CMS Updates

August 6, 2024

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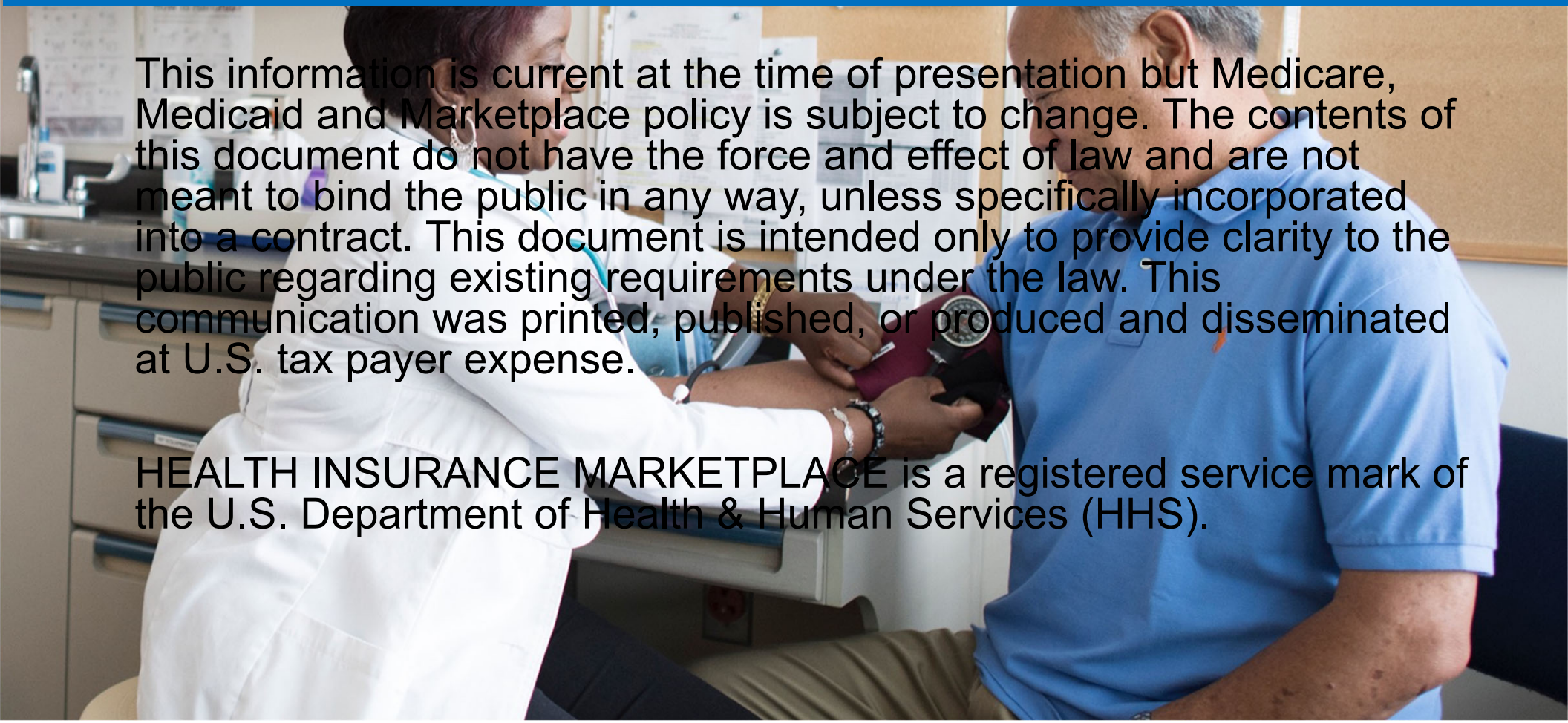

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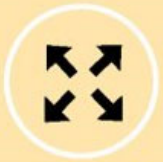
CMS Strategic Pillars

ADVANCE EQUITY

Advance health equity by addressing the health disparities that underlie our health system

EXPAND ACCESS

Build on the Affordable Care Act and expand access to quality, affordable health coverage and care



ENGAGE PARTNERS

Engage our partners and the communities we serve throughout the policymaking and implementation process

DRIVE INNOVATION

Drive Innovation to tackle our health system challenges and promote value-based, person-centered care

PROTECT PROGRAMS

Protect our programs' sustainability for future generations by serving as a responsible steward of public funds

FOSTER EXCELLENCE

Foster a positive and inclusive workplace and workforce, and promote excellence in all aspects of CMS's operations

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Who Are We?

https://www.cms.gov/leadership/office-program-operations-local-engagement
https://www.cms.gov/pillar/expand-access

OPOLE = Office of Program Operations and Local Engagement

- OPOLE is responsible for consistently and effectively implementing the Agency's local outreach strategy and messaging.
- Based on local interactions with beneficiaries and stakeholders, OPOLE can inform CMS about the on the ground impact of its policies, programs, and initiatives.

