

Biosimilars

F O R U M

September 6, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1676-P

The Biosimilars Forum appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Proposed Rule, " Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program Model" (CMS-1676-P).

The founding members of the Biosimilars Forum represent the majority of companies with the most significant U.S. biosimilars development portfolios, including: Amgen, Boehringer Ingelheim, Coherus BioSciences, Fresenius-Kabi SwissBioSim (formerly EMD Serono), Merck & Co., Pfizer, Samsung Bioepis, Sandoz, and Teva.

The Forum is a non-profit organization whose mission is to educate stakeholders on the value of biosimilars and advance biosimilars in the United States with the intent of expanding access of biological medicines and improving health care. The Forum is a voluntary group working on a consensus basis to develop policy positions to ensure the United States has a competitive, safe, and sustainable biosimilars market, providing more options to patients and physicians. The Biosimilars Forum provides evidence-based information to inform and support public policies that encourage access, awareness and adoption of biosimilars.

Background

In the 2016 Medicare Physician Fee Schedule (MPFS) Final Rule, CMS finalized a proposal that the payment amount for a biosimilar biological product is based on the average sales price (ASP) of all National Drug Codes (NDCs) assigned to the biosimilar biological products included within the same billing and payment code (80 FR 71096 through 71101). Beginning on January 1, 2016, products that rely on a common reference product's biologics license application are grouped into the same payment calculation for determining a single ASP payment limit and that a single Healthcare Common Procedure Coding System (HCPCS) code is used for such biosimilar products.

In the Calendar Year (CY) 2018 MPFS proposed rule, CMS did not make a specific proposal but requested public comment on its current policy specifically seeking the following information:

- New or updated information of the effects of the current biosimilar payment policy that is based on experience with the US marketplace including material, such as market analyses or research articles that provide data insight into the current economics of the market. CMS notes this includes patient, plan, and manufacturer data both domestic and, where applicable, from European markets, which may provide insights for the US market.
- Data to demonstrate how individual HCPCS codes could impact the biosimilar market, including innovation, the number of biosimilar products introduced to the market, patient access, and drug spending.
- Comments regarding other novel payment policies that would foster competition, increase access, and drive cost savings in the market. These solutions may include legislation, demonstrations, and administrative options.

The Forum addresses each of these points below and commends the agency for revisiting the existing biosimilar reimbursement policy as part of the solicitation for comment in the CY 2018 MPFS Proposed Rule. The Forum as well as patients, providers, and Members of Congress have long expressed concern that the long-term stability of the biosimilar market will be jeopardized unless CMS reverses its current policy.

Accordingly, we continue to press upon CMS the importance of employing a policy that assigns each biosimilar a unique HCPCS code for billing and payment effective January 1, 2018. The proposed rule states “[CMS is] not making a proposal to change the existing payment policy in this proposed rule.” For the reasons discussed below, it is imperative that this policy be reversed as soon as possible, and to take effect in CY 2018, in order to prevent lasting damage to the viability of this nascent biosimilars market. To achieve this objective, the Forum has provided suggested preamble language (below) and Code of Federal Regulations (CFR) text to facilitate the agency’s adoption of the policy we request.

As we will discuss, without such a change, the industry may introduce fewer biosimilars into the market, resulting in less competition, higher prices for payers and patients, and fewer options for Medicare beneficiaries. This is an urgent issue, and we are specifically requesting that CMS reverse the existing policy in the CY 2018 MPFS Final Rule. While CMS did not specifically propose a change to its policy on coding and payment of biosimilars, we believe there is good cause to waive notice and comment rulemaking to finalize a policy change in the CY 2018 MPFS final rule, and we will also provide precedent for when CMS undertook changes in a final rule without specifically proposing the changes it adopted. Addressing this policy at a later date would result in significant continued instability in the market, dissuading potential biosimilar manufacturers from entering the space and incentivizing companies with biosimilar products in their pipelines to leave, thus cratering a nascent industry that holds tremendous promise for the Medicare program and its beneficiaries.

Specific Request

The Biosimilar Forum is requesting that CMS include a revised biosimilar reimbursement policy in the CY 2018 MPFS Final Rule. Rather than continue the current policy adopted beginning in 2016 that groups all biosimilars with a single reference product into a single HCPCS billing and payment code, effective January 1, 2018, the Biosimilar Forum requests that each biosimilar have its own HCPCS code for billing and payment.

Suggested Preamble Language:

Upon further reflection due to the discussions we have had with stakeholders on this issue and the information they have provided to us, we agree that the possible reduction in uptake of biosimilars currently on the market, as well as substantial risk of reduced future development of biosimilars, justifies an immediate change to our policy. As manufacturers are expected to halt future development of biosimilars without an immediate change in policy, the future savings associated with biosimilars will be lost to Medicare, its beneficiaries, and the health system as a whole. At that point, it may be too late to change Medicare's policy to spur the development of biosimilars as current multi-year development programs will be shut down. Given the high costs and time investment of product development and the potentially changing marketplace for health care services due to delivery system payment reforms, it may not be possible to restart the biosimilar development process.

Conversely, if our policy were to be changed such that each biosimilar has its own code and payment amount as stakeholders are requesting, we have confidence that the biosimilar industry would continue to introduce more biosimilars in future years, resulting in increased savings for Medicare and its beneficiaries and the health care system. Further, while the current reimbursement policy provides only price as a measure of reimbursement, a reimbursement scheme with individual HCPCS codes would allow payers, manufacturers, and patients to more accurately measure the wealth of investments tied to reimbursement development, including quality and innovation, across the maximum number of treatable conditions. Finally, as biosimilars enter the market, we would be able to monitor effectively the market and the effect on pricing and payment in response to our policy to ensure the viability of the biosimilars market as it develops.

In short, we agree there is more risk to this nascent industry with our current policy than there would be with an alternative policy that provides for a single HCPCS code for billing and payment for each biosimilar. We believe that commenters presented four key points that have convinced us that a policy change is in order. First, public comments provided us with examples of how the biosimilar industry developed in Europe. Biosimilars have been available in the European markets for more than a decade. Public commenters presented us with the example of Austria, which has developed a pricing system that is most similar to Medicare's current policy of grouping all biosimilars with a single reference product into one code with a single payment amount. In Austria, there is tiered pricing for generic products, and biosimilars are paid in the generic tier. After the launch of a new biosimilar, the product was labeled as a generic and priced accordingly. As a result, the distributor decided not to apply for retail sector reimbursement in Austria and now the treatment is available only through hospitals, restricting patient and provider access.

Second, CMS decided to require modifiers to be added to claims to identify a specific manufacturer's biosimilar product. While pharmacovigilance is within the mission of the Food and Drug Administration (FDA) and not CMS, we believe it is important to be able to track these very new pharmaceutical products by manufacturer in the event a safety issue arises. Even though a common HCPCS code may be used for multiple biosimilar products, the modifier allows each unique manufacturer's product to be identified on the claim. However, public commenters correctly noted that the modifiers only apply to Medicare; therefore, tracking of adverse events across other payers will likely prove challenging. As HCPCS is the Health Insurance Portability and Accountability Act standard code set required for use by all payers, unique HCPCS codes for each biosimilar will allow for better pharmacovigilance than our current policy.

Third, the requirement to add a modifier to the claim is unique to biosimilars and does not apply to any other pharmaceutical product. This administrative requirement places an additional, unnecessary burden on providers that could be easily remedied through unique billing and payment codes. In this and other recent rules, we have asked for public comments on how to improve the efficiency of Medicare and other programs under our authority and specifically requested public comments on ways of reducing administrative burdens on health care providers. By adopting unique HCPCS codes for each biosimilar product, we can dispense with the need to include an additional modifier on the claim and can reduce administrative burden.

Fourth and finally, public commenters expressed concern that our current policy risks future development of the biosimilar industry because of the potential for rapidly declining prices when multiple biosimilars are grouped in a single code and priced the same. Future biosimilar development may be seriously curtailed if manufacturers do not believe market prices are high enough to recoup development costs. Public commenters indicate that the alternative policy does not present the same risk. We agree and believe that it will always be possible to change our policy from unique codes for each biosimilar to a single code for multiple biosimilars when they have the same reference product at a point in the future when the biosimilar industry is more fully developed. However, if our current policy of a single code for multiple biosimilars inhibits development, the benefits of a robust biosimilar industry may be delayed for an indefinite period of time.

Our current policy on this issue may be found at 42 CFR part 414, subpart K, § 414.904(j). For the reasons stated above, we are issuing a new interim final rule with comment period to establish, effective January 1, 2018, a new policy that establishes a unique HCPCS code and payment amount for each biosimilar biological product. Unlike our current policy, where the general rule is that we will group all biosimilar products with a single reference product under a single HCPCS code for billing and payment but have the flexibility to create separate codes for billing and payment when there is a policy need, the new policy will always result in a new biosimilar product having its own HCPCS code.

Under the Administrative Procedures Act (APA) and section 1871 of the Act, an agency ordinarily publishes a notice of proposed rulemaking in the Federal Register to provide for a period for public comment before a provision takes effect. However, an agency can waive this procedure if the agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and the agency incorporates a statement of its finding and the reasons for those findings when adopting the policy.

In this circumstance, we believe it would be contrary to the public interest to go through a full notice and comment procedure after soliciting comments in this year's MPFS proposed rule to change this policy. As noted above, we believe our current policy poses a substantial risk of reduced future development of biosimilars. If manufacturers do not believe there is sufficient payment to recoup development costs, further development of biosimilars may be halted. While we could change this policy using next year's MPFS rule effective January 1, 2019 or through a freestanding rule that would make the new policy effective at an earlier date but later than January 1, 2018, both options would be insufficient to provide the assurance the biosimilar industry needs to continue biosimilar development. Our concern is not with the biosimilar industry itself but the public interest in continued development of lower cost pharmaceutical products that would benefit Medicare and its beneficiaries. Once development is halted, it is not easily restarted and there could be many years of delay before additional biosimilar products come on the market. We believe this result would be contrary to the public interest.

Further, we believe the public was given input generally on notice that CMS was interested in changing this policy and could comment accordingly even though we did not explicitly propose a specific change. Absent legislation, the regulatory policy choices in this circumstance are binary—to either group each biosimilar with the same reference product in the same HCPCS code or to give each biosimilar its own code.¹ As grouping each biosimilar with the same reference product in the same HCPCS code is our current policy, the only alternative policy is to give each biosimilar biological product its own HCPCS code and payment amount. By requesting public comment on this issue, the public was on notice that CMS was interested in either continuing current policy or adopting the one and only alternative that we would be able to adopt under current law. Given the public interest in the future development of biosimilars, we do not believe it would be in the public interest to delay the policy we are adopting in this interim final rule by as much as a year merely to reiterate discussion from this year’s MPFS proposed rule in a future proposed rule and explicitly propose the policy we are adopting now.

We are interested in public comments on the interim final rule policy we are adopting.

Code of Federal Regulations Text:

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

- 1. Section 414.904 is amended by revising paragraph (j) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(j) *Biosimilar biological products.* (1) Effective January 1, 2016, the payment amount for each biosimilar biological drug product (as defined in § 414.902) for all NDCs assigned to such product is the sum of the average sales price of all NDCs assigned to that biosimilar biological product and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference drug product (as defined in § 414.902).

(2) Effective January 1, 2018, (i) CMS will assign each biosimilar a unique HCPCS code including biosimilars for which payment has been made pursuant to paragraph (j)(1) and (ii) the payment amount for such HCPCS code for all NDCs assigned to such HCPCS code is the sum of the average sales price of all NDCs assigned to the biosimilar biological product as determined under section 1847A(b)(6) of the Act

¹ While there is a third option—include the reference product and all of its biosimilars in a single code—this option would require a statutory change. The statute mandates that the biological is paid at ASP + 6 percent, whereas the biosimilar is paid at ASP + 6 percent of the price of the reference biological. This third option would not only be counter to the policy direction we would like to take, it would also not be within our regulatory authority.

and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference drug product (as defined in §414.902).

Waiver of Proposed Rulemaking

One concern the agency may have about adopting our request is the APA requirement that notice and comment rulemaking be undertaken before a new policy takes effect. In the case of CMS' comment solicitation on Medicare policy for coding and payment of biosimilars, CMS did not explicitly propose a new policy. However, for the reasons explained above in the draft preamble language, we believe it would be in the public interest to waive notice and comment rulemaking as is permitted under the APA if the agency finds good cause for doing so and states that good cause in the rulemaking where the new policy is being adopted. In summary, we believe those reasons are:

1. Not undertaking a change in policy for 2018 could inhibit continued development of biosimilars and delay the benefits that lower cost pharmaceutical products will have for our health care system; and
2. The public was effectively on notice through the comment solicitation that CMS was considering changing the policy even though a change was not explicitly proposed. As the policy choices are essentially binary (one code for multiple biosimilars or one code for each biosimilar), the public was on notice that CMS was considering and sought comment on the only potential alternative to the current policy: a unique code for each biosimilar product. It would not be in the public interest to delay a new policy beyond January 1, 2018 merely to reiterate the comment solicitation from this year's proposed rule with the only difference being that CMS explicitly proposes the only alternative there is to the current policy.

We further believe that there is precedent, as well as a parallel example in this year's MPFS rule, where CMS indicates it may adopt a policy in the final rule without having specifically proposed it first.

In the CY 2018 Hospital Outpatient Prospective Payment System (OPPS) proposed rule published on July 20, 2017 (just one day before the publication of the CY 2018 MPFS proposed rule), CMS requested comment on the laboratory date of service rule (See 82 FR 33650 – 33653). Like it did in the comment solicitation for biosimilars, CMS outlined the policy's history as well as concerns that it had received from stakeholders, including access to molecular and genetic tests and the potential delays in care for patients with cancer and other serious medical conditions. The agency then requested public comment on those concerns and outlined potential policy options that could be adopted as alternatives to the current policy. CMS did not specifically propose to adopt any of those alternatives. However, at the end of the discussion, CMS indicated "we would consider finalizing the modifications described in this section" (82 FR 33653), which suggests to us that CMS is considering finalizing changes to the laboratory date of service rule effective January 1, 2018 in the CY 2018 OPPS final rule even though they did not specifically propose changes. Contrast this language with the final two sentences at the end of the comment solicitation on biosimilars that states "please note that this is a solicitation for comments on this issue for future consideration. We are not making a proposal to change the existing payment policy in this proposed rule (82 FR 34091)." The language at the end of the biosimilar comment solicitation suggests to us that CMS is not considering a change in the biosimilar coding and payment policy in the CY 2018 MPFS final rule.

