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May 9, 2016

The Honorable Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1670-P: Medicare Program Part B Drug Payment Model

Dear Acting Administrator Slavitt:

We appreciate the opportunity to provide comments on the proposed Medicare Program Part B Drug Payment Model proposed rule (CMS-1670-P). The Generic Pharmaceutical Association (GPhA) represents manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceuticals chemicals, and suppliers of other goods and services to the generic industry. GPhA's mission is to improve the lives of patients and the U.S. healthcare system by advancing timely access to affordable generic medications. The Biosimilars Council, a division of GPhA, works to ensure a positive environment for patient access to biosimilar medicines. The Biosimilars Council is a leading source for information about the safety and efficacy of these more affordable alternatives to costly brand biologic medicines.

CMS is proposing a nationwide model to test whether alternative drug payment designs will lead to a reduction in Medicare spending, while maintaining or improving the quality of care provided.[1] Both GPhA and the Biosimilars Council share CMS' stated goal of reducing overall Medicare expenditures, while maintaining or improving the quality of care provided to beneficiaries. Generic prescription drugs and biosimilars are uniquely positioned to help CMS achieve this goal.

However, we have serious concerns that the demonstration, as proposed, risks limiting the savings created through open market competition, particularly in the nascent biosimilars market. We strongly encourage the agency to carefully consider thoughtful changes to both phases of the demonstration in order to maintain robust competition, and a strong incentive to invest in affordable medicine, where possible. Most importantly, CMS should ensure that Phase II of the proposal does not create an environment where generic or biosimilar products are compared with anything other than their intended reference product. Regardless of the final policies implemented, CMS must not erode the economic incentives that drive the U.S. healthcare system to lower-cost therapeutic alternatives when clinically appropriate.

[1] 81 FR 13230 (March 11, 2016).

The Hatch-Waxman Act, as well as the Biologics Price Competition and Innovation Act (BPCIA), create a carefully balanced framework designed to incentivize pharmaceutical manufacturers for both innovation and price competition. Any value-based tools which CMS implements must not undermine this balance. Specifically, products which function in well-established multi-source environments must be allowed to continue to operate in an unencumbered market, while products in newly developing markets must be allowed the opportunity to compete with their reference products in competitive pricing markets without comparisons to other options they were never designed to compete against.

For over 30 years, generic manufacturers have successfully fostered a competitive marketplace that has expanded patient access to life-saving medication while helping to reduce health care costs. Biosimilars, a market that is currently in its infancy, hold the promise of reducing spending and expanding beneficiary access to high-cost biologics. It is imperative that CMS maintains this market dynamic with any new payment policies, and not reduce incentives for manufacturers to develop lower-cost alternatives. Any short term savings resulting from such comparison, would over the long term reduce competitive options (and perhaps greater savings) and access to important, affordable medical alternatives.

Phase I: Ensure Any Changes to Reimbursement Calculations Incentivize Competition

CMS Should Alter Proposed Payment Limit to Account for the Effects of Sequestration

CMS must fully consider the true impact of sequestration on the demonstration, particularly for providers that are assigned to receive payment set at 102.5% of ASP, plus a flat administrative fee. Once sequestration is applied, real payment limits will be closer to 100.86% of ASP for this group. We believe that for biosimilar products and some specialty generics this reduction in payment may increase the number of providers who are unable to acquire prescription drugs at or below the payment amount, leading to beneficiary access issues. The reduced payment methodology also does not take into account the fact that some Part B prescription drugs, especially anti-cancer therapies, have high storage and handling costs that are unavoidable.[2] Reducing payment for these products even more may severely limit beneficiary access.

We therefore ask CMS to reconsider the proposed payment limit to more fully account for the effects of sequestration in order to prevent barriers to patient access. If the agency chooses to move forward with the reimbursement rate as proposed, CMS should closely monitor beneficiary access and be prepared to make adjustments as necessary to ensure that all Medicare beneficiaries have access to the prescription drug products that they need.

[2] For example, see the Centers for Disease Control and Prevention National Institute for Occupational Safety and Health, "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings" (http://www.cdc.gov/niosh/docs/2004-165/).

For Any Biosimilar Included in Model, the Biosimilar's Add-On Percentage Must Continue to Be Based on the ASP of Reference Product

If CMS decides to include any biosimilars in the proposed model, the agency by statute must retain the incentives included in the BPCIA intended to promote biosimilar utilization. Specifically, the percentage add-on calculated from the ASP should be based on the ASP of the reference product, as is done under current payment policy. This would maintain continuity with Congressional intent in establishing overall Medicare payment policy for biosimilars.[3] We request that CMS clearly confirm in the final rule the intent to continue to base the ASP add-on percentage (either +6% or +2.5%) on the ASP of the reference product.