Who do we serve?

- Over 160 million people throughout the United States accessing health coverage through Medicare, Medicaid, Children's Health Insurance Program (CHIP), and the Marketplace.
- Region 5 states: Illinois, Indiana, Michigan, Minnesota, Ohio & Wisconsin

How OPOLE Can Help:

- **OPOLE teaches people about CMS policies, programs, and initiatives.**
  - OPOLE is happy to share CMS updates with you.
  - OPOLE can present for you.
  - OPOLE can provide resources to support you in your outreach and education.
  - OPOLE invites its partners to CMS trainings.
- **Do you need technical assistance?**
  - OPOLE can find the answer or resource you need.
  - OPOLE can connect you throughout CMS.
- **Can OPOLE invite you to CMS activities?**
  - CMS hosts listening sessions, dignitary visits, and other activities. OPOLE may ask for your participation and feedback during these sessions.

Submit a Speaking Engagement Request

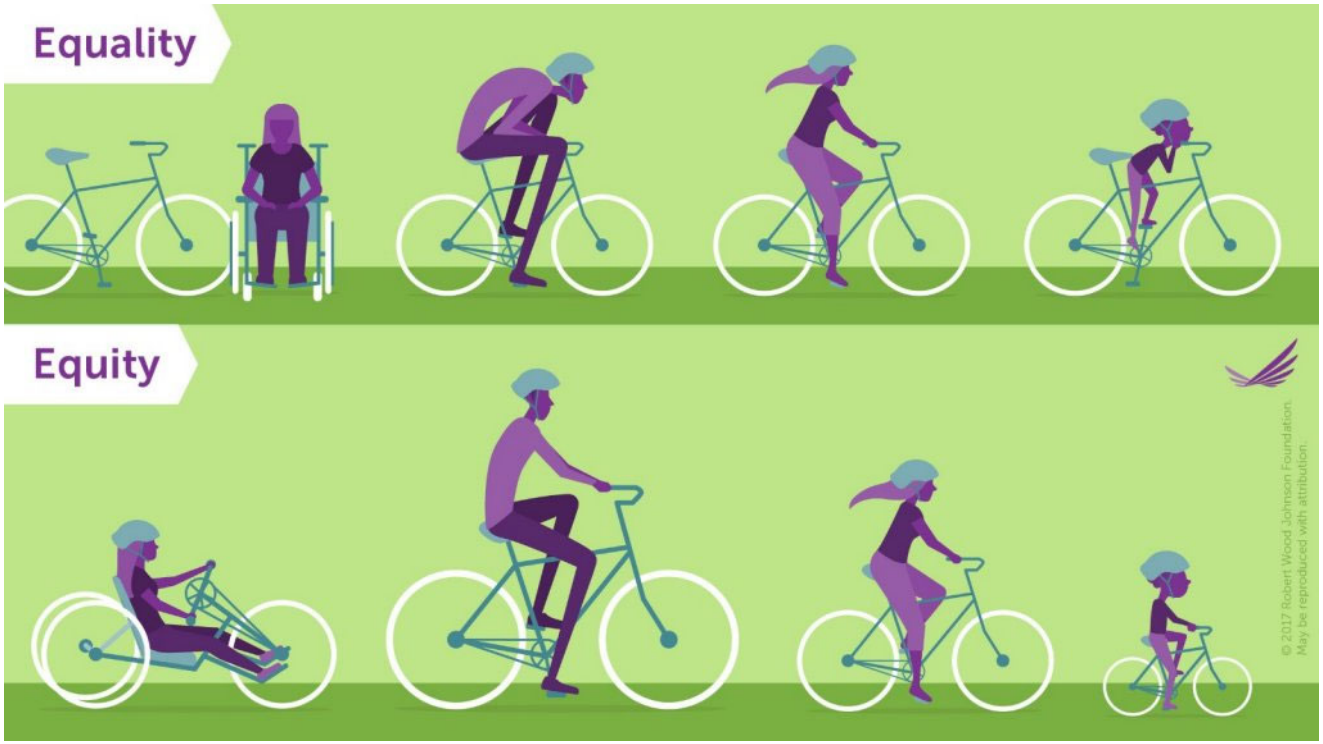
Register for **"Real Time"** with CMS Chicago

