as well -- facet joint injections and nerve destruction -- starting in March 2023.

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E/M 2023

Overall Changes for 2023

- E/M Introductory Guidelines are revised related to
  - Hospital Inpatient and Observation Care Services codes 99221-99223, 99231-99239,
  - Consultations codes 99242-99245, 99252-99255,
  - Emergency Department Services codes 99281-99285,
  - Nursing Facility Services codes 99304-99310, 99315, 99316,
  - Home or Residence Services codes 99341, 99342, 99344, 99345, 99347-99350
- Except ED Department codes for which TIME is not a factor, most of these have changed documentation criteria to MDM or Time.

Deletions for 2023

- Observation Services 99217-99220
- Consultations 99241 and 99251
- Nursing Facility Services 99318
- Domiciliary, Rest Home or Custodial Care Services 99324-99328, 99334-99337, 99339, 99340
- Deletion of Home or Residence Service 99343
- Deletion of Prolonged Services Codes 99354-99357

The Definition of a New Patient

- A new patient is one who has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three years.
- When advanced practice nurses and physician assistants are working with physicians, they are considered as working in the exact same specialty and subspecialty as the physician.

- This definition will not be wholly adopted by Medicare as they have no subspecialties.

Initial Versus Subsequent Services

- Some categories apply to both new and established patients (e.g., hospital inpatient or observation care). These categories differentiate services by whether the service is the initial service or a subsequent service. For the purpose of distinguishing between initial or subsequent visits, professional services are those face-to-face services rendered by physicians and other qualified health care professionals who may report evaluation and management services.
  - An initial service is when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, during the inpatient, observation, or nursing facility admission and stay.
  - Same limitations for Medicare.

Services Reported Separately (MDM)

- Tests that do not require separate interpretation (e.g., tests that are results only) and are analyzed as part of MDM do not count as an independent interpretation, but may be counted as ordered or reviewed for selecting an MDM level.
  - The performance of diagnostic tests/studies for which specific CPT codes are available may be reported separately, in addition to the appropriate E/M code.
  - The interpretation of the results of diagnostic tests/studies (i.e., professional component) with preparation of a separate distinctly identifiable signed written report may also be reported separately, using the appropriate CPT code and, if required, with modifier 26 appended.
- This is a clarification from the 2021 guidelines.

Revisions to the MDM Chart

- The new AMA document includes revisions to the MDM chart.
  - Under low complexity of problems addressed, “1 acute, uncomplicated illness or injury requiring hospital inpatient or observation level of care," will be added to the list.
  - In addition, there are two revisions to the examples for high risk of morbidity. Parenteral controlled substances will be added to the list of examples and “Decision regarding hospitalization” will be revised to “Decision regarding hospitalization or escalation of hospital-level care.”
  - We will have a new Cheat Sheet for RxVantage members soon.

Problems Addressed

- A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified health care professional reporting the service. This includes consideration of further testing or treatment that may not be elected by virtue of risk/benefit analysis or patient/parent/guardian/surrogate choice.
  - Notation in the patient's medical record that another professional is managing the problem without additional assessment or care coordination documented does not qualify as being addressed or managed by the physician or other qualified health care professional reporting the service.
  - Referral without evaluation (by history, examination, or diagnostic study(ies) or consideration of treatment does not qualify as being addressed or managed by the physician or other qualified health care professional reporting the service.
  - For hospital inpatient and observation care services, the problem addressed is the problem status on the date of the encounter, which may be significantly different than on admission. It is the problem being managed or co-managed by the reporting physician or other qualified health care professional and may not be the cause of admission or continued stay.

Definition of An Independent Historian (MDM)

- Independent historian(s): An individual (e.g., parent, guardian, surrogate, spouse, witness) who provides a history in addition to a history provided by the patient who is unable to provide a complete or reliable history (e.g., due to developmental stage, dementia, or psychosis) or because a confirmatory history is judged to be necessary.
- In the case where there may be conflict or poor communication between multiple historians and more than one historian is needed, the independent historian requirement is met.
- It does not include translation services.
- The independent history does not need to be obtained in person but does need to be obtained directly from the historian providing the independent information.

