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January 31, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G-Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-9898-NC; Request for Information; Essential Health Benefits

Dear Administrator Brooks-LaSure:

On behalf of the nearly 60 million American adults and 300,000 children living with arthritis, the Arthritis Foundation is pleased to offer comments on the CMS request for information (RFI) related to Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (ACA). Arthritis is the leading cause of disability in the US, and people living with the disease rely on affordable, continuous access to health care to manage their symptoms.

In 2023 we formally launched a multi-year project called Ideal Model of Care with the goal of addressing the major gaps and barriers patients face in achieving their optimal health care. We have collected over 3,500 survey responses from patients, facilitated a series of focus groups, and conducted dozens of expert interviews to better understand the challenges patients face across the continuum of their care and the solutions that would best remedy those challenges. Our comments are largely informed by this data, which showed affordability, accessibility, and care coordination as the top three domains in which patients experience challenges. The Arthritis Foundation appreciates the Administration's continued efforts to take meaningful actions to support people seeking health insurance and ensuring reasonable cost-sharing and access to care for patients.

We are pleased that CMS is conducting a review of the ACA's ten defined Essential Health Benefits, which establish a minimum for all Marketplace plans and for those in the Medicaid expansion population. Overall, the EHB regulations generally work for patients, though there are much needed areas for improvement and enforcement of the EHB regulations. We encourage the Department continue to use its broad authority under the ACA to update and strengthen EHB standards to ensure plans cover all of the benefits and services patients need.

Barriers of Accessing Services Due to Coverage or Cost

Cost Barriers
Costs associated with prescription drugs, and specialty drugs in particular, have risen at a particularly high rate in recent years. Spending on inflammatory drugs like those used to treat autoimmune forms of arthritis tops all other therapeutic areas, making up 35% of

specialty pharmacy spending.[1] Like with premiums and deductibles, payers, pharmacy benefit managers (PBMs), and health care purchasers have responded with ways to curtail drug utilization and/or spending, such as requiring patients to pay co-insurance for specialty drugs, or requiring step therapy or prior authorization. These policies can have a perverse impact for people with chronic diseases who rely on consistent utilization of health care to manage their disease.

Biologic medications to treat arthritis range from an average retail price of approximately $5,000 to over $8,000, which means a patient could be required to pay more than $4,000 out-of-pocket for one prescription; even a lower level 20% co-insurance, a patient would pay over $1,000, which is unattainable for many people.

In a 2021 Arthritis Foundation survey, 37% of respondents reported difficulty affording their out-of-pocket costs in the past year. Of that set of respondents, 54% say they have incurred debt or suffered financial hardship as a result. Difficulty affording out-of-pocket medical expenses had an impact on care: 45% of all surveyed indicated they delayed refilling a prescription, 41% say their health care worsened, and 41% switched medications as a result. Further, patients often pay on their own for ancillary supports, such as gym memberships, specialized exercise equipment or orthotic walking shoes, further contributing to high overall costs. High out-of-pocket costs for prescription drugs can lead to worsening of disease and higher downstream health care costs.

While considering effective efforts to control the costs of EHBs, it is important to examine patient impact and the holistic need for adherence – overall patient impact of adherence and costs need to be considered differently as their total health costs look different. We encourage CMS to consider the unintended consequences to any cost control mechanisms as well as issuing regulations to require insurers count copay assistance toward cost-sharing requirements. We urge CMS to keep in mind the lifetime and annual dollar costs patients incur and consider appropriate limits.

We support CMS' proposals to continue requiring insurers to offer standardized plans with copays instead of co-insurance, which is especially important for people with high drug costs. As we mentioned in our PY23 comments, the Arthritis Foundation has long been concerned about the rising rate of co-insurance and the impact this has on a patient's ability to afford their medications. We appreciate that CMS has conducted listening sessions and meetings with various stakeholders to gain input on a range of questions from healthcare.gov displays to number of plan choices and which drugs should be available pre-deductible. Should CMS embark on a similar strategy for PY 24, we would welcome the opportunity to participate, and once again urge CMS to allow drugs for chronic diseases like arthritis to be listed as pre-deductible benefits.