In neither case has CMS explicitly proposed a change in policy, yet in one case there is an implication that the agency would finalize a policy without specifically proposing it while in the other the agency is

suggesting the opposite. In our view, if there is a good cause to waive notice and comment rulemaking to adopt either or both of these policies, CMS should proceed accordingly. The agency's statement of intent at the end of each of these respective sections has no meaning with respect to the APA requirements and should have no bearing on CMS' final decision as to whether to proceed with finalizing a change to the laboratory date of service rule or the change we are requesting for the biosimilar coding and payment policy effective January 1, 2018.

With respect to CMS' established precedent of finalizing policy without having specifically proposed it, we believe the Fiscal Year (FY) 2006 hospital inpatient prospective payment system (IPPS) final rule published on August 12, 2005 (70 FR 47289) provides at least one example. In response to one public comment, CMS deleted diagnosis-related groups (DRGs) 107, 109, 111, 116, 478, 516, 517, 526, and 527 and created new DRGs 547 through 558 in their place. We could find no evidence that CMS proposed these changes much less solicited comments on them. The final rule changes are found in the discussion of Major Diagnostic Category (MDC) 5 (Diseases and Disorders of the Circulatory System). There is no discussion of this issue in the corresponding section of the IPPS proposed rule (70 FR 23454). The closest evidence we could find to CMS making a related proposal is in the FY 2006 IPPS proposed rule published on May 4, 2005. In CMS' review of Medicare Payment Advisory Commission's recommendations on Physician-Owned Specialty Hospitals, CMS stated:

Another option we are considering is a selective review of the specific DRGs, such as cardiac, orthopedic, and surgical DRGs, that are alleged to be overpaid and that create incentives for physicians to form specialty hospitals. We expect to selectively review particular DRGs based on statistical criteria such as the range or standard deviation among charges for cases included within the DRG (70 FR 23454)."

Compared to this precedent, we believe the comment solicitation in the proposed rule for biosimilars (and the lab date-of-service rule, as well) provides ample notice to the public that CMS was considering a potential change in policy on this issue for the final rule.

Specific Comments to the Proposed Rule

It is important to note since the issuance of the CY 2016 MPFS Final Rule, there has been considerable additional information provided to CMS by stakeholders. This has included detailed economic forecasts and other stakeholder input regarding the adverse impact of a single payment for all biosimilars related to a reference biologic. Much of this information has been informed by a growing biosimilar market in the United States.

There are now six biosimilars – Zarxio®, Inflectra®, Erelzi®, Amjevita®, Renflexis® and Cyltezo™ – approved by the FDA.² When CMS finalized their reimbursement policy in 2015, there was only one biosimilar approved by the FDA. FDA notes that as of FY 2016 more than 60 biosimilars are in development for more than 20 reference products. However, the market viability of these products and further biosimilar development is at risk because of the reimbursement policy that CMS adopted two years ago.

In the proposed rule, CMS seeks specific comment assessing the effects of the Medicare payment policy on the biosimilar biological product marketplace, particularly if the policy is fostering a robust and

² Two biosimilars for reference products Herceptin® and Avastin® were unanimously approved by FDA's Oncologic Drugs Advisory Committee (ODAC) and are pending FDA approval.

competitive marketplace and encouraging innovation. CMS is also interested in better understanding if and how the innate differences in biological products and their current regulatory environment should be reflected in Medicare payment policy for biosimilars.

New or Updated Information of the Effects of the Current Biosimilar Policy:

Specifically, CMS seeks new or updated information of the effects of the current biosimilar payment policy that is based on experience with the US marketplace including material, “such as market analyses or research articles that provide data and insight into the current economics of the biosimilar market place.”³ CMS notes “this includes patient, plan, and manufacturer data both domestic and, where applicable, from European markets, that may provide insight” for the US market.⁴

Budget Impact Model

Below you will find a summary of an updated policy budget impact model that estimates how the CMS coding and payment decision threatens the potential sustainability of the biosimilars marketplace. The entire model is attached.

While CMS’ policy has been estimated to save \$49.9 billion to the Medicare program over 10 years, the savings could be much less if the development of future biosimilars is imperiled by the current policy. Alternatively, an appropriate 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 percent (\$65.0 billion in total over 10 years). As discussed in the attached model, the additional savings are generated primarily through the potential for increased biosimilar availability, long-term price competition among manufacturers of biosimilar products and reference products, and higher rates of utilization over time.

Moran Report

Additionally, attached you will find a report from the Moran Company, *The Role of Coding in the Development of the Biosimilar Market: Considerations for Policymakers*. The report underscores the importance of ensuring sustainability for all stakeholders. Focusing on price alone risks constraining the longer-term opportunities for savings by making the market less attractive for manufacturers, thus reducing incentives to invest in the development and commercialization of subsequent waves of biosimilar products. By driving out competition, there is enhanced risk of reducing the level of physician choice and potentially limiting patient access to treatment. Above all, payers like Medicare must understand that a focus on short-term savings may appear attractive but will prove limiting in the long term.⁵

European Examples

There is a lack of uniformity in health sector payment systems and drug payment methodologies in general across European Union (EU) nations that have access to biosimilars. As such, there is not one specific country’s approach that will be sufficiently comparable to the U.S. market. However, given that

³ 82 FR 34091.

⁴ Ibid.

⁵ “The Role of Coding in the Development of the Biosimilar Market: Considerations for Policymakers,” The Moran Group, July 2015.

the EU's biosimilar experience is more extensive than the U.S.'s – with over 30 products in seven therapeutic classes – lessons learned from the European experience show that biosimilars have the potential to lead to cost savings as a result of competitive, marked-based dynamics.^{6,7} These dynamics are best facilitated in the U.S. through the provision of individual HCPCS codes, which will enable manufacturers to compete without the risk of triggering a race to the bottom and, potentially, market exit. To demonstrate this, QuintileIMS™ released a report in May of 2017 titled, *The Impact of Biosimilar Competition in Europe*, which provides a multitude of observations on the biosimilars market in Europe.⁸

Key observations in the report include:

- The introduction of a biosimilar results in competition that reduces prices. The increased competition impacts not only the price of the reference product but the price of the entire class. It can have almost as significant an impact on the total market price as on the biosimilar/reference product price. Assigning individual HCPCS codes to biosimilars would enable this type of healthy market competition, rather than a race to the bottom among the biosimilars in a code.⁹
- Market savings occur even if the biosimilar market share is low or it does not end up as the product sold in a transaction. The mere introduction of the biosimilar can affect competitive dynamics. To reach savings, competition among multiple biosimilars is not necessary, which is very different than in generic markets.¹⁰
- In terms of specific experiences, countries such as Germany have seen an increase in competition and greater patient access through enhanced biosimilar reimbursement approaches. Germany has successfully fostered sustainable biosimilar competition by employing regular price adoptions, educating physicians, and implementing measures designed to stimulate biosimilar prescribing.
- Not all biosimilar policies in Europe have worked well for the overall healthcare system. For example, Austria requires a mandatory price scheme, which has led to some biosimilars being excluded in the marketplace. Austria operates a tiered pricing system for generic products into which biosimilars are lumped. After the launch of biosimilar infliximab, manufactured by Celltrion (Remsima®, distributed by Astro Pharma, and Inflectra®, distributed by Hospira), the product was labeled as a generic and priced accordingly. As a result, the distributor decided not to apply for retail sector reimbursement in Austria and now the treatment is available only through hospitals, restricting patient and provider access.

⁶ Biosimilars approved in Europe. *Generics and Biosimilars Initiative (GABI)*. 7 July 2017. <http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe>.

⁷ Rémuzat C. et al. Key drivers for market penetration of biosimilars in Europe. *Journal of Market Access & Health Policy*. 30 Jan. 2017; 5(1).

⁸ "The Impact of Biosimilar Competition in Europe." QuintilesIMS Report. May 2017.

⁹ Id. p. 3.

¹⁰ Id. p. 4.

In addition, other studies have noted that the uptake of biosimilars is inversely correlated to overall health system spending.¹¹ Thus, countries such as Poland, Greece, and Hungary, which utilize robust cost containment measures and have historically been precluded from access to traditional biologics, are able to participate in the biosimilars market.¹² For these and other markets, the presence of biosimilars and their lower costs compared with innovator biologics has greatly increased patient access to these drugs.

Data to Demonstrate How Individual HCPCS Codes Could Impact The Biosimilar Market:

Specifically, CMS seeks data to demonstrate how individual HCPCS codes could impact the biosimilar market, including innovation, the number of biosimilar products introduced to the market, patient access, and drug spending.¹³

It is important to acknowledge the high barriers of entry that exist in the biosimilar market. For instance, development costs are directly tied to the complexity of the molecule in production. The U.S. Federal Trade Commission (FTC) estimates that biosimilar products are likely to take 8 to 10 years to develop, with development costs ranging from \$100 million to \$200 million,¹⁴ while the development of small molecule generic drugs, which are far less complex, typically takes only 3 to 5 years and costs between \$1 and \$5 million.¹⁵

Besides the estimated \$100 to \$200 million in development costs, there are also the costs of developing a manufacturing process and, in some cases, significant investment to build a suitable manufacturing facility, which in some cases is estimated to be \$250 million to \$1 billion.¹⁶ According to the FTC, “substantial costs to obtain FDA approval, plus the substantial fixed costs to develop manufacturing capacity, will likely limit the number of competitors that undertake entry with follow-on biologic products.”¹⁷ Given these already existing barriers to market entry, CMS’ proposal to assign one HCPCS code to all biosimilar products of a reference biological and its effect on market prices will likely force biosimilar manufacturers to scale back investment and development in this emerging sector, which would reduce effective treatment options for patients and the clinicians providing their care.

CMS characterizes its proposed payment methodology for biosimilars as similar to the ASP calculation for multisource drugs. Even putting aside CMS’ mischaracterization of biosimilars as being similar to multiple source or generic drugs, and despite existing inconsistencies, discussed below, in how it characterizes biosimilars across Medicare and Medicaid, CMS has not accounted for the serious unintended consequences its policy will bring to the nascent biosimilar market. Under the CMS policy, biosimilars will be paid at the same rate under Medicare Part B no matter the differences in the FDA-approved indications of each biosimilar product or the extent of interchangeability with the reference

¹¹ Rémuzat C. et al. Key drivers for market penetration of biosimilars in Europe. *Journal of Market Access & Health Policy*. 30 Jan. 2017; 5(1).

¹² Ibid.

¹³ 82 FR 34091.

¹⁴ These figures have likely increased since publication of the report in 2009.

¹⁵ FTC Report, “Emerging Health Care Issues: Follow-on Biologic Drug Competition,” June 2009.

¹⁶ Harding, David, “White Paper: Gaining Market Share in the Generic Drug Industry Through Acquisitions and Partnerships,” 2010.

¹⁷ Id.

biological. A biosimilar approved for all indications for a reference product would be paid at the exact same rate as a biosimilar that is approved to treat only one indication.

Under CMS' current reimbursement policy, these more broadly developed products – those seeking the maximum number of indications – will be unable to compete, even if their prices are lower than the reference biologic, thereby reducing the number of competitive products in the market. In addition to fewer treatment options for patients, evidence suggests that as more products leave the market and competition is reduced, prices of the remaining products will rise, which will effectively defeat the purpose of the current policy.¹⁸

The existing CMS' policy risks creating an adverse impact on the viability of biosimilars in the U.S. as manufacturers will have less incentive to invest in biosimilar development if they cannot have a period of profitability that allows them to recoup their development costs. As originator biologics have exclusivity and other provisions to incentivize entry into the market, biosimilar manufacturers should be able to be incentivized to enter the market through a stable reimbursement scheme afforded by separate HCPCS codes in order to more accurately recover the heavy development and manufacturing costs associated with biosimilar production. Indeed, without an appropriate reimbursement framework for the largest segment of coverage – Medicare – there is no future for these products. While CMS' policy may drive prices down in the near term, it does little to encourage market competition between manufacturers of biologics and biosimilar manufactures in the long term as the biosimilar market simply will offer less incentive investment to develop biosimilars. As noted earlier, 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 percent for a total of \$65.0 billion in total over 10 years.

The U.S. is on the brink of seeing the potential impact a competitive biosimilar market could have on drug prices and accessibility. Merck & Co. and Samsung Bioepis announced in late July the launch of Renflexis®, the second FDA-approved biosimilar referencing Johnson & Johnson (J&J) 's Remicade® (infliximab). Merck set the list price for the tumor necrosis factor (TNF) blocker at \$753.39 per dose, a 35 percent discount to the current list price of Remicade®. That is the steepest discount offered for a biosimilar in the U.S. Pfizer Inc. launched the first Remicade® biosimilar – Inflectra® – at a 15 percent discount in November 2016 (later dropped to a 19 percent discount). With the launch of Renflexis®, Remicade® becomes the first biologic to have two biosimilars on the U.S. market. This pricing strategy demonstrates the importance of having multiple biosimilars introduced into the market for the same reference product. If there is inadequate reimbursement for biosimilars, there is a risk that in other markets there will be a lack of robust competition.

In fact, the existing CMS policy, as noted in the attached Moran study, creates a race to the bottom. In many cases there is a risk that only one biosimilar will survive this competition; other biosimilar competitors will either withdraw from the market or will be deterred from entry in the first place even though their prices may be lower than the reference biologic. If manufactures do not believe they can recoup their costs, they will not invest in developing new biosimilars.

¹⁸ "The Role of Coding in the Development of the Biosimilar Market: Considerations for Policymakers," The Moran Group. July 2015.

Other Novel Payment Policies That Would Foster Competition:

Specifically, CMS seeks comments regarding other novel payment policies that would foster competition, increase access, and drive cost savings in the market. These solutions may include legislation, demonstrations, and administrative options.¹⁹

The Forum has long advocated that the optimal biosimilar reimbursement policy, given their review and approval on an individual basis, is one of unique billing and payment codes for each biosimilar, a policy that not only aligns with the FDA's guidances on biosimilars but also supports the development of biosimilars and promotes robust market competition with both the biosimilar and reference product that will in turn drive down costs.^{20,21} Studies have shown that robust competition is a sustainable way to reduce costs, especially in the biologics market.²² The Forum is opposed to other approaches that would allow blended coding and payment for all innovator biologics and their biosimilars as these policies would have dampening effects on the long-term competition needed to grow the biosimilars market and generate cost savings.

