AMERICAN COLLEGE OF RHEUMATOLOGY
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Submitted electronically via Regulations.gov

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Commenting on Medicare Program; Part B Drug Payment Model Proposed Rule: Centers for Medicare & Medicaid Services, 81 FR 13229

Dear Acting Administrator Slavitt:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and health professionals, appreciates the opportunity to respond to the Part B Drug Payment Model program proposed rule. We welcome the opportunity to provide our concerns on the impact changes to the alternative drug payment design (ASP) will have on our ability to provide quality care to the 50 million Americans living with rheumatic diseases.

Rheumatologists provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. Rheumatologists provide face-to-face, primarily non-procedure-based care, and serve patients with serious conditions that can be difficult to diagnose and treat, including rheumatoid arthritis, systemic lupus erythematosus, and other debilitating diseases. Early and appropriate treatment by rheumatologists slows disease progression, improves patient outcomes, and reduces the need for costly downstream procedures and care that is complicated and made more expensive by advanced disease states. We appreciate the opportunity to provide our input on CMS's proposed rule to significantly alter the way that Medicare reimburses for Part B.

As the principal organization representing rheumatologists, we are deeply concerned with the proposed new payment model. Regrettably, CMS did not engage the physician community on the best ways to address the complex policy issues surrounding effectively treating patients with different needs. The complexity of this issue does not allow for a "one-size-fits all" solution, especially for rheumatology patients and rheumatologists.

While rheumatologists can control many factors over the course of the treatment, we cannot control how drug manufacturers set their prices. Further, unlike the wide-array of treatment options available to many specialties, **our patients and physicians have a limited number of drug and biologic treatments available**. Although we certainly seek to control costs for patients and Medicare wherever possible, the proposed new methodology does not adequately consider the higher average costs many of our physicians have acquiring, handling, administering, and billing for drugs and biologics. We are deeply concerned that because the new methodology will frequently not properly cover the costs of physician administration of infused drugs, they will be forced to stop offering patients the ability to receive infusion treatments. As a result, **patients will be forced to seek more costly or less safe infusion treatment from outpatient services and freestanding infusion treatment centers without onsite physician supervision or forgo treatment altogether**. Such a result runs counter to the new innovative payment delivery reforms that CMS has been seeking to promote through MACRA.

The ACR urges CMS to withdraw this proposal and consider an alternative payment methodology that meets CMS's primary goals and objectives in implementing this program. If the proposed new methodology is implemented, we request that CMS begin by implementing the methodology in a ***limited geographic area*** to evaluate and identify weaknesses of the methodology, including issues of beneficiary access, before implementing the model nationally.

Executive Summary

1. The underlying proposal relies on reducing Part B drug pricing by encouraging physicians to prescribe lower cost products. However, less expensive alternatives do not exist for Part B for rheumatology patients. Policies that appear to reduce costs may in-fact result in higher spending as beneficiaries are driven to more expensive provider settings. The ACR believes this proposal should be withdrawn, modified to a pilot in a limited geographic area, or CMS should exempt rheumatologists who have limited prescribing options.

2. If implemented, CMS should evaluate changes to the Part B program in a smaller demonstration program and evaluate four core components: 1) availability of quality and affordable services; 2) availability of alternative therapeutic products with price differentials; 3) average total per patient Medicare costs by drug for demonstration project participants, as well as average per beneficiary costs; and 4) phasing-in changes to allow manufacturers, suppliers, and physicians to adjust their operations to ensure that beneficiaries' access to care is not disrupted.

3. CMS should align or consider MACRA timeframes and changes and the impact of these new changes on Medicare beneficiaries' access of care to physician services.

4. The ACR is prepared to work with CMS to identify new alternatives to improve the delivery, payment, and cost of care to Medicare beneficiaries living with rheumatic disease.

The following are general responses to the proposed demonstration model.

New Model Testing

Timing

This model requires mandatory participation by physicians in alternative payment designs for Part B drugs. The ACR believes that rheumatologists, like other physicians, are motivated by the best interests of their patients, not by the financial incentives in the reimbursement system. Like other physicians, we cannot control the cost of drugs, the cost of the coinsurance of drugs and services, and the costs of acquiring drugs and infusing them for our patients – especially when there are limited treatment options.

We understand and share the concern regarding the rising costs and spending associated with drugs and biologics. However, rather than reducing costs to Medicare, this proposal will likely cause a see-saw effect whereby reimbursement decreases for physicians, physicians then stop offering in-office infusion treatments because Medicare's reimbursement is insufficient, and patients therefore seek infusion treatment at hospitals where Medicare's costs are higher.

