August 17, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments on CMS-4215-P: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program Proposed Rule

Dear Administrator Oz:

On behalf of Georgia Life Sciences (GLS), I submit these comments on CMS-4215-P, the proposed rule concerning the Medicare Drug Price Negotiation Program (DPNP) and the Medicare Prescription Drug Benefit Program. GLS is the statewide trade association representing Georgia's life sciences community, including biotechnology and biopharmaceutical companies, medical technology companies, research universities and institutions, healthcare organizations, manufacturers, emerging companies, and partners engaged in the discovery, development, manufacture, and delivery of innovative therapies and technologies.

GLS supports policies that improve affordability and patient access while preserving the incentives needed to discover new medicines and continue improving existing therapies. We are concerned that the proposed modification to the fixed combination drug policy could treat separately developed and FDA-approved products as the same qualifying single source drug (QSSD), discouraging clinically meaningful post-approval innovation and introducing uncertainty into long-term research and investment decisions.

Recognize distinct FDA approvals when identifying QSSDs

FDA has the scientific and regulatory expertise, statutory role, and established processes to determine whether a medicine warrants a distinct New Drug Application (NDA) or Biologics License Application (BLA). A separate approval reflects independent regulatory review and may follow substantial clinical development, formulation work, manufacturing investment, and evidence generation. CMS should respect these regulatory distinctions when identifying QSSDs for the DPNP.

The proposed policy modification could instead require CMS to determine whether an additional active ingredient or component is sufficiently meaningful to distinguish a later product from an earlier one for negotiation purposes. That approach would place CMS in the position of creating a parallel drug-identification framework based on scientific and regulatory judgments already entrusted to FDA. It would also make outcomes less clear for manufacturers, investors, patients, providers, and CMS itself.

An objective standard tied to distinct FDA applications is clearer and more administrable. Accordingly, GLS urges CMS to identify QSSDs by reference to unique NDAs and BLAs and to withdraw the proposed modification to the fixed combination drug policy. Separately approved or licensed products should be treated as distinct QSSDs consistent with FDA's determinations.

Protect post-approval innovation and investment

Biomedical innovation does not end at a medicine's initial approval. Significant advances occur after a therapy first reaches patients through new indications, formulations, routes of administration, delivery technologies, combinations, and other improvements. Research cited in stakeholder materials indicates that approximately half of new indications and approximately three-quarters of industry-funded clinical trials stem from post-approval research and development. These investments can expand the patients who benefit while making treatment safer, less burdensome, more accessible, or more efficient to deliver.

This matters to Georgia's life sciences ecosystem. Our state is strengthening the full pathway from research and commercialization through manufacturing and patient care. Established companies, emerging innovators, academic and research institutions, healthcare systems, and investors make long-term decisions in an environment shaped by both scientific risk and public policy. They need predictable rules that recognize and value meaningful improvements to existing therapies.

Aggregating a separately developed and FDA-approved product with an earlier therapy under one QSSD and one Maximum Fair Price risks signaling that substantial additional clinical and regulatory investment may receive little or no recognition. Over time, that could redirect investment away from improvements that benefit patients and the healthcare delivery system. CMS should avoid a policy that inadvertently penalizes continued innovation after initial approval.

Preserve patient access and site-of-care benefits

The consequences extend beyond research investment. Innovations in formulation and administration can materially reduce the burden of treatment for patients, caregivers, and providers. For some patients, a brief subcutaneous injection may replace hours in an infusion chair and reduce burdens associated with venous access, implanted ports, ongoing maintenance, infection risk, and repeated visits to specialized facilities. Stakeholder evidence also indicates that subcutaneous administration can reduce preparation and administration time and lower direct provider costs in appropriate circumstances.

These benefits are especially important in Georgia. Patients in rural and underserved communities may travel long distances to reach an infusion center or specialty provider, miss work, arrange transportation or childcare, and depend on sites of care with limited capacity. Treatment options that reduce administration time or reliance on resource-intensive settings can improve convenience, support community-based care, and preserve scarce infusion capacity for patients who need it most.

A policy that weakens incentives to develop less burdensome routes of administration could have the opposite effect: greater reliance on hospital infusion centers, fewer flexible treatment options, and additional strain on patients and the healthcare system. CMS should assess patient experience, travel burden, caregiver time, provider capacity, and total cost of care—not only the price of a product—before adopting a policy that may affect such innovations.

Ensure predictability, analysis, and stakeholder engagement

The DPNP will influence research, financing, development, and commercialization decisions made many years before a product may be selected for negotiation. Clear rules are therefore essential. A framework grounded in distinct FDA regulatory approvals offers a stable, transparent benchmark. Case-by-case CMS assessments of whether a component is sufficiently meaningful would create uncertainty about future treatment of products and could alter investment decisions well before CMS makes any formal determination.

GLS's primary recommendation is that CMS withdraw the proposed fixed combination drug policy modification and recognize separately approved or licensed products as distinct QSSDs. If CMS nevertheless believes a change is warranted, the agency should first conduct and publish a robust economic and policy analysis. That analysis should consider effects on post-approval research and development, capital allocation, patient access, site-of-care utilization, provider capacity, competition, long-term Medicare spending, and the overall cost of care.

CMS should also engage meaningfully with patients, caregivers, clinicians, health systems, developers, investors, and other affected stakeholders before finalizing any change. Stakeholder input can help the agency understand downstream effects that may not be visible through a narrow pricing analysis and can support a policy that is both administrable and durable.

Conclusion

Georgia Life Sciences appreciates CMS's efforts to improve affordability for Medicare beneficiaries. That objective should advance alongside patient access, efficient healthcare delivery, and continued scientific progress. For the reasons above, GLS respectfully urges CMS to identify QSSDs based on distinct FDA-approved NDAs and BLAs, respect FDA's role in determining when products warrant separate approval, and withdraw the proposed modification to the fixed combination drug policy. A predictable framework grounded in FDA determinations will better support meaningful post-approval innovation and the patients and communities that depend on it.

Thank you for considering these comments. Georgia Life Sciences welcomes the opportunity to provide additional information and engage further with CMS on these important issues.

Sincerely,

Maria Thacker Goethe, MPH
President & CEO
Georgia Life Sciences