The Forum strongly believes in order to deliver on the promise biosimilars hold for both lower costs and increased access, we need a robust, competitive, and sustainable market that recognizes the differentiated benefits of each unique biosimilar, including price and other attributes. For the market to thrive, each biosimilar requires a separate HCPCS billing code and associated payment rate with which we can measure both its market performance and its differentiated attributes.

Barriers to Realizing the Benefit of Biosimilars

Biosimilar medicines are poised to play a central role in enabling Medicare and the overall healthcare system to achieve significant savings over the next decade and beyond. However, this potential is at risk. The importance of adopting a reimbursement policy that reduces the barriers and optimizes the benefits offered by biosimilar medicines cannot be overstated.

Blended Reimbursement Impedes Physician Education and Choice

One of the several challenges facing biosimilar adoption in the U.S. is limited physician experience with biosimilars while having lengthy experience and familiarity with existing biologic therapies. Recent survey data among physicians who prescribe biologics indicated several major knowledge gaps concerning biosimilars, including defining biosimilars, understanding the approval process for these drugs, and understanding comparable safety and immunogenicity between an originator and its biosimilars.²³ Consequently, it is incumbent upon manufactures to educate physicians about these highly complex molecules and provide significant evidence of the clinical benefits of biosimilars. A clear

¹⁹ 82 FR 34091.

²⁰ Food and Drug Administration. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry. April 2015.

²¹ Food and Drug Administration. Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009: Guidance for Industry. April 2015.

²² Morton FS and LT Boller. Enabling competition in pharmaceutical markets. *Brookings Institution*. May 2017. https://www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf.

²³ Cohen H et al. Awareness, knowledge, and perceptions of biosimilars among specialty physicians. *Advances in Therapy*. December 2016; 33(12):2160-2172.

understanding of the scientific principles of biosimilars and access to information on licensed biosimilars are important for physicians to make informed and appropriate treatment choices for their patients.

Accordingly, biosimilars manufacturers are developing education programs and services offerings to educate physicians on the approval pathway, quality, safety, efficacy, and benefits of these products. Upfront investments will likely require a strong emphasis on physician and patient education to address utilization as well as supply chain investments to better enable access to the medication. These investments can only be made if there is an appropriate reimbursement framework in place to incentivize companies to make these investments and instill long-term confidence in the market. And, as mentioned previously, the biosimilars experience in the EU has shown that these educational investments are necessary for sustainable uptake, especially compared with the generics market. Indeed, survey data in Europe has indicated that education and understanding by stakeholders, including physicians and patients, through educational materials and unbiased information was crucial for growth of the biosimilars marketplace in the EU and the substantial savings that has been shown there.²⁴

Accordingly, physicians expect that biosimilars manufacturers will provide the same level of education and support services that are provided for the reference product. In addition to clinical information for providers, reference biologics manufacturers offer reimbursement support to explain the coding and payment landscape for these medicines and provide benefit verification and co-pay assistance for commercially insured patients. Thus, biosimilars manufacturers need to have adequate reimbursement to support providing similar services as manufacturers of reference biologics.

Blended Reimbursement Compromises Patient Care and Safety

Although sufficiently similar to the reference product, each biosimilar could be different in the number of indications it is approved for and whether or not it is interchangeable from its reference product or another manufacturer's biosimilar for the same reference product. Physicians already have a significant need for education and experience with biosimilars. CMS' biosimilar reimbursement policy only increases these challenges as multiple different products will be identified by a single code and payment amount. The current CMS policy promotes the scenario in the clinic where a physician cannot readily identify each biosimilar by its unique billing code on a pre-typed drug formulary or prescribing application, which could then lead to prescribing and medication errors. This will, in turn, lead to less adoption of biosimilars.

Blended Reimbursement Discourages Biosimilar Innovation

Under the current CMS policy of a shared billing and payment code, a biosimilar's sole relevant measure for reimbursement is price, rather than the biosimilars unique attributes. In addition to failing to recognize the unique, FDA-evaluated clinical attributes of each biosimilar, CMS' current reimbursement policy excludes from reimbursement important, patient-centric considerations including variation in delivery devices, patient support programs, number of indications covered, and the reliability of the

²⁴ European Generic medicines Association. GfK Market Access. Factors supporting a sustainable European biosimilar medicines market. 2014 Sept. 9. http://www.medicinesforeurope.com/wp-content/uploads/2016/03/GfK_Final_Report-Factors_Supporting_a_Sustainable_European_Biosimilar_Medicines_Market.pdf.

manufacturer in supplying a product. Failure to allow for differentiation in pricing discourages – and arguably makes cost prohibitive – a focus on differentiation via services and other offerings.

Blended Coding Requires Additional Administrative Burden

Biosimilars provide new opportunities for reducing healthcare costs and providing more treatment options for patients; however, they have only had recent utilization in the U.S. with the first FDA approval in 2015. With the lack of experience with these products in the U.S. comes the need to better understand and track how these products are being utilized. To address this issue, CMS requires each claim for payment for a biosimilar product to include a modifier identifying the product's manufacturer. However, if the HCPCS code and modifier do not appear on CMS's quarterly update notifying providers of billing and coding changes, then it is not required to utilize a modifier. In addition, if there is not a HCPCS code that can adequately describe biosimilars as they enter the market, providers can bill using a miscellaneous or "not otherwise classified" code. In this case, when a miscellaneous code is used, a manufacturer modifier is not required.²⁵

When a biosimilar product does not have a modifier and a provider has to bill with a miscellaneous code, it could delay reimbursement and potentially place providers at financial risk. Should this occur, this could be detrimental to biosimilar adoption, as any claim rejections or delayed time to reimbursement could create reluctance among providers to prescribe biosimilars. This is significant when you consider that modifiers are not required for other drugs and biologics for pharmacovigilance purposes or otherwise. This additional administrative requirement, unique to biosimilars, places an additional, unnecessary burden on providers that could be easily remedied through unique billing and payment codes.

In addition, as more biosimilars enter the market and more modifiers are added, it is likely this situation will complicate billing procedures and cause additional frustration and confusion. First, there could be an educational deficit among the provider's office staff when billing, as they might not be aware that billing with a modifier should be used when applicable. It could also be looked at as tedious, as this is another step (unique to biosimilars) required when submitting a claim, leading to lower utilization of biosimilars due to increased administrative burden.

Outside of Medicare, according to a recent payer study conducted by Xcenda, 65 percent of payer respondents do not require the use of a randomly assigned modifier code to specify the manufacturer for claims of biosimilars. Further, among payers that do require use of modifiers, there is great inconsistency in regard to how the modifiers are applied – 64 percent of survey respondents noted that they rarely require the use of modifiers above and beyond Medicare requirements. This data is supported by a separate study performed by Avalere, which analyzed the use of modifiers across Medicare and multiple commercial payers. For example, Avalere's data indicate that 93 percent of Medicare claims utilize the modifier assigned to the biosimilar Zarxio while 0 percent of claims filed by commercial payers used said modifier.²⁶ These statistics alone demonstrate the significant compromise of adverse event tracking outside of Medicare. However, since the blended J-code policy extends across all payers, there is limited ability for a payer to manage this more effectively.

²⁵ Centers for Medicare & Medicaid Services. Part B biosimilar biological product payment and required modifiers. July 26, 2017.

²⁶ Avalere-produced analysis on behalf of Amgen examining the effect of HCPCS modifiers in tracking utilization of biosimilars, powered by MORE2 Registry, August 2017. Amgen data on file.

The Xcenda payer survey also noted that there is considerable lack of support from payers for several CMS biosimilar policies. Notably, over 75 percent of respondents believe blended codes may have a negative effect on pharmacovigilance. Further, respondents felt that grouping all biosimilars to a branded reference product together creates confusion around the fact that all biosimilars to a reference product are not biosimilar to each other. Finally, respondents noted that maintaining a separate code for the brand discourages the use of the biosimilar and does not promote competition between biosimilars and the brand.

The factors noted above have yielded a complex landscape with wide variations and inconsistencies across payers. These complexities can easily be remedied through unique coding for each biosimilar product.

Blended Reimbursement Inaccurately Treats Biosimilars as Multisource Generic Drugs

CMS has characterized its proposed policy for the payment of biosimilar products under Medicare Part B as “similar to the ASP calculation for multisource drugs.”²⁷ It is important to note that biosimilar products are not generic versions of their reference biological, nor are they multisource drugs. The FDA has made public statements acknowledging that biosimilars are not generics, and accordingly has created a separate approval process for biosimilar products.²⁸

Biosimilars are manufactured using a genetically controlled and a scientifically different process from how generic drugs are produced. While generic drugs are generally manufactured through the combination of chemicals that typically result in exact copies of the brand drug each time, biosimilars are made by living cells that produce, modify, and assemble proteins into large, highly complex similar molecules. Biologics cannot be rapidly or easily produced like small molecule generic copies. Biosimilars are also classified as “highly similar” – rather than bioequivalent – to the reference product, whereas all small molecule generics are bioequivalent to their reference products. Additionally, one biosimilar product sponsor can seek for approval by FDA of their biosimilar for just one indicated use of the reference biologic, whereas other biosimilars for the same reference product can be developed to obtain FDA approval for all non-exclusive indications. Thus, biosimilar products of one reference biological can vary in terms of approved clinical uses and interchangeability.

However, CMS’s proposal fails to account for these differences, and instead assigns the same HCPCS code across multiple biosimilar products with a range of approved medical uses. Further, the inaccurate classification of biosimilars as generics within Medicare Part B can have its own, unique adverse effects on market stability and achieving long-term, sustainable cost control through competition. There have been several examples of the adverse consequences for price stability of grouping a generic drug and a brand product within Medicare Part B under the same HCPCS code. For instance, based on our review of quarterly ASP prices on the CMS website, generic entry of Oxaliplatin (brand name Eloxatin®) created a significant drop in price upon first introduction, ultimately driving a 97 percent drop in price within a two-year time period. This and other rapid and severe price decreases create a “race to the bottom” that would be unsustainable in a nascent biosimilars market and highlight the hazards of mischaracterizing biosimilars as small molecule generic drugs. If this same experience were repeated for biosimilars, any future development of biosimilars would likely be significantly curtailed as the longer

²⁷ Id.

²⁸ See FDA website at www.fda.gov, FDA Information for Consumers (Biosimilars).

development period and higher costs associated with biosimilars than generic products could make this industry unviable.

Blended Reimbursement under Medicare Part B is Inconsistent with How CMS itself Defines Biosimilars under Medicaid and Medicare Part D

CMS' intent to treat biosimilars as multisource drugs for payment purposes conflicts with its own position on biosimilars under Medicaid and Medicare Part D. For example, under Section 1927 of the *Social Security Act*, biosimilars manufacturers are clearly required to enter into a Medicaid rebate agreement as a condition of coverage under the Medicaid program, because biosimilars are "covered outpatient drugs" that are "licensed under section 351 of the Public Health Service Act."²⁹

In determining the amount of the rebate to be paid for biosimilars, CMS needed to determine if they should fall into the category "single source drugs and innovator multisource drugs" or the "other drugs" category, which is defined as "other than single source drugs and innovator multiple source drugs."³⁰ In its Medicaid Drug Rebate ("MDR") Program Notice released on March 30, 2015, CMS states, "[f]or purposes of the Medicaid Drug Rebate (MDR) program, the definition of single source drugs found at 42 C.F.R. § 447.502 includes covered outpatient drugs licensed under a BLA [biologics license application]. Therefore, in light of this provision, biosimilar biological products fall within the definition of single source drugs in the MDR program."³¹

This decision is reinforced by the statutory definition of "multiple source drug" in the context of the MDR Program. This definition states that "the term 'multiple source drug' means, with respect to a rebate period, a covered outpatient drug...for which there is at least one other drug product which – (1) is rated as therapeutically equivalent (under the FDA's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'), (2) ... is pharmaceutically equivalent and bioequivalent..., as determined by the Food and Drug Administration, and (3) is sold or marketed in the United States during the period."³²

Conditions (1) and (2) in the above definition are clearly not applicable to the very nature of biosimilars, and CMS' decision not to consider biosimilar products as "multiple source drugs" in the context of the MDR program reflects that incongruity. However, the inconsistency inherent in CMS's decision to then classify biosimilars as "multiple source drugs" in the context of Part B reimbursement is highly questionable and troubling for companies in the process of developing biosimilars for the U.S. market.

Finally, CMS explicitly states that biosimilars are not generic drugs nor multiple source drugs under Medicare Part D, and as a result requires the same level of patient cost-sharing as would apply for single source drugs.³³ Simply put, by CMS' own acknowledgement in the context of other federal health programs, biosimilars are not multiple source drugs and should not be reimbursed under a payment methodology designed for multiple source drugs.

²⁹ Social Security Act, § 1927(k)(2) and § 1927(k)(2)(B)(ii).

³⁰ Id., § 1927(k)(2),(3).

³¹ CMS Medicaid Rebate Release No. 92, (March 30, 2015).

³² Social Security Act, § 1927(k)(7)(A)(i).

³³ CMS Memo from Amy K. Larrick, Acting Director, Medicare Drug Benefit or C & D Data Group to Part D Sponsors, "Part D Requirements for Biosimilar Follow-On Biological Products (March 30, 2015).

Conclusion

As noted throughout these comments and the attached references, there are multiple, well-supported arguments that lead to the conclusion that CMS' current biosimilar reimbursement policy is inadequate and needs immediate revision.

With the recent approval of two biosimilars that share the same reference product, it is now more pressing than ever to address this flawed reimbursement policy and to change it. CMS' call for comments on this policy is a critical opportunity for the agency to take immediate action. Reducing barriers and allowing the new biosimilar marketplace in the U.S. to develop and become sustainable can lead to greater patient access and lower costs for patients and healthcare systems. It is time for CMS to help so many who are facing serious diseases and disorders and who could benefit from biosimilars.

