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May 9, 2016

RE: Comments by the Coalition of State Rheumatology Organizations on "Medicare Program; Part B Drug Payment Model" (CMS-1670-P)

To Whom It May Concern:

The Coalition of State Rheumatology Organizations, or CSRO, is a group of state and regional professional rheumatology societies formed in order to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our coalition serves the practicing rheumatologist in charge of patient care for these illnesses.

Appropriate Medicare coverage of and reimbursement for treatment are critical for our patients, which is why we are very concerned about the Part B Drug Payment Model ("the Model") proposed by CMS.

THE MODEL

CMS proposes to modify the average sales price (ASP) add-on amount over the course of a two-phase demonstration. Under Phase I, CMS would create two study cohorts; one cohort would receive Part B drug payments under the current payment methodology (ASP+6 percent), whereas the other cohort would receive a reduced add-on payment (ASP+2.5 percent) plus a flat fee of $16.80. Under Phase II, CMS would create two additional study cohorts of the same but add value-based purchasing (VBP) tools currently employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. CMS proposes that Phase I would begin in Summer 2016; Phase II would begin as soon as January 1, 2017. Specific to the VBP strategies, CMS proposes to allow 30 days for public comment and would provide a minimum of 45 days public notice before implementation.

As rheumatologists, we are on the frontlines treating actual patients with Part B drugs. We are keenly aware of the unsustainable rise in drug costs and the effects of those costs on our patients' ability to adhere to their treatment regimens. While we appreciate CMS's attention to the topic of drug costs, we feel that this proposal is misguided. As CMS acknowledges in the rule, the proposed approach "does not directly address the manufacturer's ASP, which is a more significant driver of drug expenditures than the add-on payment amount for Part B drugs." Given that a slash to the ASP add-on is unlikely to actually lower costs for patients (and, as explained below, may

increase it in some cases) and may jeopardize access, **we urge CMS to withdraw the Model**. Our concerns are explained in detail below.

PROCESS CONCERNS

In early February 2016, CMS posted guidelines to contractors about the Medicare Part B Drug Payment Model, which proposed changes to the Average Sales Price (ASP) methodology for Part B drug reimbursement. This demonstration project would be mandatory for zip codes identified by CMS. This posting appeared to have happened erroneously, as the agency quickly removed the guidelines from its website. The posting and subsequent hasty removal greatly worried the provider, patient, and manufacturer communities, as it indicated a major payment change was well underway, even though CMS had not engaged in any pre-rulemaking dialogue such as town halls or Requests for Information.

Rather than pause to address these concerns, CMS only seemed to accelerate its timeline for beginning this sweeping payment demonstration. Within a month, CMS issued the proposed rule containing the Model. We believe that this retreat, followed by the hasty rollout, indicates that the Agency knew how concerning the proposed change would be to the community.

Executive Order 13563 (January 11, 2011) explains that, "*Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.*" Apart from the erroneous posting for contractors described above, CMS did not engage affected stakeholders in an open, transparent manner to inform, and thus improve, the proposed regulation.

Given that CMS has employed pre-rulemaking engagement strategies in developing the requirements associated with new physician payment programs established under the Medicare Access and CHIP Reauthorization Act (MACRA), we do not understand why CMS refused to utilize this process for the Part B Drug Model, particularly in light of the tremendous impact it will have on providers and beneficiaries. We see CMS' process as a blatant overstep and abuse of its statutory authority.

PROCEDURAL CONCERNS

The Affordable Care Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries. However,

the scope of the Model far exceeds any reasonable definition of a "test" and is so expansive as to constitute a program change.

First, with very limited exceptions, **the Model will include all Part B drugs**. Second, CMS proposes to **mandate participation by all providers** who prescribe Part B drugs. The model can no longer be considered a "demonstration" when it is scaled nationwide (excluding Maryland) and will apply to all Part B medicines. Third, the length of the demo – five years – is an unusually long time period for a project that is intended to merely test a new payment structure. Given that **Congress statutorily defined the ASP methodology and add-on in section 303 of the Medicare Modernization Act of 2003**, it is an inappropriate overreach of regulatory authority for CMS to force changes to this formula.

