August 14, 2026

Administrator Mehmet Oz
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically via www.regulations.gov

Re: Medicare Drug Price Negotiation Program Proposed Rule, CMS-4215-P

Dear Administrator Oz:

The Medicare Drug Price Negotiation Program holds significant potential to lower the cost of prescription drugs for America's seniors. The Alliance of Community Health Plans (ACHP) has long advocated for robust drug pricing reform, including allowing Medicare to negotiate for drugs without generic or biosimilar competition. We support CMS efforts to strengthen the program while preserving health plans' ability to manage formularies based on clinical evidence and value.

ACHP member companies collaborate with their provider partners to deliver higher-quality coverage and care to tens of millions of Americans across nearly all 50 states and D.C. Our provider-aligned member plans are committed to delivering affordable, comprehensive coverage and believe Americans deserve the best health care in the world. We support policy approaches that are simple, transparent and consistently applied across the industry.

We appreciate the opportunity to provide comments to strengthen Medicare drug pricing negotiation.

Publication of Negotiation-Eligible Drugs

ACHP supports publishing a ranked list of up to 30 negotiation-eligible drugs by February 1, two years before each applicable price year. Publishing this list would provide plans, providers, manufacturers and other stakeholders with greater visibility into the drug selection process and support formulary planning, contracting, forecasting and bid development. CMS should consider publishing a preliminary, nonbinding watch list before the statutory selection date to give additional time for forecasting, contracting and operational planning.

CMS should clearly state that the ranked list is intended to improve transparency and planning but does not guarantee future selection, as eligibility may change because of generic or biosimilar entry, biosimilar delays or other statutory exclusions. CMS should publish sufficient information to make the list operationally useful, including associated active moieties or ingredients, National Drug Codes (NDC) and Healthcare Common Procedure Coding System (HCPCS) codes where feasible. Additionally, CMS should identify drugs excluded from the final ranking because of an approved biosimilar delay or another statutory exclusion.

ACHP recommends CMS work with Congress to permit selecting an additional drug from the published list when a selected drug is deselected because of generic or biosimilar entry. Generic and biosimilar competition is a positive market development, but deselection should not result in Medicare

negotiating fewer drugs than authorized for the applicable year. The replacement should generally be the next highest-ranked drug that remains negotiation-eligible. CMS should also establish clear notice and timing standards for replacement selection.

Fixed-Combination Drug Policy

ACHP supports identifying potential qualifying single-source drugs and including all dosage forms and strengths offered by the same New Drug Application or Biologics License Application holder. Without this clarification, the existing policy could create an opportunity for utilization and expenditures to shift across related formulations, potentially delaying selection for negotiation or limiting application of the maximum fair price. The proposed policy appropriately addresses this program integrity risk.

CMS should maintain a narrow standard focused on formulations in which the added ingredient primarily enables an alternative route of administration. CMS should further distinguish those products from formulations that demonstrate meaningful differences in clinical outcomes, safety or total cost of care. Relevant considerations may include improved clinical outcomes or safety, meaningful improvements in adherence, reduced administration burden, reduced provider resource use and demonstrable reductions in total cost of care. CMS should explain its decisions and provide stakeholders with sufficient information to understand how the final criteria were applied.

Bona Fide Marketing and Deselection

ACHP recommends CMS apply the bona fide marketing and deselection provisions based on whether generic or biosimilar competition is meaningful across the dosage forms and strengths used by Medicare beneficiaries. CMS should interpret the bona fide marketing and deselection provisions so that generic or biosimilar entry for a single, minimally utilized dosage form or strength does not terminate the maximum fair price for the remaining, highly utilized presentations. FDA approval or licensure alone does not demonstrate that a competing product is sufficiently available or positioned to create meaningful price competition. CMS should evaluate the share of Medicare utilization represented by the competing presentation, whether it is clinically substitutable for the highly utilized dosage forms and strengths, its availability across wholesalers, pharmacies and provider settings and whether manufacturing capacity and supply are sufficient to support sustained competition.

CMS should also continue monitoring competition after deselection. If a competing product is withdrawn, experiences sustained supply limitations or otherwise ceases to be bona fide marketed, CMS should restore the original drug to negotiation eligibility at the earliest legally permissible date. **CMS should provide plans with at least 90 days' advance notice before any change in selection status takes effect and, when feasible, align the effective date with the start of an applicable price year.**

Part D Formulary Flexibility

ACHP recommends CMS maintain a flexible approach to formulary inclusion of selected drugs and refrain from imposing explicit tier placement, utilization management or other special formulary requirements. Selection for negotiation establishes a maximum fair price, but it does not mean the selected drug is clinically preferable to all therapeutic alternatives or warrants preferred formulary status. The statutory formulary inclusion requirement ensures beneficiary access to selected drugs.

Existing Part D formulary review, exceptions, appeals and nondiscrimination requirements provide additional protections.

CMS should establish clear, enforceable standards identifying the formulary placement and utilization management approaches plans may apply to selected drugs. ACHP member plans have had limited success obtaining CMS approval for nonpreferred placement or utilization management of selected drugs, even when supported by clinical evidence and value considerations. If a formulary contains a therapeutically appropriate alternative that is more cost-effective, that should be sufficient justification for CMS to permit a higher tier placement for the selected drug.

Health plans must retain the ability to use evidence-based formulary tools, including tier placement, prior authorization, step therapy, quantity limits and indication-specific coverage criteria. These tools support safe, effective and affordable treatment. Clear, consistent standards would improve predictability and help plans design formularies that preserve beneficiary access to selected drugs while supporting clinically appropriate and cost-effective care for individual patients.

Implementation Considerations

ACHP encourages CMS to provide clear operational guidance, machine-readable data files and sufficient lead time before any change within the Medicare Drug Price Negotiation Program takes effect. CMS should publish complete and validated NDC and HCPCS mappings, establish prospective effective dates for file changes and provide at least 90 days' notice of selection, replacement, deselection or maximum fair price status changes that require plan system or formulary updates. CMS should align material changes with the beginning of a plan year whenever feasible and provide additional notice when changes affect formulary submissions, bids, provider contracts or beneficiary communications.

ACHP looks forward to continuing to work with CMS to ensure the Medicare Drug Pricing Negotiation program delivers lower drug costs to patients while preserving meaningful competition and health plans' ability to manage formularies based on clinical evidence. Please contact Carmen Witsken, Senior Manager of Pharmacy Policy, at cwitsken@achp.org with questions or to discuss our recommendations further.

Sincerely,

Michael Bagel

Michael Bagel
Vice President, Public Policy
ACHP