Issuing unique HCPCS codes to each individual biosimilar is essential to ensure a robust, competitive biosimilar market. The Forum has long advocated for a reversal of the existing reimbursement policy, and such a reversal is also supported by an array of patient and provider groups.³⁴

Thus, we strongly encourage CMS to reverse its position, espoused by the previous Administration, on biosimilar reimbursement in the context of **this year's** Final Rule, redrafting the relevant language to assign to each biosimilar a separate and distinct billing and reimbursement code. In doing so, physicians, as well as their patients with some of the most difficult diseases to treat in the United States, including cancer, anemia, and autoimmune disorders such as rheumatoid arthritis and psoriasis, will have access to these lifesaving therapies.

If you have any questions or need any additional information, please contact Michael Werner (michael.werner@hklaw.com) or Miranda Franco (miranda.franco@hklaw.com).

Sincerely,



Stacie Phan, President

Attached:

- Xcenda Economic Budget Model
- Moran Report
- 2015 and 2017 Congressional Letters

³⁴ A delegation of 52 House Members and nine Senators supported reversal of the CMS policy in 2017. Their letters, submitted to CMS earlier this year, may be found in the Appendix.



Estimating the Budgetary Impact of Biosimilar Coding Policies Under Medicare Part B

Biosimilars
FORUM

Executive Summary

The Centers for Medicare & Medicaid Services (CMS) has finalized a policy that groups all biosimilars to a reference product under a single Healthcare Common Procedure Coding System (HCPCS) billing code and payment rate. This report discusses the potential long-term effects of this policy on Medicare Part B drug spending and the future development of the biosimilars market compared to an alternative policy option, which would provide each biosimilar with its own billing code and separate payment rate.

WHILE CMS' POLICY IS ESTIMATED TO OFFER
\$49.9 Billion in savings to the Medicare program over 10 years, an
alternative coding policy could increase savings by an additional
\$15.1 BILLION OR 30%
(\$65.0B in total over 10 years)

This report details the findings of a budget impact analyses, which shows that over time, a separate coding and payment policy could offer even greater savings to the Medicare program, as it could encourage greater price competition and uptake of biosimilar products in the marketplace.



What Is a Biosimilar?

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

Biosimilars offer opportunities for significant cost savings relative to the reference products from which they are developed. Bringing a brand drug to market is estimated to cost \$2.6 billion and take 10 or more years, while a single biosimilar is projected to take between 8 to 10 years to develop, at a cost of \$100 million to \$200 million.^{3,4} The lower development costs and abbreviated licensing pathway mean biosimilars are likely to be offered at prices lower than those of branded reference drugs. **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.**^{5,6}

It is important to note, however, that the cost to develop complex biosimilars is significantly higher than generics, which are manufactured via relatively simple chemical synthesis. Traditional, small-molecule generics typically take 3 to 5 years to develop, at a cost of \$1 million to \$5 million, because their composition does not require the incorporation of biological sources.⁴

Biosimilars Reimbursement Landscape

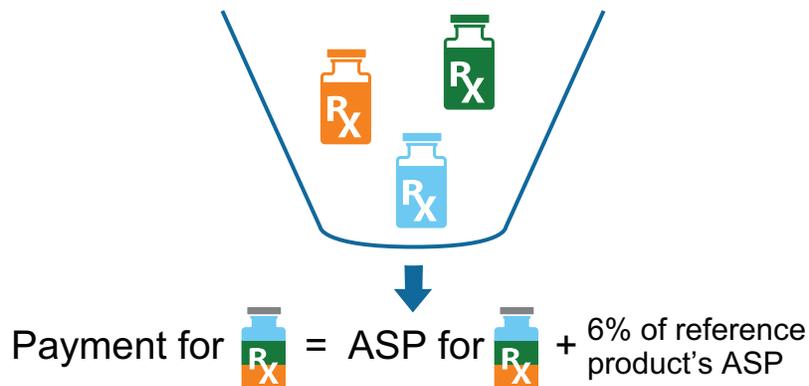
The current estimated biosimilars pipeline suggests that the majority of biosimilars coming to market are anticipated to be physician-administered products that treat conditions prevalent in the Medicare population. Because of this, the Medicare Part B program, administered by CMS, is likely to be a significant payer for biosimilars in the US.

In November 2015, CMS finalized a controversial, and potentially debilitating, payment rule for biosimilars (often referred to as the J-code issue).⁷ It announced that as of January 1, 2016, all biosimilars relative to the same reference product will also share the same HCPCS code and payment rate, separate from the reference product. 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 still maintain their separate HCPCS codes and individual ASPs.

REFERENCE PRODUCT REIMBURSEMENT

$$\text{Payment for } \text{Rx} = \text{ASP for } \text{Rx} + 6\%$$

BIOSIMILAR PRODUCT REIMBURSEMENT



^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%.

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, biosimilars. CMS itself recognizes some complications around its own policy; for example, rather than provide separate HCPCS and payment rates for simplicity, Medicare is requiring providers to add a modifier (eg, ABCD) to their Part B claims to specify which biosimilar manufacturer's product was administered to the patient.⁸ In contrast, CMS is not requiring use of modifiers for the reference product. The use of a modifier is a partial solution that pertains only to Medicare claims; many private payers and state Medicaid programs do not have billing systems that support the use of the CMS-assigned modifier, yet they do have requirements to use HCPCS codes as determined by CMS.

Many stakeholders have expressed serious concern with this blended ASP approach for biosimilars that CMS adopted, as they believe CMS is circumventing how Congress intended Medicare to reimburse biosimilars, as written in the ACA.⁹ Because CMS also administers the Medicaid program, and private payers often look to Medicare for guidance on payment policy, this coding policy could cause unintended consequences across the entire marketplace.

Additionally, because biosimilars may only be approved for some of the indications as their reference product, and not all biosimilars may be approved for the same indications, grouping these products together under a single HCPCS code and payment rate could also cause confusion among physicians and patients.^{10,b} A lack of assurance that all products reported under one code share indications could lead to unintended off-label use. This could actually prompt physicians to continue using reference drugs, with their clearer coding guidance, instead of making the switch to biosimilars.

Reimbursement policies must be structured to incentivize physician uptake and manufacturer participation to ensure a robust market. Manufacturers will be critical in encouraging uptake of biosimilars through increased competition, marketing, and education, as low prices and limited uptake alone will not sustain a market. While CMS' payment policy for biosimilars may reap short-term cost savings, it could also have a chilling effect on future manufacturer investment in biosimilars due to uncertainty over the ability to recoup development costs.

^b Biosimilars may be approved for different indications based on manufacturer determination, patent protections, orphan designations, or other reasons as determined by the FDA.



Estimating Medicare Part B Savings for Biosimilars

The Biosimilars Forum has pursued an effort aimed at defining and quantifying the impact of the CMS coding and payment biosimilars policy on the Medicare Part B program. Three budget impact models were developed to demonstrate the effect that biosimilars could have on Medicare Part B drug spending:

<p>Baseline</p>	<p>Assumes the non-existence of biosimilars. Medicare Part B drug spending in 2015 for reference products likely to have a biosimilar by 2027 was used to project annual spending through 2027 using annual growth rates estimated by the Congressional Budget Office (CBO) June 2017 Medicare baseline¹¹</p>
<p>CMS Current Policy</p>	<p>Assigns a separate HCPCS code and payment rate for all biosimilars to a specified reference biologic</p>
<p>Alternative Model</p>	<p>Assumes each biosimilar would be assigned its own HCPCS code, as guidance provided on biosimilar coding does not suggest other coding alternatives (eg, grouping reference products and biosimilars into a single HCPCS code)</p>

Methodology

The models were built based on 19 reference products that are anticipated to have biosimilar counterparts by 2027 (**Table 1**). These 19 reference products represented approximately 58% of total Part B drug spending in 2015 (\$9.1B out of \$15.9B).^c

^c Medicare 5% Part B Standard Analytic Files. Data are weighted to reflect national estimates for the entire Medicare fee-for-service population.

The year of biosimilar availability was based on when the reference product is expected to lose its exclusivity or 2018, whichever is later. Additionally, reference products were placed in either the “high-penetration group” or the “low-penetration group,” based on Medicare Part B spending in 2015.^d Reference products in the high-penetration group were likely to attract more biosimilar manufacturers due to their higher utilization potential, resulting in a greater number of market entrants. This could increase the availability and awareness of biosimilar alternatives in these markets.

Table 1. Reference Products Expected to Have Biosimilars by 2027

Reference Product	Estimated 2015 Medicare Part B Spending, USD (\$ millions)*	First Year Biosimilar Could Be Available (ie, year exclusivity expires or 2018, whichever is later)	Market Penetration Category
ACTEMRA®	\$135.4	2022	Low
Aranesp®	\$217.2	2018	High
AVASTIN®	\$775.3	2018	High
BOTOX®	\$213.6	2018	Low
ERBITUX®	\$124.9	2018	Low
EYLEA®	\$1,967.7	2023	High
Herceptin®	\$418.1	2018	High
Lucentis®	\$1,242.6	2018	High
Neulasta®	\$806.6	2018	High
NEUPOGEN®	\$91.3	2015	Low
ORENCIA®	\$370.0	2018	High
PROCRIT®	\$268.9	2018	High
REMICADE®	\$925.3	2016	High
RITUXAN®	\$1,040.9	2018	High
SIMPONI®	\$105.8	2025	Low
Soliris®	\$100.4	2019	Low
STELARA®	\$5.7	2025	Low
TYSABRI®	\$177.3	2018	Low
XOLAIR®	\$161.8	2018	Low
TOTAL SPENDING	\$9,148.7		

*Source: Medicare 5% Standard Analytics Files, 2015 Part B physician office and hospital outpatient facility claims. Estimates are weighted to represent the US Medicare fee-for-service population.

^dProducts in the high-penetration group had >\$200 million in estimated Medicare payments in 2015.

Uptake Rate

For the CMS Current Policy, Year 1 uptake was estimated at 15%, increasing to 35% by Year 10. These estimates were based on the 2008 pre-ACA CBO estimates of biosimilar uptake. CBO's Year 1 estimate of 10% was increased slightly to 15% for this model, as it appeared artificially low; however, it was included in the sensitivity analyses as presented in Appendix B.⁵ Under the Alternative Model, uptake in Year 1 for low-penetration products was assumed to be slightly higher for new patients and follow CMS policy for all other patients; for high-penetration products, estimated uptake was increased by 5% (25% for new patients and 20% for all other patients in Year 1). The uptake for high-penetration products was increased slightly to reflect the additional awareness manufacturers may raise around these products in the marketplace compared to low-penetration products.

Table 2. Estimated Uptake Rate of Biosimilars at Year 1 and Year 10

		CMS Current Policy (High-penetration and Low-penetration)	Alternative Model	
			High-penetration	Low-penetration
Year 1	New patients	15%	25%	20%
	Other	15%	20%	15%
Year 10	New patients	35%	65%	60%
	Other	35%	60%	55%

Year 10 uptake rate estimates were set higher than the CBO estimates used for the CMS policy for the following reasons:

- The Alternative Model would increase physician confidence in using biosimilars from a reimbursement perspective. Under current CMS policy, physicians may be encouraged to continue using the reference product to eliminate uncertainty around reimbursement. With separate HCPCS codes and payment rates, physicians would be able to buy the lower-cost biosimilars without the concern of losing money when CMS publishes quarterly ASP files.^e
- Assigning biosimilars to their own separate HCPCS codes and payment rates could encourage more biosimilar manufacturers to develop and market products, as well as provide assistance services to patients and healthcare providers to encourage uptake.

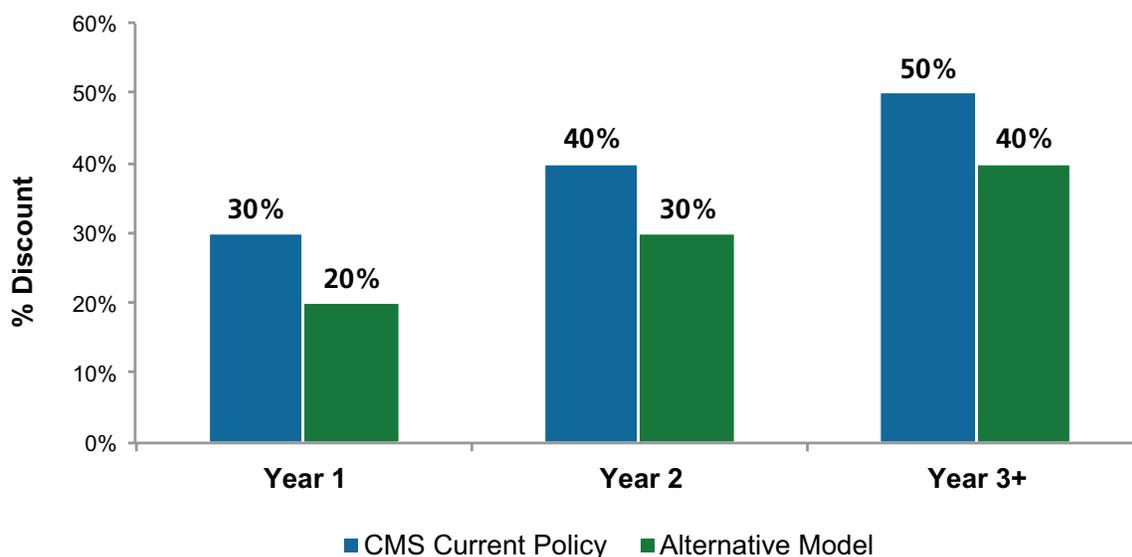
A logarithmic growth rate was applied to all products in the CMS Current Policy model, as well as the Alternative Model high-penetration biosimilars, to calculate expected uptake in Years 2 through 9. This assumes that uptake will increase year-over-year, but will level-out in the future as a product has been in the market for several years and providers have become comfortable with its use. For the Alternative Model low-penetration reference products, it was assumed there would be simple, linear growth to reflect fewer manufacturers developing and marketing these products from the start.

^e ASP files are updated quarterly and reflect the ASP for a drug from 2 quarters back (ie, 2017 Q3 ASP payment rates are based on 2017 Q1 ASP filings from the manufacturer). Therefore, if the ASP for a product is continuously decreasing, practices may choose to use products that have their own established ASP with less fluctuation.

