January 24, 2024

House Health and Human Services Committee
Virginia House of Delegates, House Committee Room C-206
1000 Bank Street
Richmond, VA 23219

Dear Chair Sickles and Members of the Committee:

On behalf of the Arthritis Foundation, representing the nearly 60 million Americans and 26% of Virginia residents living with doctor-diagnosed arthritis, we would like to provide comment on HB 570, a bill to create a Prescription Drug Affordability Board (PDAB). People with autoimmune forms of arthritis often rely on biologic medications to maintain their health, and as these are expensive medications, issues of high drug costs and access are always a top priority.

Affordability looms large for people who rely on specialty drugs to manage their disease: in a 2021 survey we conducted, 37% of those surveyed had trouble affording their out-of-pocket costs in the previous year. Of those, 54% said they had incurred debt or suffered financial hardship because of it. Trouble affording out-of-pocket medical expenses had a significant impact on care: 45% delayed refilling a prescription, 41% say their health care worsened, and 41% switched medications as a result.

While we laud the focus on lowering prescription drug costs, we feel that the system is too interconnected to single out any one industry. Rebating of biologic medications to treat arthritis is very common between manufacturers and PBMs and plays a major role in the overall costs of the drugs. Affordability reviews can shed light on many factors that influence affordability of prescription drugs, but without any purview over payers, pharmacy benefit managers (PBMs), distributers, and others in the supply chain, Boards are severely limited in the impact they can make.

Our comments focus on three areas: the broad range of factors that contribute to patient affordability and accessibility of prescription drugs; patient engagement recommendations; and examples of Arthritis Foundation involvement in value assessment activities.

Factors that contribute to patient affordability and accessibility

There are many reasons patients may have difficulty affording their out-of-pocket costs, but the increase of high-deductible health plans and co-insurance play a role. Currently, patients typically pay cost-sharing based on list price, rather than net price, of medications. This is particularly problematic for patients who pay co-insurance for their medications, which can reach up to 50%. Biologic medications to treat arthritis range

from an average retail price of $5,000 to +$8,000, which means a patient could be required to pay more than $4,000 out-of-pocket for one prescription, and even at the lower end assuming a 20% co-insurance, a patient would pay over $1,000. This is simply out of reach for many patients.

The use of copay accumulator programs which prevent patients from counting copay assistance towards their cost-sharing exacerbates affordability problems. Patients often rely on copay assistance because of these high rates of co-insurance and deductibles. A patient with 20% co-insurance on a $5,000 per month drug must turn to copay assistance to help shoulder their cost-sharing because very few patients have $1,000+ to put towards one prescription medication every month. Based on our survey data on the impact of accumulators on arthritis patients, these programs lead to the same adherence barriers mentioned previously. VA was one of the first states to pass legislation banning the use of copay accumulators, and we would urge the Board to consider the impact of this law in its criteria for determining affordability.

An important area of potential cost savings is the entrance of biosimilars onto the market. 2023 marked the first year biosimilars for Humira came to market, ushering in an opportunity to greatly reduce costs for the health system and for arthritis patients. However, some of the largest Pharmacy Benefit Managers (PBMs) have required patients to step through the brand drug before being able to access the biosimilar, effectively shutting out the biosimilar. The rebates that can be extracted by brand manufacturers make it difficult for biosimilars to compete, even if offered at parity on drug formularies.

We would like to note that many biosimilars manufacturers have introduced a two-tiered pricing system, with one price on average 5% below the brand list price and the other price on average 50% lower. The idea is that the lower list price is attractive to integrated health systems and other payers without competitive rebate systems, and the higher price is necessary for the biosimilar to compete with the brand drug in a rebating environment. HB 570 would include biosimilars as eligible for affordability reviews if the price is not at least 20% lower than the brand drug. Should the legislature move forward, we urge you to consider this tiered pricing system and the impact of these types of rebating policies on patients and the health care system as a whole.

There are other factors that impact affordability as well, including caregiver expense and/or productivity loss, and the indirect costs associated with the administrative management of health care, which many of our patients have likened to a “full time job.” Any Board should look at affordability holistically, considering the myriad factors that contribute to affordability.