Biologics have provided major relief for patients diagnosed with debilitating rheumatic diseases. Due to their unique complexity, biologics are also associated with higher treatment costs. While a policy that seeks to shift patients away from higher-cost drugs may appear to be good policy, biologics provide benefits to patients and Medicare by controlling rheumatic symptoms. Inflammatory rheumatic diseases are the leading cause of disability in America. The Centers for Disease Control and Prevention has estimated that rheumatic diseases result in $47 billion a year in indirect costs, such as lost wages, to the United States. With the effective treatment that biologics provide, more beneficiaries can continue to be productive members of society. Further, unlike regular drugs, biologics **cannot** be easily interchanged or switched for less expensive options. A biologic that provides effective treatment for a patient is often times the only effective drug or biologic for that particular patient. Therefore, we believe alternative methods to capture the acquisition and administration of these products should be considered.

We believe there are significant substantive issues with this proposal that justify withdrawal to include more stakeholder input. If the proposal is not withdrawn, we believe Phase I's timeline does not provide enough time to evaluate operational changes necessary to ensure beneficiary care is not interrupted, and urge CMS to provide at least a 180-day delay between the Final Rule and enactment of Phase 1. In addition, we strongly encourage CMS to delay implementing Phase II until no earlier than January 1, 2018 to allow for more time to evaluate the impacts of Phase I. Because value is central to Phase II, the second phase should not begin until CMS works with stakeholders, including physicians, to understand value in their areas, how to calculate and

assess value, and what changes must be made to meet the underlying goals of reducing the cost of drugs.

Geographical Impact and Types of Drugs

If this proposal is implemented, we encourage CMS to implement it narrowly in order to reduce the proposal deficiencies from disrupting beneficiary care. We believe this should be done by narrowing the applicability of the proposal by exempting certain size physician practices, physicians in rural and medically underserved areas, and those drugs where there is either modest price differential or no meaningful therapeutic substitution. As rheumatology practices and the medications they use fit all of these characteristics, it would be administratively simplest to exempt rheumatologists from this demonstration. Otherwise, each of the following should be exempted from the proposal:

1. Physician groups of 25 or fewer professionals;
2. Physician-owned practices that are located in rural and medically underserved areas;
3. Reimbursement changes for drugs and biologics that do not have an alternative drug or biologic with more than a 20% ASP differential; or
4. Drugs and biologics where there are 3 or less members of the drug class or biologics.

Geographic and Size of Practice Limitations

We are significantly concerned about the impact this proposed demonstration will have on rheumatology practices that are small, particularly those with 25 or fewer professionals, and provide a low volume of treatment, as well as those serving beneficiaries in underserved areas.

We are concerned that absent changes in this proposal, Medicare beneficiaries served by physicians meeting the above conditions may lose the ability to access services. If Medicare's reimbursement is inadequate to cover the provider's costs of ***acquiring*** **and** ***administering*** the drug, providers will cease offering the treatment. Such a consequence would particularly harm beneficiaries in rural and medically underserved areas where there are already few options for beneficiaries to receive the care they need.

ACR has published data indicating that there are significant numbers of underserved areas where patients must travel long distances in order to access vital services. Most of these areas are served by small practices. Without a safety net, patient care will be severely compromised. If the proposal unfairly restricts access to care, Medicare will fail to meet its mandate of treating all patients equally and fairly.

Reimbursement Should Accurately Reflect Physicians' Administering Costs

We believe that it is essential that CMS conduct an analysis to determine the administering costs that physicians incur so that CMS can determine appropriate reimbursement. It is fundamental that in determining the Medicare reimbursement rate for drugs and biologics that

the physician's actual cost of acquiring and administering these drugs and biologics be considered in the final calculation of cost. Administering drugs and biologics comes with additional fixed quantifiable associated costs such as storage, supplies, and handling costs.

We propose that a flat-fee reimbursement structure based on data could reduce the inequities in the present reimbursement system. We encourage CMS to re-evaluate the fixed fee and align such an add-on payment to reflect costs of administering the infusion. While using the Average Sales Price (ASP) as submitted by the drug or biological manufacturer is helpful in setting a benchmark of the cost drug itself, ASP incorporates rebates and discounts that typically only hospitals and other large purchasers are able to secure. As result, the average physician practice pays far more than ASP when purchasing the drug or biologic from the manufacturer. Thus, before other costs to the physician are even factored in, many physicians are receiving reimbursement that often fails to break-even or is only breaking-even.

ASP does not factor in costs physicians incur administering drugs and biologics. Manufacturers calculate ASP based on sales to all purchasers and include volume discounts, prompt-pay discounts, chargebacks, and rebates (excluding Medicaid best price and 340B covered entities). In addition, this calculation is made following every quarter even though the cost to purchase each drug increases each quarter. Therefore, when a physician purchases a drug at today's price, the reimbursement is actually based on the price from the previous 6 months, which often times is lower.

