

Centers for Medicare & Medicaid Services' Biosimilar Coding and Payment Policy Could Stifle Biosimilar Innovation and Patient Access

A biosimilar is a biological product licensed by the Food and Drug Administration (FDA) based on its comparability to an already FDA-approved reference product. A biosimilar is highly similar, but not identical, to its reference product, and has been proven to have the same clinical effect.¹ Licensure of a biosimilar follows an abbreviated regulatory pathway created by the Affordable Care Act (ACA).²

Policy experts have estimated that **biosimilars could yield discounts of 20% to 40% compared to reference products**, offering considerable savings to federal and state governments, health insurers, employers, and patients.

In November 2015, the Centers for Medicare & Medicaid Services (CMS) finalized a controversial Medicare payment rule for biosimilars: all biosimilars relative to the same reference product will share the same Healthcare Common Procedure Coding System (HCPCS) code and payment rate, separate from the reference product.³ This creates a single, blended Medicare reimbursement rate for the biosimilars based on the average sales price (ASP) of all biosimilars to a reference product, plus 6% of the ASP for the reference biologic.^a According to the Medicare payment rule, reference products will still maintain their separate HCPCS codes and individual ASPs. CMS' decision to group biosimilars into a single HCPCS code with a blended payment rate for provider use is a striking contradiction to the complexity associated with biologics, and therefore to biosimilars, too.

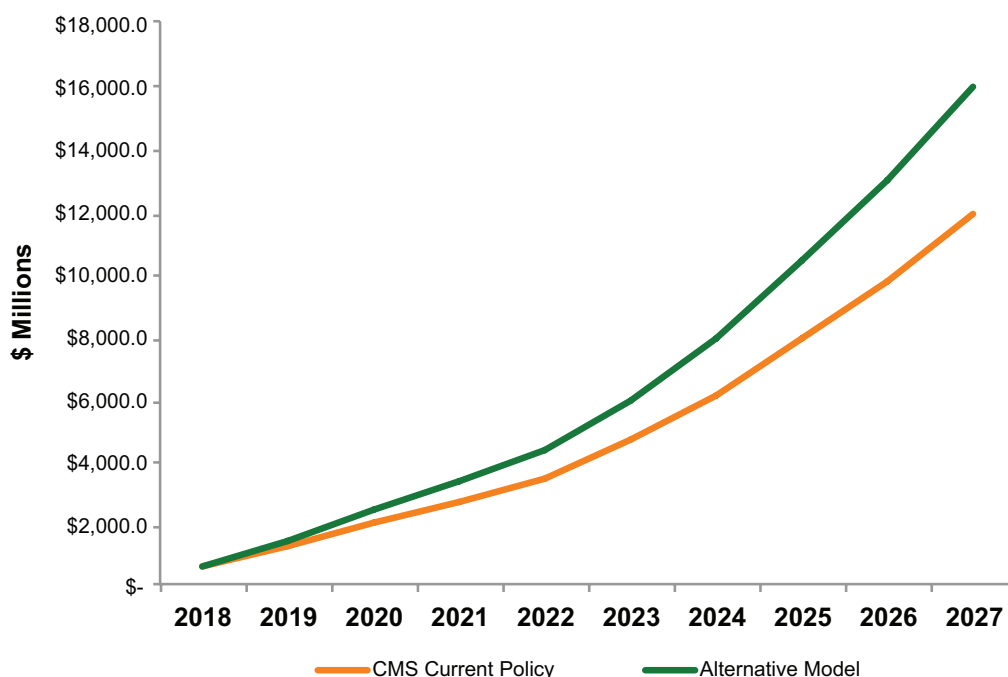
While CMS' policy is estimated to offer \$49.9 billion in savings to the Medicare program over 10 years, an alternative coding policy, which would provide each biosimilar with its own billing code and separate payment rate, could increase savings by an additional \$15.1 billion, or 30% (\$65.0 billion in total over 10 years).

Estimated Savings to Medicare Part B Drug Spending (\$ Millions)

	5-Year Total 2018-2022	10-Year Total 2018-2027
CMS Current Policy	\$9,735	\$49,919
Alternative Model	\$11,969	\$65,010
Difference (Alternative Model – CMS Current Policy)	\$2,235 (23%)	\$15,091 (30%)

^a By law, biosimilars receive 6% of the reference product's ASP. Due to sequestration, however, the effective add-on payment amount is 4.3%.

Estimated Medicare Part B Savings for the CMS Current Policy and the Alternative Model, 2018–2027 (\$ Millions)



This model considers the following to estimate cost-savings:

The uptake rate of biosimilars could be higher over the long term for an alternative coding policy, as manufacturers would be encouraged to develop products for providers and their patients.

The discount of biosimilars could be slightly higher under the CMS policy, as each biosimilar entering the market would enter at a lower price, thereby driving the volume-weighted ASP downward toward an unsustainable rate. This, in turn, could limit the number of manufacturers entering an unstable market.

Manufacturers may leave the marketplace entirely or decide to sidestep the biosimilar regulatory pathway in order to pursue a competitive Biologics License Application. This longer and more expensive route could limit product availability and increase pricing.

Reference products would maintain their own code and ASP independently from biosimilars. Under an alternative payment policy, these products would compete on a level playing field with biosimilar alternatives.

A separate coding and payment policy could offer greater savings to the Medicare program, as it could encourage greater price competition and uptake of biosimilar products in the marketplace. Ultimately, patients would benefit the most from a payment policy that offers prescribing alternatives, achieves long-term savings, and supports a competitive marketplace.

1. Food & Drug Administration. Information for healthcare professionals (biosimilars). <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm241719.htm>. Accessed August 17, 2017.
2. Affordable Care Act. §7002: Approval pathway for biosimilar biological products. May 1, 2010. <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/ucm216146.pdf>. Accessed August 17, 2017.
3. Centers for Medicare & Medicaid Services. Federal Register: Revisions to payment policies under the Physician Fee Schedule and other revisions to Part B for CY 2016; Final Rule: §70885. November 16, 2015. <https://www.federalregister.gov/documents/2015/11/16/2015-28005/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions>. Accessed August 17, 2017.