Finally, formulary design and utilization management policies play a major role in patient access. Most health plans place biologic medications for autoimmune forms of arthritis on higher tiers and specialty tiers, which often require higher rates of utilization management protocols like step therapy and prior authorization. Arthritis patients are

particularly susceptible to these kinds of practices; Avalere data shows a 163% growth in step therapy for RA single-source brand drugs from 2014-2020. Arthritis Foundation data demonstrates that inappropriate utilization of these practices can lead to delays in care, resulting in negative financial, emotional, and physical consequences. A 2016 study we conducted indicated that over 50% of respondents were required to try two or more drugs before they could receive the drug prescribed by their provider. The same survey showed that patients on average had to try 2 or 3 drugs before finding one that worked for them. Therefore, formulary decisions like step therapy protocols can have large implications on a patient's disease progression and management.

Arthritis Foundation data demonstrates that inappropriate use of utilization management (UM) such as step therapy and prior authorization can lead to delays in care, resulting in negative financial, emotional, and physical consequences. A 2023 Arthritis Foundation survey on utilization management issues found the following:

- Nearly 60% of patients reported having difficulty getting their doctor-prescribed medication.
- Over 70% of patients surveyed have experienced step therapy multiple times, with 12% having experienced it 5 or more times.
- Nearly half of patients indicated they experienced joint damage due to the step therapy protocols,
    - 25% developed non-joint related health complications, and
    - 70% of patients reported suffering from stress, depression, and anxiety as a result.
- More than half of patients indicated their arthritis was at least somewhat well-managed prior to step therapy.
- While more than half of patients requested an exception to the step therapy requirement, it was only granted about 1/3rd of the time with the most likely reason cited for the exemption request was due to having already tried and failed the drug the health plan was requiring.
- Over 70% of patients had to go through prior authorization process because their health plan required it.

Patient Engagement Process

Engaging with the patient community early and often throughout the legislative process is vital, and we encourage you to prioritize the following:

- Coordinating with the patient advocacy community well in advance of any legislative processes to help ensure a patient-centered approach.
- Ensuring any legislation includes requirements for patient representation on the Board and any advisory councils. We appreciate that HB570 includes patient representation in its proposed stakeholder council, and urge that patient representatives also be included on the Board.
- Requiring any affordability reviews to incorporate real-world evidence and patient-centered value assessment methodologies.

- Requiring a robust and diverse range of patient stakeholder opportunities throughout the Board processes.

Value Assessment Examples

The Arthritis Foundation has engaged in two RA-specific value assessment-related efforts since 2016, in addition to publishing a position statement on patient-centered value assessment. We hope these examples and our principles around how to conduct patient-centered affordability reviews will be instructive, and we urge you to incorporate these safeguards in any language moving forward.

Arthritis Foundation Position Statement

In 2022 we published a position statement on patient-centered value assessment that guides all our activities in this field. Our position statement lays out 6 principles for patient-centered value assessment we urge the legislature to consider in its deliberations, including:

1. Utilizing patient-centered methodologies. Key points include:

- A widely used approach for estimating quality and quantity of life in economic mode is calculating Quality Adjusted Life Years (QALYs). QALYs may contribute to informing a value assessment. However, data inputs used to calculate QALYs do not holistically reflect patient experiences, preferences, goals and benefit-risk tolerance.
- Current approaches to calculating QALYs often rely on generic questionnaires, which may not reflect health-related quality of life as defined by arthritis patients, nor where patients are in their disease or treatment journey. Further, QALYs can be discriminatory by placing a lower value on treatments that extend the lives of people living with disabilities and chronic conditions. Economic models calculated using QALYs should only be used in combination with other value assessment methods and should only play a partial role in the comprehensive assessment of treatments. Instead of using a QALY-only value assessment model, we would suggest the following:
    - Value assessments must use multiple additional criteria and methods to account for patient preferences, goals and experiences.
    - Value assessors and others who utilize QALYs should improve the way in which they use QALYs, ensuring that surveys are disease-specific and given at intervals that are most appropriate for that particular disease. Survey tools should be fit-for-purpose such that policymakers assessing arthritis treatments can evaluate:
        - Was the tool appropriate for arthritis?
        - Did it have questions related to the disease?
        - Did it consider validated joint-specific measurement tools?
- We support the utilization of methods like Multi-Criteria Decision Analysis (MCDA) which can incorporate patient preference data, Patient Reported Outcomes data, and other sources of data that measure value to the patient.

