December 2, 2024

Issue Brief: Medicare Policy and Technical Changes for CY 2026

Background

This proposed rule makes changes to several CMS programs, including Medicare Advantage, Medicare Part D, and Programs of All-Inclusive Costs for the Elderly (PACE). The proposal includes coverage of anti-obesity medication, clarification and streamlining of prior authorization requirements, and changes to the drug price negotiation program. Given the ongoing policy debates around many of these issues, the proposed rule is likely to spark intense debate and extensive stakeholder feedback. However, because a new administration will take office before comments are submitted on Jan. 27, 2025, there is uncertainty about how much, if any, of the rule will be retained and/or finalized.

Key Proposed Changes

- Coverage of Anti-Obesity Medications: CMS does not currently cover medications solely for weight loss, such as GLP-1 medications, although they can be covered for other indications such as Type 2 diabetes. CMS proposes to "permit coverage of anti-obesity medications for the treatment of obesity when such drugs are indicated to reduce excess body weight and maintain weight reduction long-term for individuals with obesity." The rule notes that Medicaid and Medicare Part D coverage of anti-obesity medications will only be covered for clinical obesity, not just for overweight, unless the beneficiary has a comorbid condition for which the medication is indicated.

  Both cost implications and questions about long-term use of GLP-1 medications are likely to play a major role in debate on this provision of the proposed rule. Because we do not yet know who will be leading CMS, it is hard to predict how the new Administration will approach coverage of anti-obesity medication. Dr. Oz, the current nominee to lead CMS, has supported GLP-1 medications in the past, but Robert F. Kennedy, Jr., the nominee for HHS Secretary, has expressed skepticism about the drugs. Although ASHP has policy supporting access to medication for chronic conditions, we do not currently have policy specific to coverage of GLP-1s.

- Streamlining Prior Authorization Requirements: CMS proposes to improve the prior authorization process for Medicare Advantage, noting the very high percentage of claims denials overturned on appeal and the very low percentage of claims that are appealed. CMS proposes changes to increase transparency and to limit unnecessary utilization management. Specifically, plans will be required to make information on appeals rights and processes publicly available, to end retrospective denial of claims (which leaves providers without payment for services rendered), and require plans to provide more detailed information to CMS about initial coverage decisions and plan-level appeals.

  Again, with the transition to a new administration, it is difficult to predict how this provision will be viewed. With the new administration's focus on reducing administrative burden and cutting waste, they may be inclined to keep or even expand these provisions.

- Guardrails for Artificial Intelligence (AI): In follow up to the Biden Administration's Executive Order on Artificial Intelligence, CMS proposes to place limits on the use of AI in healthcare to ensure it does not negatively impact health equity. Specifically, the rule requires "MA plans to

ensure services are provided equitably, irrespective of delivery method or origin, whether from human or automated systems… and [to] comply with section 1852(b) of the Social Security Act and 42 CFR 422.110(a) and other applicable regulations and requirements and provide equitable access to services and not discriminate on the basis of any factor that is related to the enrollee's health status."

The incoming Administration has indicated that it will be friendly to the use of AI across the federal government. Should they view this proposal as unnecessarily limiting to the use of AI in healthcare, it will likely be rescinded.

- Network Adequacy and Medication Therapy Management: The rule also includes two provisions specific to pharmacy – increasing transparency in Part D networks and expanding Part D medication therapy management.

    - *Network Adequacy:* Under the rule, Part D plans and PBMs must provide contracted pharmacies information about which plans are in network before enrollment or when requested by a pharmacy. Further, contracted pharmacies will have the same notice period to terminate network enrollment without cause as Part D plans and PBMs have to terminate network contracts without cause.

    - *MTM*: CMS proposes to expand the covered list of conditions eligible for Part D MTM to dementias other than Alzheimer's disease.

  These two provisions of the proposed rule are relatively uncontroversial outside of the universe of plan sponsors and PBMs. If the proposed rule is not wholly rescinded, there is a reasonable likelihood that these provisions will survive, especially given widespread bipartisan skepticism about the role of PBMs in Medicare Part D.

- Medicare Drug Pricing Negotiation Program: CMS proposes that plan sponsors require contract pharmacies to enroll in the Medicare Transaction Facilitator Data Model as part of ongoing implementation of the Inflation Reduction Act.

  ASHP has been heavily engaged in implementation of the IRA drug pricing provisions. Although we are broadly supportive of drug price negotiation, we believe the current framework is infeasible for both community and hospital pharmacies and have asked for changes from the Biden administration. We anticipate that the new Administration will want to place its own stamp on the program, and we plan to work closely them to tailor the program to ensure it successfully reduces costs for providers and beneficiaries.

Applicability and Timing

December 2, 2024

As noted above, comments for this proposed rule are due Jan. 27, 2025. The new Administration takes office on Jan. 20, 2025 and will begin reviewing rules during the transition period. Because the proposed rule has not been finalized, should the new Administration decide not to move forward with it, it can simply allow the rule to remain open or rescind it altogether. ASHP will be closely monitoring the activity of the transition team as well as CMS next steps on the rule and will update members as new information becomes available. Question or concerns on the rule can be sent to Jillanne Schulte Wall, senior director of health and regulatory policy.