Initial & Subsequent Inpatient or Observation Care

Code	MDM	Time
99221	Straightforward or Low	40 mins
99222	Moderate	55 mins
99223	High	75 mins
99231	Straightforward or Low	25 mins
99232	Moderate	35 mins
99233	High	50 mins

Inpatient or Observation Care Admission & Discharge the Same Day

Code	MDM	Time
99234	Straightforward or Low	45 mins
99235	Moderate	70 mins
99236	High	85 mins

Hospital Discharge Services

Code	MDM	Time
99238	N/A	≤ 30 mins
99239	N/A	> 30 mins

Emergency Department Services

Code	MDM	Time
99281	No presence of MD	N/A
99282	Straightforward or Limited	N/A
99283	Low	N/A
99284	Moderate	N/A
99285	High	N/A

REVIEW: Office/Outpatient Prolonged Services

Extended Services 2021

Codes plus add-on	CPT Time 99417	CMS Time G2212
99205 plus add-on x1	75-89 minutes	89-103 minutes
99205 plus add-on x2	90-104 minutes	104-118 minutes
99205 plus add-on x3	> 105 minutes*	> 119 minutes*
99215 plus add-on x1	55-69 minutes	69-83 minutes
99215 plus add-on x2	70-84 minutes	84-98 minutes
99215 plus add-on x3	> 85 minutes*	> 99 minutes*

Can bill for each additional 15 minutes

Prolonged Services: CPT

Code	Patient Contact	Minimum Reportable Time	Use in Conjunction with	DON'T report with
99417	Face-to-face and/or non-FTF	Reported with 99205 ≥ 75 mins Reported with 99215 ≥ 55 mins Total encounter time	99205, 99215, 99245, 99345, 99350, 99483	On same date of service: 90833, 90836, 90838, 99358, 99359, 99415, 99416
99418	Face-to-face and/or non-FTF	Reported with 99233 ≥ 65 mins Reported with 99310 ≥ 60 mins Total encounter time	99223, 99233, 99236, 99255, 99306, 99310	On same date of service: 90833, 90836, 99358, 99359

But CMS Says Nooooo

HCPCS	Short Descriptor
G0316	Prolonged inpatient or observation services by physician or other QHP
G0317	Prolonged nursing facility services by physician or other QHP
G0318	Prolonged home or residence services by physician or other QHP
G3002	Chronic pain treatment monthly bundle
G3003	Addition 15m pain management

Source - CMS-1770-F, Table 13: Services Finalized for Permanent Addition to the Medicare Telehealth Services List on a Category 1 Basis.

Medicare Prolonged Services

TABLE 24: Required Time Thresholds to Report Other E/M Prolonged Services

Primary E/M Service	Prolonged Code*	Time Threshold to Report Prolonged	Count physician/NPP time spent within this time period (surveyed timeframe)
Initial IP/Obs. Visit (99223)	G0316	105 minutes	Date of visit
Subsequent IP/Obs. Visit (99233)	G0316	80 minutes	Date of visit
IP/Obs. Same-Day Admission/Discharge (99236)	G0316	125 minutes	Date of visit to 3 days after
IP/Obs. Discharge Day Management (99238-9)	n/a	n/a	n/a
Emergency Department Visits	n/a	n/a	n/a
Initial NF Visit (99306)	G0317	95 minutes	1 day before visit + date of visit +3 days after
Subsequent NF Visit (99310)	G0317	85 minutes	1 day before visit + date of visit +3 days after
NF Discharge Day Management	n/a	n/a	n/a
Home/Residence Visit New Pt (99345)	G0318	140 minutes	3 days before visit + date of visit + 7 days after
Home/Residence Visit Estab. Pt (99350)	G0318	110 minutes	3 days before visit + date of visit + 7 days after
Cognitive Assessment and Care Planning (99483)	G2212	100 minutes	3 days before visit + date of visit + 7 days after
Consults	n/a	n/a	n/a

* Time must be used to select visit level. Prolonged service time can be reported when furnished on any date within

One More CMS Wrinkle…

“We proposed to change the status indicator for CPT codes 99358 and 99359 to “I,” which indicates that these codes are not valid for Medicare purposes, and that Medicare uses another code for reporting of, and payment for, these services.”