2. Utilizing real-world evidence. Clinical trial data is insufficient to capture the heterogeneity of disease, market access factors and other environmental factors crucial for understanding the impact of the treatment on the disease population. Value assessments cannot fully incorporate all necessary and relevant data to be truly patient-centered until the treatment being assessed is on market. Value assessments should be updated regularly to take into account cost and formulary data, patient-reported outcomes data and any other real-world data that would inform true cost-effectiveness.

3. Utilizing comprehensive claims data, such as all payer claims databases (APCD) to inform models. Robust APCDs can help inform value assessment analyses by providing data across sites of care and longitudinally about patients, allowing value assessors to identify trends and patterns in health care costs and better tailor coverage and cost decisions. The VA APCD can provide valuable information through the assessment process.

4. Prioritizing transparency. Transparency across the health care ecosystem — from manufacturers to payers, pharmacy benefit managers and value assessors — is essential for implementing patient-centered value assessment. Currently, it is difficult to know the full set of processes and factors that contribute to any given value assessment — and importantly how payers and other stakeholders are utilizing them. We believe value assessors should be transparent about their methods and allow sufficient time for public input throughout the process. We believe payers should be transparent about how they are utilizing value assessments in their formulary decisions. And value assessors, payers and others should establish a continuous feedback loop with the patient community to inform post-value assessment decision making and any subsequent updates.

5. Meaningful Patient Engagement. A truly patient-centered value assessment would engage patients in a meaningful way from start to finish. Key points for the legislature to consider are:

- Patient engagement should never be considered a check-the-box activity. Instead, patients should be equal stakeholders throughout the process, and patient representatives should have voting privileges in any advisory councils or roundtables.
- The value assessment should not be the beginning or end of patient engagement. Patients should be part of the decision-making process during clinical trial design to ensure manufacturers are measuring endpoints that matter to patients.
- Pharmacy benefit managers and payers should include patients in their formulary review processes to ensure they have a robust understanding of the patient experience. For example, detailed data on the impact of step therapy on patient health outcomes can more precisely guide appropriate step therapy protocols, including the number of steps included in a protocol and the appeals process.

- Manufacturers should incorporate patient preference data in their clinical trial design and should include patients in the identification of study endpoints.
- Patient representatives should be invited to serve on Pharmacy and Therapeutic (P&T) Committees and other forums that determine formulary coverage decisions.
- Any committee or board considering cost effectiveness should include robust patient representation, including voting membership and extensive quantitative and qualitative patient data.
- Patient representatives should be invited to craft value assessment methodologies and strategies, including legislative and regulatory processes and value assessment methodology design.

Should the VA legislature move forward with this legislation, we urge you to require a robust, structured process for patient engagement in Board activities and decisions. Engaging a diverse set of patients and patient groups can ensure the Board has a robust set of quantitative and qualitative patient data to better inform its methods.

6. Value-based Insurance Design (VBID). Value-based agreements and other value-based policies can help bridge the gaps in real-world value-based care. There are many examples of value-based care models in rheumatology, orthopedics, and other arthritis-related specialties to draw from — and there are specific ways state and federal policymakers can promote value-based policies. While aspects of VBID may fall outside the scope of this bill, for context we want to highlight two areas in which we believe states can have an impact in promoting value-based insurance design:

- States should incentivize Medicaid programs and state payers to use patient-centered value assessment and consider value-based agreements.
- State reinsurance programs can be a good tool for ensuring better access in a way that reduces health care costs.

