Insight

Beyond the Headlines: What's Changing in Medicare

JOHN WALKER | JULY 15, 2025

Executive Summary

- While lawmakers and regulators have typically avoided program changes to Medicare that could negatively impact beneficiary care and access, they have made significant modifications to its administrative systems over the last year.
- Among these modifications are those to Medicare's payment programs, incentive systems, coding methodology, and cost sharing.
- This insight walks through these modifications and what they mean for the Medicare program.

Introduction

While Medicare has been largely off limits to any reform to maintain the program's solvency, legislation and statutory annual rulemaking on the Medicare program has altered its payment programs, incentive systems, coding methodology, and cost sharing. Over the past year, for example, the Centers for Medicare and Medicaid Services (CMS) updated more than 20 prospective payment schedules and Congress passed a number of laws that impacted the Medicare program for plan year 2025. Some of these changes, discussed below, are organized by date and represent updates whose impacts may be underappreciated. They include:

- Drug Exemptions to the Medicare Drug Negotiation Program (MDNP)
- Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC)
- End-Stage Renal Disease Payment System (ESRD PPS)

- Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) Coding
- Insulin and Vaccine Cost Sharing
- Medicare Part D Drug Cap

This insight walks through these modifications and what they mean for the Medicare program.

Expanding Drugs Exempt from the Medicare Drug Negotiation Program

The Medicare Drug Negotiation Program under the Inflation Reduction Act (IRA) requires Medicare to select, negotiate, and set prices for high-utilization pharmaceuticals following a set of parameters that provided certain exemptions for drugs from this pricing model. One of these, the orphan drug exemption, allows a drug that was only approved to treat a rare disease to be excluded from the negotiation selection process. If the drug received any other indication, however, it would immediately be eligible for negotiation.

This provision in the recently enacted H.R. 1 further clarifies MDNP drug eligibility by providing increased program exemptions and protection periods to treatment options and drugs that are used exclusively to treat a rare disease. Specifically, this provision changes the original MDNP orphan drug eligibility clause by allowing any orphan drug without an indicator for a non-rare disease – regardless of how many rare diseases the drug is used to treat – to continue to be exempt from MDNP. This provision also revises the onset of the MDNP drug protection period (seven years for a small-molecule drug and 11 years for a biologic) to begin only after a drug receives a non-rare disease indicator.

Roughly 15 percent of orphan drugs have at least two rare disease indications; as a result, the broadening of the MDNP orphan drug exception would reduce the number of drugs available for MDNP negotiation. While this may limit Medicare's future ability to negotiate prices on select drugs – trading the ability to compel manufacturers to accept price caps on a class of drugs for less than 5 percent of known rare diseases – it would yield positive results by allowing for greater drug innovation. Orphan drugs have constituted roughly 40 percent of all innovative pharmaceuticals over the past 40 years, and this provision would directly reduce the risk to manufacturers associated with innovating a new drug. The re-incentivizing of innovation from this provision could have a considerable impact on the development of novel drugs and positively impact the Medicare populations who utilize them.

Federally Qualified Health Center and Rural Health Clinic Coding Updates

Effective January 1, 2025, CMS altered coding parameters utilized by FQHCs and RHCs by

removing a generalized code under the Healthcare Common Procedure Coding System (HCPCS) and replacing it with a directory of detailed managed care codes called Current Procedural Terminology (CPT) codes. This change effectively created a new coding environment that FQHCs and RHCs can use to more accurately define the amount of time and level of care provided. Providers utilize coding to define and charge Medicare for any services they provide to a beneficiary.

FQHCs serve medically underserved areas, and RHCs are in rural areas that either qualify as or are designated health care professional shortage areas. Because of these shortages and other complicating factors, patients located in areas served by FQHCs and RHCs often also experience increased instances of complex health challenges that require additional provider attention and time. When initially implemented, the general HCPCS code attempted to manage this by tying a pre-set payment to a minimum amount of patient facing time (20 minutes). While provider payments were tied to the 20-minute minimum, once that limit was hit providers would receive no additional compensation for any further time spent with a patient – effectively disincentivizing providers from offering a more complete assessment of the continuum of care in a single visit. CMS' new coding rule attempts to shift this by reducing the base amount offered to providers for a minimum level of care, while adding CPT coding tiers with accompanying payments – at 20, 40, and 60 minutes of care, respectively – that can nearly double the payment rates previously offered under the HCPCS code.

Currently, CMS has extended a transitional period allowance to providers until September 2025 as they prepare to shift from the HCPCS code to the CPT coding system. While providers still have a few months left with the generalized HCPCS code, the full adoption of the CPT schema is likely to have a considerable impact on Medicare by incentivizing providers to offer a more complete continuum of care. Furthermore, because of higher care needs among populations catered to by FQHCs and RHCs, this update may have the added benefit of improving patient care outcomes and reducing Medicare's spending on costly chronic disease.

End-Stage Renal Disease Prospective Payment System Updates

On November 1, 2024, CMS issued a final rule implementing several updates and changes to the ESRD PPS. Among changes to the ESRD PPS wage index and base rate, CMS opted to alter the systems bundled payment mechanism to include certain oral-only renal dialysis drugs.

Since 2014, CMS has repeatedly attempted to streamline and bundle coverage of these drugs under the ESRD PPS. To encourage broader ESRD facility adoption of these oral

drugs before rolling out updated bundled payment rates, CMS implemented a two-year minimum financial incentive program – called the Transitional Drug Add-on Payment Adjustment (TDAPA) – designed to reward ESRD facilities that adopt the desired drugs with an additional payment based on 100 percent of the given drug's average sale price.