[1] Trilliant Health. "2022 Trends Shaping the Health Economy." October 2022. https://www.trillianthealth.com/insights/reports/2022-health-economy-trends

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Copay Accumulators and Maximizer Programs

As you know, accumulators and maximizers are both features or programs within an insurance plan whereby a manufacturer's payments do not count toward the patient's deductible and out-of-pocket (OOP) maximum. In accumulator programs, the manufacturer copay card or coupon funds prescriptions until reaching the maximum value on the card. Then, the patient's OOP costs begin counting toward their annual deductible and OOP max. Whereas in a maximizer program, that maximum value of the manufacturer's coupon/card applies evenly throughout the benefit year. A review of 2021 health insurance plans offered through the ACA marketplace found that HHS rules have allowed copay accumulator adjustment policies to grow – with 45 states + DC having at least one plan with a copay accumulator policy, and in 32 states, at least two-thirds of plans included an accumulator.[2]

In a typical scenario, the patient goes to a doctor's appointment to discuss potential treatments. They satisfy any insurance-mandated prior authorization or step therapy requirements, then go to fill the prescription, not knowing the cost comparisons until arriving at the pharmacy counter. The patient must weigh whether they can afford their out-of-pocket liability, which is often based on a percentage of the list price of the drug, then identify any cost-sharing assistance if they cannot. Regardless of the cost-sharing source, it is a payment for a drug that plans should recognize.

Importantly, it is critical to point out that the patient has already satisfied any utilization management requirements by the health plan, meaning the health plan has deemed the drug appropriate for the patient before the accumulator kicks in. This negates the argument that accumulators are necessary to curb inappropriate utilization of higher-cost drugs. Both patient and physicians are often unaware when an accumulator program is in place under a patient's coverage, leading to surprises when the patient finds out that their deductible and/or out-of-pocket max has not been met and thus are financially obligated to pay the cost of the drug. Even if the drugs prescribed were affordable for the individual, which they often are not, accumulator programs increase difficulty or patients to budgeting annually.

The Arthritis Foundation maintains that inappropriate use of accumulators increases health costs. Of particular concern is that accumulator adjustment programs double-dip; the insurer keeps the assistance payment in addition to any co-pays paid directly by the patient. These practices represent ethical, if not legal, questions, and we urge CMS to ensure that Exchange plans do not use these programs.

With maximizers, a loophole under the ACA allows many employer-sponsored health plans to deem certain categories of prescription drugs as "non-essential," even when they are life-saving or necessary. When a covered drug is deemed "non-essential," the insurer will not count any cost-sharing toward the patient's deductible and out-of-pocket maximum. Millions of patients who depend on financial assistance to afford their

[2] The AIDS Institute. "An Updated Report on Copay Accumulators." March 2021. https://aidsinstitute.net/documents/2021_TAI_Double-Dipping_Final-031621.pdf

medications are now told that the money must come out of their own pocket before they can fill their medications. These programs put patients in a vulnerable position by essentially un-insuring them from their specialty drug benefits and routing them through third-party assistance programs to access their medications. By not counting the assistance toward a patient's cost-sharing, plans target those who need help most. The overwhelming share of medicines that are subject to accumulator programs have no generic or biosimilar equivalents, an estimated 95%, leaving patients without a less expensive alternative. These programs disproportionately impact the most vulnerable patients who rely on certain medicines.

We are also concerned about the rise of Alternative Funding Programs, which we believe have arisen at least in part as a response to the progress we have made protecting copay assistance at the state level and raising visibility about the negative impacts of accumulator and maximizer programs. We have seen the negative impact of copay accumulator policies on people living with arthritis through patient data and stories since 2017. Our data indicates that when faced with a large, unexpected charge for a prescription drug – which is often how patients identify they are subject to an accumulator – they abandon their prescription, delay their fill, or call their provider to ask to be switched to another drug.

We urge CMS to re-examine its position on issuer policies (e.g., copayment accumulator programs for prescription drugs) that impact out-of-pocket costs but often are undisclosed before plan enrollment. We further urge HHS clarify that copay assistance can apply to a patient's cost-sharing obligations, and to prohibit the use of copay accumulator policies. CMS should clarify the Patient Protection and Affordable Care Act (ACA) definition of cost-sharing to ensure payments made "by or on behalf of" patients count toward their deductible and/or out-of-pocket maximum and to close the EHB loophole, ensuring that health plans consider any covered item or service as part of their EHB package.

Utilization Management

Utilization management – including step therapy (or "fail first") protocols and prior authorization (PA) – is a set of formal techniques used by an insurance carrier or delegate of the insurer, such as a pharmacy benefit manager or third-party administrator. These techniques are designed to monitor the use, or evaluate the medical necessity, of appropriateness, efficacy or efficiency of health care services, procedures, or settings.

The use of these programs often creates significant barriers to quality patient care, delaying treatment and contributing to negative patient outcomes. Utilization management protocols can lead to delays in access to the medications that offer the greatest potential medical benefit to people with arthritis. Because arthritis is a chronic, degenerative disease, delays in treatment can worsen disease progression and even cause permanent damage and disability. In some cases, patients may have no alternate therapy for an extended period if the drug initially prescribed was rejected.