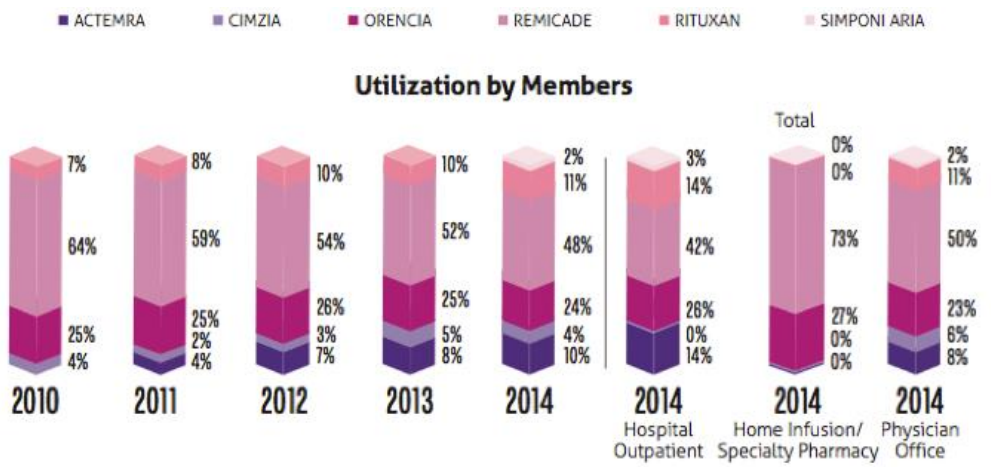
Finally, the ACA explicitly states that no ACA provision, including the provision creating CMMI, can result in a reduction of guaranteed Medicare benefits. We outline below how we believe that the Model will jeopardize beneficiary access – and thus may be a potential violation of ACA section 3601, which provides, in relevant part, that nothing contained in the ACA "shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act."

SUBSTANTIVE CONCERNS

Prescriber Behavior

In the proposed rule, CMS notes that the "ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs[.]" In other words, CMS implies that clinical decision-making by physicians is driven by the opportunity to maximize revenue. Yet, a recent report by Magellan studied utilization of rheumatoid arthritis medicines and found that physicians are not routinely prescribing the most expensive product. In fact, in 2014, in the physician's office, Remicade was used 50% of the time. Rituxan was prescribed only 11% of the time, despite the fact that "Rituxan ($20,205) and Orencia ($15,892) costs were higher than Remicade ($15,312)[.]"[1] The entire graph is included below:

[1] Magellan Rx Management, "Medical Pharmacy Trend Report" 2015 Sixth Edition.



We acknowledge that CMS cites data MedPAC data in support of its assertion that clinical decisions are driven by revenue generation, but we hope that the Magellan data will at least give the Agency pause that there are conflicting data on this point and that, as such, these data should not drive a Medicare program overhaul as expansive as this one.

Patient Access

Because the Model will include nearly all Part B drugs, we are concerned that rheumatologists may be forced to switch patients to alternative drug therapies, even if those patients are stable on their current medicines. This may be the case when the treating physician can no longer offer infusion, but there is no nearby hospital-based infusion center that the patient can travel to. Switching stable patients for non-clinical reasons violates the most basic teachings of rheumatology as it can result in loss of control over the disease – control that may not be regained even if the patient is switched back to the original product. This places patients at unnecessary risk and increases healthcare costs due to the potential for adverse reactions and loss of effectiveness.

As noted above, physicians may be forced to send patients to the closest hospital outpatient department to receive the needed medications. CSRO surveyed its members to better ascertain the behavioral response to the CMS proposal, and 73.08% of respondents said that infusible Part B biologic options would no longer be available for Medicare patients in their offices. 44.87% of respondents noted that they would refer to hospitals or external infusion centers to continue therapy. The full survey response is attached.

Hospital referrals will create financial challenges for patients who cannot afford the higher cost-sharing – for the exact same treatment. In Part B, most beneficiaries have wraparound coverage, so while the patients may not bear the

increased financial costs directly, traveling to the hospital outpatient department is inconvenient and can be challenging for patients with rheumatoid arthritis, depending on the distance to the nearest hospital-based infusion center. It also runs counter to the goals of the Model, as the cost to the Medicare program will be significantly higher when patients must receive therapy in the outpatient department instead of the physician's office. Oddly, CMS states in the preamble of the proposed rule that growth in drug spending has largely been driven by spending on separately paid drugs in the hospital outpatient setting, which more than doubled between 2007 and 2015, from $3 billion to $8 billion, respectively.

The following graph illustrates the varying cost of medicines, depending on the setting, and supports the fact that the physician's office is the cheapest setting to infuse rheumatologic medicines.

