Sean Cavanaugh's Hearing
"Examining Implementation of the Biologics Price Competition and Innovation Act"
Before
E&C Health Subcommittee

February 4, 2016

Attachment — Additional Questions for the Record

The Honorable Joseph R. Pitts

1. **In its draft naming guidance, FDA seems to make the case that distinguishing biosimilars from their reference product and other biosimilars is critical to patient safety. If this is the case, why did CMS not share this view and take the opportunity to have different J-codes for biosimilars?**

Answer: Patient safety is always a top priority at CMS and we agree that it is important to be able to track the specific biosimilar a particular beneficiary receives. Naming guidance and billing codes are designed for different purposes and therefore decisions about how to name a product and how to bill for it are based on different factors. Billing codes are not clinical tools, nor are they used by the physician to identify a drug at the point of prescribing; instead, billing codes identify drugs during the claims and payment process. The purpose of a HCPCS billing code (i.e., J-code) is to facilitate the appropriate payment of a drug claim.

With this issue, as well as other issues, we worked closely with our colleagues at FDA. After reviewing the comments we received in response to our proposed rule and collaborating with the FDA, CMS implemented a requirement that claims for biosimilars must include a modifier that identifies the manufacturer of the specific product. We have also published guidance on the use of the coding modifier for biosimilars, which is available on our website.[1] This coding modifier was established so that CMS may track and better understand how biosimilar products are used in Medicare Part B. The modifier will also allow the FDA and others to utilize CMS claims data when studying the safety of specific biosimilar products by enabling the identification of the specific biosimilar that a particular individual received. With regard to tracking usage, this modifier should provide the same pharmacovigilence benefit that a separate J-code would.

2. **There appears to be a disconnect between what the FDA may do in this space and CMS reimbursement policy. For example, the FDA may approve a product for a subset of indications of its reference product with interchangeability. However, combining all products into 1 code inherently removes the incentive for innovation and the development of biosimilars with multiple indications and interchangeability with the reference product. This could potentially reduce ultimate savings by decreasing the amount of products that could be interchangeable with the reference product? Did CMS consider these impacts to innovation and Medicare program costs?**

[1] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html

Answer: The Affordable Care Act includes two provisions for biosimilars: one setting forth a Medicare Part B payment methodology (section 3139); and one setting forth an approval pathway (section 7002). Payment and approval issues overlap, but they are not identical.

In developing payment policy for biosimilars, CMS considered the great promise that biosimilars hold for all Americans, including Medicare beneficiaries. CMS is committed to a payment approach that will provide a fair payment in a healthy marketplace. Overall, competition resulting from the availability of generic alternatives in the drug marketplace has lowered the price and improved the availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries – improving price and access. While we appreciate that there are differences between multiple source drugs and biosimilars, from a payment policy perspective, it is also reasonable to treat them similarly. They both have significant similarities with their predecessor product (a reference product for biosimilars and an innovator product for generics) and they are both approved through an abbreviated pathway. Further, we believe that biosimilars and multiple source drugs will have similar marketplace attributes; like generics, biosimilars will compete for market share with each other as well as with the reference product. Given the robust marketplace for biologicals, we do not believe that a payment policy that encourages greater competition will drive manufacturers out of the market. In addition, how the payment provision in section 3139 of the Affordable Care Act addresses interchangeability also supports the position that biosimilars can be treated like multiple source drugs. Under section 1847A of the Social Security Act, the potential for interchangeability does not factor into how payment is determined for a biosimilar. Neither the definitions in section 1847A, nor the requirements for how payment amounts are calculated treat biosimilars that are interchangeable (and could be potentially substituted much like generic drugs) differently from other biosimilars.

It is important for Medicare beneficiaries and the biosimilar industry that CMS create, maintain, and if necessary refine or further develop payment policies that support innovation, access, and affordability of these medications. We will monitor developments as more biosimilars enter the market and will consider future refinements to policy as needed, based on actual experience with this new segment of the market. We look forward to continuing to work with this Committee and to gathering feedback from providers, suppliers, and other stakeholders in order to better inform our guidance and regulations.