ASP for Biosimilar Products Compared to Reference Product

According to many estimates, biosimilars are expected to be discounted, on average, by 20% to 40% relative to reference products; these ranges have been included in the Alternative Model.^{5,6} Under the CMS Current Policy, it is anticipated that grouping all biosimilars to a reference product under a single HCPCS code could result in deeper discounts (10% larger discount per year, 30–50%), as biosimilars sharing a code would likely have a “race to the bottom” on pricing. The ASP-based payment methodology benefits manufacturers who offer the least expensive products; therefore, each biosimilar entering the market would enter at a lower price than those currently on the market, driving the volume-weighted ASP downward toward an unsustainable rate. As a result, manufacturers could choose to exit the market, or not even enter it at all.¹²

Figure 1. Estimated Discounts for Biosimilars by Year

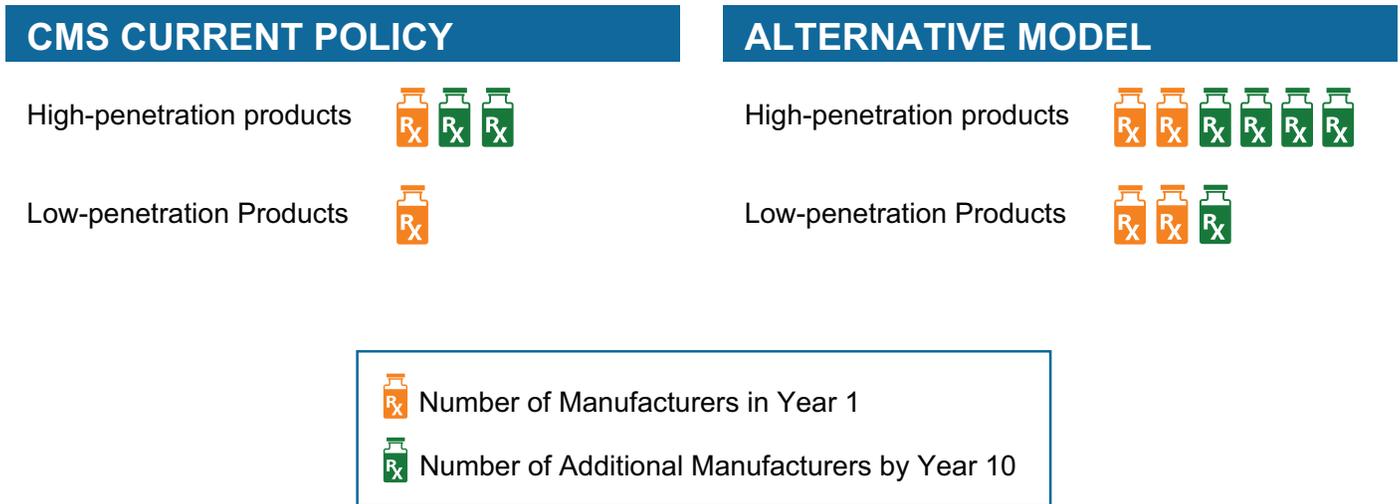


Manufacturers Developing and Marketing Biosimilars

In addition to considering pricing for biosimilars, the availability of products in the marketplace could have a significant effect on uptake. Under the CMS Current Policy, this model assumes there will be between 1 and 3 biosimilar manufacturers bringing products to market for high-penetration reference products over 10 years, as suggested by the CBO, and potentially a sole manufacturer for low-penetration products.⁵

Under the Alternative Model, competition is likely to increase over the long term, giving the opportunity for manufacturers to make the business case to bring these products to market; therefore, this model assumes that 2 to 6 manufacturers could develop biosimilars for high-penetration reference products over 10 years, and 2 to 3 manufacturers could develop biosimilars for low-penetration reference products. A linear year-to-year growth rate was assumed for the number of manufacturers between Years 2 through 9.

Figure 2. Estimated Number of Biosimilar Manufacturers by Year



Change in ASP for the Reference Product

Under the CMS Current Policy, the model assumes the ASP for the reference product will be unaffected by the introduction of biosimilars. Since the reference product will maintain its own, separate HCPCS code and payment rate, it would not be forced to respond to the entrance of biosimilars in the marketplace. Healthcare providers may be more willing to continue prescribing these products because the price will fluctuate less, and the reference product’s reimbursement will remain steady as a result.

Under the Alternative Model, the ASP for the reference product could decrease slightly as a result of a more vibrant, competitive marketplace with biosimilars controlling their own ASP and naturally competing more aggressively with the reference product in addition to competing among themselves. In this case, the biosimilar would be on a more even footing with the reference product, which could force the reference product’s manufacturer to respond to market pressures by lowering prices. This model assumes the ASP for the reference product would decrease by 3% in Year 2 after losing exclusivity, and by 5% by Year 3.



Results: Model Estimates

The baseline model predicts that Medicare Part B drug spending for the 19 reference products included in this analysis will increase from **\$9.1B in 2015 to \$20.5B by 2027**.^f While both the CMS Current Policy and the Alternative Model suggest this baseline spending could be reduced with the introduction of biosimilars to the marketplace, the long-term savings of the Alternative Model are significantly higher due to the estimated increase in product uptake and the willingness of manufacturers to bring products to patients.

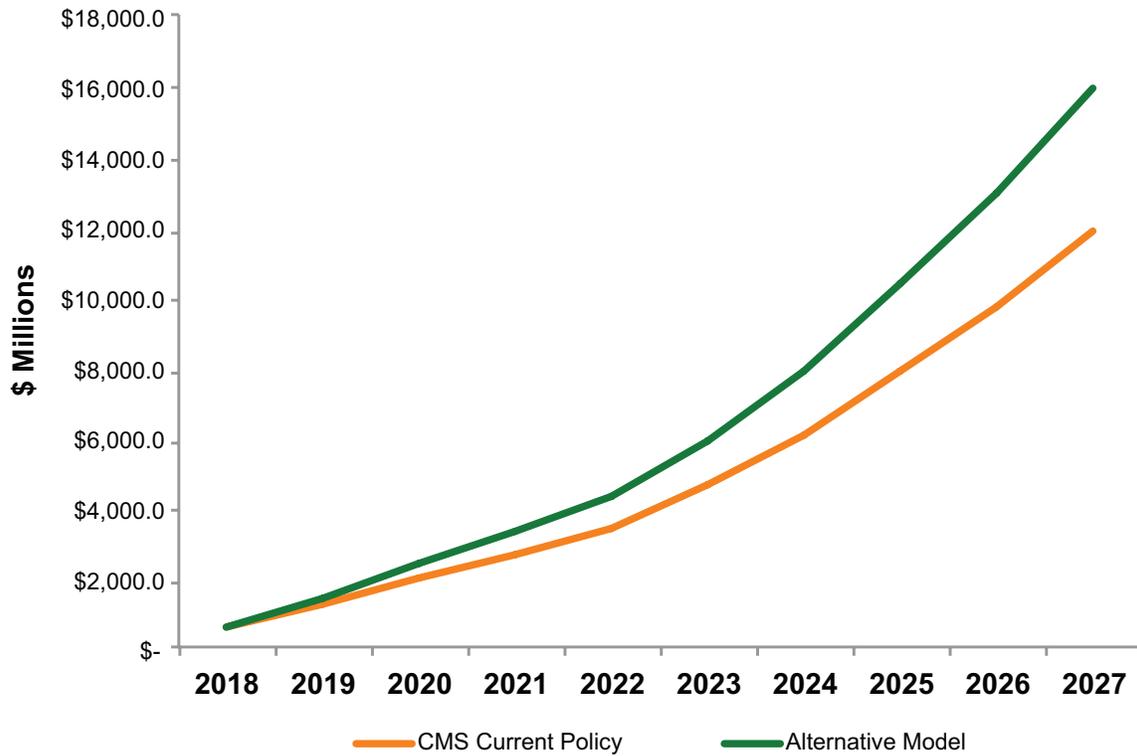
Cost savings are estimated to be \$49.9B for the CMS Current Policy and \$65.0B over 10 years for the Alternative Model. The Alternative Model suggests a 30% increase in cost savings over 10 years (\$15.1B) relative to the CMS Current Policy. Over the long term, the differential in cost savings, as shown in Figure 3, could continue to grow, offering even greater savings to the Medicare program if biosimilars were assigned separate HCPCS codes and payment rates.

Table 3. 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%)

^f These estimates include Medicare spending only and do not include payments made by secondary payers or beneficiary copayments.

Figure 3. Estimated Medicare Part B Savings for the CMS Current Policy and the Alternative Model, 2018–2027 (\$ Millions)



Sensitivity analyses were developed to compare alternative uptake rates across the 2 policies. The Alternative Model is favorable in almost every scenario, suggesting it produces a more robust biosimilars market over time. Additional detail is provided in Appendix B.

Conclusion

Budget impact modeling indicates that while the CMS Current Policy for biosimilars could offer short-term savings to the Medicare program, an alternative policy that allows each biosimilar to have its own, unique HCPCS code and separate payment rate could produce even greater savings. A vibrant, competitive biosimilars marketplace could increase awareness of biosimilars as a whole, as more manufacturers would be contributing to provider and patient education initiatives to drive long-term uptake of these products. The CMS Current Policy on payment for biosimilars is likely to dissuade investment in biosimilar research and production from the outset. This could ultimately limit access to these products for Medicare patients, as well as those covered by other payers who use Medicare policy as guidance for coverage, coding, and payment determinations. Faced with the reality of grouped pricing that does not take into account each biosimilar being different from the other (unlike small-molecule generics), manufacturers will likely delay or forego investment in developing biosimilars. **It is imperative that steps are taken immediately to ensure policymakers are aware of the long-term effects associated with CMS' policy, as it will have a significant impact on the growth of the biosimilars market over the next 5 to 10 years.**

To avoid the shortcomings of CMS' biosimilar coding and pricing policy, manufacturers may leave the marketplace entirely or decide to sidestep the biosimilar regulatory pathway in favor of pursuing the longer, more expensive route of submitting a competitive Biologics License Application. Since this route would drive the costs of competitive development up to traditional biologic levels, the resultant product would have to be priced accordingly to recoup development costs. Consequently, this pathway would diminish the potential cost savings of a biosimilar, and, in turn could ultimately delay patient access to more affordable medications.

Ultimately, patients who could benefit from the availability of biosimilars are likely to lose the most. Under Medicare's payment policy for biosimilars, manufacturers and physicians would both shy away from adoption, thereby increasing costs and limiting treatment options available to patients. Patients would benefit the most from a payment policy that achieves long-term savings and supports a competitive marketplace.

Appendix A. Annual Model Estimates

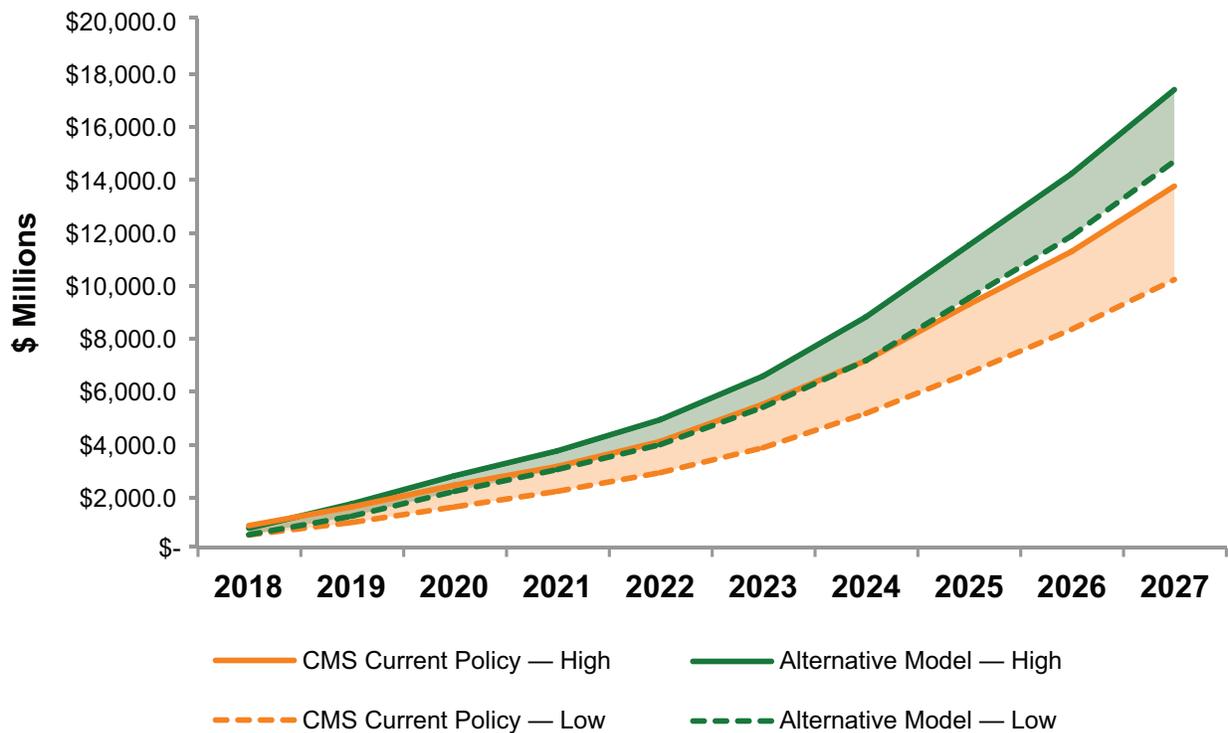
Estimated Medicare Savings (\$ Millions)

	Baseline (19 Reference Products)	CMS Policy	Alternative Model	Difference in Estimated Cost-savings (Alternative-CMS)
2018	\$10,722	\$588	\$586	\$(2)
2019	\$11,398	\$1,199	\$1,379	\$180
2020	\$12,218	\$1,964	\$2,412	\$448
2021	\$13,233	\$2,614	\$3,285	\$671
2022	\$14,265	\$3,370	\$4,308	\$938
2023	\$15,349	\$4,601	\$5,852	\$1,252
2024	\$16,500	\$6,083	\$7,881	\$1,799
2025	\$17,688	\$7,893	\$10,406	\$2,513
2026	\$18,908	\$9,723	\$12,952	\$3,229
2027	\$20,459	\$11,885	\$15,948	\$4,063
5-Year Total	\$61,836	\$9,735	\$11,969	\$2,235
10-Year Total	\$150,740	\$49,919	\$65,010	\$15,091

Appendix B. Sensitivity Analysis

Because the marketplace for biosimilars is still relatively unknown, sensitivity analyses were completed around uptake rate estimates, as these were the most significant drivers of the model (followed by biosimilar discounts). For the lower uptake rate analysis, all estimates in Table 2 were reduced by 5 percentage points; for the higher bound uptake rate analysis, they were increased by 5 percentage points. This analysis suggests that the Alternative Model could offer up to \$71.4B in annual savings over 10 years, whereas the CMS best-case uptake scenario could only offer up to \$58.2B.

