

February 19, 2019

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

Submitted electronically via regulations.gov

RE: [CMS-9926-P] PPACA; HHS Notice of Benefit and Payment Parameters for 2020

Dear Administrator Verma:

On behalf of the more than 54 million Americans and 300,000 children in the United States with doctor-diagnosed arthritis, the Arthritis Foundation appreciates the opportunity to comment on the notice of benefit and payment parameters (NBPP) for 2020.

Arthritis is an umbrella term to describe more than 100 types of diseases related to the bones and joints. This chronic disease is America's number one cause of disability and is expected to conservatively impact nearly 80 million Americans by 2040. By any measure, arthritis is an urgent national priority that remains underappreciated in the spheres of federal public health research and medical innovation. While life-changing medicines have undoubtedly transformed the lives of people with arthritis, many challenges remain, from high out-of-pocket costs to continuous administrative burdens, all on top of managing their chronic diseases. Drug pricing and affordability continue to weigh on our community and we appreciate attention the administration has paid to solving these issues.

We also applaud CMS for its ongoing work to reduce regulatory burdens, efforts to increase health care transparency, and empower patients through improved tools and resources. However, the Arthritis Foundation is concerned about several proposals outlined in the NBPP that we believe would exacerbate access to health care and increase costs for patients obtaining care both on and off the health insurance exchanges. Below please find our comments on the proposed rule.

Cost-Sharing and Drug Manufacturer Coupons

CMS proposes to allow issuers to exclude, beginning next year, any form of direct manufacturer support to insured patients from counting toward applicable cost-sharing limits or out-of-pocket costs

if a brand name drug has a medically-appropriate generic equivalent available. In industry parlance, this type of policy is known as an accumulator adjustment program. CMS expresses concern that copayment assistance from manufacturers may be increasing overall drug costs and leading to unnecessary spending.

In our comments to the administration last year regarding the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, we noted that while the Arthritis Foundation does not take a position on copayment cards, we do recognize that without them many people with arthritis simply could not afford their medications and that some form of financial support is necessary – whether through the manufacturer, discount cards, charitable assistance, or other sources. Data from the Arthritis Foundation Helpline consistently shows that medication access challenges are a top reason people contact us. Under an accumulator adjustment program, patients are still allowed to apply a manufacturer copayment card to pay for their medications up to the full limit of the cards, but when that limit is met, the patient is required to pay their full deductible before cost-sharing protections kick in. People with inflammatory forms of arthritis, such as rheumatoid arthritis (RA), do not have generics or significantly lower-cost alternatives available and implementation of accumulator programs is deeply concerning.

Proposals affecting access to needed medication for the management of arthritis should prioritize the patient and provider relationship, support rather than exacerbate medication adherence, and prevent further disease progression and joint degradation. Based on the information presented in the proposed rule, the Arthritis Foundation could be supportive of the policy if it is applied only to small molecule drugs, is limited only to manufacturer assistance, and affects only qualified health plans (QHPs). However, this support is dependent on whether elements of the proposal are clarified further by the agency. We urge CMS to address these concerns and act on the following recommendations:

- Carve out exceptions for when a generic equivalent is unavailable so that copayment assistance can be used, and counted toward deductibles and cost-sharing, for branded medications.
- Provide for an exception if a patient has already stepped through a generic drug to reach the brand medication.
- Clarify whether this policy applies only to small molecule drugs and/or large molecule drugs.
- Clarify the definition of “generic equivalent.”
- Clarify the process by which a generic alternative is deemed to be “medically appropriate.” Relatedly, there may be instances where a provider determines that a brand drug is “medically appropriate” for their patient; it is unclear how CMS would treat copayment assistance under such a circumstance.
- Require the issuer to notify the patient in advance, in writing, that copayment assistance will be excluded from any calculation of annual out-of-pocket limits. We have seen that

commercial market plans have implemented similar policies with little to no notification to the patient.

- Ensure patients have the ability to appeal a health plan's determination to exclude manufacturer copayment assistance in a way similar to the process for appeal of formulary exceptions.
- Ensure implementation of this policy does not increase administrative burden for patients and providers.
- Plans must be monitored by CMS to ensure there are no negative impacts to patient adherence.

We look forward to CMS elaborating further on components of this policy that are unclear, and recommend the agency take an incremental approach related to the inappropriate use of copayment assistance for instances where such misuse is clear and obvious.

Silver Loading

The Arthritis Foundation supports continuing to permit silver loading for 2020. Instituting a ban on silver loading in the absence of a solution that ensures health plans are reimbursed for cost-sharing reduction (CSR) subsidies would be untenable for both the plans and their enrollees. We urge CMS to work with Congress on a comprehensive bipartisan solution with respect to CSRs, affordability, and market stabilization.

Annual Premium Adjustment and Out-of-Pocket Limits

CMS proposes to change the premium adjustment factor formula that is used to calculate the rate at which the annual limit on cost-sharing is increased. Beginning in the NBPP for plan year 2015, the agency determined that this rate would be based on employer-sponsored insurance premiums. CMS proposes to use an alternative measure that would adjust the premium factor based on the average private health insurance premium. The agency notes the new adjustment factor would be 1.29 percent for 2020, representing a 30 percent increase over the 2013-2019 period. This increase is likely means millions of individuals eligible for subsidies will see an increase in premiums.

Additionally, the proposed change to the premium adjustment factor will affect the rate of growth in the maximum out-of-pocket (MOOP) limit on cost-sharing for 2020. CMS notes that the MOOP for individuals would increase by \$200 to \$8,200, and by \$400 for family coverage to \$16,400.