Brand Name	Cost per Unit			Cost per Claim		
	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office	Hospital Outpatient	Home Infusion/ Specialty Pharmacy	Physician Office
Botox	$5.89	$5.57	$5.54	$910	$1,101	$776
Gammagard Liquid	$42.83	$50.31	$46.81	$2,833	$4,569	$3,909
Gamunex-C/Gammaked	$47.29	$42.80	$41.42	$3,859	$3,836	$2,441
Herceptin	$93.87		$80.61	$3,754		$2,800
Neulasta	$2,392	$4,691	$3,501	$2,392	$4,691	$3,501
Orencia	$28.97	$28.89	$27.32	$2,147	$2,889	$2,109
Remicade	$82.40	$84.51	$74.66	$3,948	$4,486	$3,438
Soliris	$209.85		$189.44	$19,387		$16,671
Xgeva/Prolia	$17.69	$18.71	$14.57	$1,817	$1,283	$1,139
Yervoy	$181.62		$127.62	$39,377		$32,183

Finally, not all patients have hospitals nearby that offer infusions. We have found that most of the hospitals still offering infusion centers are 340B hospitals. Non-340B hospitals have mostly closed down their infusion centers due to a lack of profitability. Since 340B hospitals are not present in every area of the country, this may force beneficiaries to travel long distances to receive treatment, should their physician be unable to continue infusing them.

Sustainability

The proposed rule specifically requests feedback on the effect of the Model on solo and small practices. The current six percent add-on already results in practices without volume purchasing power being "underwater" on several products. A reduction from 6% to 2.5% plus a $16.80 flat fee will result in unsustainable cuts, especially considering that CMS has not incorporated the impact of sequestration in its calculations. Specifically, the current reimbursement level is actually ASP plus 4.4% and, **accounting for**

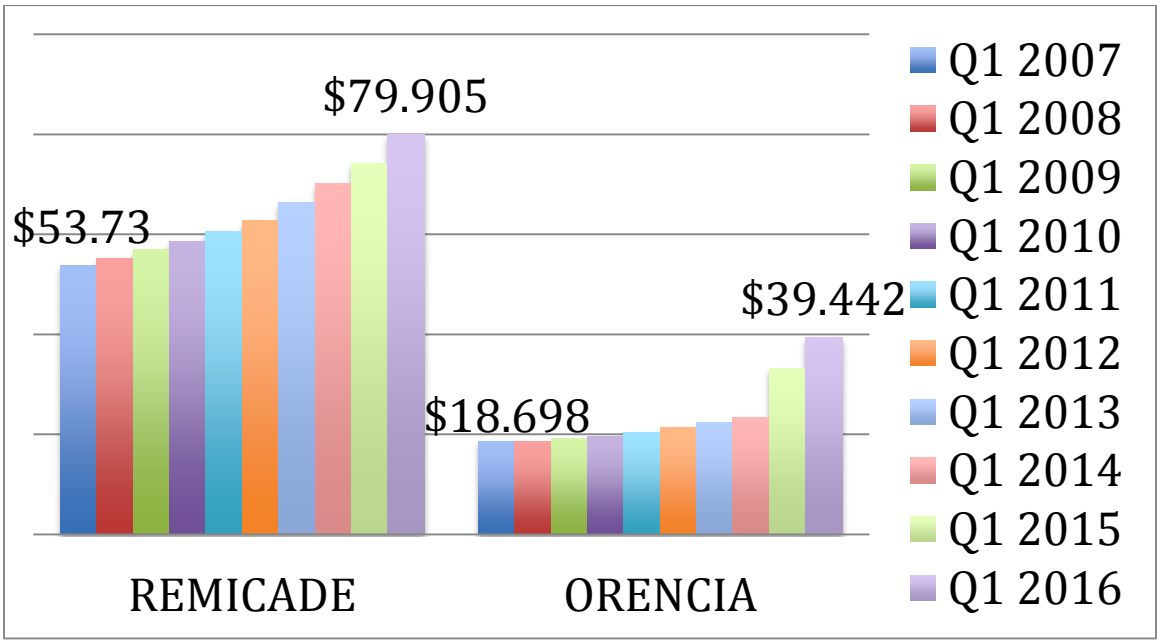
sequestration means the new rate will be ASP plus 0.86% with a flat fee. We gathered some illustrative data from CSRO member practices:

Practice Location	Practice Size	Drug	Purchase Price	Reimbursement Level (reflecting sequestration)	Differential	% +/-
Bethlehem, PA	2	Rituxan	$7,328.12	$7,567.10	$238.98	3.26%
Fremont, CA	2	Prolia	$904.41	$914.47	$10.06	1.11%
West Chester, PA	2	Benlysta	$3,715.20	$3,752.84	$37.64	1.01%
New Orleans, LA	4	Actemra	$2,408.96	$2,395.61	$-13.34	-0.55%
Riverview, FL	1	Euflexxa	$148.00	$146.71	$-1.29	-0.87

We hope that this data can help illustrate a few things. First, rheumatology practices are not getting wealthy off Part B drug purchases and, in fact, some practices are underwater on certain products. Second, there is no one factor that predicts whether a practice will be able to purchase at ASP. It depends on the volume of the purchase, the size of the practice, the ability to negotiate a rebate, and other factors. We would be happy to gather additional data from practices, should the agency wish to delve into these financial details.