“We are also finalizing our proposal to change the status indicator for prolonged CPT codes 99358 and 99359 to “I,” which indicates CMS-1770-F653 that these codes are not valid for Medicare purposes, and that Medicare uses another code for reporting of, and payment for, these services.”

U.S. National Service Data

E/M Profiling All Practices by Payer – Established Patients in Oncology

Procedure Code	Payer Type	Distinct Count	Percent
99211	BCBS	12174	1%
99212	BCBS	15517	2%
99213	BCBS	271160	32%
99214	BCBS	446887	52%
99215	BCBS	105873	12%

Procedure Code	Payer Type	Distinct Count	Percent
99211	Commercial/Other	24325	1%
99212	Commercial/Other	29701	2%
99213	Commercial/Other	540544	32%
99214	Commercial/Other	897187	53%
99215	Commercial/Other	197525	12%

Procedure Code	Payer Type	Distinct Count	Percent
99211	Medicaid	1253	1%
99212	Medicaid	1061	1%
99213	Medicaid	27715	29%
99214	Medicaid	50854	54%
99215	Medicaid	13100	14%

Procedure Code	Payer Type	Distinct Count	Percent
99211	Medicare	45103	3%
99212	Medicare	26734	1%
99213	Medicare	556096	31%
99214	Medicare	964782	54%
99215	Medicare	206596	11%

The Inflation Reduction Act

ACA Changes

- **American Rescue Plan Act (ARPA)** expanded the premium tax credits for a two-year period, making them more generous for lower-income beneficiaries and also extending them beyond the 400 percent FPL cut-off by capping beneficiary premiums at no more than 8.5 percent of an individual's income for a silver plan.
- The ARPA tax credits were originally set to expire on Jan. 1, 2023. Under the IRA, these credits are now extended *for another three years*.

Medicare Drug Pricing Negotiation

- The legislation allows the Medicare program to set the price of certain high-expenditure prescription drugs.
- Negotiation is limited to the single-source drugs with the highest-spend in Part B or Part D for
  - 1)U.S. Food and Drug Administration (FDA)-approved drugs for which at least seven years have elapsed from approval and for which there is no generic on the market and
  - 2) FDA-licensed biologics for which at least 11 years have elapsed since licensure and for which there is no biosimilar on the market. Small biotech drugs (until 2028), orphan drugs, low-spend Medicare drugs and plasma-derived products are excluded from price negotiation.

Price Negotiations (Cont'd)

- Drugs subject to the new negotiated price requirement will be initially selected in 2023, and the agreed upon will be applied beginning in 2026.
  - Drugs must be selected by the Centers for Medicare & Medicaid Services (CMS) and an agreement must be reached with the manufacturer two years before the negotiated price will apply.
  - The calendar of events is as follows:
    - 2026 (only Part D drugs eligible for negotiation): 10 drugs based on Part D spending
    - 2027 (only Part D drugs eligible for negotiation): 15 drugs based on Part D spending
    - 2028 (first year both Part B and D drugs are eligible for negotiation): 15 drugs based on combined Part B and Part D spending
    - 2029 and beyond: 20 drugs based on combined Part B and Part D spending

Drug Negotiations (Cont'd)

- Once a negotiated price is set, the manufacturer would be required to offer the drug at the maximum fair price (MFP) with respect to Medicare beneficiaries. The MFP represents the ceiling on a drug's negotiated Part B or Part D price.
- MFP cannot exceed certain specified percentages of a drug's nonfederal average manufacturer price (non-FAMP) or an amount reflecting an average market price and determined by the number of years since a drug's FDA approval.
- The bill also allows for a delay in the negotiation of no more than two years for certain drugs where there is is a "high likelihood … that a biosimilar of the reference biologic product within the coming two years.

