September 24, 2018

SUBMITTED VIA REGULATIONS.GOV

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (CMS 1695-P)

Dear Administrator Verma:

Mylan appreciates the opportunity to provide comments in response to the *Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (hereinafter, "proposed rule").*[1]

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Mylan is the second largest provider of prescription medicine in the U.S. and has one of industry's largest generic portfolios. Mylan's generic medicines saved the U.S. $50 billion in the last two years based on IQVIA's annual savings reports for 2016 and 2017. We seek to enhance access to high-quality, affordable medicines for patients worldwide. As part of that mission, Mylan is taking a leading role in the development of biosimilars and interchangeable biologics for the U.S. marketplace. Mylan's global product pipeline includes 20 biosimilar and insulin analog products, including now nine of the world's top 10 biologics focused on the areas of oncology, immunology, endocrinology and ophthalmology. Two of the twelve biosimilars approved by the U.S. FDA as of August 2018 are Mylan products. Mylan has invested $1 billion to bring biosimilars to market and thus has a strong interest in ensuring that CMS's biosimilar-related policies are consistent with patient access to less costly, high-quality medications.

[1] 83 FR 35704 (July 31, 2018)

Below we provide comments on a number of issues raised in the OPPS proposed rule. As an overview, our comments focus on:

1. Non-pass-through biosimilars acquired under the 340B program: Mylan urges CMS to finalize the proposal to reimburse non-pass-through biosimilars acquired under the 340B program at average sales price (ASP) minus 22.5 percent of the biosimilar's ASP.

2. Competitive Acquisition Program (CAP): Mylan urges CMS to take a measured approach to test a future CAP model, first testing the model on a narrow subset of products that excludes biosimilars and their reference products to avoid unintended consequences with a new program. A thorough evaluation of the impact of the first phase of the model, along with opportunity for public comment, should be conducted before it is broadened to include additional products. The model should be voluntary and a reduction of the ASP "add-on" payment (for providers not participating in the CAP) should not be used to incent participation in or impact payment for products outside the model.

3. Value-based tools to increase access to biosimilars: Mylan urges CMS to consider testing value-based tools, outside of a CAP model, aimed at increasing beneficiary access to biosimilars.

I. Non-Pass-Through Biosimilars Acquired under the 340B Program

Mylan supports the proposal to change the payment rate for non-pass-through biosimilars acquired under the 340B program from the current ASP minus 22.5 percent of the reference product's ASP to ASP minus 22.5 percent of the biosimilar's ASP. The current policy unfairly penalizes biosimilars by setting reimbursement for these products at a lower payment amount given that the reference product's ASP is higher than that of the biosimilar. We applaud CMS for recognizing that the current policy could have the unintended effect of discouraging providers and beneficiaries from selecting biosimilars, and putting forth a proposal to correct this inequity. We urge CMS to finalize the proposal.

II. CAP RFI

The proposed rule includes a request for information (RFI) from the CMS Center for Medicare and Medicaid Innovation (Innovation Center) seeking public feedback on a potential alternative payment model design under Medicare Part B that would build upon the CAP established under section 1847B of the Social Security Act.

Mylan urges CMS to consider the following elements to guide any potential CAP model:

- **Pursue Multi-Phase Implementation:** Although Mylan acknowledges that there may be merit in testing a CAP model to address certain challenges observed within the Part B market, we urge CMS to take a measured approach in testing the model, focusing first

on a narrow subset of products to assess the impact of tested interventions and course-correct before any broader roll-out. A CAP program would represent a fundamental shift in payment for Part B drugs, and although elements of the CAP may have the potential to address specific challenges related to lack of competition in some drug categories within Part B, the model has not yet proven to be functional or sustainable. In fact, the original version of the 2007 and 2008 CAP model failed, as it could not attract participation from providers and vendors, and payment amounts for drugs were higher than under the traditional ASP-based reimbursement structure.[2] Thus, we urge CMS to test a CAP model on a narrow group of products, and thoroughly evaluate the impact of the model before broadening its scope to include additional products. Any products included must be targeted to those for which a CAP model has been assessed as the most appropriate option to encourage competition and access; if an alternative intervention is likely to create greater competition, inclusion in a CAP model is not appropriate.