CMS needs to make reimbursement rates for drugs and biologics site-neutral so that all physicians are able to equitably treat patients. Large organizations with ready cash or credit are able to purchase large quantities of drugs at the beginning of each new quarter and administer the drug at the updated payment level. By contrast, small physician groups may not be able to acquire a drug or biological at a price lower or equal to the ASP. As the June 2015 MedPAC report[1] concluded, the types of changes proposed to the current reimbursement for Part B drugs may cause small purchasers to pay higher prices than larger purchasers because of volume and prompt pay discounts. The reports specifically states that "variation in drug acquisition prices across providers would likely mean that some providers, especially small providers, would not be able to purchase some expensive drugs."[2] In our experience, acquisition costs typically follow a bell-curve, where high-volume practices acquire drugs below ASP, a majority of practices acquire drugs near ASP, and low-volume practices acquire drugs above ASP. We propose that a flat-fee reimbursement structure could reduce the inequities in the present reimbursement system, if such reimbursement reflects and covers actual costs.

An analysis by the healthcare consulting firm Avalere found that the proposed Part B Rule would redistribute Part B spending across provider types. Specialists, such as rheumatologists, who rely on more expensive drugs, because they are the most effective treatment for patients, would see their Medicare reimbursement rate plummet. Under the proposed rule,

[1] MEDPAC, REPORT TO CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM (June 2015).
[2] *Id.* at 70.

rheumatologists would see an average cut of 6% in their reimbursement rate. Such a cut would cause drastic changes in rheumatologists' treatment, but it would not result in savings for Medicare. Under the proposal, Avalere's analysis found that drugs that cost physicians more than $480 per day would receive less reimbursement under the new model. In contrast, products costing less than $480 would receive higher payments than they receive today. **Many of these drugs do not have a less costly alternative drug or biologic to prescribe.**
For many rheumatologists the decreased reimbursement rate will leave them unable to cover their actual costs of procuring, storing, and administering infusions. In such a case, it is highly likely these physicians will instead stop offering infusion treatments in their offices and refer patients to hospitals for treatment, where Medicare costs are higher. Therefore, this CMS policy would limit patients' access to treatment, and increase costs.

Finally, access and controlling costs are dependent on having a sufficient number of physicians in a community. As a study from the Health Care Cost Institute in March 2016[3] examining the impact of provider consolidation on outpatient prescription drug-based cancer care spending found, increased medical provider consolidation with hospitals and/or health systems results in significant increased spending on outpatient prescription drug-based cancer treatment. Even minor increases in consolidation led to much higher treatment spending. For example, a one percentage point increase in the proportion of medical providers affiliated with hospitals and/or health systems resulted in a 34% increase in average per-person annual spending and a 23% increase in the average per-person price of treatment.[4]

Exemption for Therapeutic Classes of Drugs and Biologics without Significant Pricing Differential or Alternatives

Unlike many other areas of medicine where physicians have access to a wide-array of treatment options for their patients, rheumatology faces unique challenges. Rheumatologists and their patients have few treatment options and the costs associated with these treatments do not vary widely. We propose that the model should include an exemption for a drug when there are three or less members of the drug or biologic class.

In addition, we believe that CMS should evaluate undertaking a demonstration proposal to permit physicians to pool together in order to purchase drugs from manufacturers. Under existing antitrust law, physicians may be precluded from joining together with other non-affiliated physicians to negotiate drug prices. With proper waivers of these restrictions from the Department of Justice, Federal Trade Commission, and the Department of Health and Human Services, CMS could evaluate models of care that reduce the acquisition costs, and therefore spending on drugs. As previously discussed, the Average Sales Price does not reflect the various acquisition costs that physicians must pay to obtain drugs and biologics from manufacturers.

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[3] HEALTH CARE COST INSTITUTE, *The impact of provider consolidation on outpatient prescription drug-based cancer care spending*, *available at* http://www.healthcostinstitute.org/files/HCCI-Issue-Brief-Impact-of-Provider-Consolidation.pdf.
[4] *Id.*

Under the suggested proposal, a waiver would help physician groups purchase drugs in larger volume, thereby allowing access to larger discounts.

Evaluation of the Model

CMS should also evaluate the quality and efficacy of the care, not just the fixed costs. The issue of the quality of the service, access to care, and long-term total costs for the Medicare beneficiary should be addressed. We request details of how CMS plans to measure quality in all of the different areas/specialties affected by the demonstration, as quality outcomes will be different in all areas. CMS should work with specialty groups to understand how quality should be measured in order to ensure patients are getting quality treatment.

Overlap with Other CMS Programs and CMMI Models

The ACR is concerned about the interplay with this proposed rule, the implementation of MACRA, and other CMMI models. CMS is presently drafting new rules to govern physician payments that will measure resource use, quality, and cost measures. For example, the Part B proposal will impact the Merit-Based Incentive Payment System (MIPS), which will impact physician services and the peer-to-peer evaluation of treatment trends.