3. **Do you fear that physicians will be confused with a payment policy that equalizes payment among biosimilars when even those with the same reference product, may have different indications and thus are not clinically interchangeable?**

Answer: Billing codes are not clinical tools, nor are they used by the physician at the point of prescribing to identify a drug; instead, billing codes identify drugs during the claims and payment process. We are not aware of situations where providers have assumed that drug or biological products grouped together for payment purposes under Part B are clinically equivalent, or that confusion regarding coverage, billing, coding, or medical records has resulted.

4. **How will CMS ensure that patients receive the most clinically appropriate biosimilar therapy if the biosimilar best for that patient is reimbursed potentially below the provider acquisition cost because CMS's payment policy does not differentiate these important clinical differences?**

Answer: Our experience with the Average Sales Price (ASP) methodology over the last eleven years leads us to believe that this sort of problem is unlikely. This is a theoretical concern that could exist for most drugs and biologicals that are paid under the ASP methodology when more than one product is within the same billing code – whether generic drugs or biologicals and branded drugs. We are unaware of any significant access issues related to ASP determination for HCPCS billing codes that include generic drugs and brand drugs, or multiple branded drugs or biologicals. However, as we stated in the final rule, CMS is committed to considering whether refinements to the biosimilar payment policy may be necessary as the market develops.

5. **How will CMS ensure that the policy does not result in a shift in the site of care from physicians' offices to more expensive settings (thereby also increasing patient cost-sharing obligations), given that hospitals are more capable of absorbing losses on drug reimbursement?**

Answer: As discussed in answer # 2, CMS is committed to a payment policy that will result in a fair payment in a healthy marketplace. For many reasons, physicians prefer to furnish care in their offices when it is clinically acceptable. As stated in the final rule, CMS is committed to considering whether refinements to the biosimilar payment policy may be necessary as the market develops.

6. **Did CMS consider that despite the potential uniqueness of future biosimilars within a class, all being grouped under the same code, cause confusion among patients?**

Answer: CMS understands that beneficiaries work with their providers to identify appropriate medical treatments. While a beneficiary may talk to a physician about a particular drug or biosimilar that they've heard of, that conversation is not likely to be based upon information pertaining to the billing code, but rather on publicly available information on the attributes of a particular product. We are not aware of situations where patients have been confused because of biologicals or drugs using the same billing code.

7. **What role could pharmacy benefit managers (PBMs) play in tracking adverse events if products share the same code? What role would insurers play in tracking product-specific biosimilar adverse events?**

Answer: Patient safety is always a top priority at CMS and we agree that it is important to be able to track the specific biosimilar a particular beneficiary receives. Naming guidance and billing codes are designed for different purposes and therefore decisions about how to name a product and how to bill for it are based on different factors. Billing codes are not clinical tools, nor are they used by the physician to identify a drug at the point of prescribing; instead, billing codes identify drugs during the claims and payment process. The purpose of a HCPCS billing code (i.e., J-code) is to facilitate the appropriate payment of a drug claim.

With this issue, as well as other issues, we worked closely with our colleagues at FDA. After reviewing the comments we received in response to our proposed rule and collaborating with the FDA, CMS implemented a requirement that claims for biosimilars must include a modifier that identifies the manufacturer of the specific product. We have also published guidance on the use

of the coding modifier for biosimilars, which is available on our website.[2] This coding modifier was established so that CMS may track and better understand how biosimilar products are used in Medicare Part B. The modifier will also allow the FDA and others to utilize CMS claims data when studying the safety of specific biosimilar products by enabling the identification of the specific biosimilar that a particular individual received. With regard to tracking usage, this modifier should provide the same pharmacovigilence benefit that a separate J-code would. PBMs and private insurers could use the same or a different system to track the specific biosimilar received by each patient. It should also be noted that some pharmacy plans might not use the same coding system for drugs as Medicare Part B does. For example, pharmacy plans might use the National Drug Code system (NDC), and the NDC system provides for product-specific adverse event analysis in those claims data.