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Before specialty drugs are dispensed, many insurance companies require a complex process called prior authorization. Physicians must fill out a prior authorization form whenever they prescribe a specialty medication or treatment that is restricted or not covered under the insurer's formulary, placing an unnecessary burden on patients, pharmacies, and doctors. In the current system, each insurer uses its own unique and distinct form, and physicians may have to spend many hours familiarizing themselves with and completing dozens of forms of varying lengths and complexities. As a result, prior authorization typically causes lengthy delays in treatment, thereby restricting a person's access to vital care.

Related, step therapy is a complex form of prior authorization in which health insurers require patients to try and fail one or more insurer-preferred medications before the insurer will cover the medication initially prescribed and agreed upon by the patient and their provider. Because it may take months for patients to prove failure, medically inappropriate step therapy delays access to needed care and can result in devastating health outcomes. A 2016 Arthritis Foundation study indicated that over 50% of respondents were required to try two or more drugs before they could receive the drug prescribed by their provider; of those respondents, step therapy was stopped 39% of the time because the drug was ineffective and 20% of the time because of worsening health conditions.

A recent study on commercial plans found that nearly 40% of prescriptions were subject to step therapy and that protocols greatly varied from plan to plan, even for the same condition.[3] Without certain guardrails, insurance-mandated step therapy can be ineffective at controlling costs, burdensome to providers, and harmful to patients. A 2021 study estimated that utilization management (UM) including step therapy is associated with over $90 billion in annual costs to the healthcare system.[4] This estimate included the cost to insurers of implementing UM, the cost to providers of fighting UM, and the cost to patients of striving for continuity of care including paying out of pocket during periods when they are insured but lack coverage.

To date, at least 35 states have passed step therapy reform laws and over 30 states passed prior authorization reforms. However, many enrollees in plans that provide EHB remain without protections. To address this gap, CMS should update the exceptions process outlined in section (c) of 45 CFR §156.122 to clarify that it applies to utilization management, including insurance-mandated prior authorization and step therapy. Appropriate use of insurance-mandated utilization management programs should include guardrails to protect patients. These protections should ensure health plans offer a transparent exceptions process for patients and providers, establish medically reasonable circumstances for when a health plan should grant an exception request, and require plans to respond to such an exceptions request in a timely manner.

[3] Variation In Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans. Kelly L. Lenahan, Donald E. Nichols, Rebecca M. Gertler, and James D. Chambers. Health Affairs 2021 40:11, 1749-1757.
[4] Howell S, Yin PT, Robinson JC. Quantifying The Economic Burden of Drug Utilization Management on Payers, Manufacturers, Physicians, And Patients. Health Aff (Millwood). 2021 Aug;40(8):1206-1214.

Biosimilars

A new area of focus beginning in 2023 is the introduction of biosimilars to the pharmacy benefit, as the first biosimilar for Humira comes to market this week, with others to follow later in the year. While we do not have specific policy on where to place biosimilars on formularies, we do believe that biosimilars should be available to patients through formularies; that they should be available at lower costs; and that health plans should not require patients to step through the brand drug before gaining access to the biosimilar. We would welcome the opportunity to work with CMS to ensure future guidelines address the questions around biosimilars, recognizing that they are not generics but also not brand products, and sit in a unique space.

Telehealth

Telehealth has and will continue to play a role in access for patients. Improving digital infrastructure and system interoperability is a key component to achieving better health outcomes through technology. While not all appointments for patients living with arthritis are appropriate for telehealth, it can allow increased access opportunities. We encourage HHS to keep in mind that network provider access through telehealth should supplement not supplant network provider access to in-person visits. In all cases, consumers must retain the right and ability to choose between receiving care in-person or via telehealth. We also note that audio-only visits have been important to expand access to individuals who lack the broadband or devices needed for video-enabled visits.

Addressing Gaps in Coverage

We urge HHS to obtain data from insurers to identify gaps in coverage rather than put the burden on consumers to identify and report such gaps. The burdensome appeals and complaints filing system further complicates patients' access to care and prolongs resolving their problems with their health coverage. Often, they do not have the resources to pursue such resolve.

Preventive Services

Preventive services provided at no cost to consumers are one of the most widely used and important benefits. Many plans in state exchanges did not provide adequate information to determine what treatments were covered, which is a barrier to access in and of itself. We therefore urge the Department to strengthen enforcement and provide clearer guidance to ensure robust coverage of preventive services without cost-sharing.