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



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The Role of Coding in the Development of the Biosimilar Market:

**Considerations for
Policymakers**

July 2015

The Role of Coding in the Development of the Biosimilar Market: Considerations for Policymakers

As the first biosimilars make their way to market in the United States based on the Food and Drug Administration's (FDA) implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCIA),¹ the Centers for Medicare & Medicaid Services (CMS) also has an important role to play in the development of the biosimilar marketplace. CMS has recently proposed a policy under which all biosimilars with a common reference biologic would be placed into a single code for billing and payment.²

The Moran Company was asked by our client, Hospira, to consider the potential economic impact of such a decision on the biosimilar marketplace. In order to reach a conclusion on this question, we reviewed relevant literature, focusing particularly on competition among generic drugs, since biosimilar competition is relatively new. We also conducted an analysis of the impact on pricing of analogous coding situations to shed light on the potential impact of the CMS policy.

Statement of the Policy Question

With its recent Proposed Rule and other discussion,³ CMS has begun the process of determining how biosimilars will be reimbursed in the Medicare program, which we expect will influence the formation of the market. The agency characterizes its decision to put all biosimilars for a common reference biologic into a single HCPCS code as “similar to the ASP calculation for multiple source drugs.”⁴ This characterization ignores a fundamental difference between the proposed CMS policy for biosimilars and the current system for small molecule generic drugs. The BPCIA requires that innovator biologics will continue to be coded separately from biosimilars. Small molecule generics, by contrast, are typically in the same HCPCS code as their branded counterparts. The CMS proposal for biosimilar coding creates a two tier system for reference biologics and their corresponding biosimilars which could result in a less stable market for biosimilars over time. As CMS and other policymakers contemplate policy options for biosimilar coding, they will need to consider which coding policy will result in a robust, sustainable biosimilars market over the long term.

Highlights of Our Findings

- In the small molecule market, assigning generics and their branded counterparts to the same HCPCS code when they are deemed equivalent by the FDA was intended to

¹ The BPCIA was enacted in Title VII of the Affordable Care Act.

² Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; 80 Fed. Reg. 135 at 41801 (July 15, 2015) (hereafter, “Proposed Rule”).

³ Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/May-7-2015-DrugAgenda.pdf>

⁴ Proposed Rule at 41801.

encourage greater price competition. BPCIA prevents this policy from being applied to the biosimilars market; reference biologics will require a HCPCS code distinct from biosimilars.

- CMS has proposed “joint” or “lump” coding of all biosimilars for each reference product, further adding to the complexity of the market, which will potentially include several layers of approved biologics: interchangeable or non-interchangeable biosimilars, their reference biologics and potentially competing biologics that are not approved as biosimilars and have not been used as reference products.
- Given the significant investment required to bring a biosimilar to market, these products are inherently more risky for manufacturers to bring to market than small molecule generic drugs. A decision to put all biosimilars for a reference biologic into one HCPCS code, while the reference biologic enjoys its own code, would create considerable additional risk for biosimilar manufacturers, potentially discouraging investment in biosimilar development.
- Policymakers evaluating alternative coding policies need to consider the differing market dynamics that will be created depending on how biosimilar products will be coded for reimbursement purposes. Under a lump coding policy, the reimbursement rate will advantage customers of the lowest-priced biosimilars, while penalizing customers of biosimilars whose sales prices are above the blended ASP. Each additional entrant to the market will drive the Medicare reimbursement rate lower.
- Under this scenario, manufacturers of Medicare-sensitive products may find it uneconomic to remain in the market even if they are priced at a substantial discount to the reference biologic. Moreover, potential biosimilar manufacturers evaluating the potential risk of this sort of market outcome may be deterred from entry. In either case, the number of biosimilar suppliers would be limited, reducing competition in the marketplace overtime, causing prices to rise.
- The pricing structure in a lumpcoded biosimilar market is highly likely to equilibrate into duopolistic competition between the reference product and the least-cost biosimilar. As both microeconomic theory and this analysis suggest, prices in such markets can be expected to be substantially higher than would prevail if additional biosimilar competition was encouraged to enter.
- Policymakers need to decide what objective they are trying to achieve. If the focus of policy is on minimizing Medicare reimbursement for individual biosimilars, then lump coding is the shortest route to that objective. But, if the objective is to lower the total social cost of biologics, while maintaining a robust supply, there is a strong case to be made that lump coding will prove counter-productive, by restricting long-term competition against reference biologics.

The balance of this paper presents an overview of the literature we reviewed, and more details on the theories underlying our analysis.

State of the Literature on the Economics of Generic Entry

Classic drugs, such as aspirin, are chemically synthesized; their active ingredients are “small molecules.” The FDA describes generic small molecule drugs at the highest level as identical to their branded counterparts in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.⁵ Most sources estimate that small molecule generics cost between \$1 million and \$5 million to develop, far less than the cost to develop a new branded drug.⁶ Generic development is fairly straightforward and less costly because producers are not starting from scratch, and they can rely on the safety and efficacy trials of the branded drug by demonstrating bioequivalence.⁷ In the decades following the passage of the Hatch-Waxman Act, which created an abbreviated FDA approval process for generic drugs, generic drugs have become an important part of the pharmaceutical landscape.⁸ More than 80% of all prescriptions are for generics.⁹

Market size a predictor of generic entry

Numerous researchers have explored generic entry. Most agree that market size is a key determinant for entry. Generally, revenue serves as an indicator of market size. A study examining generic entry for 98 drugs that lost patent protection between 1986 and 1992, found that brand revenue the year before patent expiration is the largest predictor of generic entry, with higher revenues attracting more entrants.¹⁰ In a later analysis of 40 drugs that first encountered generic competition between 1992 and 1998, researchers found that generic entry was greatest for “blockbuster” drugs, those with pre-generic sales of \$500 million or greater.¹¹

Generic prices decrease as entrants increase

In addition, researchers generally find that as the number of generic entrants increase, generic prices decrease. Researchers looking at drug prices for thirty drugs that lost patent protection between 1976 and 1987 found that with a single generic entrant, generic price is approximately 60 percent of the branded drug price. Generic price drops further to 46% and 34% of the branded

⁵US Food and Drug Administration (FDA), “Generic Drugs Questions and Answers,”

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>

⁶For example, David Harding, “Gaining Market Share in the Generic Drug Industry Through Acquisitions and Partnerships,” Thomson Reuters, December 2010, p. 6

⁷FDA, “Generic Drugs Questions and Answers”

⁸Garth Boehm, Lixin Yao, Liang Han, Qiang Zheng, “Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984,” *Acta Pharmaceutica Sinica B*, 3(5), 2013, p. 298

⁹FDA, “Office of Generic Drugs Reorganization”,

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm378126.htm>

¹⁰Fiona Scott Morton, “Barriers to Entry, Brand Advertising, and Generic Entry in the US Pharmaceutical Industry,” 1998, p. 15

¹¹Atanu Saha, Henry Grabowski, Howard Birnbaum, Paul Greenberg, Oded Bizan, “Generic Competition in the US Pharmaceutical Industry,” *International Journal of the Economics of Business*, 13(1) February 2006, p. 18

drug price with 5 and 10 generic entrants, respectively.¹² In analyzing their 1994 retail pharmacy data set, comprised of 112 branded drugs with generic entrants, the Congressional Budget Office (CBO) found that with one to ten generic manufacturers, generic prices were on average 61% of the branded price; with 11 to 24 generic manufacturers, the percentage fell to less than 50%.¹³

The Intersection of Biosimilars with this literature

A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.¹⁴ While there is some disagreement in definition, biologics are generally thought of as large molecules, derived from proteins in living cells.¹⁵ For this reason, biosimilars are not copies of their reference products as chemically derived generics are to branded drugs.¹⁶ In the US there will be a multi-tiered system of biologics: reference biologics, biosimilars, interchangeable biosimilars, and biologics within the same therapeutic class. How CMS will code each of these to ensure a level playing field, attractiveness of the new market to manufacturers, and long-term sustainability over short-term savings has yet to be clarified.

Fewer biosimilar entrants

Given the relative newness of biosimilar competition, empirical evidence regarding the effects of biosimilar entry is thin. However, there has been a great deal of discussion about the expected impact of biosimilar entry in the literature. Biologics present an enormous market. In recent years, biologics have been among the top selling drugs.¹⁷ Yet, despite this large market, most experts predict that the number of entrants into the biosimilars market will be far smaller compared to what was observed in the small molecule market. CBO anticipates between one and three biosimilar entrants per typical innovator biologic.¹⁸ After modeling a break-even analysis, one author questions whether there will be entry for any biologics besides blockbusters.¹⁹

Cost and capacity hurdles

Experts cite numerous reasons for the smaller number of entrants, one being cost and capability. According to the CBO, the development and production of a biosimilar is more complex and costly than for the typical generic drug. Other researchers note that capital investment in property, plant, and equipment, specifically cell culture facilities, are higher for biosimilars than

¹²Richard Caves, Michael Whinston, Mark Hurwitz, Ariel Pakes, Peter Temin, "Patent Expiration, Entry, and Competition in the US Pharmaceutical Industry," Brookings, 1991, p. 36

¹³US Congressional Budget Office (CBO), "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," Government Printing Office, 1998, p. 32

¹⁴FDA, "Information for Consumers (Biosimilars),"

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm>

¹⁵Thomas Morrow, Linda Hull Felcone, "Defining the Difference: What Makes Biologics Unique." *Biotechnology Healthcare*, 1(4), 2004, p. 25

¹⁶FDA, "Information for Consumers (Biosimilars)"

¹⁷Peter Ubel, "The Best-Selling Biologic Drugs," *Forbes*, December 16, 2014,

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¹⁸CBO, "Congressional Budget Office Cost Estimate: S. 1695 Biologics Price Competition and Innovation Act of 2007," June 25, 2008, p. 6

¹⁹Alex Brill, "The Economic Viability of a U.S. Biosimilars Industry," Matrix Global Advisors, February 2015, p. 2

for small molecule generics; manufacturing and material costs will be greater, as well.²⁰ Some estimates of biosimilar development range from \$100 million to \$250 million.²¹ The complexity also means that firms looking at entry may face very different costs.

Entry a function of risk

Market entry is also a function of risk.²² While the higher costs noted above may serve as a practical impediment to entry, higher costs also represent greater financial risk. The costs to develop a biosimilar and get through the approval process are sunk costs that pharmaceutical producers are betting on being able to recoup over the life of the product. Issues with development, approval, competition, and pricing erosions serve as threats to this upfront investment.

Biosimilars will continue to face competition from the reference biologic (as well as biologics in the same therapeutic class). While this is also true of generic drugs, experts anticipate competition from the reference biologic to be greater than that posed by branded drugs. The Federal Trade Commission (FTC) characterized the level of competition between the biosimilar and its reference drug to be more like brand-to-brand competition than brand-to-generic competition. Further, the FTC suggests that originators could retain as much as 70 to 90 percent of their market share after biosimilar entry.²³

One reason for potentially greater competition with the reference biologic relates to interchangeability. In the small molecule drug market, the majority of states have policies in place that encourage generic substitution. To aid states in creating their policies, the FDA puts out an “Orange Book” which includes ratings based on therapeutic equivalent evaluations. According to the FDA, “a therapeutically equivalent drug can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.”²⁴ To be deemed therapeutically equivalent, a generic must, among other criteria be bioequivalent. As part of the FDA approval process for generics, generic applicants must demonstrate bioequivalence, with the most common method being through a single dose, two-treatment, crossover-designed study in 24-36 normal adult volunteers.²⁵

For biosimilars to meet the standard of interchangeability, an applicant must demonstrate that the biosimilar can be expected to produce the same clinical result as the reference product and, if administered more than once, the risk of switching between the biosimilar and reference product is not greater than if the patient only used the reference product. According to the draft guidance the FDA put out in May 2015, “it would be difficult as a scientific matter for a prospective

²⁰Henry Grabowski, Iain Cockburn, Genia Long. “The Market For Follow-On Biologics: How Will It Evolve?” *Health Affairs*, 25(5), September 1, 2006, p. 1294

²¹For example, Henry Grabowski, Rahul Guha, Maria Salgado, “Regulatory and Cost Barriers Are Likely To Limit Biosimilar Development and Expected Savings in the Near Future,” *Health Affairs*, 33(6) June 1, 2014, p. 1050

²²Grabowski et al., 2006, p. 1297

²³Federal Trade Commission (FTC), “Emerging Health Care Issues: Follow-on Biologic Drug Competition,” June 2009, pp. iii-v

²⁴FDA, “Orange Book Preface,” <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>

²⁵Ibid

biosimilar applicant to establish interchangeability in an original 351(k) application²⁶ given the statutory standards for interchangeability.” Further, the FDA notes that it is still considering the type of information that would be needed to determine a biosimilar is interchangeable with a reference product.²⁷ The FDA will publish a “Purple Book” of interchangeable and non-interchangeable biosimilars. CMS is currently silent on how they will code these multiple layers of biologics.

Interchangeability ratings and subsequent substitution aided in the growth of the generic drug market.²⁸ Without interchangeability, physicians may be less willing to prescribe biosimilars. In particular, they may be disinclined to switch patients who are already on and responding well to a reference biologic.²⁹ Therefore, biosimilars may be primarily competing for new patient starts rather than those already on the reference biologic.³⁰ These biosimilars—both interchangeable and non-interchangeable—will be competing against each other as well in a coding system that creates an unequal playing field relative to their reference products.

Another risk biosimilar manufacturers will face is the development of “biobetters.” Biobetters are biologics that offer improvements over the originator biologic through modifications to the originator molecule and manufacturing process.³¹ Unlike small-molecules, large molecules, by virtue of being large, lend themselves to greater manipulation. Biobetter products are already underway for several originators experiencing the introduction of biosimilars in the EU.³² CBO noted that in the long run, “the potential for innovator companies to modify existing product lines could become an increasingly significant constraint on the ability of FOBs [follow-on biologics] to compete.”³³

Market Dynamics under Alternative Coding Policies

Policymakers evaluating alternative coding policies need to consider the differing market dynamics that will be created depending on how biosimilar products will be coded for reimbursement purposes.

