

July 20, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services Attention: CMS–2482-P

RE: Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate, and Third Party Liability (TPL) Requirements (CMS 2482-P)

Dear Administrator Verma:

The Arthritis Foundation, representing the 54 million American adults and children with doctor-diagnosed arthritis, is pleased to offer comments on the proposed rule Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate, and Third Party Liability Requirements. We are supportive of efforts to enhance VBP and appreciate that CMS is addressing some of the barriers to increasing the ability of healthcare stakeholders to engage in VBP. However, we have concerns about certain provisions and potential impacts to patient access. Below please find our specific comments.

The Promise of VBP

We are supportive of CMS's effort to reform best price, as we have long heard from stakeholders across the health care system that it is a major barrier to implementing VBP. The Arthritis Foundation believes value-based care holds great promise in improving patient outcomes while lowering costs. Arthritis is a chronic condition that can be difficult to treat. People with autoimmune forms of the disease must often try multiple biologic medications before finding one that will keep them stable, and over time these drugs can lose their efficacy, forcing patients back to the drawing board. Compounding the challenges in finding the right treatment is the fact that many people with arthritis often have co-morbidities that require continuous management, such as diabetes and heart disease. There is no doubt that expensive specialty medications, fragmented care, and administrative burdens on patients all contribute to higher overall health care costs, and that innovations in value-based care can improve each of these challenges.

There are multiple examples of VBP in rheumatology that have shown promise. An example featured on an American College of Rheumatology podcast in 2019 highlighted a practice that entered into a value-based contract with a payer based on a treatment pathway that built clinical guidelines into an Electronic Health Record system as decision

support tools.¹ They modeled the treatment pathway retroactively for three years to prove that it saves money, and the results have been positive. It has greatly reduced the number of prior authorizations, which has saved money, and has served as a good quality care initiative as providers are keen to apply the initiative to all payers and patients, not just those in the VBC.

Definitions and Patient Engagement

As active members of the National Health Council’s patient engagement activities, we support the request in their comments to “require substantive input from patients when establishing criteria for ‘evidence-based measures’ or ‘outcomes-based measures’ and defining ‘substantial’ to ensure that VBPs demonstrate desired outcomes for patients.”

We appreciate that CMS is seeking suggestions for measures to be used in the definition of VBP. Value-based care is only truly value-based if it reflects value to the patient, and it is critical for any health care stakeholder to recognize that each patient is different and has different outcome goals. Further, the outcome of a therapy is dependent on many factors, both clinical and contextual. From surveys and focus groups we have conducted in recent years, we know that issues like financial burden, co-morbidities, life changes, ease of use, and administrative burden all weigh heavily on medication adherence and treatment success. Common themes and questions we hear from patients include:

- If the up-front costs of a drug are too high, they may ask their doctor to switch medications or consider delaying or skipping their fill
- The administrative burden of prior authorization and step therapy can feel like a full-time job, and often weighs more heavily than efficacy of a drug during treatment selection
- If it is a self-injectable drug, how easy is it for someone who has joint damage in their hands to administer?
- Is it safe to take a biologic amid a pandemic? Will it increase the likelihood of getting the disease? Environmental circumstances like these lead some patients to consider stopping their medication even if it is not in their best clinical interest

While not all of these factors will be relevant to a particular VBP, they are important for understanding the common reasons patients are or are not adherent to medications, and the considerations that contribute towards the success of a drug regimen from the patient point of view. As you move forward, we encourage CMS to work closely with patient groups, and with the National Health Council who has contributed a large body of work to the topics of value and patient engagement, and have developed rubrics and tools that would be incredibly valuable as CMS finalizes definitions around VBP.

¹ “Value-Based Care in Rheumatology.” *ACR on Air*. Episode 003. Air date Sep 17, 2019. <https://www.rheumatology.org/Learning-Center/Publications-Communications/Podcast>

Revisions to Medicaid Drug Rebates

We are concerned about the provision in the proposed rule requiring manufacturers to deduct the value of any cost-sharing assistance from best price and Average Manufacturer Price (AMP). Specifically, we are concerned about the impact to patients who are in health plans with accumulator adjustment programs. Rheumatology is a therapeutic area with one of the largest potential impacts from these programs, as biologic medications can come with high cost-sharing and many patients rely on co-pay assistance to afford their medications. Considering the increasing number of high deductible health plans and requirements for co-insurance for specialty drugs, it is not uncommon for people with arthritis to reach their maximum out-of-pocket in the first two or three months of the plan year. Further, there are no generic alternatives for biologic medications in rheumatology, so there are not significantly lower-cost medications people with arthritis can take. This means policies like accumulator adjustment programs have a disproportionate impact on people in therapeutic areas like rheumatology without achieving the intended goal of lowering costs. In fact, our data shows that when faced with high unexpected charges for medications, patients either delay their fill, abandon their fill, or ask their doctor to be switched to another drug in which they can receive co-pay assistance, contrary to clinical best practice.

With that in mind, we urge CMS to take a more thorough approach toward identifying the right ways to revise best price calculations. Currently there is a lack of transparency in the system, whereby manufacturers are not aware of which health plans use accumulator adjustment programs. At a minimum, we encourage CMS to:

- Consider what feedback loop would need to be established in order to make this proposal operational
- Ensure safeguards to prevent unintended consequences like higher patient cost-sharing
- Clarify the payer role in ensuring patients receive the full benefit of co-pay assistance

The proposed rule in its current form would perpetuate a trend that is growing across insurance markets, most recently with the finalization of the 2021 Notice of Benefit and Payment Parameters, which does not include co-pay assistance in the calculation of cost-sharing, but crucially does not make an exception for classes of drugs with no generic alternatives. This is fundamentally moving health care in the wrong direction, with patients experiencing even more access barriers that make it more difficult to adhere to their treatment plan, without achieving lower health system costs.

Thank you for the opportunity to comment on this proposed rule. We are eager to work with the Administration on increasing innovation and value-based care, which will

ultimately benefit patients and lower overall healthcare costs. Please reach out to me at ahyde@arthritis.org with any questions or if we can be assistance moving forward.

Sincerely,



Anna Hyde
Vice President of Advocacy and Access
Arthritis Foundation