CMS Should Reverse Current Coding Policy and Payment Policy and Assign Non-Interchangeable Biosimilars Unique HCPCS Codes and ASP Calculations

GPhA and the Biosimilars Council maintain our opposition to CMS' coding and payment policy for non-interchangeable biosimilars, as outlined in our public comments submitted in 2015. The policy was finalized in 2015 and took effect on January 1, 2016. The current coding policy and ASP calculation methodology for non-interchangeable biosimilars presents a major departure from previous CMS policy and unfairly disadvantages non-interchangeable biosimilars. We continue to believe that CMS should reverse current HCPCS coding policy with respect to non-interchangeable biosimilars, and assign each non-interchangeable biosimilar a unique HCPCS code.

The Biosimilars Council strongly believes that having all non-interchangeable biosimilars combined in a single payment calculation creates significant disincentives for manufacturers to invest the additional capital in developing biosimilar products. Each biosimilar that has not also been determined to be interchangeable (i.e. non-interchangeable) should be paid at uniquely-calculated payment rate based on that biosimilar's ASP. Medicare payment policy that sets payment limits for all biosimilars associated with a particular reference product under a single, blended ASP could limit Medicare beneficiary access to non-interchangeable products for which Medicare pays less than the product's ASP.

Phase II: Maintain Adequate Protections for Price-Based Competition in Valued-Based Models

Any Evaluation of Value-Based Purchasing (VBP) Tools Must Consider the Total Cost of Patient Care Outside of Pharmaceutical Costs

As CMS moves forward with implementation and eventual evaluation of the VBP phase of the model, it is critical that the agency consider the impact on the total cost of patient care, and not just the impact on pharmaceutical spending. The Social Security Act authorizes the Center for Medicare and Medicaid Innovation (CMMI) to select "models that are expected to reduce program costs under the applicable title

[3] Sec. 1847A(b)(8)(B) of the Social Security Act requires the 6% add-on amount for biosimilars to be based on the ASP for the reference product.

while preserving or enhancing the quality of care…"[4] Furthermore, the Social Security Act directs CMMI to consider the "changes in spending under the applicable titles by reason of the model."[5]

Prescription drug spending does not occur in a vacuum, and it is possible that spending on prescription drugs can increase, or remain steady, while overall healthcare costs decrease. For example, an oncology bundled payment pilot program operated by UnitedHealthcare found that participants had improved survival rates and overall lower healthcare spending, but spending on prescription drugs actually increased.[6] Any evaluation tools must look at the total health care costs associated with beneficiaries' treatment, and not just examine the impact of the model on spending for prescription drugs.

Any Value-Based Model Must Maintain Direct, Price-Based Competition Between Reference Products and Their Lower-Cost Alternatives

GPhA and the Biosimilars Council believe that several of the VBP tools proposed under the model would eliminate price competition as an effective tool in lowering overall spending. Specifically, reference pricing, indication-based pricing and risk-sharing agreements could all potentially remove incentives for providers to choose the lower-cost therapeutic alternative that is clinically appropriate.

Generics and biosimilars are developed under the presumption that once approved, they will compete with their reference brand products. By creating other points of reference in situations in which there are multiple therapeutic alternatives, CMS risks reducing the incentives for manufacturers to enter aggressively priced markets. This is particularly concerning for biosimilar manufacturers who face significant research and development costs associated with bringing new products to market.

The Medicare program's statutory beneficiary cost-sharing requirements also act as a natural incentive to select lower-cost alternatives, since beneficiary cost-sharing is directly related to the cost of the product. This dynamic acts as a counter-check to the incentive for providers to choose the highest-cost therapeutic alternative in an effort to increase revenue. Any changes to cost-sharing requirements should be designed in a manner so that they do not act as a disincentive to use lower-cost alternatives.

The agency's stated goal for the use of reference pricing is to eliminate "the direct link between the purchase prices paid by suppliers and providers for Part B drugs and payment rates for those drugs from insurers, thereby providing stronger incentives to evaluate outcomes and cost together when determining treatment regimens."[7] However, cost cannot be separated from the concept of value, and CMS must maintain the incentive for providers to choose the lower-cost therapeutic option that is clinically appropriate. It is not unreasonable to presume that in a reference pricing situation, a single-source manufacturer will choose to reduce pricing to the reference price, or below. This may reduce differences between the prices of branded and generic products and lower incentives for providers to use the lower-cost alternative.