Outreach Campaigns & Initiatives

- Medicare Open Enrollment
- Marketplace Open Enrollment
- Immunizations
- Medicaid Renewals
- Inflation Reduction Act
- Behavioral Health
- Monthly Health Observances
- CMS National Training Program
- No Surprises Act
- Social Determinants of Health
- Rural Health
- Health Equity
- Coverage to Care

Health Equity

CMS defines health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health.



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CMS Framework for Health Equity

- Operationalize health equity across all CMS programs: Medicare, Marketplace, Medicaid, and CHIP
- Is evidence-based and informed by decades of research and stakeholder input
- Review the framework: https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity

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CMS Framework for Health Equity: 5 Priority Areas

Priority 1: Expand the Collection, Reporting, and Analysis of Standardized Data

Priority 2: Assess Causes of Disparities Within CMS Programs, and Address Inequities in Policies and Operations to Close Gaps

Priority 3: Build Capacity of Health Care Organizations and the Workforce to Reduce Health and Health Care Disparities

Priority 4: Advance Language Access, Health Literacy, and the Provision of Culturally Tailored Services

Priority 5: Increase All Forms of Accessibility to Health Care Services & Coverage

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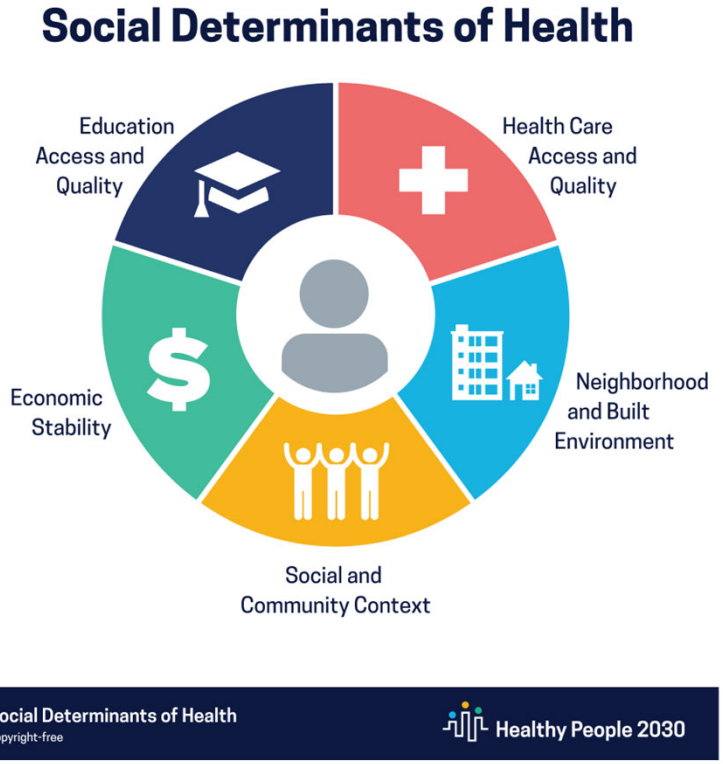
Social Determinants of Health (SDOH)



What are Social Determinants of Health?

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[1]

Why are SDOH important?

It's estimated that between 70-90% of health is determined by SDOH. This doesn't mean that the clinical encounter doesn't matter – but instead, that health and health outcomes are influenced by the context of a person's place and space in society.

1 Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Retrieved July 15, 2022, from https://health.gov/healthypeople/objectives-and-data/social-determinants-health

CMS Accomplishments for 2023: Health Equity

- Through the Maternity Care Action Plan, CMS is seizing every opportunity to improve maternity care access and quality, improve health outcomes, and reduce disparities.

- CMS established the first-ever Birthing-Friendly designation, a consumer-friendly indicator that a hospital or health system is committed to improving maternal health. This designation is displayed on the Care Compare section of the CMS website.

- CMS announced the Transforming Maternal Health (TMaH) Model that aims to reduce disparities in maternal health care access and treatment, improve outcomes and experiences for mothers and their newborns, and reduce overall Medicaid program expenditures.