The Honorable Michael Burgess

1. **In a letter to the Senate HELP committee dated June 26, 2007, the Secretary of HHS stated that companies seeking interchangeability determinations should be required to provide clinical evidence for every indication of use approved for the reference product. The Secretary expressed concern that otherwise a patient might be switched to a product that hadn't been shown to be interchangeable for the patient's disease. Does this still reflect the agency's thinking on interchangeability? If not, why? If so, please explain why the agency has selected a reimbursement model that treats all biosimilars of a single reference product the same, regardless of the number of indications for which a biosimilar has produced clinical evidence?**

Answer: The Affordable Care Act includes two provisions for biosimilars: one setting forth a Medicare Part B payment methodology (section 3139); and one setting forth an approval pathway (section 7002). Payment and approval issues overlap, but they are not identical.

In developing payment policy for biosimilars, CMS considered the great promise that biosimilars hold for all Americans, including Medicare beneficiaries. CMS is committed to a payment approach that will provide a fair payment in a healthy marketplace. Overall, competition resulting from the availability of generic alternatives in the drug marketplace has lowered the price and enhanced the availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries – improving price and access. While we appreciate that there are differences between multiple source drugs and biosimilars, from a payment policy perspective, it is reasonable to treat them similarly. They both have significant similarities with their reference product and they are both approved through an abbreviated pathway. Further, we believe that biosimilars and multiple source drugs will have similar marketplace attributes; like generics, biosimilars will compete for market share with each other as well as with the reference product. Given the robust marketplace for biologicals, we do not believe that a payment policy that encourages greater competition will drive manufacturers out of the market. In addition, how the payment provision in section 3139 of the Affordable Care Act addresses interchangeability also supports the position that biosimilars can be treated like multiple source drugs. Under section 1847A of the Social Security Act, the potential for interchangeability does not factor into how payment is determined for a biosimilar. Neither the definitions in section 1847A, nor the

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requirements for how payment amounts are calculated treat biosimilars that are interchangeable (and could be potentially substituted much like generic drugs) differently from other biosimilars.

It is important for Medicare beneficiaries and the biosimilar industry that CMS create, maintain, and if necessary refine or further develop payment policies that support innovation, access, and affordability of these medications. We will monitor developments as more biosimilars enter the market and will consider future refinements to policy as needed, based on actual experience with this new segment of the market. We look forward to continuing to work with this Committee and to gathering feedback from providers, suppliers, and other stakeholders in order to better inform our guidance and regulations.

2. Did CMS have any discussions with FDA regarding the potential effects the reimbursement policy could have on the biosimilars marketplace? If not, why? If so, please describe what factors were addressed in those discussions.

Answer: CMS and FDA work closely together in a number of areas, and each agency plays a critical role. FDA's expertise allows them to make important decisions around issues of the safety and efficacy of prescription drugs and medical devices, and CMS's expertise allows us to create payment policies that that will provide a fair payment in a healthy marketplace. After reviewing the comments we received in response to our proposed rule and collaborating with the FDA, CMS implemented a requirement that claims for biosimilars must include a modifier that identifies the manufacturer of the specific product. We have also published guidance on the use of the coding modifier for biosimilars, which is available on our website.[3] This coding modifier was established so that CMS may track and better understand how biosimilar products are used in Medicare Part B. The modifier will also allow the FDA and others to utilize CMS claims data when studying the safety of specific biosimilar products by enabling the identification of the specific biosimilar that a particular individual received. With regard to tracking usage, this modifier should provide the same pharmacovigilence benefit that a separate J-code would.

