June 26, 2025

Chris Klomp
Deputy Administrator and Director
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Requests for Comments on Medicare Drug Price Negotiation Program Draft Guidance

Dear Deputy Administrator Klomp,

On behalf of the Council for Innovation Promotion (C4IP), I appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) draft guidance for the third cycle of negotiations under the Medicare Drug Price Negotiation Program.

C4IP is a bipartisan coalition founded and chaired by former directors of the U.S. Patent and Trademark Office (USPTO) from previous Democratic and Republican administrations — whose board also includes two retired judges from the Court of Appeals for the Federal Circuit. We are dedicated to supporting a strong and effective patent system that bolsters U.S. innovation, strengthens our nation's economic competitiveness, and fuels investment in technology that improves lives everywhere.

Unfortunately, certain aspects of CMS's draft guidance threaten to undermine these goals by devaluing the intellectual property (IP) protections that support life-saving and life-enhancing medical innovation.

Specifically, CMS proposes that certain reformulated drugs — such as those employing new administration routes — may not be treated as separate "Qualifying Single Source Drugs" (QSSDs) under the Inflation Reduction Act if the agency deems the differences not "clinically meaningful." CMS further indicates that reformulations may be excluded from QSSD designation if their added ingredients are "not therapeutically active against the disease state."

The impact of this change would be profound, affecting the meaningfulness of U.S.-granted patent rights. Under CMS's proposal, a newly approved medicine could face price controls on day one — effectively nullifying the value of its patents.

This would directly undermine incentives for follow-on innovation: improvements made after a product's initial approval that build on the original invention to enhance patient care. These advances can significantly improve compliance, convenience, or quality of life, and include a wide range of developments — from new delivery methods to extended-release formulations.

Reformulated therapies fall squarely within this category. These products retain the same active ingredient but incorporate targeted changes to how the drug is delivered — for example, shifting from an intravenous infusion to a subcutaneous injection, modifying the release profile, or adapting the dosage form to improve compliance. Some reformulations also involve updates to inactive ingredients that enhance stability or tolerability. Bringing these therapies to market requires additional research, development, and regulatory engagement — efforts that depend on patent protection to justify the investment.

By collapsing these reformulated products into the same pricing category as their predecessors, CMS would erode their commercial viability, disincentivize follow-on innovation more broadly, and signal that the government may disregard exclusive patent rights whenever they conflict with price-setting objectives.

Consider the example of improved routes of administration for certain immunotherapies, from infused to subcutaneous application, such as Merck's Keytruda and Bristol Myers Squibb's Opdivo. These new products were developed to reduce infusion times, improve patient compliance, and expand access to outpatient and rural settings. They required new clinical trials, FDA review, and demonstrated novelty sufficient to secure independent patent protection.

Yet, under CMS's proposal, these formulations may not qualify as distinct QSSDs, effectively overriding the inventions protected in corresponding patents, and could be bundled with their intravenous predecessors. This practice would disregard the depth of scientific inquiry and the development rigor behind the innovation required to bring them to market.

Advances on version 1.0 of the medicine — such as modified dosing schedules, subcutaneous alternatives to infusions, or formulation changes that improve tolerability — are patient-centered, evidence-based responses to clinical needs. They involve years of research, significant capital investment, and extensive regulatory engagement. The result is improved adherence, expanded access, and better outcomes.

Insulin provides a clear example of how follow-on improvements can lead to substantial long-term benefits. Before insulin was first injected in 1922 to treat diabetes — isolated from the pancreases of cattle — the average lifespan for a person with type 1 diabetes was just under three years. Over the past century, sustained, patent-backed innovation has transformed the therapy, yielding multiple versions: from biosynthetic human insulin to ultra-long-acting and rapid-acting insulins. These advancements have enabled better glycemic control, reduced the risk of hypoglycemia, and supported greater adherence. As a result, people with type 1 diabetes now live well into their 60s, with average life expectancy reaching 68 for women and 66 for men.

Examples like this highlight what is at stake if CMS moves forward with its current approach. There is no justification for collapsing two distinct therapies into a single pricing category. A policy that treats subcutaneous or long-acting formulations as interchangeable with their infused or immediate-release counterparts undermines the IP rights that make such advancements possible. If time-limited exclusivity holds no practical value at launch, it fundamentally distorts the risk-reward calculus for companies evaluating whether to pursue resource-intensive follow-on innovation.

Over time, undermining the enforceability and value of patents would disincentivize the kind of iterative progress that drives sustained therapeutic advancement, delivering more tailored, accessible, and tolerable treatment options to patients. Notably, improved versions of earlier therapies make up over 60% of the World Health Organization's "Essential Medicines" — underscoring the critical role follow-on innovations play in meeting global health needs.

More broadly, if valid patents can be overridden at the government's discretion, it destabilizes the innovation framework as a whole. It weakens incentives for high-risk R&D, deters private investment, and introduces uncertainty across all industries that depend on predictable and enforceable IP protections. Such a precedent would do lasting harm to America's standing as a global leader in medical and technological innovation.

C4IP strongly urges CMS to reconsider the policy direction reflected in the draft guidance and affirm that reformulated drugs with distinct FDA approvals and valid patents must be treated as separate products in the negotiation process. That clarity is essential to sustaining medical innovation, ensuring future breakthroughs reach the patients who need them, and preserving the integrity of the U.S. patent system.

Thank you for the opportunity to comment.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)