- CMS released the CMS Sickle Cell Disease (SCD) Action Plan, which highlights CMS actions in four key areas: expanding coverage and access; improving quality and the continuum of care; advancing equity and engagement; and examining data and analytics.

- The Contract Year 2024 Medicare Advantage and Part D Final Rule strengthened behavioral health network adequacy in Medicare Advantage and advanced health equity through changes to the Star Ratings program, which will reward Medicare Advantage and Part D plans that provide excellent coverage for underserved populations.

CMS Accomplishments for 2023: Health Equity (cont.)

- The Oral Health Cross-Cutting Initiative (Oral Health CCI) was launched in 2023. Under the Oral Health CCI, CMS considers opportunities to expand access to oral health coverage using existing authorities and health plan flexibilities for Medicare, Medicaid, CHIP, and the Marketplaces. Access to oral health services is critical to achieve the best health possible.

- CMS awarded a new cohort of grants to minority-serving institutions through the Minority Research Grant Program (MRGP). The grant will support researchers across the country using CMS data to understand and help eliminate barriers to access, quality, and outcomes among underserved and Tribal communities.

- CMS expanded coverage in the Medicare Annual Wellness Visit (AWV) to include an optional Social Determinants of Health (SDOH) Risk Assessment, administered by way of a standardized, evidence based SDOH risk assessment tool.

- CMS implemented the first ever voluntary hospital reporting Social Determinants of Health (SDOH) measures, such as the Facility Commitment to Equity measure and the SDOH screening measure in a number of CMS quality reporting and value-based purchasing programs.

- In 2023, CMS introduced “Rewarding Excellent Care for Underserved Populations” in the Hospital Value-Based Purchasing Program and Skilled Nursing Facility Value-Based Purchasing Program, which rewards these providers if they provide high quality care and serve a high proportion of underserved patients.

Recent CMS Announcements

- Announced April 4, 2024 - Contract Year (CY) 2025 Medicare Advantage and Part D Final Rule
  - Requires that Medicare Advantage plans include an expert in health equity on their utilization management committees and for the committees to conduct an annual health equity analysis of the plans' prior authorization policies and procedures.

- Announced August 1, 2024 FY2025 Hospital Inpatient PPS and LTC Hospital Final Rule

https://www.cms.gov/newsroom/fact-sheets/fy-2025-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective-0

Recent CMS Announcements

- **CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1809-P)**

- **CMS Releases Oral Health Cross-Cutting Initiative Fact Sheet**

https://www.cms.gov/files/document/oral-health-cci-fact-sheet.pdf

Chronic Care Management (CCM)

- CCM is care coordination outside of a regular office visit for patients with 2+ chronic conditions expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation or decompensation, or functional decline.
- It provides access to care outside of and in between doctors' visits.
- CCM services can also help reduce geographic and racial or ethnic health care disparities.

Inflation Reduction Act (IRA)

Overview of the Provisions of the New Prescription Drug Law

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Overview of the Inflation Reduction Act

- The Inflation Reduction Act (IRA) was signed into law in August 2022.
- The new law makes improvements to Medicare that will expand benefits, lower drug costs, and improve the sustainability of the Medicare program for generations to come.
- The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare, both now and in the long run.

Inflation Reduction Act (IRA) CMS Provisions

- Places a $35 monthly out-of-pocket cap on Medicare-covered insulins
- Makes ACIP-recommended vaccines free under Medicare Part D prescription drug coverage
- Temporarily increases Medicare payment for qualifying biosimilars to encourage use
- Requires manufacturers to pay rebates to Medicare if their price increases for certain drugs exceed inflation
- Makes Medicare Part D prescription drug coverage more affordable

Inflation Reduction Act CMS Provisions (continued)

- This Year: People with very high prescription drug costs will no longer pay once they reach the “catastrophic phase”
- This Year: Full low-income subsidy expanded for people with low incomes, lowering premiums and out-of-pocket costs for their prescription drug coverage
- 2025: All people with Medicare Part D will have a $2,000 annual out-of-pocket cap on their drug costs
- Allows Medicare to negotiate the price of certain high-cost, brand name prescription drugs

The Medicare Drug Price Negotiation Program (1 of 3)

- Medicare will be able to negotiate (and re-negotiate) drug prices of certain high expenditure Medicare drugs with drug manufacturers

- For the drug companies of selected drugs that elect to participate in the Negotiation Program, the maximum fair prices that are negotiated will apply beginning in 2026

The Medicare Drug Price Negotiation Program (2 of 3)

- For the first year of the Negotiation Program, CMS selected 10 high expenditure, single source drugs for negotiation on August 29th, 2023

- On October 2nd, CMS announced that the drug companies who manufacture all 10 drugs selected for the Medicare Drug Price Negotiation Program for the first cycle have chosen to participate in the Negotiation Program.