<u>The Honorable Gus Bilirakis</u>

1. Mr. Cavanagh, as you have heard in this hearing and from outside stakeholders, there has been a lot of concern about grouping biosimilars together for the purposes of coding and payment. In the final regulations for Medicare's Part B biosimilar regulations, CMS wrote: "We also note that the proposed revised regulation text would not preclude CMS from separating some, or all, of a group of biosimilars for payments – and the creation of one or more separate HCPCS codes – should a program need to do so arise."

a. What type of incident, complication, need, or problem, would have to happen for CMS to change its position?

Answer: The field of biosimilars is a new advancement in health technology and holds great promise for future improvements in health value and outcomes. CMS policies will continue to ensure Medicare beneficiaries have access to biosimilars and other innovative treatments that

[3] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html

receive FDA approval. It is important for Medicare beneficiaries and the biosimilar industry that CMS create, maintain, and if necessary refine or further develop payment policies that support innovation, access, and affordability of these medications. We will monitor developments as more biosimilars enter the market and will consider future refinements to policy as needed, based on actual experience with this new segment of the market. We look forward to continuing to work with this Committee and to gathering feedback from providers, suppliers, and other stakeholders in order to inform our guidance and regulations.

b. Shouldn't we determine how the biosimilar marketplace will look, and see how biosimilars are integrated into clinical practices, based on actual experience, before setting a policy that you admit may need refinement?

Answer: We believe it is important to implement a Medicare payment policy for biosimilars now, before the second biosimilar for any reference product becomes available, in order to provide certainty for providers and suppliers who will be billing Medicare for these products in the near term. As noted above, we will monitor developments as more biosimilars enter the market and will consider future refinements to policy as needed, based on actual experience with this new segment of the market.

2. Mr. Cavanagh, as I understand it, Medicaid is covering biosimilars as a single source drug, something used for brand name drugs, rather than covering biosimilars as a generic drug. Yet, the Medicare regulations for biosimilars have CMS using a template based on generics. Why does CMS have two different lines of thinking on biosimilars?

Answer: Because of different statutory requirements, Medicare Part B pays for drugs differently from Medicaid. Drug payment methodologies under these programs are authorized under different titles of the Social Security Act, and although they share some similarities, for the most part these payment approaches do not overlap. The different statutory and operational requirements of each program can lead to differences between how drugs and biologicals are treated under each program.

<u>The Honorable Chris Collins</u>

CMS recently determined that biosimilar medicines to a single reference product will have the same billing code. However, in many clinical care settings, the use of unique HCPCS (Healthcare Common Procedure Code System) codes are essential to facilitate accurate attribution of adverse events. As more biosimilar medicines are approved, this issue will become larger.

1. How will CMS ensure that proper, adverse event tracking is not compromised by this payment policy?

Answer:
Patient safety is always a top priority at CMS and we agree that it is important to be able to track the specific biosimilar a particular beneficiary receives. Naming guidance and billing codes are designed for different purposes and therefore decisions about how to name a product and how to bill for it are based on different factors. Billing codes are not clinical tools, nor are they used by

the physician to identify a drug at the point of prescribing; instead, billing codes identify drugs during the claims and payment process. The purpose of a HCPCS billing code (i.e., J-code) is to facilitate the appropriate payment of a drug claim.

With this issue, as well as other issues, we worked closely with our colleagues at FDA. After reviewing the comments we received in response to our proposed rule and collaborating with the FDA, CMS implemented a requirement that claims for biosimilars must include a modifier that identifies the manufacturer of the specific product. We have also published guidance on the use of the coding modifier for biosimilars, which is available on our website.[4] This coding modifier was established so that CMS may track and better understand how biosimilar products are used in Medicare Part B. The modifier will also allow the FDA and others to utilize CMS claims data when studying the safety of specific biosimilar products by enabling the identification of the specific biosimilar that a particular individual received. With regard to tracking usage, this modifier should provide the same pharmacovigilence benefit that a separate J-code would.