- **Exclude Biosimilars:** Mylan urges CMS to exclude biosimilars and their respective reference products from the initial testing phases of the model and to only consider their inclusion after the model has been evaluated and deemed both a viable alternative to the traditional Part B ASP-based reimbursement structure, and the optimal approach to encouraging biosimilar competition. Mylan is committed to biosimilars and strongly believes in the potential of biosimilar medicines to deliver affordable life-saving treatments to patients, while providing cost savings to the health care system. Despite significant investments by Mylan and other biosimilar developers, however, the biosimilar industry in the U.S. remains in a nascent stage. In fact, of the 12 FDA-approved biosimilars, only four are commercially available.

  The limited uptake of biosimilars in the U.S. can be attributed to a number of factors including, but not limited to: high development costs, a lack of regulatory certainty, market access tactics by brand-name manufacturers including 'patent thickets', and perhaps most importantly - insufficient provider and patient incentives for use of biosimilars. Including biosimilars in an unpredictable CAP model would only increase the uncertainty associated with bringing a biosimilar to market and further disrupt a fledgling industry that must already endure many barriers to entry and competition. Mylan applauds HHS Secretary Alex Azar for recognizing the importance of a vibrant biosimilar market and the Agency's commitment "to foster and nurture a new, competitive biosimilar drug market."[3] Ensuring that biosimilars are not subject to drastic departures from existing practice coinciding with their entry into the market will help ensure physician acceptance and support the viability of a sustainable biosimilar market. Moreover, as discussed below, to further foster a robust biosimilar market, we

[2] Centers for Medicare and Medicaid Services, Office of Research, Development, and Information, *Evaluation of the Competitive Acquisition Program for Part B Drugs, Final Report* (December 2009), *available at:* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf

[3] White House Press Briefing, May 11, 2018

urge CMS to test value-based models, outside of a CAP model, aimed at promoting the use of biosimilars in the Medicare program.

- **Allow Voluntary Enrollment:** A CAP model should be voluntary, and not mandate provider participation. Providers should have the flexibility to participate in a CAP model and select the product acquisition arrangement that best meets their needs and those of their patients. Additionally, providers who enroll in the CAP should not be locked-in to a contract with a CAP vendor for an entire year. Providers should have the ability to switch vendors or to exit the CAP before their contract expires if they experience problems with the CAP.

- **Eliminate Rebate Mechanism from Utilization Management:** Mylan is concerned that a CAP program will incorporate utilization management similar to Part D, which is limiting patient access to more affordable medicines approved by FDA as alternatives to originator reference products. Under Part D, covered medicines that are placed on a plan's formulary are segmented into tiers that determine how much a patient will pay for each product. Generic tiers have the lowest co-pays and coinsurance for patients. Historically, generic medicines have been added to more preferred formularies immediately upon FDA approval and placed on favored tiers to encourage maximum generic utilization, as well as offer the most savings for payors along with the lowest out of pocket costs for patients.

  Today, however, plans are increasingly using even the prospect of generic entry to leverage greater rebates from brands and lower the actuarial value of each tier. Lower-cost generics are no longer automatically placed on formularies and generic tiers. Instead, plans are increasingly choosing not to list generics on formularies, or are listing generics in higher cost-sharing tiers. Patients are now increasingly burdened with the same high cost-sharing for a brand and its lower-priced generic; cost-sharing can sometimes exceed the actual price of the generic.

  Avalere recently published a study documenting this trend, noting "[o]ver time, Part D plans have also placed an increasing number of generic drugs on brand tiers. In response to this trend, as well as plan sponsor feedback, CMS announced a major change to the formulary structure of the Part D program in May 2016, allowing plan sponsors to create a 'non-preferred drug' tier that explicitly includes both brand and generic drugs."[4] This shift in CMS policy by the previous Administration effectively gave Part D plans a license to expand the movement of generics into non-generic tiers, counter to the intended design of generic tiers to encourage generic utilization and reduce patient out of pocket costs.

