June 15, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary, Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (CMS-0062-P)

Dear Secretary Kennedy,

The Medicaid and CHIP Payment and Access Commission (MACPAC) appreciates the opportunity to comment on the notice of proposed rulemaking (NPRM) on interoperability standards and prior authorization for drugs published on April 14, 2026 (CMS 2026). MACPAC is a nonpartisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states on a wide array of issues affecting Medicaid and the State Children's Health Insurance Program (CHIP).

This proposed rule includes a number of provisions to implement interoperability standards for impacted payers, including Medicaid and CHIP, to improve the exchange of data and information on prior authorization (PA) related to prescription drugs. This proposed rule builds on the standards put into place through the 2020 Centers for Medicare & Medicaid Services (CMS) Interoperability and Patient Access final rule and the 2024 CMS Interoperability and Prior Authorization final rule that applied to non-drug items and services (CMS 2024, 2020).

MACPAC appreciates this opportunity to share insights from our extensive body of work on PA and denials and appeals in the Medicaid program. In MACPAC's March 2024 *Report to Congress on Medicaid and CHIP*, the Commission identified gaps in the monitoring and oversight of the denials and appeals process in Medicaid managed care and made recommendations to increase transparency through improved data collection and reporting on denials of services and the outcomes of appeals. In our June 2026 *Report to Congress on Medicaid and CHIP*, we examined the use of automation tools, such as artificial intelligence (AI), in parts of the PA process, including submitting requests and making PA determinations. Through this work, MACPAC found that there is limited transparency into how automation is being used in Medicaid PA processes

and its impacts on beneficiaries and the program. The Commission made recommendations to CMS to clarify the need for an individual with appropriate expertise to review and authorize all decisions to deny service authorizations and to states to modify existing processes and reporting requirements to oversee the use of automation in PA.

The Commission supports efforts in this proposed rule to improve transparency into the PA process and report data on the volume and outcomes of PA decisions for both drugs and non-drug items and services. The Commission asks CMS to consider reporting these data at a more granular level to better monitor PA outcomes for specific populations and services. In addition, this letter concludes with a technical consideration regarding the PA decision timelines for drugs that are provided as part of, or incident to and in the same setting as, certain non-drug items and services.

Specific reason for denial

The proposed rule requires that for rating periods beginning on or after January 1, 2026, managed care plans' notice of adverse benefit determination for any item or service must include a specific reason for the denial, regardless of the method used to communicate that information. The specific reason for denial must be included for prescription drugs beginning October 1, 2027.

In our work on denials and appeals in Medicaid managed care, we found that denial notices can lack clarity. Beneficiary advocates and providers shared that many beneficiaries receive only generic reasons for their denial, which can lead to confusion. Most focus group participants shared that they did not understand the managed care plan's rationale for denying the service or upholding a denial after the appeal. In our March 2024 report to Congress, the Commission recommended that CMS should issue guidance to improve the clarity and content of denial notices and share information on approaches managed care organizations can leverage to fulfill their requirements to provide beneficiary assistance in filing appeals. The inclusion of a specific reason for the denial in the notice of adverse benefit determination can ensure that the beneficiary and their provider receive more clarity into the reason for denial and can better respond upon an appeal.

Additionally, delays in mail delivery of denial notices can be a barrier to beneficiaries filing a timely appeal. Our research found that notices often arrived late, leaving several focus group participants with insufficient time to request an appeal. In some cases, beneficiaries never received a denial letter. These concerns were echoed in interviews with both state officials and stakeholders. Beneficiaries across all focus groups expressed support for adding more ways for beneficiaries to receive denial notices (e.g., text, e-mail, phone). The requirement for states to support an electronic prior authorization process and make information on prior authorizations requests and decisions accessible electronically, through an application programming interface, can help beneficiaries and their providers monitor the status of prior authorization requests and get notified of adverse benefit determinations in a timelier manner. This can help reduce administrative burden on beneficiaries and providers while promoting a more transparent and understandable process.

Publicly reporting prior authorization metrics

The proposed rule adds public reporting of PA metrics for prescription drugs for rating periods beginning on or after January 1, 2028. Additionally, for rating periods beginning on or after January 1, 2026, the rule would add a requirement to report on the total number of PA requests that were approved, denied, approved after appeals, and remained denied after appeal for non-drug items and services. These reporting metrics are in addition to the percentages that were required under the 2024 CMS Interoperability and Prior Authorization final rule.

In our March 2024 report to Congress, the Commission recommended that CMS should update regulations to require that states collect and report data on denials, the extent to which beneficiaries elect to continue receiving benefits while appeals are pending, and appeal outcomes to improve the performance of the managed care program. Additionally, CMS should update the Managed Care Program Annual Report (MCPAR) template to include these data. The 2024 CMS Interoperability and Prior Authorization final rule added reporting on the percentage of prior authorizations that were denied and appealed, and these data have been added to the MCPAR template.