We urge CMS to refrain from implementing both of these adjustments, which we believe will manifest in higher patient contributions toward their care and reduced access to treatments and services.

Special Enrollment Period

CMS proposes to allow exchanges, at their option, to provide a special enrollment period for individuals who experience a decrease in household income that would trigger a new determination of eligibility for enrollment. The Arthritis Foundation supports this proposal and recommends CMS require, rather than make optional, this special enrollment period for state-based exchanges.

Auto-Enrollment

CMS seeks comment on whether the agency should change, in future rulemaking, the process for automatic re-enrollment in plans offered through either federally-facilitated, or state-based, exchanges. Presently, consumers are re-enrolled in their current plan if they do not act to change their plan. According to CMS, about one-quarter of consumers were automatically renewed for the 2019 plan year. The Arthritis Foundation disagrees with CMS that auto-enrollment policies should be modified. We urge the agency to continue the practice without any changes going forward.

Navigators and Web Brokers

The Arthritis Foundation continues to be concerned about the administration's assessment of the importance of navigators in assisting consumers with enrollment in qualified health plans as well as post-enrollment activities. Such activities include understanding basic concepts and rights related to health coverage, health literacy, components of the premium tax credit reconciliation process, referrals to licensed tax advisers, among other topics. CMS proposes to make these post-enrollment activities optional for navigator programs for the purposes of increasing flexibility. This means that navigators for federally-facilitated exchanges would not need to be trained on the nearly two dozen required training topics. We believe that navigators serve an important role, especially for certain populations such as African Americans and Hispanic Americans who report worse impacts and daily limitations from arthritis. As a result, we do not agree with CMS that navigator policies should be changed further.

Similarly, while we recognize that web brokers have played a role in the enrollment process, we disagree with CMS that these online brokers should be allowed to facilitate marketplace enrollment. One concern is that web brokers could direct consumers with chronic diseases toward association or short-term health plans and avoid sharing detailed information about the costs and benefits of those insurance products.

Mid-Year Formulary Switching

CMS proposes to allow an issuer to modify the plan formulary by removing a brand drug when a generic equivalent to a prescription drug becomes available. An issuer would also be permitted to

move a brand drug to a different cost-sharing tier. CMS further proposes to require health insurance issuers to provide written notice 60 days in advance in instances of a mid-year formulary change. The notification would be required to identify the name of the brand drug subject to the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, and specify the date the changes will become effective. The notice would state the appeals processes available.

The Arthritis Foundation supports proposals that will help lower the cost of health care, including increased use of generic medications, as appropriate. We support switching to a lower cost small molecule generic drug, but as before, call on CMS to clarify whether this proposal would only apply to small molecule generic drugs.

We believe CMS should also finalize a 120-day advance notice requirement, which would be a more appropriate period of time to allow a patient to work with his or her provider to file an exceptions request, especially if they have a chronic disease like arthritis. A cornerstone of the Arthritis Foundation's principles for health care is that patients who are stable on a medication should be able to remain on that medication. Policies that intrude upon this tenet give us pause.

Therapeutic Substitution

CMS requests comment on the potential to institute therapeutic substitution. Therapeutic substitution consists of substituting chemically different compounds within the same class for one another, for instance one biologic or biosimilar for another. Unlike generic medications, which are exact copies of chemically designed medicines, biosimilars are not-quite-exact copies of biologics. Biologics are impossible to replicate perfectly because they are very large and complex molecules derived from living substances, such as human and animal cells, yeast, and bacteria.

The Arthritis Foundation believes that CMS should be guided by existing statute regarding therapeutic substitution. At this time, the statute states this can occur only with interchangeability. Until that guidance is finalized, CMS should not move forward with therapeutic substitution policies. If the administration desires to change existing statute, we encourage cooperation with Congress to reform it.

Essential Health Benefits (EHB)

CMS proposes to allow health plans to choose not to count toward the annual limit on cost-sharing some or all of the amounts paid toward a brand drug (that is, as non-EHB), if a generic drug is available and medically appropriate, unless coverage of the brand drug is determined to be required under an exception process.

The Arthritis Foundation strongly opposes this proposal. We believe this policy marks further erosion of the EHBs following the prior year's regulation, which finalized sweeping changes to permit states to select a set of benefits for its EHB benchmark under three different options. If finalized, this proposal would allow insurers to impose lifetime and annual dollar limits on brand drugs since they would be considered non-EHB.

As we have noted several times to CMS, treatment of RA, for instance, can involve trying many different therapies over time with one study estimating that rheumatologists switch their patients to another biologic over 90 percent of the time following an inadequate response.¹ Non-branded treatment options remain limited; currently, only two of the FDA-approved biosimilars for RA have launched in the United States. The Arthritis Foundation encourages the administration to continue efforts to bolster the biosimilar market. We believe biosimilars hold great promise to lower out-of-pocket costs and CMS should act to ensure patients have access to as many treatment options as possible.

The Arthritis Foundation appreciates the opportunity to comment on the proposed rule and looks forward to continued discussions with the administration on solutions that balance issues of drug pricing and affordability with access to life-changing treatments. Please contact Vincent Pacileo, Director of Federal Affairs, at vpacileo@arthritis.org, with questions or for more information.

Sincerely,



Anna Hyde
Vice President, Advocacy and Access
Arthritis Foundation

¹ Kamal KM, Madhavan SS, Hornsby JA, Miller LA, Kavookjian J, Scott V: Use of tumor necrosis factor inhibitors in rheumatoid arthritis: a national survey of practicing United States rheumatologists. <https://www.ncbi.nlm.nih.gov/pubmed/16997599>