  Mylan recently highlighted this concern in our response to HHS' Drug Pricing Blueprint:

[4] Avalere, "Generic Drugs in Medicare Part D, Trends in Tier Structure and Placement Study," May 22, 2018

By disadvantaging generics on formularies, this practice threatens future generic and biosimilar savings, particularly for high cost medicines that lack competition. Last year, the top 20 most costly medicines overall in America had sales of $100 billion according to IQVIA, and as of June 2018, only two of these products had generic or biosimilar competition on the market. Remicade® and Copaxone® collectively had ~$10 billion in 2017 sales. Both have had lower cost biosimilar and generic competition for more than a year, but those competitors have only garnered 3% and 15% market share, respectively. Additionally, many formularies are not even covering these lower cost alternatives for patients and payors – an almost unheard-of phenomenon, denying patient access to the important, less costly alternatives for such expensive brand medicines.

CMS alone spent $1.4 billion in 2016 on Copaxone, according to the recently released CMS Dashboard. Nearly a year after generic launch, eight of the top 10 Medicare Part D plans do not even have generic Copaxone on their formularies. This represents a complete reversal of the longstanding approach of incentivizing generic utilization. In the two Part D plans that do cover generics to Copaxone, generics are in the same formulary tier as the brand (the specialty tier, which currently does not have a distinct tier for generics or biosimilars). These generic alternatives should have saved the overall U.S. healthcare system billions of dollars. To date, however, Multiple Sclerosis patients only have access to these more affordable equivalents to Copaxone 15% of the time because of formulary and coverage decisions. Patients and payors – the government, healthcare plans and employers – are experiencing this restricted access to more affordable generics.

In response to these observations, Mylan's response to the Drug Pricing Blueprint urged CMS to revisit and rescind its May 2016 guidance allowing plans to create a 'non-preferred drug' tier in Part D incorporating both brands and generics, and instead encourage maximum utilization for generics and biosimilars through Medicare. As Mylan noted, Part D plans should be encouraged to place biosimilars and generics on the most favorable and lowest cost sharing tiers relative to the reference brand product, and a specialty tier should be created for specialty generics and biosimilars that provides more favorable cost-sharing to incentivize robust usage of lower cost generics and biosimilars.

If conduct continues to materially impact generic and biosimilar utilization, many generic and biosimilar companies may fully forgo developing such complex and investment-intensive products in the future, eliminating even the prospect of competition. FDA Commissioner Scott Gottlieb, MD, recently described this precisely in the context of biosimilars: "I worry that companies are going to pull out and not want to develop biosimilars that cost anywhere between $100-300 million to develop…if they know that they can't penetrate the market… an example of where the structure of the

pricing environment frustrates our public health goals.[5]" As Dr. Gottlieb put it, "once biosimilar makers see that the system is rigged against them, what's the incentive for a biosimilar maker to pour money into future investments to develop these lower cost alternatives?"[6]

Opening the door to utilization management in Part B without carefully safe-guarding the principles of fostering sustainable off-patent competition could have detrimental consequences for the future of biosimilar competition. Any utilization management considered for Part B, whether part of a CAP model or independent of a potential CAP program, should not allow for use of such tactics or related rebate mechanisms with respect to biosimilars.

- **Vendor Selection**: The type of organizations sought as candidates for the model vendors is highly dependent on the goal of the future model. In the last iteration of the CAP program from 2006-2008, the business model that was deemed to conform most to the legislated program design was specialty pharmacy. This previously presented challenges to vendor selection given the highly concentrated nature of the specialty pharmacy market at that time and low interest in participation among eligible vendors. Given further concentration since that time, CMS should be mindful such impact may have on selection and outcomes. Additionally, the CAP model should avoid tying vendor compensation to pricing. Vendor compensation should be based on an administrative payment through a flat fee structure instead of linking to percentage of savings from negotiated products. For example, group purchasing organizations typically negotiate contracts outlining acquisition prices for group members, but do not receive payment based on the negotiated prices and instead are paid based on group member utilization of the negotiated contract. Similarly, the CAP-like model vendor should be paid a fair market value fee for services rendered, thereby de-linking vendor remuneration from prices while aligning to performance in successfully meeting provider objectives.