Habilitative and rehabilitative services and devices

We applaud CMS for recognizing deficiencies in how Qualified Health Plan's (QHP) cover habilitative services. Many children and adults with arthritis rely on habilitative services to help them manage daily tasks and having adequate access to these services is important to their daily lives. Using a uniform definition will help eliminate confusion by

issuers and consumers about what this coverage must include. It is important to use a robust definition of habilitative services, and we recommend that CMS consider the definition used by the National Association of Insurance Commissioners, as recommended by the Habilitation Benefits Coalition and the Consortium of Citizens with Disabilities.

Dental Services

The benchmark process preferences plans focused on the health needs of adults and there has been significant variation across state EHB benchmarks in the coverage of benefits and services. We encourage the inclusion of routine non-pediatric dental services as an EHB. Specialized dental care is an essential component of the medical treatment of those affected by systemic autoimmune disease and should thus be covered by medical rather than dental insurance. In addition, it is important to note that poor oral health and lack of specialized dental care can exacerbate the systemic symptoms that occur in autoimmune disease patients, leading to the development of new symptoms and worsening existing disease complications. Quality of life in autoimmune disease patients can be substantially improved through better oral care and limiting systemic repercussions caused by oral involvement in such patients. Dentists are critical to diagnosis and subsequent treatment of oral and systemic aspects of autoimmune disease.

Coverage of Prescription Drugs as EHB

We appreciate that CMS is seeking input of prescription drug coverage. It is important that we expand coverage as much as possible so that patients have access to needed treatments. Plans currently satisfy EHB standards for prescription drugs if, among other things, they cover the greater of one drug per U.S. Pharmacopeia (USP) class and category or the number of such drugs included in the state's benchmark plan. This standard has not been updated since the EHB rules came into effect in 2014. Some medications on which patients rely are not part of the USP classifications system, which classifies Medicare Part D drugs but does not include Part B drugs.

The marketplace coverage requirement greatly differs from the Medicare Part D framework, which requires plans to cover at least two drugs per class and "all or substantially all" drugs in specified classes that are critical to vulnerable populations. This can make it effectively impossible for a consumer to determine whether a plan provides adequate coverage for their needs.

We support requiring greater consistency and detail in the information states submit for their EHB-benchmark plans and urge CMS to work with a diverse set of patient advocates to assure that any changes to the model result in comprehensive and affordable coverage of treatments that all patients need. Further, we urge you to ensure significant resources are devoted to enforcing existing EHB standards. We also urge CMS to ensure that EHB requirements are crafted to minimize the risk of adverse selection and inadequate coverage and ensure a streamlined process by which patients have full

transparency about premium subsidy and tax credit eligibility and can choose the plan that is best suited for their financial and health care needs.

Substitution of EHB

We thank CMS' reversal of the 2019 Payment Notice provision amending the ACA regulations to grant flexibility for states to permit issuer substitution of benefits between EHB categories. We opposed this decision in 2019 and applaud CMS for rescinding previous viewpoints on EHBs articulating that the potential for benefit category substitution as particularly harmful for chronic disease patients. Insurers should not be able to limit access to medically necessary services to individuals under a certain age, such as patients diagnosed with Juvenile Arthritis, especially when such age restrictions lack a clinical basis and are presumed discriminatory.

Patient Engagement

Many patients feel like they have little agency or control in these larger health trends. Chief among the reasons is a lack of transparency into the decisions, processes, and data points that could help patients better navigate their health care. The ACA authorizes HHS to update and expand EHB administratively, addressing coverage gaps without the need for congressional action. The ACA also requires HHS to periodically review EHB and report to Congress on EHB effectiveness and impacts. HHS should establish a framework for reviewing and updating EHBs. The process for review of EHBs must be transparent, with mechanisms in place to allow for regular and meaningful patient engagement on their experience with coverage. In addition, quality data about patient experience with denials, complaints and appeals should be available and transparent. HHS should create an independent advisory council to assist in reviewing and updating EHBs. Patient and consumer representatives should be adequately represented on the council. There should be flexibility available to HHS and the advisory council to make recommendations as to how benefits can be modified to address identified gaps in access.

Conclusion

Thank you for the opportunity to provide comments on the RFI on Essential Health Benefits. Should you have questions or if we can be of assistance, please contact Alisa Vidulich, Policy Director, at avidulich@arthritis.org or Anna Hyde, VP of Advocacy and Access, at ahyde@arthritis.org. We look forward to continuing to collaborate with you.

Sincerely,

Anna Hyde

Anna Hyde
Vice President of Advocacy and Access
Arthritis Foundation