- CMS will select up to an additional 15 drugs for negotiation for 2027, up to an additional 15 drugs (including drugs covered under Part B) for 2028, and up to an additional 20 drugs for 2029 and subsequent years

The Medicare Drug Price Negotiation Program (3 of 3)

The negotiated maximum fair prices for the first 10 drugs will apply beginning in 2026

October 1, 2023
Deadline for companies of drugs selected for the Negotiation Program to sign agreements to participate in the negotiation process for 2026.

October 2, 2023
Deadline for companies of drugs selected for the Negotiation Program to submit manufacturer-specific data to CMS to consider in the negotiation of maximum fair price.

February 1, 2024
CMS sends initial offers of a maximum fair price with a justification for a selected drug to each company participating in the Negotiation Program. The negotiation period begins.

March 2, 2024
Companies have 30 days from receiving offers of a maximum fair price for a drug to accept the offer or propose a counteroffer, if desired.

August 1, 2024
The negotiation period ends.

September 1, 2024
CMS will publish maximum fair prices for drugs selected for negotiation for 2026.

Drug Inflation Rebates in Medicare

Requires drug companies that raise prices for certain products faster than the rate of inflation to pay Medicare Part B or Part D a rebate

- Rebates calculated quarterly (Part B) or annually (Part D)
- Liability for rebates began as of October 1, 2022 for Part D and as of January 1, 2023 for Part B
- Lower out-of-pocket costs under Part B: Q1 2024 (January 1st, 2024 – March 31st, 2024) beneficiaries may pay reduced inflation-adjusted coinsurance rates for 48 Part B rebatable drugs

Drug Price Inflation Rebates in Medicare (continued)

- Requires CMS to monitor drug prices during the applicable period, compare them to the benchmark price (adjusted for inflation), make adjustments in certain cases (e.g. drugs shortages), and invoice manufacturers for the remaining difference

- In each case, we are to identify and exclude 340B units from rebate billings (began January 1, 2023 for Part B and starting January 1, 2026 for Part D). This is to avoid manufacturers paying a Medicare inflation rebate and a 340B discount on the same drug.

- Under the Medicare Part B Drug Inflation Rebates, which began in April 1, 2023, if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beneficiary coinsurance is equal to 20% of the inflation-adjusted payment amount

Part D Improvements

Redesigns the Part D benefit and revises its parameters as follows:

- People with very high prescription drug costs will no longer pay once they reach the “catastrophic phase”
- Provides for Part D premium stabilization beginning this year, by capping base beneficiary premium increases per year to no more than 6% through 2029
- Beginning in 2025:
    - People with Medicare prescription drug coverage will benefit from a yearly cap ($2,000 in 2025) on what they pay out-of-pocket for covered prescription drugs, starting in 2025. They’ll also have the option to pay their prescription costs in monthly amounts spread over the year rather than all at once, beginning in 2025.
    - The new discount program will require drug manufacturers to pay discounts on certain brand-name drugs and other types of drugs called biologics and biosimilars, both in the initial coverage phase and in the catastrophic phase of the Medicare prescription drug benefit. In general, manufacturers must provide a 10% discount in the initial phase and a 20% discount in the catastrophic phase.