It will take time for CMS to ultimately shift from a TDAPA incentive to a combined ESRD PPS bundled rate, but this shift from stratifying care and drug coverage across Parts B and D to bundling drug and care coverage under Part B will have a positive impact on Medicare. Specifically, because ESRD care is resource intensive, this streamlining of drug and care coverage under a ESRD PPS bundle will not only save Medicare money by packaging the cost of these drugs with other care – allowing the government to pay a lower pre-set rate to cover a patient's continuum of end-stage care – but would also greatly reduce the administrative burden patients face when seeking end-stage renal care.

Outpatient Prospective Payment System and Ambulatory Surgical Center Updates

In late 2024, CMS finalized its calendar year (CY) 2025 OPPS and ASC Payment System final rule. Among myriad updates, CMS increased OPPS and ASC payment rates by 2.9 percent (a 0.3 percentage point increase on the prior CY 2024 update). This annual increase closely mirrors prior-year increases and is based on a measure of the specific inflation experienced by health care providers – meaning OPPS and ASC payment rates can partially track inflation. While it is beneficial for payment systems to index to inflation to ensure rates do not fall significantly behind the economic landscape, it's also important to note that a level of inelasticity in year-to-year payment rates is also beneficial as it prevents yearly growth rates from spiking too high in response to transitory inflation. As an example, inflation has significantly fluctuated over the past decade, with years such as 2015 and 2020 experiencing relatively low inflation – 0.7 and 1.4 percent, respectively – and other years such as 2021 and 2022 experiencing decades – high inflation – at 7 and 6.5 percent, respectively. Throughout this variable inflation across the past decade, CMS has continued to generally approve a relatively inelastic rate increase at an average of 2.4 percent. Although this process controls inflationary spikes while offering providers gradually increasing reimbursement rates, OPPS and ASC's role in the Medicare reimbursement system means it has a larger than appreciated role.

Facility fees, which are based on OPPS and ASC rates, enable certain hospital-based health systems to claim increased fees on the same service, no matter where the service is provided, such as a hospital outpatient department or hospital-affiliated physician office. Not only has this inequity of payment incentivized independent physician offices to consolidate into hospital-owned outpatient facilities, but it has also significantly increased the financial burden of beneficiary care on Medicare without resulting in a corresponding

increase in the quality of that care. For example, were a Medicare beneficiary to walk into a physician's office today and request a skin allergy test, Medicare would be charged $176.01 for the service. Assuming the same beneficiary, level of care, and service but changing the care location to a hospital-owned outpatient clinic, Medicare would be charged more than four times the original physician office rate at $719.16 – even though both locations provide a comparable level of care and service.

Although the 2.9 percent increase appears to be a minor overall increase, the real impact of this increase – as discussed above – is larger than it appears due to the high utilization of this particular PPS.

Inflation Reduction Act Rulemaking

Insulin and Vaccine Cost-sharing

In April 2025, CMS finalized its insulin cost-sharing rule, updating provisions in Medicare Part B and Part D designed to reduce the cost of insulin for qualifying Medicare enrollees. Specifically, CMS' rule updates the "covered insulin product cost sharing amount" so that from 2026 onward, the applicable cost-sharing amount of a covered insulin product cannot exceed the lowest of $35, 25 percent of the maximum fair price under the Medicare drug negotiation program, or 25 percent of the negotiated price in a prescription drug plan. CMS also finalized its vaccine cost-sharing rule, eliminating all costs to enrollees associated with receiving any adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) and covered under Medicare Part D.

These updates build on previous legislative action to improve insulin and vaccine cost-sharing first codified in the IRA. While there have yet to be any programmatic updates, recent changes at the ACIP may influence which vaccines are eligible for coverage and cost-sharing under Parts B and D. Should any vaccine recommendations be changed, this will affect beneficiaries' ability to receive vaccinations. This could have considerable impacts on Medicare, as adult vaccination programs return up to 19 times their initial investments when accounting for lost wages, care needs, and other economic and social considerations. As such, considering that the average high-dose influenza vaccine for an adult over 65 is roughly $105, and the average cost of care when a 65-year-old-plus beneficiary gets the flu (including the initial hospitalization) is roughly $14,494, for every beneficiary that receives a flu vaccination, Medicare prevents an additional $14,494 in care spending.

Part D Drug Cap

Congress redesigned Medicare Part D in the IRA by phasing out the program's gap and catastrophic phase coverage in favor of a reengineered prescription drug plan that

culminated in a flat annual out-of-pocket beneficiary cap. This broad limit on cost-sharing changed how much beneficiaries and the federal government each paid for Part D drugs. As currently administered, enrollees pay a deductible – up to $590 per year – after which an enrollee enters the initial coverage phase of their plan and is subsequently responsible for 25 percent of the total cost of their prescriptions for the remainder of the year, until the cap is reached. Once an enrollee reaches an annual out-of-pocket spending cap of $2,000, Medicare then assumes the entire cost of the enrollee's remaining annual drug coverage. While this cap was set at $2,000 for 2025, it will increase each year, indexed to inflation.

In 2025, roughly 11 million Part D enrollees are projected to reach their annual out of pocket cap, with 64 percent of these enrollees saving more than $1500 annually. If these projections hold true, Medicare Part D could be expected to cover roughly $10.5 billion in additional drug spending in 2025 compared to 2024. While this additional $10.5 billion is a drop in the bucket compared to the total yearly Medicare spending, it's likely that the price tag associated with this Part D cap will continue to grow as larger proportions of the U.S. population reach a qualifying age and lives longer. Over time, these trends will have an increasing impact on Medicare financing.

Conclusion

While Medicare has been largely off limits to any reforms that work to maintain program solvency, legislative and regulatory actions have altered various administrative and coverage provisions. These updates may have underappreciated impacts on the program and should continue to be analyzed.