- **Maintain ASP "Add-On" Payment Outside the CAP:** A CAP model should not attempt to incentivize provider participation in the CAP by reducing, eliminating or gradually phasing out the current 6 percent "add-on" payment to ASP reimbursement under Part B for providers that do not participate in the CAP, or for products that fall outside the CAP scope. The Medicare Payment Advisory Commission (MedPAC) recommended reducing the "add-on" payment as an incentive to participate in their Drug Value Program (DVP).[7] Reducing the 6 percent "add-on" payment would penalize providers for deciding not to participate in the CAP, even though the CAP may not be in the best interest of their patients and/or practice. Providers should be able to make a meaningful choice between participating in a CAP or maintaining the traditional ASP-based

[5] The Atlantic's *The State of Care: Patient Access & Affordability,* FDA Commissioner Scott Gottlieb, May 23, 2018

[6] FDA Commissioner Scott Gottlieb, AHIP 2018

[7] MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2017), pg. 32, *available at:* http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf

reimbursement structure based on their patient and practice needs. By significantly reducing or eliminating the "add-on" payment, providers will be effectively forced to participate in a CAP model and potentially risk their patients' access to critical drugs that the CAP may not cover. Additionally, in a phased implementation of CAP, products not yet included in a CAP model should not be penalized and paid for at lower rates in anticipation of potential future inclusion in a CAP model. A CAP model should not create new barriers to care for Medicare beneficiaries.

- **Exclude CAP Negotiated Prices from ASP Reporting Requirements:** During the testing phase of a CAP model, prices negotiated in the CAP demonstration should be excluded from ASP reporting requirements, as was the case during the first iteration of the CAP program. Doing so would ensure that the model does not negatively impact reimbursement for those who elect not to participate in the CAP, and outside the Medicare setting.

- **Allow Provider Flexibility to Meet Beneficiary Needs:** A CAP model should ensure that providers have the flexibility to meet the needs of beneficiaries including the potential to alter the dose, formulation, or even drug at the point of care if necessary. As such, Mylan urges CMS to include appropriate safeguards that would allow for this flexibility should a future CAP model pursue a similar procurement mechanism as the previous iteration of CAP. Specifically, a CAP should incorporate protections provided by the "furnish as written" and "emergency restocking" provisions of the earlier iteration of the model.

III. VALUE-BASED TOOLS

Although Mylan appreciates that the Innovation Center is considering testing value-based tools as part of the CAP model, we urge the Innovation Center to consider testing value-based tools that increase access to biosimilars outside a CAP model. As discussed above, including biosimilars in a CAP model may further disrupt a biosimilar market that is in its infancy and must already endure many barriers to entry and competition. Nevertheless, CMS should still consider testing value-based models that incent or promote the use of biosimilars because they are inherently high-value cost-saving therapies that, according to the FDA, offer the same clinical outcomes as higher-cost reference biologics. We applaud the Administration's recognition of the importance of a vibrant biosimilar market and the Agency's commitment "to foster and nurture a new, competitive biosimilar drug market."[8]

To further this end, below we discuss certain value-based arrangements that CMS should consider.

Biosimilar Value-Based Arrangements that CMS Should Consider

[8] White House Press Briefing, May 11, 2018.

CMS should consider the following value-based arrangements for biosimilars:

- Eliminating Patient Coinsurance for Biosimilars Under Part B: CMS should consider pursuing a value-based pricing strategy that involves eliminating Part B patient coinsurance amounts for biosimilars. Although many Medicare beneficiaries have supplemental coverage (which reduces or eliminates cost sharing), eliminating cost sharing for biosimilars will provide an appropriate incentive to encourage the use of these high-value products. Specifically, the model should waive beneficiary cost sharing for biosimilars; cost-sharing changes could be applied at the HCPCS level. Of course, eliminating patient coinsurance would not be expected to change the overall payment amount for a biosimilar; rather, it would change the beneficiary's payment percentage. Such an approach would increase access to biosimilars and provide an opportunity for program savings associated with utilizing the lower-cost biosimilar and forgoing the higher cost biologic. The Medicare cost of covering the full price of a biosimilar priced 20% below the originator biologic is the same as Medicare covering 80% of the higher originator price, with the added benefits of reducing patient hardship resulting from out-of-pocket expenses and fostering a competitive biosimilar market.