Institute of Clinical and Economic Review (ICER) RA Review 2017
The Arthritis Foundation participated in an Institute of Clinical and Economic Review (ICER) review of RA drugs in 2016-2017 and as part of this effort we conducted a survey of RA patients' experience with taking biologics. Among the findings: a majority had taken multiple biologics over the course of their RA and many switched early in treatment, including 56% of respondents who had been on or taken Enbrel for less than two years. The most cited reason across all biologics was the drug did not work. Specific to Enbrel, 48% cited it did not work, 19% had bad side effects, and 9% had insurance changes. 35% of respondents indicated challenges accessing their medications and when asked the impact of insufficient treatment, 57% cited they had to take additional medications for things like pain, depression, and anxiety; 42% missed work or school; 40% experienced joint damage or worsening of disease; 22% developed non joint-related

symptoms related to their disease; 19% had to leave their job or school; and 11% had to be hospitalized.

As a result of this survey, ICER took into consideration the high level of variability in treatment efficacy and the consequences of disruptions of treatment and indicated in the final report that step therapy is not appropriate in all cases.

Innovation and Value Initiative (IVI) RA Model and White Paper 2021
In its update to its RA model in 2019, IVI worked with the Arthritis Foundation to identify RA patients with whom to conduct a focus group in order to better incorporate patient experience data into their modeling. The focus group yielded important and invaluable insights and as a result we co-authored a white paper highlighting the key themes and best practices for this patient-centered approach. From the paper:

- Traditional clinical trials and research do not always capture the full complexity of living with RA, including comorbid conditions, fatigue, mental health, and the impact of hormonal changes.
- Access to effective treatment may be driven by insurance coverage or haphazard testing of treatments rather than by clinical guidelines.
- Costs related to RA include far more than direct medication costs and need to be captured.
- While RA is a progressive disease, people living with it are seeking independence and normalcy versus just symptom management.

The focus groups revealed a diverse range of experiences. From the paper:

- While severity of RA and response to treatment vary among individuals, commonly experienced symptoms include significant joint pain and weakness, stiffness, and fatigue.
- Most participants described fatigue as a largely unaddressed impact of RA, and a factor further exacerbated by many of the RA treatments as a side effect.
- Multiple individuals pointed to hormonal changes (puberty, pregnancy, menopause, etc.) as “triggers” to the onset of symptoms or treatment failures.
- Nearly every participant described significant psychological impacts of the disease, including depression, anxiety, and social isolation.
- Co-occurring conditions are common, and when present, complicate outcomes. Multiple participants reported co-occurring health conditions, including type 1 diabetes, fibromyalgia, spondyloarthropathy, lupus, anxiety, and depression.

The paper noted that even with only 14 participants, there was wide diversity in time to diagnosis (between 6 months and 5 years) and time to finding an effective treatment (between 1 year and never); treatment experiences from the paper:

- Participants reported that treatment choices appeared to be based on trial and error or insurance coverage, rather than clinical guidelines or assessment by their clinician.

- Many had difficulty finding effective treatment over time. Most were concerned about the durability of treatment and the lack of clarity about what might trigger sudden change or failure of a treatment. Several reported never finding a fully effective treatment option despite extensive regimen testing.
- Multiple individuals were concerned about running out of treatment options; there was a sense that each treatment had a "shelf life" or limited time horizon.
- Participants reflected a common experience or understanding that insurance coverage, socioeconomic status, and race impact the quality of and access to treatment.
- Participants described the impact of treatment on choices to have children, how having children impacts treatment options, and the ability to have children.

Also from the paper:
Other areas of less frequently measured costs that have high impact on patients' experiences and outcomes include:

- Time spent in seeking, receiving, and recovering from treatment, with some calculating this cost to be upwards of a month a year.
- Diminished ability to work and lost wages due to early retirement or career impact, including choosing lower paying jobs to ensure health insurance access.
- Heavy burden of RA on caregivers (spouses, parents, and siblings), such as anxiety, missed work time, childcare, and job choice based on health insurance.
- Ancillary costs of seeking and receiving treatment, including transportation costs, non-medical supportive expenses (e.g., assistive devices), and non-covered benefits.

We hope these insights and examples will be valuable to the VA legislature as it considers legislation for the 2024 session. We welcome the opportunity to provide further insights and to serve as a resource to you in the coming weeks and months ahead. Thank you for your consideration, and we look forward to engaging with you in the future.

Sincerely,

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