



September 19, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services (CMS)
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

RE: Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2018 proposed July 13, 2017 (CMS-1676-P);
allowing biosimilars that reference the same biologic to use unique billing codes

Dear Administrator Verma:

We appreciate the opportunity to provide a supplemental submission to our original comments on the proposed payment for biosimilar biological products under Section 1847A of the Social Security Act, included in the *Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018* proposed rule (CMS-1676-P).

As discussed in our initial comments, the Biosimilars Council believes CMS should assign each non-interchangeable biosimilar a unique billing code and payment rate to ensure that the Medicare Part B reimbursement framework creates an environment where biosimilars can not only compete amongst themselves, but also against the brand reference product. Over time, this biosimilar competition would significantly drive down the cost of the product, as well make the market more attractive to future entrants. More products increase patient access while lowering cost.

Therefore, we appreciate CMS's request for "data to demonstrate how individual HCPCS codes could impact the biosimilar market" and "market analyses or research articles that provide data and insight into the current economics of the biosimilar marketplace."

To that end, attached please find a report from The Moran Company (TMC) that analyzes the federal budgetary implications of our recommended change to the current CMS policy. **The report indicates that if CMS were to require individual codes for biosimilars, the result could be \$11.4 billion in savings to the federal government over the FY2018 to FY2027 budget window.**

We believe this analysis provides a clear picture of the harm to patients and the nascent biosimilars industry caused by current policy and the important potential for separate codes to lower costs for patients and payors.

We appreciate the opportunity to provide this supplemental report, and look forward to working with CMS to expand patient access to biosimilar medicines. If you have any additional questions, please contact Christine Simmon, Executive Director of the Biosimilars Council, at (202) 249-7100 or Christine.Simmon@accessiblemeds.org.

Sincerely,

A handwritten signature in blue ink, appearing to read 'C. M. S.', is positioned below the word 'Sincerely,'.

Christine Simmon
Executive Director, Biosimilars Council
Senior Vice President Policy & Strategic Alliances, AAM

Attachment

Discrete Codes for Biosimilars:

Fiscal Implications

September 2017

The Fiscal Implications of Discrete Codes for Biosimilars

In the 2016 Physician Fee Schedule Final Rule, the Centers for Medicare & Medicaid Services (CMS) finalized a provision¹ that groups all biosimilars of a reference biologic under a single Healthcare Common Procedure Coding System (HCPCS) billing code and payment rate. A variety of stakeholders have raised concerns about the CMS policy, and the agency itself has asked for comments on whether the policy should be revisited.

We were asked by our client, the Association for Accessible Medicines (AAM), to analyze how the Congressional Budget Office (CBO) might “score” the budgetary implications of a policy to reverse the CMS decision. This report provides the results of our analysis.

Highlights of Our Findings:

- In prior work, we examined how the CMS coding decision might affect the development of the market for biosimilars and found that bundling biosimilars for each reference biologic into a single code could cause instability in the market for biosimilars.²
- We found that the decision could result in short term price savings, but rising costs over time as some biosimilar manufacturers exited the market for particular products, or decided not to enter at all.
- Using assumptions developed from this analysis, we constructed a model to estimate the effect of a policy that would reverse the CMS policy and require discrete codes for biosimilars.
- Using that model, we estimate that a policy to reverse the CMS decision and provide discrete codes for biosimilars would result in \$11.4 billion in savings to the federal government over the 2018 to 2027 budget scoring window.
- We cannot warrant that CBO will adopt identical assumptions about the structure of the biosimilar market to those that we have applied—and differing assumptions could cause their estimates of the impact of the policy to differ materially from those we have presented.

The balance of this paper provides more details on our findings.

Discussion of Prior Analysis

In prior work, The Moran Company (TMC) analyzed the literature on competition in the marketplace for generic drugs and considered how the biosimilar marketplace might differ—particularly in light of this CMS policy to bundle all biosimilars for each reference biologic into a single code. We found that the biosimilar market is likely to differ in many respects from the market for small molecule generic drugs, perhaps most notably because of the significantly higher level of investment necessary to bring a biosimilar to market. This investment level

¹ 2016 Physician Fee Schedule Final Rule, Section 42 CFR 414.904(j)

² *The Role of Coding in the Development of the Biosimilar Market: Considerations for Policymakers*. The Moran Company (July 2015). http://www.biosimilarsforum.org/sites/default/files/uploads/press-releases/the_role_of_cms_coding_in_the_development_of_the_us_biosimilar_market_20_.pdf

makes the biosimilar marketplace significantly more risky for manufacturers—which the CMS coding decision compounds. We found in that report that the CMS decision would advantage customers of the lowest-price biosimilars, while penalizing those whose sales prices were above the blended Average Sales Price (ASP) for each bundled code. This would create a pricing dynamic which at some point would drive manufacturers out of the market for that biosimilar. Moreover, manufacturers evaluating whether to enter the market for a particular biosimilar might decide not to do so. In either case, by limiting the number of manufacturers competing against a reference biologic, prices would rise—particularly if a duopoly of the reference biologic and a single biosimilar emerges.