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[4] Sec. 1115A(b)(2)(A) of the Social Security Act.
[5] Sec. 1115A(b)(4)(A)(ii) of the Social Security Act.
[6] UnitedHealth Group: Study: New Cancer Care Payment Model Reduced Health Care Costs, Maintained Outcomes 2014 (http://www.unitedhealthgroup.com/newsroom/articles/feed/unitedhealthcare/2014/0708cancercarepaymentstudy.asp).
[7] 81 FR 13243 (March 11, 2016).

Value-Based Purchasing Tools Should Only Be Applied to Biosimilars When an Applicable Reference Product is Subject to the Tool

The biosimilars market is in its infancy; to date, there have only been two products approved by the U.S. Food and Drug Administration (FDA). The two currently U.S. approved biosimilars, filgrastim and infliximab, are quite different in a number of ways. Whether it be the product itself, therapeutic area, type of disease treatment, patient types, site of care, administration of drug, etc., these differences reflect the need for a better understanding of what VBP tools will be utilized.

Because the biosimilars market is new and currently limited to two products, GPhA and the Biosimilars Council believe it is too early to determine appropriate VBP tools for biosimilars. It is also too early to determine which VBP tools will be most effective in accomplishing the CMS objectives. Some of these VBP tools may or may not differ from what is being offered or proposed today. With additional biosimilars to be approved in other therapeutic areas in the future, similar questions will surface in regards to which VBP tools are needed, which are the most effective, and which satisfy the overall goal of CMS. These questions on biosimilars should be addressed prior to implementation of any VBP tool for biosimilars.

For these reasons, GPhA and the Biosimilars Council believe that CMS should avoid applying VBP tools to biosimilar products, unless the same VBP tool is also applied to its reference product.

Value-Based Purchasing Tool Implementation Should Occur in a Deliberate Fashion and Allow for Adequate Stakeholder Input

GPhA and the Biosimilars Council appreciate CMS' proposal to implement a public review and comment period before finalizing any VBP tools. This period is essential to make sure all stakeholders have the ability to provide input, and that any decisions related to VBP tools are implemented in a transparent manner. Similarly, the agency should make sure that both phases of the model are implemented in a deliberate fashion. The proposed timeline for implementation (late 2016 implementation of the first phase and January 1, 2017 implementation date for the second phase) appears to be aggressive in light of assurances by the agency that public stakeholder input will be considered.

We urge CMS to make sure that the public has an adequate opportunity to provide input on the model in all stages on implementation. We appreciate that CMS has decided to use formal notice and comment rulemaking for the proposal, but the lack of specific details in the proposed rule itself are concerning. It is understandable that CMS wishes to gather input from stakeholders along the full model development process. However, it is essential that all stakeholders have the ability to participate in a public, transparent forum to provide input.

Other Concerns: CMS Should Reevaluate the Scope of the Proposed Demo to Best Create a Model that Will Truly Test Innovative Payment Models

GPhA and the Biosimilars Council recognize the authority of CMMI to develop innovative models to create better value for patients. However, the scope of this proposed demo risks fundamentally changing how prescription drugs are paid for throughout the Medicare Part B program, without sufficiently testing the effects of such a change on the multi-source market. As referenced earlier, the biosimilars market is still in its infancy.

It is particularly important to note that with the only two products on the market, for two separate reference products, there is no way to effectively measure the impact of any changes to this incredibly small market. Additionally, any new biosimilars entering the market would only ever exist under the demonstration, and therefore there would be no prior experience as to how the market functioned before. **Therefore, we believe that the demonstration, as designed, will create an environment that will make it particularly difficult to measure the effects of newly proposed payment models on the biosimilars market's ability to reduce costs.** Any number of risks, including providers shifting patients to geographic areas not subject to value-based tools, provider supply cost issues associated with fluctuating payments, and others risk skewing results in a way that provides no real insight into the economic effects of these newly-developing markets.

For these reasons, GPhA and the Biosimilars Council encourage CMS to consider reevaluating the scale of the demonstration to more effectively test specific reimbursement models. Specifically, CMS could restrict the demonstration to smaller geographic areas, as it has done with other CMMI initiatives, or to specific therapeutic classes of products.

