

# **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 provision<sup>1</sup> 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.<sup>2</sup>
- 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

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<sup>1</sup> 2016 Physician Fee Schedule Final Rule, Section 42 CFR 414.904(j)

<sup>2</sup> *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](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.<sup>3</sup>

## 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.”<sup>4</sup> 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).

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<sup>3</sup> 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.

<sup>4</sup> 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.<sup>5</sup>
- 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.<sup>6</sup>
- 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.

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<sup>5</sup> 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>

<sup>6</sup> 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**

	<b>Changes in Direct Federal Spending</b>										
	<i>(\$ in billions, by fiscal year)</i>										
<b>Discrete Codes for Biosimilars</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>	<b>2027</b>	<b>2018-2027</b>
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	<b>\$287.0</b>
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)	<b>(\$8.4)</b>
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)	<b>(\$24.6)</b>
Difference	0.23	0.23	0.02	(0.74)	(1.83)	(1.99)	(2.25)	(2.62)	(3.28)	(3.96)	<b>(\$16.2)</b>
Demand Offset	(\$0.07)	(0.07)	(0.01)	0.22	0.55	0.60	0.67	0.79	0.98	1.19	<b>\$4.9</b>
Subtotal	0.16	0.16	0.01	(0.52)	(1.28)	(1.39)	(1.57)	(1.84)	(2.30)	(2.77)	<b>(\$11.3)</b>
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)	<b>(\$6.6)</b>
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)	<b>(\$4.8)</b>
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)	<b>(\$11.4)</b>