Part D Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices (ACIP)

- Requires Part D sponsors to eliminate the deductible and other cost sharing with respect ot the ACIP-recommended adult vaccines
- Includes:
  - Shingles
  - RSV
  - Other recommended vaccines
- Effective Date: January 1, 2023

Improving Access to Adult Vaccines Under Medicaid & CHIP

- State Medicaid and CHIP programs are required to provide coverage for approved adult vaccines recommended by the ACIP (and their administration) without cost sharing

- **Effective Date:** October 1, 2023 (the first day of the first fiscal quarter that begins on or after the date that is one year after enactment)

Expansion of Extra Help

- Since January 1, 2024, nearly 300,000 low-income people with Medicare currently enrolled in the Extra Help program are newly eligible for expanded benefits including no deductible, no premiums and fixed, lowered copayments for certain medications. An additional 3 million people could benefit from the Extra Help program now but aren't currently enrolled

- Expands eligibility for the full low-income subsidy (LIS) benefit (also known as "Extra Help") to individuals with limited resources and incomes up to 150% of the federal poverty level

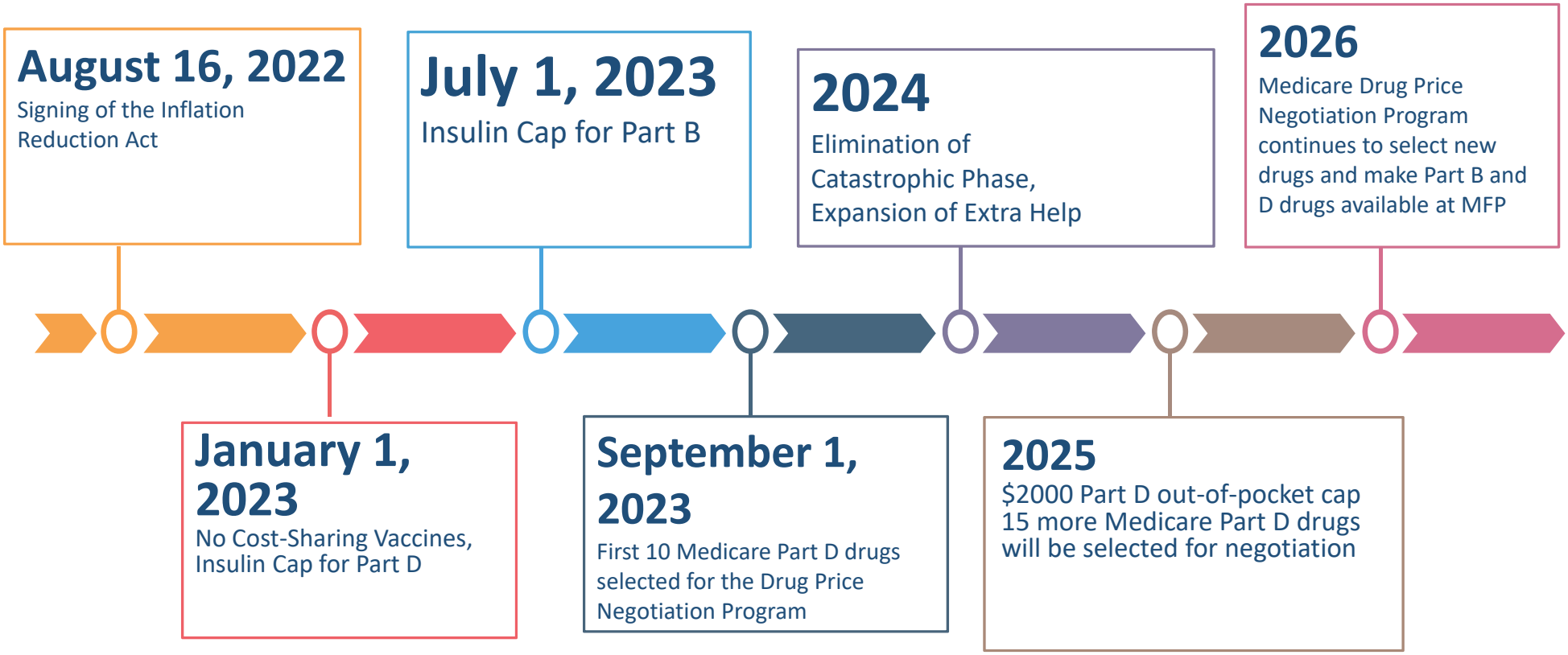
- People with Medicare who are currently enrolled in partial Extra Help have been automatically converted to full Extra Help; they don't need to take any action

Insulin & Medicare Coverage

The cost of a month's supply of each covered insulin product is currently capped at $35, and people with Medicare don't have to pay a deductible for insulin

- As of January 1, 2023, people enrolled in a Medicare prescription drug plan don't pay more than $35 for a month's supply of each insulin covered by their Medicare prescription drug plan and dispensed at a pharmacy or through a mail-order pharmacy. Also, Part D deductibles no longer apply to the covered insulin product
- As of July 1, 2023, for insulin (delivered through a durable medical equipment pump) covered by Part B and Medicare Advantage Plans
- For a 60- or 90-day supply of insulin, the cost can't be more than $35 for each month's supply of each covered insulin