CMS Should Reevaluate the Proposed Implementation Timeline to Account for Other Anticipated Changes to the Physician Payment System

The proposed implementation timeline for the model is aggressive. The agency proposes to implement Phase I of the model in late 2016, and Phase II of the model on January 1, 2017. Given the concerns raised by stakeholders concerning the potential impact of pricing methodology changes on beneficiary access, as well as other potential unintended consequences outlined above, we recommend that the implementation be delayed until CMS can adequately ensure that any proposals will not do significant harm to patient access or affordability.

A delay would also give CMS the opportunity to make sure that changes proposed under this model will comport with changes finalized under the recently-released Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models proposed rule (CMS-5517-P), which was released on April 27, 2016.[8] The proposed changes to physician services payment generally under fee-for-service Medicare are scheduled to become effective January 1, 2019. The implementation of this significant payment reform

[8] The proposed rule is scheduled to be published in the May 9, 2016 edition of the *Federal Register*. The rule is available online: https://www.federalregister.gov/articles/2016/05/09/2016-10032/medicare-program-merit-based-incentive-payment-system-and-alternative-payment-model-incentive-under.

would occur during the proposed Part B drug payment model. Overlapping two different payment reforms at once will make it difficult to determine which reform led to specific outcomes.

For example, in the Regulatory Impact Analysis section of the Part B drug payment model proposed rule (CMS-1670-P), CMS identified the top five physician specialties by total Part B drug payment: hematology/oncology, ophthalmology, pharmacy (including specialty and DME), rheumatology, and medical oncology.[9] In the Regulatory Impact Analysis section of the MIPS/APM proposed rule, the majority of the practitioners in those same specialties are expected to receive a positive payment adjustment under MIPS.[10] The physician service payment reforms may negate or otherwise influence physician behavior in response to the proposed payment reform for Part B drugs, but it will be difficult to distinguish the impact of each reform individually.

The Final Rule Must Include Additional Details Surrounding the Proposal to Waive the Statutory Definitions of Single-Source and Multiple-Source Products

Under the proposal, CMS includes a waiver of the statutory definitions of single-source drug or biological, and multiple-source drug or biosimilar.[11] However, there is not much additional detail included in the proposal itself as to how the agency envisions implementing this authority, beyond "to test whether paying these types of drugs and biologicals using the pricing approaches described in this proposed rule will reduce expenditures while maintaining or improving quality of care."[12] An illustration involving equal or benchmarked payment for drug products in a single therapeutic class is used as a possible example of this authority, but it is reasonable to presume that additional potential examples exist. Without adequate details as to how the agency envisions exercising this authority, it is difficult to provide comments on this waiver proposal.

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For these reasons, we respectfully request that CMS reflect the following policies in its final rule:

Phase I:

- CMS should alter the proposed payment limit to account for the effects of sequestration.
- For any biosimilars included in the model, the biosimilar's add-on percentage must be based on the ASP of the reference product.
- CMS should reverse current coding and payment policy for non-interchangeable biosimilars, and assign non-interchangeable biosimilars unique HCPCS codes and ASP calculations.

Phase II:

- Any value-based model must maintain direct, price-based competition between reference products and their lower-cost alternatives.
- Any evaluation of value-based purchasing tools must consider the total cost of patient care outside of pharmaceutical costs.

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[9] 81 FR 13255 (March 11, 2016).
[10] The proposed rule is scheduled to be published in the May 9, 2016 edition of the *Federal Register*. The rule is available online: https://www.federalregister.gov/articles/2016/05/09/2016-10032/medicare-program-merit-based-incentive-payment-system-and-alternative-payment-model-incentive-under.
[11] 81 FR 13260 (March 11, 2016).
[12] 81 FR 13251 (March 11, 2016).

- Value-based purchasing tools should only be applied to biosimilars when an applicable reference product is also subject to the tool.

Other Concerns:

- CMS should reevaluate the scope of the proposed demonstration to best create a model that will truly test innovative payment models.
- CMS should also reevaluate the implementation timeline for the model and consider the potential impact of other anticipated physician payment reforms on the model itself.
- The final rule must include additional details surrounding the proposal to waive the statutory definitions of single-source and multiple-source products.

We appreciate the opportunity to provide these comments, and we look forward to working with CMS to expand beneficiary access to affordable alternatives to high-cost products. If you have any additional questions, please do not hesitate to contact Christine Simmon, Senior Vice President Policy & Strategic Alliances at (202) 249-7116 or csimmon@gphaonline.org.

Sincerely,

Christine Simmon
Senior Vice President Policy & Strategic Alliances