While we believe there are likely to be adjustments to this model, some physicians may refer patients to outpatient hospitals, while other physicians in certain Zip codes will not face any changes to their practices. Such valuation cannot be evaluated if different physicians in different locations are faced with changing underlying criteria in the treatment of their patients. The potential concurrent changes and resulting uncertain effect on physicians' practices has caused significant concern. We encourage CMS to delay implementation of this Part B program and to evaluate its potential effect across all new payment and quality requirements before it is implemented.

Specifically, we believe CMS should evaluate the demonstration's effect on certain Medicare Administrative Contractors' (MACs) authority to change reimbursement codes, which distorts the demonstration as all physicians may not be similarly reimbursed. CMS should consider an exemption in cases where MACs are downcoding infusions from complex to simple administration. Without such an exemption, we believe there will be problems with data integrity and the ability to compare peers.

Adjustments to Payment Structure

Under Phase I, CMS has proposed that those participating will be paid a flat fee of $16.80 plus 2.5% for Part B drugs. We request that CMS consider conducting a formal study process to evaluate the amount of the flat fee. As MedPAC has noted, the proposed flat fee of $16.80 is an arbitrary number that does not appear to be based on actual costs. Such a significant formula should be based on a proper formal analysis of the true administering costs practitioners incur beyond ASP, including acquisition and storage costs. One specific example of a storage cost that

varies with the cost of the drug is insurance. Practices typically carry insurance policies that cover, among other property, risk of loss of expensive stored medication.

We also recognize that CMS must control spending and costs on drugs. As earlier stated, we propose CMS evaluate placing a dollar-figure add-on on the percentage CMS pays of ASP. The fixed dollar amount should take into account the costs of storing, administering, and supplies. For example, CMS could use a formula for reimbursement of ASP + 6% or $500 (whichever is lower). This formula would allow CMS to effectively target spending on expensive drugs, while leaving in place reimbursement rates for cheaper drugs.

Phase II

We strongly encourage CMS to evaluate the impact of the Phase I program before designing and launching Phase II. CMS has the attention of the physician community in supporting a movement to value-based purchasing and the ACR is ready to begin offering constructive solutions and data requirements for a constructive dialog. Because of the limitations on the transparency of pricing issues, we believe some short-term activities under the authority of CMMI could permit some evaluation of alternative payment models that provide value to the Medicare program and ensure beneficiary access.

Discounting or Eliminating Patient Coinsurance Amounts

CMS has stated that one of the primary goals of the Part B proposal is to create positive incentives for the selection of high performing drugs, including reducing or eliminating patient cost sharing to improve patients' access and appropriate use of effective drugs. **We support reducing beneficiaries' cost-sharing for those Part B drugs that are deemed to be high-value.** Rheumatologists depend on biologics associated with higher costs purely because they provide a high-value reward to patients and the healthcare system.

Legal Authority

Under the Affordable Care Act, the Secretary has been provided authority to test payment and delivery of service models provided that as precondition to even the first phase of testing "there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." Social Security Act § 1115A (b)(2).

Despite this requirement, Phase I of this proposed rule extends to roughly 75% of all Medicare beneficiaries. In addition, there is no "evidence that the model addresses a *defined population*." *Id.* (emphasis added). Extending a model to three-quarters of the Medicare population raises an issue as to whether CMS is effectively amending title XVIII, an authority it clearly does not have under "demonstration" project authority. The authority granted under the demonstration project authority was deliberate and intended to improve the delivery of care by applying proposed changes on small populations to test whether the proposed change to the system

would be efficient for all concerned. We urge CMS to engage the physician and consumer community on reframing the issues to ensure there is no disruption of care for Medicare beneficiaries and that costs do not increase as a result of this proposed demonstration project.

We share CMS's goal of providing patients with cost-effective treatment, but effectiveness can be measured in many ways. As previously discussed, a policy that reduces reimbursement to physicians may appear to save money, but its resulting outcome, pushing beneficiaries to more expensive care at HOPDs, demonstrates that the real-world effect is increased costs to Medicare. Further, for chronic illnesses, like rheumatic diseases, effectiveness must be measured over the long-term. Medicare must recognize that a proposal that may reduce costs now, but results in longer-term treatment for its beneficiaries, has not benefited the beneficiary or Medicare.

The American College of Rheumatology appreciates the work that CMS does and the opportunity to respond to this proposal. We look forward to being a resource to you and to working with the agency. Please contact Adam Cooper, Senior Director of Government Affairs, at acooper@rheumatology.org or (404) 633-3777 if you have questions or if we can be of assistance.

Sincerely,

Joan M. Von Feldt, MD, MSEd
President, American College of Rheumatology