These findings suggest that the CMS coding decision provides short term savings through enhanced competition between biosimilars, but with a potential for prices to rise significantly over time. Thus, our model scores a policy to reverse the CMS policy as cost in the short-term, but producing significant savings over time.³

Methodology for Our Current Model

We constructed a baseline for biologic pharmaceutical spending in Medicare Part B using the 2017 Outpatient Prospective Payment System (OPPS) Part B Cost Statistics file and the 2016 Physician Supplier Procedure Summary Master File (PSPS) data, in conjunction with the Food and Drug Administration’s (FDA) release of the “Purple Book.”⁴ We estimate total spending for Part B biologics administered in the physician office and hospital outpatient departments to be \$287 billion during the scoring window. Note, the development of this score was based on top biological products, or products with Part B spending above \$150 million in 2016, because we believe that smaller products are unlikely to justify the level of investment necessary for biosimilar competition.

We then used our baseline to score the impact of the policy, using the following assumptions:

- We applied an annual growth rate which was developed using a blend of Part B and D projections from the June 2017 CBO Medicare baseline, to determine the applicable forecast of Part B drug spending.
- We aligned with CBO’s assumptions from its 2008 score of the legislation that created a pathway for biosimilar approvals similar to the language that was ultimately adopted in the Affordable Care Act (ACA).

³ In addition to our prior analysis, one issue we considered, but have not explicitly modeled here, is the possibility that manufacturers considering the high risk of the biosimilar market with uncertain returns may prefer to create new biologics which could compete in their own codes rather than biosimilars. To the extent that these manufacturers were able to market their products as improvements to existing biologics, they could seek a price premium, rather than a discount relative to existing competitors.

⁴ The Purple Book is reference to FDA’s “Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity of Interchangeability Evaluations.” This book identifies whether a particular biological product has been determined by the FDA to be a reference biologic, a biosimilar, or to be interchangeable with a reference biological product.

- We assumed an initial uptake rate of biosimilars of 0.10 in the beginning of the window, but increased this to 0.35 in later years.⁵
- Using this same CBO score, we calculated the full value of the discounts to range from 40% off the biologic reference product in the early years of the scoring window dropping to 6% as the products mature through the window and biosimilar interaction becomes apparent.⁶
- Lastly, we adjusted our estimates to account for beneficiary premium and cost sharing effects, as well as the effect of the policy on Medicare Advantage.

Results

The estimated direct federal savings of implementing this policy is \$11.4 billion over ten years. Refer to Table A below for a summary of each adjustment built into our analysis.

⁵ Cost Estimate: S. 1695, Biologics Price Competition and Innovation Act of 2007. CBO (July 25, 2008). <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s16950.pdf>

⁶ This 6% discount assumption aligns with FDA's research that estimates the average relative price of one generic drug entering the market compared to its branded product. *Generic Competition and Drug Prices*. FDA (May 13, 2015). <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm>

Table A: Scoring of Discrete Codes for Biosimilars

Discrete Codes for Biosimilars	Changes in Direct Federal Spending										
	<i>(\$ in billions, by fiscal year)</i>										
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2018-2027
Biologic Spending Assuming No Biosimilar Entry	19.8	21.2	22.9	24.8	26.8	29.0	31.4	33.9	37.0	40.0	\$287.0
Baseline Savings Under CMS Biosimilar Coding Policy (relative to no biosimilars)	(0.45)	(0.79)	(1.08)	(1.08)	(0.50)	(0.70)	(0.87)	(1.03)	(1.02)	(0.88)	(\$8.4)
Policy Savings from Discrete Codes	(0.23)	(0.56)	(1.06)	(1.82)	(2.33)	(2.70)	(3.12)	(3.65)	(4.31)	(4.84)	(\$24.6)
Difference	0.23	0.23	0.02	(0.74)	(1.83)	(1.99)	(2.25)	(2.62)	(3.28)	(3.96)	(\$16.2)
Demand Offset	(\$0.07)	(0.07)	(0.01)	0.22	0.55	0.60	0.67	0.79	0.98	1.19	\$4.9
Subtotal	0.16	0.16	0.01	(0.52)	(1.28)	(1.39)	(1.57)	(1.84)	(2.30)	(2.77)	(\$11.3)
Adjusted for Beneficiary Share and Premiums	\$0.09	0.09	0.01	(0.30)	(0.75)	(0.82)	(0.92)	(1.07)	(1.34)	(1.62)	(\$6.6)
Adjustment for Part C Interaction	\$0.09	\$0.09	\$0.01	(\$0.26)	(\$0.61)	(\$0.64)	(\$0.69)	(\$0.78)	(\$0.93)	(\$1.08)	(\$4.8)
Net Change in Direct Federal Spending	\$0.18	\$0.18	\$0.02	(\$0.56)	(\$1.36)	(\$1.46)	(\$1.62)	(\$1.85)	(\$2.28)	(\$2.70)	(\$11.4)