Additionally, the two-quarter delay in ASP uniquely affects small and rural practices, and this would only be exacerbated by a reimbursement reduction. The ASP at which a practice is reimbursed is two quarters behind the current prices. Given the fast and sharp increases in prices each and every quarter, this often puts a practice underwater for the medicines it is purchasing, even if it is able to purchase at ASP.

With regard to sustainability for the Medicare program, a far greater concern than the add-on percentage is the underlying ASP, and the steep, fast price increases that these medicines show each quarter. We included here a graph showing price increases for two representative rheumatology products from the first quarter of 2007 through the first quarter of 2016:



As noted above, these are only two representative products, but this trend is true across all Part B rheumatologic medicines. These ASP increases are unsustainable for both the Medicare program and its beneficiaries and we would like to work with CMS to explore actual solutions to stem the increases in those underlying prices.

Value-Based Purchasing

With regard to some of the value-based purchasing ideas proposed by CMS for Phase 2, we offer the following feedback.

- A cost-sharing reduction (or even elimination) for beneficiaries would relieve a lot of the financial pressure our patients feel when they enter Medicare. In the private insurance market, patients can often use coupons to offset the large coinsurances they are responsible for. When they enter Medicare Part D, this is no longer an option as the program prohibits such assistance. For Medicare Part B, however, beneficiaries often have supplemental insurance that covers some or all of the twenty percent coinsurance for their medicines. Thus, it is unclear what a reduction in cost-sharing for Part B medicines would accomplish other than allow supplemental insurers to pay less. This would do nothing to actually reduce costs for beneficiaries. We urge CMS to look at Medicare drug coverage in its entirety and explore lifting the ban on cost-sharing assistance for Part D medicines.
- The reference pricing concept does not have enough detail at this point to

meaningfully comment on. Rheumatologic Part B medicines may be good candidates for reference pricing, since the ASPs (with the exception of one) are mostly clustered together. However, the challenge will be setting a reasonable reference price, figuring out how to make the manufacturer bear the risk in a purchasing system that currently puts the purchaser at risk, and, finally, figuring out how biosimilars will fit into such a reference pricing structure in a way that does not automatically drive all patients onto the biosimilar, even in cases when that is not clinically appropriate. We would like to work with CMS to explore this concept further.

- Indication-based pricing is a concept that is difficult to envision in rheumatology because there is no population-level data indicating what biologics work better than others for patients with rheumatoid arthritis. Indeed, there are robust rheumatology registries that have not yet yielded such data, likely because autoimmune disease may not lend itself to these types of studies. Additionally, it is unlikely that manufacturers would commit funds for head-to-head studies that may prove their product is inferior to another.

CONCLUSION

CSRO appreciates CMS's concern about high drug prices and would like to work with the Agency to find solutions. However, we must oppose the Part B Drug Payment Model as it suffers from serious procedural and substantive flaws that we believe render it unworkable – and it does nothing to actually address drug prices. We urge CMS to withdraw the Model and, with regard to value-based purchasing, begin the process of Requests for Information, Town Halls, and other pre-rulemaking opportunities to ensure that the end product is workable for all stakeholders and does not jeopardize beneficiaries' access to critically important medicines.

Please do not hesitate to reach out should you have questions or require additional information. Our D.C. staff contact is Judith Gorsuch, jgorsuch@hhs.com.

Sincerely,

Coalition of State Rheumatology Organizations
Florida Society of Rheumatology
Rheumatology Association of Iowa
California Rheumatology Alliance
Washington Rheumatology Alliance

Kentuckiana Rheumatology Alliance
Tennessee Rheumatology Society
Wisconsin Rheumatology Association
Michigan Rheumatism Society
Ohio Association of Rheumatology
Arkansas Rheumatology Association
Rheumatology Society of Delaware
Midwest Rheumatology Society
Oregon Rheumatology Alliance
Massachusetts, Maine, and New Hampshire Rheumatology Association
Alabama Society of Rheumatic Disease
Rheumatology Alliance of Louisiana
Arizona United Rheumatology Alliance
New York State Rheumatology Society
Mississippi Arthritis and Rheumatism Society
Colorado Rheumatology Alliance
North Carolina Rheumatology Association
Rheumatology Association of Minnesota and the Dakotas
National Organization of Rheumatology Managers