The Honorable Frank Pallone

Biosimilars are an exciting new frontier in American medicine. Because this is a new, emerging marketplace, we need to make sure we do everything possible to incentivize manufacturers to enter the market. For this to happen, it is important that the Administration has a clear and coherent position on biosimilars.

1. **Please describe the extent to which CMS has collaborated with FDA on implementing biosimilars policy?**
2. **Did CMS seek FDA guidance when drafting its Part B reimbursement policy?**

Answer to 1 & 2: CMS and FDA work closely together in a number of areas, and each agency plays a critical role. FDA's expertise allows them to make important decisions around issues of the safety and efficacy of prescription drugs and medical devices, and CMS's expertise allows us to create payment policies that that will provide a fair payment in a healthy marketplace. After reviewing the comments we received in response to our proposed rule and collaborating with the FDA, CMS implemented a requirement that claims for biosimilars must include a modifier that identifies the manufacturer of the specific product. We have also published guidance on the use of the coding modifier for biosimilars, which is available on our website.[5] This coding modifier was established so that CMS may track and better understand how biosimilar products are used in Medicare Part B. The modifier will also allow the FDA and others to utilize CMS claims data when studying the safety of specific biosimilar products by enabling the identification of the specific biosimilar that a particular individual received. With regard to tracking usage, this modifier should provide the same pharmacovigilence benefit that a separate J-code would.

When CMS published the final rule on Part B payments, the agency noted that many commenters were concerned that the proposed payment approach may make it more difficult to track safety monitoring of codes because individual biologic products could not

[4] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html
[5] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html

be distinguished on claims. Historically, post-approval drug safety surveillance has been a difficult endeavor. I'm concerned that due to differences between biosimilars and regular generics, that safety tracking *may be even more difficult* for biosimilars.

3. **Prior to release of the Rule, did CMS consult with FDA about the potential effects of the proposed approach on their ability to track drug safety?**
4. **Please discuss CMS' efforts to address this issue.**

Answer to 3& 4: Patient safety is always a top priority at CMS and we agree that it is important to be able to track the specific biosimilar a particular beneficiary receives. Naming guidance and billing codes are designed for different purposes and therefore decisions about how to name a product and how to bill for it are based on different factors. Billing codes are not clinical tools, nor are they used by the physician to identify a drug at the point of prescribing; instead, billing codes identify drugs during the claims and payment process. The purpose of a HCPCS billing code (i.e., J-code) is to facilitate the appropriate payment of a drug claim.

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One of the most difficult decisions to make in payment policy for prescription drugs is the balance between patient access and spurring innovation. Not unexpectedly, CMS indicated in the Part B Payment Final Rule that the agency received considerable comment on this topic.

Several stakeholders have indicated that they are concerned that grouping biosimilar products for payment purposes would discourage innovation.

5. **Can you comment on how the agency addressed these concerns in the final payment rule?**

Answer: We do not believe that our approach to Medicare Part B payment policy will stifle or damage the marketplace or impair innovation. Biological products are heavily utilized in Part B and account for a significant share of spending compared to drugs. According to a GAO report dated October 12, 2012,[7] Medicare and its beneficiaries spent $19.5 billion on Part B drugs and biologicals in 2010. The 10 most expensive products accounted for about $9.1 billion of that amount and 8 of 10 of the highest expenditure Part B drugs were biologicals. Given the robust

[6] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html
[7] http://www.gao.gov/products/GAO-13-46R (GAO–13–46R High Expenditure Part B Drugs, pages 6 and 7).

marketplace for biologicals, we do not believe that a payment policy that encourages greater competition will drive manufacturers out of the market. To the contrary, we believe there is a strong need for lower cost alternatives to high cost biologicals, and the statute provides an incentive for the development of the biosimilars market by providing for reimbursement that includes a 6 percent add-on of the more expensive reference product's ASP.

FDA has been very explicit that biosimilars are not the same as generics. However, CMS has indicated that because of the degree of similarity of biosimilars to their reference products, that the agency believes it is appropriate to price biosimilars in a similar manner to generics.