Prior to the entry of a biosimilar competitor, pricing for the reference biological of that biosimilar will presumably reflect a pricing premium over the manufacturer’s production costs due to the value of the intellectual property embedded in the product patent. When the first

²⁶Meaning an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. 351(k) refers to a section of the Public Health Service Act added by the BPCIA.

²⁷FDA, “Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,” 2015, pp. 4-7, <http://www.fda.gov/downloads/Drugs/Guidances/UCM273001.pdf>

²⁸Boehm et al., 2013, p. 298

²⁹Henry Grabowski, Genia Long, Richard Mortimer, “Implementation of the Biosimilar Pathway: Economic and Policy Issues,” *Seton Hall Law Review*, 41(2), 2011, p. 528

³⁰Ibid

³¹Grabowski et al., June 2014, p. 1048

³²Henry Grabowski, Rahul Guha, Maria Salgado, “Biosimilar Competition: Lessons from Europe.” *Nature Reviews Drug Discovery*, 13(2), 2014, p. 100.

³³CBO, 2008, p. 8

biosimilar enters the market, the reference biologic will continue to be reimbursed at its own Average Sales Price (ASP) plus 6%. Under the statute, the first biosimilar entrant will be reimbursed under a separate code, with reimbursement set to equal the biosimilar's own ASP, plus an amount equal to 6% of the reference product ASP. Assuming that the biosimilar entrant prices its product at some amount of discount to the full price of the reference biological, providers being reimbursed under Medicare may be indifferent to the choice between the reference biological and the biosimilar in economic terms, but some amount of volume can be expected to move from the reference product to the biosimilar, as private payers create financial incentives for using the biosimilar, and beneficiaries are motivated by lower cost sharing to accept the biosimilar in lieu of the branded product. At first entry, the reference biologic may or may not lower prices to combat market share shifts to the biosimilar.

At this point, Medicare coding policy doesn't matter, because each of the products in the market is being reimbursed at its own ASP plus an amount equal to 6% of the reference biologic ASP. Were a second competitor to enter, however, market dynamics would change.

When a second biosimilar enters, the choice of Medicare coding policy will have an important influence on product pricing dynamics. If each product is awarded and allowed to bill under its own code, both products will compete against the reference biologic – and each other – on price. The experience with generic entry in the small molecule market predicts that, holding reimbursement policy constant, a second (and each subsequent) competing biosimilar entrant will increase pricing pressure on all products in the market, resulting in lower prices from all market participants

If all biosimilars are required to be reimbursed under the same code, the Medicare segment of the market for the reference biologic and its biosimilar competitors may follow a different dynamic. Under such a “lump coding³⁴” policy, the ASP component of the reimbursement rate will advantage customers of the lowest-priced biosimilars, while penalizing customers whose sales prices are above the blended ASP. Each additional entrant to the market will drive the Medicare reimbursement rate lower.

The major constraint against a pricing “race to the bottom” in this scenario is that each biosimilar manufacturer will face its own costs, which may differ from manufacturer to manufacturer. Under a lump-coding policy, biosimilars that are at the upper end of the cost distribution of biosimilar products viewed in isolation may face reimbursement rates that put purchasers “under water” if cost differentials—and thus ASP differentials—approach or exceed the “6% of reference biologic ASP” payment add-on amount. Under this scenario, manufacturers of Medicare-sensitive products may find it uneconomic to remain in the market even if they are priced at a substantial discount to the reference biological. If this happens, the number of biosimilar product options is reduced, and pressure on the manufacturer of the reference biologic to cut prices is diminished. Potential biosimilar manufacturers evaluating the potential risk of this sort of market outcome may in fact be deterred from entry, since it is impossible to know, ex ante, how the manufacturer's own cost structure would compare to that of other biosimilar candidates that have not yet entered.

³⁴ We borrow this term from the days of commercial “Major Medical” policies, when all drugs covered by the policy were reimbursed at a single “per drug” rate.

Given that we lack evidence of the effects of biosimilar market entry in the U.S., it is impossible to predict what market equilibrium will be reached under a lump-coding policy. But the choice policymakers face is fairly clear. The only advantage of a lump coding policy is that it will minimize the Medicare reimbursement rate for individual biosimilars in the short-term. Yet it is quite possible that it will result in higher-than-achievable reimbursement rates over time for biosimilars and their reference biologics if competition is restricted to only the lowest-cost biosimilar manufacturers.

In deciding this question, policymakers need to decide what objective they are trying to achieve. If the focus of policy is on minimizing Medicare reimbursement for new market entrants, then lump coding is the shortest route to that objective. But if the objective is to lower the total social cost of biologics over time, there is a strong case to be made that lump coding will prove counter-productive, by restricting competition against reference biologics.

Evidence from Medicare Part B Experience

While microeconomic theory supports the concern that lump coding biosimilars could deter competition against the reference biologic, none of the countries currently reimbursing biosimilars uses that mechanism to set reimbursement rates, and hence there is no direct evidence against which to test this prediction from theory.

Current reimbursement policy under Medicare Part B in the United States does, however, provide useful evidence of the potential effects market entry and exit on market pricing.

In that program, a single reimbursement rate for a drug or biologic is set based on the ASP of all of the products assigned to a single billing code. While the purpose of that policy is to expose branded products to direct price competition with generics, it also has the effect of causing price competition among multiple brands when more than one brand is assigned to a billing code. That situation arises with some frequency since a number of products reimbursed under this framework are in fact biologics, many of which are separately branded by manufacturers even though they are assigned to a single billing code. We used this evidence to test the sensitivity pricing in this sort of market to the entry and exit of branded products within the same billing code.

We identified entry and exit “events” employing the annual coding cross-walk that maps individual product National Drug Codes (NDCs) to the HCPCS coding system employed by the CMS to reimburse drugs under Medicare part B. We assumed that a first appearance of a new branded NDC in a HCPCS code reflects the market entry of that product, while the first disappearance of the product reflected market exit. For products on the market between 2006 and 2013, for which data on ASP are available, we were able to determine the path of blended pricing across all products surrounding an entry or exit “event” within a HCPCS code.

Overall, we found 180 events occurring between 2007 and 2012 for which we could find ASP prices in the year prior to and subsequent to an event. Of these, 58 observations reflected entry events, while 122 exit events occurred in the same period.³⁵

Analysis of the pricing action around entry events reflects a pattern fully consistent with the microeconomics of generic competition.

Pricing Effect of Product Entry

Brands Pre-Event	Brands Post-Event	Number Observations	Mean Change ASP
1	2	34	-11.30%
2	3	12	-12.60%
2	4	1	-93.90%
3	4	8	-5.50%
4	5	3	-8.30%
		58	

Each row in this table shows the change in unweighted mean price (ASP + 6%) associated with events that increased the number of competitors in the event year. In the first row, for example, we found 34 events that resulted in the number of branded products increasing from 1 to 2, reflecting first entry of a brand in competition to an existing sole source brand. As predicted by theory, each additional branded entrant causes the mean ASP values to decline, on average. While the relatively small number of observations of entry by 4 or 5 brands makes the reported averages somewhat turbulent, these data strongly suggest that brands placed in price competition with multiple manufacturers will face considerably greater pricing pressure than brands facing a single branded competitor.

³⁵ Due to the way we constructed our analysis, some products sold under brand names in our sample were likely brought to market under Abbreviated New Drug Applications. As a result, our analysis is not exactly parallel to what will occur in the nascent biosimilar marketplace, but we believe that it fairly demonstrates the potential effects of the proposed CMS coding policy.

Pricing Effects of Product Exit

Brands Pre-Event	Brands Post-Event	Number Observations	Mean Change ASP
2	1	70	2.40%
3	1	17	8.90%
3	2	17	5.40%
4	1	1	112.90%
4	2	6	58.30%
4	3	6	-2.90%
5	3	1	6.10%
5	4	4	-14.10%

122

The second table shows the effect of product exit on ASP pricing. While the small number of observations of 4 and 5 brand markets makes the data for these markets somewhat murky, these findings are consistent with the prospect that exit from a market of three or more competitors will have a significant upward effect on average prices.

We undertook this analysis because we believe that inter-brand competition under the lumpcoded Part B reimbursement regime is the closest observable proxy for what will happen if CMS finalizes its proposal to lumpcode biosimilars. We believe that the results of this analysis reinforce the discussion of economic theory the prior sections of the report.

Conclusion

In advancing its proposal to lumpcode biosimilar products for each reference biologic into a single code, CMS represents that this policy would be similar to the current system that applies to small molecule generic drugs. However, this characterization ignores a key distinction. The major difference between these two regimes is that CMS is currently prohibited by statute from requiring the reference biologic to be blended into the same code as biosimilars. In that environment, the standard CMS rationale for lumpcoding brands and generics—to intensify pricing pressure on the branded drug—is totally irrelevant. In this context, lumpcoding the biosimilars separately will have the effect of either deterring entry, or accelerating the exit of biosimilar products that are price-competitive against the reference biologic, but not against the single biosimilar that is the least costly to produce at relevant levels of output. Thus, this pricing structure is highly likely to equilibrate into duopolistic competition between the reference product and the least-cost biosimilar. As both microeconomic theory and this analysis suggest, prices in such markets can be expected to be substantially higher than would prevail if additional biosimilar competition was encouraged to enter.

CMS and other policymakers, therefore, may wish to consider the long-term impact of the decision to lumpcode biosimilars on the stability of the biosimilar market over time.

U. S. House of Representatives
Washington, D. C. 20515

August 4, 2015

Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Acting Administrator Slavitt,

We write to express our serious concerns with provisions relating to biosimilar reimbursement in the Centers for Medicare and Medicaid Services' (CMS) 2016 Medicare Physician Fee Schedule proposed rule.

Specifically, we are concerned with the agency's proposal to assign all biosimilars of a single reference product one Healthcare Common Procedure Coding System (HCPCS) code and to reimburse biosimilars with the same HCPCS code based on the weighted average of their average sales price under Medicare Part B.

In this proposal, CMS treats biosimilars as if they are generic drugs. As a primary matter, it is important to recognize that traditional small-molecule pharmaceuticals and biologics are fundamentally different in their development, manufacture and chemical makeup. A biologic is a large, complex molecule, which is grown in living systems such as a microorganism, a plant or animal cell.

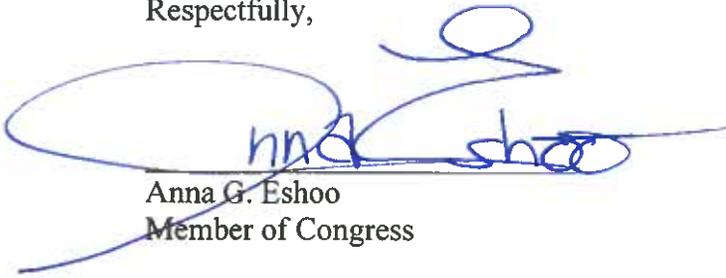
These differences are acknowledged by the statutory provisions establishing the biosimilars pathway and by the Food and Drug Administration (FDA).

Section 1847A of the Social Security Act ("SSA"), 42 U.S.C. § 1395w-3a states that the calculation for reimbursing biosimilars shall be made separately, such that each biosimilar will have its own unique payment rate and unique HCPCS code. This language reflects congressional intent to encourage a vibrant biosimilars market and we urge you to enact a final payment rule that provides each biosimilar with a unique code.

Thank you for your attention to this highly important issue and we look forward to your timely response. If you need further assistance, please contact Hannah Murphy in

Congresswoman Anna Eshoo's office at Hannah.Murphy@mail.house.gov or Krista Rosenthal in Congressman Joe Barton's office at Krista.Rosenthal@mail.house.gov.

Respectfully,



Anna G. Eshoo
Member of Congress



Joe Barton
Member of Congress



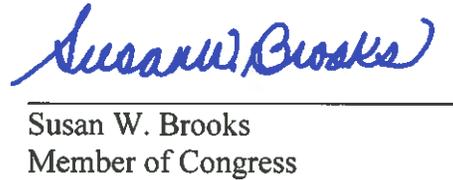
Diana DeGette
Member of Congress



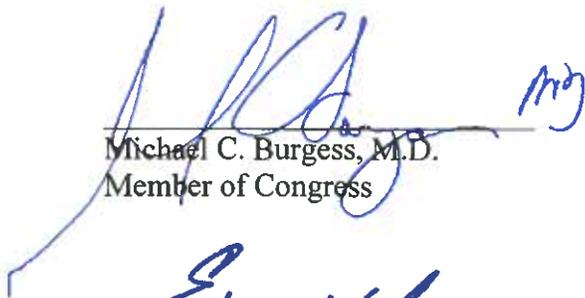
Gus Bilirakis
Member of Congress



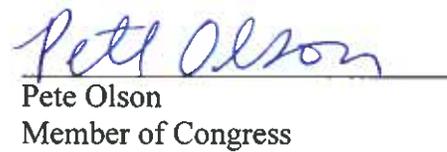
Cathy McMorris Rodgers
Member of Congress



Susan W. Brooks
Member of Congress



Michael C. Burgess, M.D.
Member of Congress



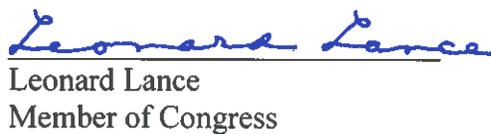
Pete Olson
Member of Congress



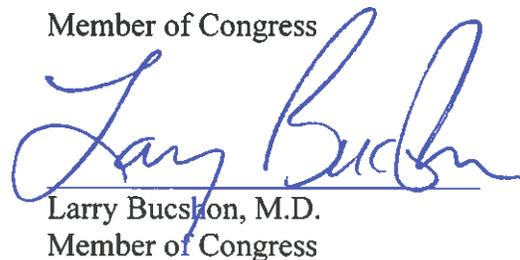
Ed Whitfield
Member of Congress



Peter Welch
Member of Congress



Leonard Lance
Member of Congress



Larry Bucshon, M.D.
Member of Congress



Bill Pascrell, Jr.
Member of Congress



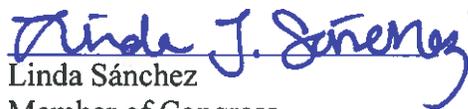
Bill Johnson
Member of Congress


Billy Long
Member of Congress


Chris Collins
Member of Congress


Patrick Meehan
Member of Congress


Brett Guthrie
Member of Congress


Linda Sánchez
Member of Congress


Kurt Schrader
Member of Congress

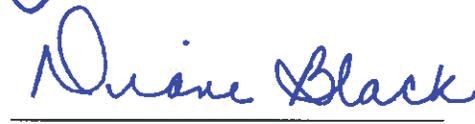

Doris Matsui
Member of Congress

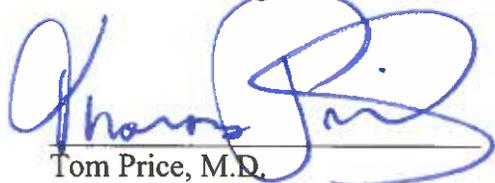

Dave Loebsack
Member of Congress


Tony Cárdenas
Member of Congress


Peter J. Roskam
Member of Congress


Vern Buchanan
Member of Congress


Diane Black
Member of Congress


Tom Price, M.D.
Member of Congress


Devin Nunes
Member of Congress



Robert E. Latta
Member of Congress



Ron Kind
Member of Congress



Lynn Jenkins
Member of Congress



Jackie Speier
Member of Congress



Robin L. Kelly
Member of Congress

United States Senate

WASHINGTON, DC 20510

October 8, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Slavitt:

We write today to express our concern regarding biosimilar reimbursement policies set forth in the Centers for Medicare & Medicaid Services' (CMS) 2016 Medicare Physician Fee Schedule (MPFS) proposed rule. Given that the pipeline and market for biosimilar drugs remain under development, we ask you to withhold the proposed Medicare reimbursement policy for biosimilars until the Food and Drug Administration (FDA) has completed regulations for these drugs and the biosimilar drugs pipeline and market are safe and stable.