Drug Negotiations (Cont'd)

- The IRA also includes enforcement provisions. Manufacturers will be subject to significant civil monetary penalties (CMPs) up to 10 times the difference between the MFP and the price charged for failing to offer the MFP with respect to a Medicare beneficiary, violating the terms of an agreement or knowingly providing false information.
- Additionally, manufacturers can be assessed an escalating excise tax beginning at 65 percent of the drug's prior year's total sales, increasing to 95 percent once the manufacturer is out of compliance for more than 270 days.
- Alternatively, the manufacturer may withdraw its products from Medicare instead of engaging in negotiations.

Inflation Rebates

Under the IRA, single-source Part B drugs and all Part D drugs, excluding certain low-spend drugs, would be required to pay a rebate on a unit of a drug paid under Part B or D where the price of the drug increases faster than inflation.

The original intent was to apply this penalty to drugs under Medicare as well as private health insurance, but because of budgetary rules, the Senate parliamentarian determined that it could only be applied to Medicare.

A manufacturer that does not pay a rebate would be subject to a civil monetary penalty (CMP) in an amount at least equal to 125 percent of the rebate amount.

Drug MOOP Caps

- ***Out-of-Pocket Cap***: While Medicare Part D has limits on patient copays, it does not have an out-of-pocket cap for Medicare beneficiaries. When a beneficiary has incurred out-of-pocket costs and discounts slightly in excess of $7,000, they reach what is known as the "catastrophic phase" of the benefit, where they pay 5 percent of the cost of their drugs (while Medicare covers 80 percent and plans cover the remaining 15 percent).
- The IRA eliminates this 5 percent cost-sharing in the catastrophic phase (effective in 2024) and caps total patient out-of-pocket costs in Part D at $2,000 (effective in 2025).

Biosimilars and More

- ***Enhanced Payments for Biosimilars***: To incentivize the uptake of biosimilars, the IRA temporarily increases the Medicare Part B add-on payment for certain biosimilars from 6 percent to 8 percent of product's average sales price (ASP) from Oct. 1, 2022, through the end of 2027. Additionally, for new biosimilars furnished on or after July 1, 2024, the IRA changes the initial period payment rate to be the lesser of the biosimilar's wholesale acquisition cost (WAC) plus 3 percent or 106 percent of the reference product's ASP.

More Patient Relief

- **Maximum Monthly Cap on Cost-Sharing Payments:** Under Prescription Drug Plans and Medicare Advantage Prescription Drug (MA-PD) Plans: The IRA creates a maximum monthly cap on cost-sharing payments beginning in 2025 and directs Prescription Drug Plan sponsors and Medicare Advantage organizations offering plans to provide beneficiaries with the option to pay copays in monthly installments.
- ***Cap on Premiums/"Premium Stabilization":*** Under the IRA, Part D plans will have a cap on the amount that they can increase premiums from year to year – 6 percent through 2029. In 2030 and subsequent years, CMS will recalculate base premiums using the original Part D premium formula.
- ***Low-Income Subsidy (LIS) Eligibility***: The IRA expands eligibility for low-income subsidies under Part D of the Medicare Program from 135 percent of the federal poverty line (FPL) to 150 percent of the FPL beginning Jan. 1, 2024.

Inflation Reduction Act (IRA) will support reduced drugs costs through Part D Benefit Design and Drug Negotiations

	2024	2025	2026	2027	2028	2029
Part D Benefit Design	Eliminates 5% coinsurance for Part D catastrophic coverage	Adds $2,000 out-of-pocket cap in Part D and other drug benefit changes				
Drug Price Negotiations			**Implements negotiated prices for certain high-cost drugs:**			
			10 Medicare Part D drugs	15 Medicare Part D drugs	15 Medicare Part D and 15 Part B drugs	20 Medicare Part D and 20 Part B drugs

2024-2029: Limits Part D premium growth to no more than 6% per year

References: 1. Kaiser Family Foundation

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