6. Can you discuss this apparent difference in opinions?

Answer: The Affordable Care Act includes two provisions for biosimilars: one setting forth a Medicare Part B payment methodology (section 3139); and one setting forth an approval pathway (section 7002). Payment and approval issues overlap, but they are not identical.

In developing payment policy for biosimilars, CMS considered the great promise that biosimilars hold for all Americans, including Medicare beneficiaries. CMS is committed to a payment approach that will provide a fair payment in a healthy marketplace. Overall, competition resulting from the availability of generic alternatives in the drug marketplace has lowered the price and improved the availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries – improving price and access. While we appreciate that there are differences between multiple source drugs and biosimilars, from a payment policy perspective, it is also reasonable to treat them similarly. They both have significant similarities with their predecessor product (a reference product for biosimilars and an innovator product for generics) and they are both approved through an abbreviated pathway. Further, we believe that biosimilars and multiple source drugs will have similar marketplace attributes; like generics, biosimilars will compete for market share with each other as well as with the reference product. Given the robust marketplace for biologicals, we do not believe that a payment policy that encourages greater competition will drive manufacturers out of the market. In addition, how the payment provision in section 3139 of the Affordable Care Act addresses interchangeability also supports the position that biosimilars can be treated like multiple source drugs. Under section 1847A of the Social Security Act, the potential for interchangeability does not factor into how payment is determined for a biosimilar. Neither the definitions in section 1847A, nor the requirements for how payment amounts are calculated treat biosimilars that are interchangeable (and could be potentially substituted much like generic drugs) differently from other biosimilars.

It is important for Medicare beneficiaries and the biosimilar industry that CMS create, maintain, and if necessary refine or further develop payment policies that support innovation, access, and affordability of these medications. We will monitor developments as more biosimilars enter the market and will consider future refinements to policy as needed, based on actual experience with this new segment of the market. We look forward to continuing to work with this Committee and to gathering feedback from providers, suppliers, and other stakeholders in order to better inform our guidance and regulations.

The FDA has taken the approach of having two differing levels of biologic drugs: Biosimilars and interchangeable biologics.

7. **Although there are currently no interchangeables at this time, has CMS considered developing a future payment structure that reflects these differences?**

Answer: The field of biosimilars is a new advancement in health technology and holds great promise for future improvements in health value and outcomes. CMS policies will continue to ensure Medicare beneficiaries have access to biosimilars and other innovative treatments that receive FDA approval. It is important for Medicare beneficiaries and the biosimilar industry that CMS create, maintain, and if necessary refine or further develop payment policies that support innovation, access, and affordability of these medications. We will monitor developments as more biosimilars enter the market and will consider future refinements to policy as needed, based on actual experience with this new segment of the market. We look forward to continuing to work with this Committee and to gathering feedback from providers, suppliers, and other stakeholders in order to better inform our guidance and regulations.

The Honorable Lois Capps

It's incredibly important for patients to be engaged in their care, but that doesn't mean anything if they cannot afford the treatments that are best suited for them. Biosimilars offer great promise in bringing these costs down and helping patients afford the treatments they need, when they need them. But there seems to be great concern about how they will be paid for. Dr. Cavanaugh, CMS has recently laid out its framework for how biosimilars will be treated in Medicare Part B. My understanding is that Medicare Part D and Medicaid have set up systems that treat biosimilars as a unique drug, whereas Part B treats biosimilars more like a traditional small molecule generic drug.

1. **Can you explain these different approaches to reimbursement and why the Part B rule treats biosimilars different than in these other federal programs?**

Answer: Payments for drugs in Medicare Part B are determined differently than payments in Medicare Part D and Medicaid because drug payment methodologies under these programs are authorized by three different parts of the Social Security Act. Although the payment approaches share some similarities, for the most part these payment approaches do not overlap. The different statutory and operational requirements of each program result in differences between how drugs and biologicals are treated under each program.