- Expectation to Use Biosimilar Upon Launch: Under Part D, starting in 2019, Part D sponsors will have the ability to immediately remove a brand drug from their formulary and replace it with its therapeutically equivalent newly-approved generic drug. Allowing plans to do so will encourage beneficiaries to obtain the generic drug rather than pay the full out-of-pocket cost of the brand. CMS should consider testing a Part B policy that mirrors this approach for biosimilars by articulating the expectation that Part B biosimilars be used over the reference brand, unless it is not possible to do so or CMS grants an exception. Doing so would increase access to these products as providers would have greater impetus to learn about biosimilars and feel confident in their use as directed by CMS. CMS should also engage in dissemination of factual information about biologic medicines, including biosimilar medicines, and work with FDA on initiatives to increase understanding, confidence and trust in biosimilar medicines among Medicare providers and patients.

- Enhancing Reimbursement for Biosimilars: CMS could consider enhancing reimbursement for biosimilars under Part B. Rather than ASP plus 6 percent, providers could be reimbursed at ASP plus 6 percent and an additional flat fee each time a biosimilar is prescribed. Another incentive for biosimilar use could be a reward payment for providers meeting certain biosimilar utilization targets set by CMS in line with the expectation that providers prescribe biosimilars when possible – for example, a bonus payment if providers prescribe biosimilars 60% of the time over a set period. This percentage target could start low and increase gradually to allow providers and patients time to become comfortable with

biosimilar medicines, and allow biosimilar manufacturers to better forecast scale-up to meet full market demand.

- Shared Savings: Another option could be engaging providers in a shared savings model that incentivizes use of biosimilars and allows providers to share in some of the savings to invest in improving patient care. Examples from other settings has shown that shared savings models can result in greater reinvestment towards patient care, improving outcomes and patient experience. One such case that has been widely presented is the experience of University Hospital Southampton in England. The hospital entered into a shared savings arrangement with the local medicines commissioning entity, resulting in the hospital retaining a portion of the savings from use of a biosimilar instead of the reference product, while the remaining savings accumulated at the commissioning group (the payor). The hospital used their portion of the savings to hire an additional nurse specialist to assist in patient care, including working with patients to improve understanding of their treatment, which in turn improved patient outcomes and quality of patient experience.[9] Parameters could be put in place to limit the use of such savings in measures that would improve patient outcomes.

IV. Conclusion

Thank you again for the opportunity to provide comment on these important issues. We remain encouraged by the emphasis the Administration has placed in improving access to less costly biosimilars, including various provisions provided as part of the Administration's Drug Pricing Blueprint.[10] As CMS recently noted, biologics that currently lack competition represent nearly 40% of spending and were responsible for 70% of drug price increases from 2011-2015. We share in the Administration's goal of creating a more vibrant biosimilar market, and we appreciate the opportunity to comment to ensure payment policy takes adequate consideration of the emerging biosimilar industry. We would be happy to provide further information regarding these comments and look forward to providing further comments as payment policy continues to evolve to fulfill the goals of HHS' Drug Pricing Blueprint.

Sincerely,

Marcie E. McClintic Coates, JD, MBA
Head of Global Policy

[9] Cummings et al, "Biosimilar Infliximab in Inflammatory Bowel Disease: Outcomes of a Managed Switching Program" Journal of Crohn's and Colitis, 2017

[10] A copy of Mylan's comments submitted in response to HHS' Drug Pricing Blueprint are available here: https://www.regulations.gov/document?D=CMS-2018-0075-2700