IRA Provision Timeline



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Key Things to Remember

- Medicare-covered insulin available at $35 for each month supply for covered insulin and no deductible is effective now
- Access to ACIP-recommended adult vaccines without cost-sharing and no deductible is effective now.
- People with Original Medicare and Medicare Advantage may, depending on their coverage, pay a lower coinsurance amount for certain Part B drugs with price increases higher than inflation since April 1, 2023.
- The new drug law expands eligibility for the full low-income subsidy benefit—known as the Extra Help program—to individuals with limited resources and incomes up to 150% of the federal poverty level beginning January 1st, 2024.

Partner Resources

- https://lowerdrugcosts.gov
- https://www.cms.gov/inflation-reduction-act-and-medicare
- https://www.cms.gov/inflation-reduction-act-and-medicare/resources-0
- CMS Newsroom (www.cms.gov/newsroom)

Hospital Price Transparency: What Hospitals Need to Know

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Hospital Price Transparency Regulation Introduction

- The Hospital Price Transparency regulation implements Section 2718(e) of the Public Health Service Act and requires each hospital operating within the United States to establish (and update) and make public a yearly list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act.

- Starting on January 1, 2021, each hospital operating in the United States was required to make this information available in two ways:

As a comprehensive machine-readable file (MRF) with all standard charges for all items and services

AND

As a display of standard charges for 300 shoppable services in a consumer-friendly format

CY 2024 OPPS/ASC Final Rule Regulatory Updates

CMS finalized new Hospital Price Transparency requirements in the CY 2024 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule. These new requirements include:

January 1, 2024 **Improving Access to Hospital Machine-Readable Files (MRFs):** Hospital websites must include a TXT file in the root folder with MRF and contact information (45 CFR 180.50(d)(6)(i)). Hospitals must place a 'footer' at the bottom of te hospital's homepage that links to the webpage that includes the machine-readable file (45 CFR 180.50(d)(6)(ii)).

July 1, 2024 **New Data Elements and Format Standardization:**

- Hospital MRFs must conform to the CMS template layout and data specifications (180.50(c)(2)).
- Expanded set of data elements including, as applicable: hospital and MRF information, each type of standard charge (including payer-specific negotiated charges by payer and plan), item/service description, relevant billing codes (180.50(b)(2)).
- Hospital must affirm that it has included all applicable standard charge information in the MRF and that the information encoded is true, accurate, and complete (180.50(a)(3)(ii)).

January 1, 2025 **Additional Required Data Elements:** Hospitals must encode additional new data elements including: 'Estimated Allowed Amount', 'Drug Unit of Measurement', 'Drug Type of Measurement', and 'Modifiers'.

New Requirements to Use a CMS Template Layout and Encode Hospital Standard Charge Information

- As of July 1, 2024, hospitals' MRF must conform to a CMS template layout, data specifications, and data dictionary.

- CMS has made the CMS template available in three non-proprietary formats: CSV "tall", CSV "wide", and JSON.

- CMS has created a GitHub repository to house the required CMS templates, and provides the data dictionary, or technical instruction, on how hospitals must encode standard charge information into machine-readable files.

The CMS Hospital Price Transparency - Data Dictionary GitHub repository is available here https://github.com/CMSgov/hospital-price-transparency.

Contact Us

https://www.cms.gov/hospital-price-transparency/contact-us

Submit a complaint

Can’t find a hospital’s standard charges online?

You may submit a complaint to CMS if it appears that a hospital has not posted information online.

For all other questions regarding Hospital Price Transparency, email the hospital price transparency team.

Presentation Feedback

Thank you for participating in this session with CMS. We appreciate your time you have spent with us. We are always trying to improve our level of service to our partners and stakeholders. You can help us do that by providing your feedback on today's session.

Please take a few moments to complete this brief, voluntary post-engagement evaluation. Just click on the link below or use the QR code. Your answers will help us improve our collaboration with you.

Activity Name: " 5-Ohio Medical Association"

***Note:** Please do not forward or post the link anywhere; this is an internal evaluation to assist us with this specific activity. Thank you!*

https://cmsgov.force.com/act/Evaluation

Q&A

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