The emergence of biosimilar drugs has the potential to revolutionize the treatment landscape for many patients by offering them more treatment options at a lower cost. By developing drugs based on the human body's own biological processes, life science companies have been able to create therapies with treatment possibilities previously unattainable through traditional drug development. It's critically important that the FDA and CMS work with patients, health care providers, and other stakeholders to ensure that the pipeline and market for biosimilar drugs are both safe and robust.

We have heard concerns from patient and physician groups, pharmacy organizations, biosimilar manufacturers, and other stakeholder organizations that reimbursement for biosimilar drugs may be important for tracking usage of these drugs for purposes of patient safety and research, medical innovation, and increasing patient access to biosimilar treatments. Accordingly, we urge CMS to withhold all formal reimbursement proposals for biosimilar drugs until the FDA has issued regulations for these drugs to help ensure the safety and stability of the biosimilar drugs pipeline and while the market for biosimilars develops.

Biosimilar drugs hold enormous promise for improving health care outcomes for patients and reducing costs for both patients and health care payers such as Medicare and Medicaid. We urge you to allow the biosimilar pipeline and market to stand up and continue to develop before implementing a final Medicare reimbursement policy.

Sincerely,



Pat Roberts
United States Senator



Thomas Carper
United States Senator



Michael B. Enzi
United States Senator



Robert Menendez
United States Senator



John Cornyn
United States Senator



Debbie Stabenow
United States Senator



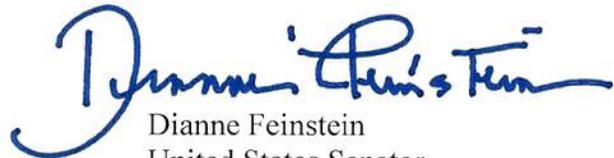
Johnny Isakson
United States Senator



Michael F. Bennet
United States Senator



Rob Portman
United States Senator



Dianne Feinstein
United States Senator



Jerry Moran
United States Senator



Mazie K. Hirono
United States Senator



Mark Kirk
United States Senator



Gary C. Peters
United States Senator



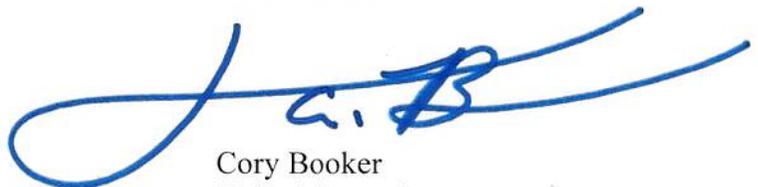
John Hoeven
United States Senator



Joe Donnelly
United States Senator



David Vitter
United States Senator



Cory Booker
United States Senator

John Barrasso
John Barrasso
United States Senator

Steve Daines
Steve Daines
United States Senator

Congress of the United States
Washington, DC 20515

May 5, 2017

The Honorable Tom Price, M.D., Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Price and Administrator Verma,

We write to encourage you to reverse the current biosimilar reimbursement policy established by the Centers for Medicare and Medicaid Services' (CMS) 2016 Medicare Physician Fee Schedule final rule.

Under the final rule issued by CMS on October 30, 2015, each follow-on biologic, or biosimilar, that is tied to a common reference product under the same Healthcare Common Procedure Coding System (HCPCS) code will be reimbursed at a single payment rate calculated based on the weighted average of their average sales price under Medicare Part B.

We urge you to reverse the current reimbursement policy and employ a separate billing code and reimbursement rate in order to give each biosimilar its own unique HCPCS code. Biologics and biosimilars are large, complex molecules grown in living systems such as a microorganism, a plant or animal cell. A reimbursement structure must appropriately reflect the complexity of these products and the differences between individual biosimilar products.

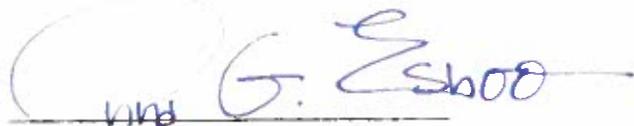
These differences are acknowledged by the statutory provisions establishing the biosimilars pathway and by the Food and Drug Administration (FDA). Section 1847A of the Social Security Act ("SSA"), 42 U.S.C. § 1395w-3a states that the calculation for reimbursing biosimilars shall be made separately, such that each biosimilar will have its own unique payment rate and unique HCPCS code.

This language reflects congressional intent to encourage a vibrant biosimilars market, and we urge you to reconcile the final payment rule to provide each biosimilar with a unique code as it is instructed to do in current statute.

Since championing the Biologics Price Competition and Innovation Act of 2009 (BPCIA), it has been our goal that biosimilars can compete with innovative biologics to increase competition and lead to more options and lower prices for patients. A fair Medicare reimbursement policy helps ensure this happens.

Thank you for your attention to this highly important issue and we look forward to your timely response. If you need further assistance, please contact Rachel Fybel in Congresswoman Anna Eshoo's office at (202) 225-8104 or Gable Brady in Congressman Joe Barton's office at (202) 225-2002.

Respectfully,


Anna G. Eshoo
Member of Congress


Joe Barton
Member of Congress


Gus Bilirakis
Member of Congress


Diana DeGette
Member of Congress


Doris Matsui
Member of Congress


Leonard Lance
Member of Congress

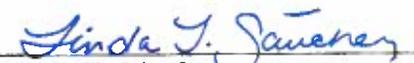

Marsha Blackburn
Member of Congress


Kurt Schrader
Member of Congress


Jackie Speier
Member of Congress

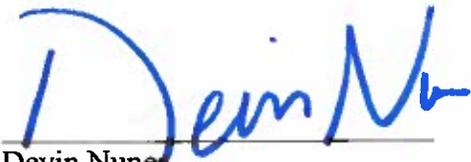

Steve Knight
Member of Congress


Billy Long
Member of Congress


Linda T. Sánchez
Member of Congress



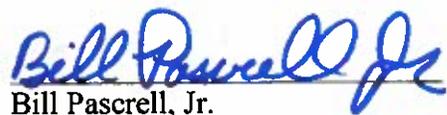
Sam Graves
Member of Congress



Devin Nunes
Member of Congress



Carlos Curbelo
Member of Congress



Bill Pascrell, Jr.
Member of Congress



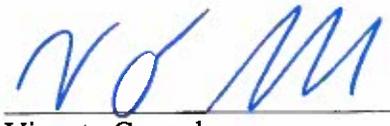
Sam Johnson
Member of Congress



Scott Peters
Member of Congress



Kenny Marchant
Member of Congress



Vicente Gonzalez
Member of Congress



Mike Kelly
Member of Congress



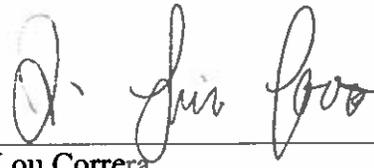
Lynn Jenkins
Member of Congress



Filemón Vela
Member of Congress



Dave Loebsack
Member of Congress



Lou Correa
Member of Congress



George Holding
Member of Congress



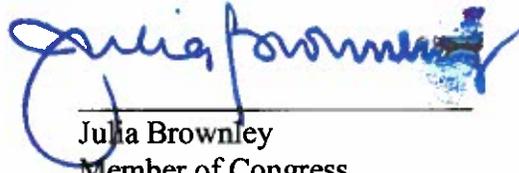
Vern Buchanan
Member of Congress



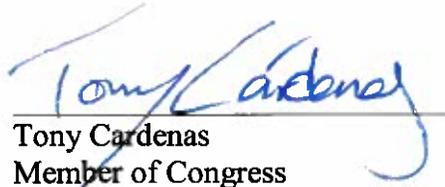
Diane Black
Member of Congress



John Shimkus
Member of Congress



Julia Brownley
Member of Congress



Tony Cardenas
Member of Congress



Patrick Meehan
Member of Congress



Pete Olson
Member of Congress



Joe Courtney
Member of Congress



Bill Johnson
Member of Congress



Norma Torres
Member of Congress



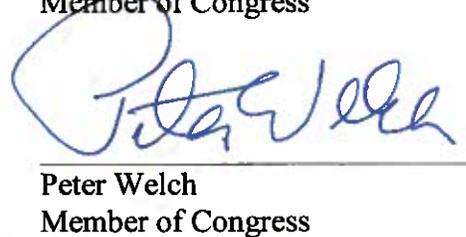
Mimi Walters
Member of Congress



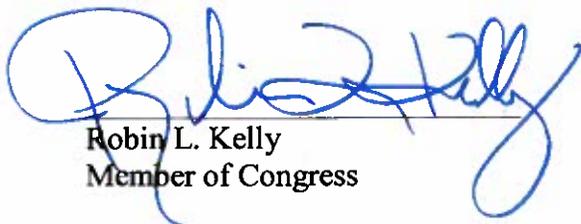
Ron Kind
Member of Congress



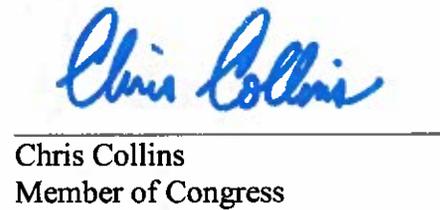
Brett Guthrie
Member of Congress



Peter Welch
Member of Congress



Robin L. Kelly
Member of Congress



Chris Collins
Member of Congress



Richard Hudson
Member of Congress



Terrie Sewell
Member of Congress



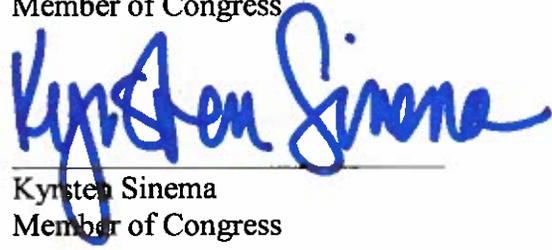
Judy Chu
Member of Congress



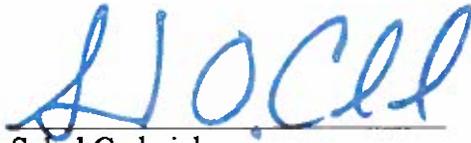
Tom Reed
Member of Congress



Earl L. 'Buddy' Carter
Member of Congress



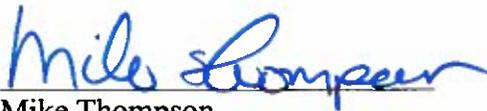
Kyrsten Sinema
Member of Congress



Salud Carbajal
Member of Congress



Nanette Diaz Barragan
Member of Congress



Mike Thompson
Member of Congress



Eric Swalwell
Member of Congress

Congress of the United States
Washington, DC 20510

May 8, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Administrator Verma:

We write today to express our concern regarding biosimilar reimbursement policies finalized in the Centers for Medicare & Medicaid Services' (CMS) 2016 Medicare Physician Fee Schedule (MPFS) rule. Given that the pipeline and market for biosimilar drugs remain under development and that physician, patient and industry stakeholders, as well as twenty Senators and 33 Representatives, requested the agency not finalize the proposed payment policy, we ask that you review this policy and consider the benefits reversing it would have for patients and the taxpayer.

The emergence of biosimilar drugs has the potential to revolutionize the treatment landscape for many patients by offering them more treatment options at a lower cost. By developing drugs based on the human body's own biological processes, life science companies have been able to create therapies with treatment possibilities previously unattainable through traditional drug development. In order for the biosimilars market to further develop and succeed, each biosimilar needs a separate Healthcare Common Procedure Coding System (HCPCS) code and associated payment rate.

We have heard concerns from patient and physician groups, pharmacy organizations, biosimilar manufacturers, and other stakeholder organizations that appropriate reimbursement for biosimilar drugs is vital to the creation of a vibrant biosimilar market. A reimbursement structure must appropriately reflect the complexity of these products and the differences between individual biosimilar products. Additionally, a more market-based policy will better support innovation, access, and affordability of these medications.

Biosimilar drugs hold enormous promise for improving health care outcomes for patients and reducing costs for both patients and health care payers such as Medicare and Medicaid. Accordingly, we urge you to reverse the current biosimilar reimbursement policy and adopt a separate coding and payment policy that will result in a robust, sustainable biosimilars market over the long term.

Sincerely,

Pat Roberts
United States Senator

Mike Enzi
United States Senator

John Cornyn
United States Senator

Rob Portman
United States Senator

Tim Scott
United States Senator

Roy Blunt
United States Senator

John Barrasso
United States Senator

John Hoeven
United States Senator

Steve Daines
United States Senator