Collecting and monitoring denial data allow states to assess the extent to which beneficiaries experience denials, and states can use these data to perform trend analysis to identify plan and program-wide issues with access to care. At the time of our study, more than half of states with managed care collect or monitor denial data from plans. Similarly, the Department of Health and Human Service Office of Inspector General found that 22 of the 37 surveyed states reported using PA denials data for oversight (OIG 2023).

The proposed rule takes steps to improve the reporting by adding the total number of PA requests, approvals, denials, and appeals to the reporting metrics for all items and services, including prescription drugs. This information will be reported in the aggregate for all non-drug items and services while prescription drugs will be separately reported in aggregate. Prior authorization reporting is important for transparency, but can also support state and federal oversight efforts to identify patterns that may indicate inappropriate restrictions on medically necessary services, emerging access concerns, or disparities in beneficiary experience. In our interviews, there was broad consensus that reviewing denials is a critical component to identifying issues with beneficiary access to care. Whereas aggregate information can be useful for monitoring and oversight of the program broadly, it may obscure specific instances of inappropriate PA denials for particular services or populations. Some states noted that breaking down denial data by service type can help identify trends specific to certain services or populations. CMS could consider requirements to report the prior authorization for certain services or populations to better monitor and identify specific access issues that may not be discernable in aggregated data.

Furthermore, in our June 2026 report to Congress, MACPAC examined the use of automation tools, such as AI, in parts of the PA process, including making PA determinations. We found that states and managed care plans deploy AI and algorithms to conduct a wide variety of functions in the Medicaid PA process. This research also identified that there is limited transparency into how automation is being used and its impacts on beneficiaries and the program. Stakeholders that we interviewed stated that they have little visibility into how and when automation is being used, how automation tools make PA decisions, and the approval and denial rates for automated systems. Absent this information, it is difficult to determine whether automated systems are making fair PA decisions or impacting beneficiaries' access to care. The Commission recommended that CMS issue guidance to state Medicaid agencies and Medicaid managed care plans specifying ways in which existing regulatory oversight processes can be used to create effective oversight of managed care plans' use of PA automation.

In our interviews, federal stakeholders stated that CMS could collect more data on automation in Medicaid PA by adding new reporting requirements to MCPAR, potentially aligned with implementation of the interoperability rule. CMS could consider additional requirements to report the PA metrics being added under this rule to include information on the use of automation tools in the PA determinations. This additional reporting could provide transparency into automation systems and help states and the federal government monitor technical issues that impact PA decisions, such as data bias or programming flaws.

Technical comments on PA standards for drugs that are not covered outpatient drugs

In the proposed rule, CMS seeks to address comments concerning a possible gap in PA timeframes for a subset of drugs that are not covered outpatient drugs. Section 1927(d)(5)(A) of the Social Security Act (the Act) establishes a 24-hour timeframe for state Medicaid fee-for-service (FFS) programs to respond to PA requests for covered outpatient drugs. The 2024 CMS Interoperability and Prior Authorization final rule established a PA decision timeframe requirement of seven calendar days for non-drug items and services. CMS has proposed that drugs that are excluded from the definition of covered outpatient drug because they are provided as part of, or incident to and in the same setting as, certain services as specified in Section 1927(k)(3) of the Act would be subject to the same PA decision timeframe requirements that apply to non-drug items and services. This would align the PA decision timeframe for those particular drugs with the services it is provided as a part of, or incident to.

CMS has stated that they do not desire to create different timeframes for PA decisions for drugs versus non-drug items and services for which reimbursement and PA requests are bundled. However, there are potential situations in which a drug that is provided as part of, or incident to those specified services in 1927(k)(3) of the Act could be a covered outpatient drug. Drugs are only excluded from the definition of covered outpatient drug when it is provided as part of or incident to and in the same setting as the specified services and for which payment may be made as part of payment for the service and not as direct reimbursement for the drug. Direct reimbursement has been defined in 42 CFR 447.502 to include an inclusive payment for the drug plus the service if: the drug, charge for the drug, and number of units are separately identified on the claim, the inclusive payment includes an amount directly attributable to the drug, and the amount paid for the drug is based on a state plan-approved payment methodology. This means that a drug bundled with those services can be considered a covered outpatient drug in certain circumstances based on the specific payment methodology used, which would create a situation where the PA decision timeframe for the drug would be different from that applied to the rest of the non-drug items and services for which reimbursement was bundled. Additionally, the provider and beneficiary will not necessarily know the specifics of the payment methodology, so these situations could complicate the PA process and create confusion on the potential for differing prior authorization timelines. CMS may want to consider whether additional regulatory clarifications are needed to reduce to potential confusion and inconsistencies in the PA process that can be created for the drug compared to the other included services solely based on the method of payment.

Thank you for the opportunity to comment on this proposed rule. The Commission appreciates CMS's efforts to improve transparency into and increase data reporting on Medicaid PA. Please let us know if there is any further information MACPAC can provide you to aid in your consideration of our comments or that would be helpful as you finalize the rule.

Sincerely,

Verlon Johnson, MPA
Chair

Medicaid and CHIP Payment
and Access Commission
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