

December 22, 2014

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave SW, Room 445-G
Washington, DC 20201

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016

The Arthritis Foundation, on behalf of the more than 50 million adults and children in the U.S. living with arthritis, welcomes the opportunity to comment on the proposed HHS Notice of Benefit and Payment Parameters for 2016. There are over 100 types of arthritis; it is a diverse disease, and people with different forms of arthritis have very different needs. It is also a chronic disease, which means that people often rely on treatment for the disease for life. Therefore, stable, reliable, consistent access to providers and treatment is critical for people who suffer from arthritis. The course of treatment often changes over time, and finding the right treatment for each patient is a nuanced process. People with inflammatory and auto-immune forms of the disease often require complex, expensive medications, and one drug in a particular drug class might work well, while a seemingly similar drug in the same class may not prove to be disease modifying.

For people with arthritis, affordability of treatment is interchangeable with access to life changing medical treatments. Increasingly, insurers are subjecting their members to 40-50% cost-sharing requirements for specialty medications, and there are no guarantees that the drug they need will be on their health plan's formulary. These insurance plan features interfere with the physician's expert opinion to decide on the optimum treatment for the patient's condition, thereby hindering and sometimes even eliminating access to treatment for life limiting diseases like arthritis under the current regulatory structure.

Below, we outline comments on the sections of the proposed rule that are particularly relevant to people with arthritis, a chronic, often complex, and often debilitating disease. The Arthritis Foundation asks for your consideration of these comments.

Exchange Functions in the Individual Market

Annual Eligibility Re-determination

Arthritis patients often require regular access to their physicians to manage their chronic health needs, in addition to medications that they might need to take for years, decades, or the rest of their lives. Maintaining health coverage from year to year is critical to avoiding potentially severe consequences from losing access to providers and treatments. While the CMS proposal to implement a re-enrollment hierarchy could financially benefit consumers, it could also be detrimental if it results in significant changes to their provider network, benefits, or cost-sharing requirements. We caution CMS to ensure that the level of coverage in any new plan is at a

minimum equal to that of their existing plan, and that there are robust mechanisms in place to ensure consumers understand the process and potential implications of opting into an alternative enrollment hierarchy. We seek further clarification on how this policy would be implemented and the effects it might have on access to physicians, service areas, and formularies. We also think consumers should be given the option to set their own trigger for being enrolled in an alternative plan, so they have more control over the decision-making process and the financial implications.

Health Insurance Issuer Standards Under the ACA

Provision of EHB

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.

Collection of Data to Define Essential Health Benefits

We appreciate that CMS is seeking to update the benchmark plans used to determine EHBs. While basing benchmarks on 2014 plans is an improvement, ultimately a methodology needs to be implemented that keeps pace with an evolving health care system. People with arthritis have chronic and often complex health needs. Benchmark plans must offer sufficient coverage to accommodate the needs of this population.

Prescription Drug Benefits

Drug Classification System. We agree that the United States Pharmacopeia (USP) Medicare Model Guidelines is not an appropriate system to use for a population as diverse as that in the Exchanges. We believe that moving to a pharmacy and therapeutics (P&T) Committee model alone is not sufficient, and that there should be a hybrid approach. If CMS uses a P&T committee model, it is important to have representatives on the committee with strong expertise in inflammatory chronic disease management. There are complex forms of arthritis that require very specific treatment regimens, and a robust understanding of these complexities should be well represented by any committee that is making decisions about drug coverage. We recommend that the P&T committee also either add patient representatives to the panel, or create a patient advisory board that can provide input on the patient experience during committee deliberations. Regardless of what structures are put in place – P&T Committee, AHFS, or a hybrid - it is important that any mechanism establishes a floor for the minimum level of benefits, to establish uniformity and to ensure patients receive adequate drug coverage.

Exceptions Process. We are supportive of the exceptions process CMS has proposed. Despite the fact that the EHB standards require at least one drug per class to be covered, the treatment of arthritis can be extremely nuanced and, as stated above, one drug in a class might work well while a seemingly similar drug in the same class might not. It is important that patients have access to the drugs that work best for them, at a price that does not make them inaccessible, even if they are not on their health plan's formulary. The proposed exceptions process would allow a pathway for patients to access drugs off formulary.

We appreciate the clarification that drugs covered through the exceptions process would also count towards the annual limitation on cost-sharing. This is extremely important, as some drugs that treat arthritis can cost thousands of dollars out-of-pocket.

In the event that an exception is denied, we believe it is important to have a system in place to review the decision. We agree with the CMS proposal to provide an independent external review process in the event an exception is denied. We agree that the timing of the original exceptions process should also apply to the external review. Since people with arthritis often rely on medications for years or even decades, we seek clarification on whether a granted exception would apply to the life of the prescription or the plan year.

Transparency. People with substantial prescription drug needs, especially those living with chronic conditions such as rheumatoid arthritis, need the ability to access information and make comparisons of health insurance plans. We applaud CMS's proposal to require more detailed information in health plan drug lists. We agree that the drug lists should contain information about tiering and utilization management, and that this information should be available to both enrollees and prospective enrollees. We urge CMS to also require drug lists to include information on out-of-pocket costs, including co-insurance and deductibles *for each medication*. This information should be presented as both a percentage and a dollar value to make it clear to patients what their financial responsibility would be across plans. Plans should also disclose formulary changes on a monthly basis and within 72 hours during open enrollment. Requiring the information to be available in a machine-readable format will also help enrollees and other stakeholders access the information more easily, and there should also be alternative methods for formulary listings to those people without internet access.

Retail Pharmacies. We appreciate the proposal to require health plans to offer the ability for enrollees to access prescription drugs at retail pharmacies. We agree that health plans should be required to indicate any restrictions on their formularies. We seek clarification on how restricted access will be defined, and how specialty pharmacies will be incorporated into this policy.

Transition Fills. As has been stated, treating arthritis is often a nuanced and complex process. It can take years to stabilize a patient on the right medications, and switching medications can often have a detrimental impact on disease management. Utilization management tools like step therapy and prior authorization are often used for the more expensive and complex drugs, which particularly affects people with auto-immune forms of arthritis. For this reason, it is important that stable patients are able to remain on their medications, regardless of switching health plans. Therefore, we agree that there should be a transition period for patients to remain on their medications while navigating any utilization management tools their new health plans might require. **We believe that stable patients should not be required to go through a step therapy protocol more than once.** We strongly encourage that the transition period be extended to 60 days to ensure adequate time for patients to complete the utilization management review process.

Prohibition on Discrimination

Arthritis is a chronic condition, and therefore people who suffer from the disease have chronic health needs. It is important to protect this patient population from discriminatory practices, such as putting most drugs for a particular condition in the highest cost-sharing tier. We appreciate the fact that CMS draws attention to this form of discrimination in the proposed rule. Many people with arthritis rely on specialty drugs that can result in thousands of dollars in out-of-pocket costs, as a result of practices such as the use of specialty tiers. However, we urge CMS to provide additional clarification on how patients will be protected from discrimination and how these policies will be enforced. We also encourage CMS to develop discrimination tests outside of the prescription drug benefit, to identify discriminatory cost-sharing practices across benefits and services.

It is very important that people with arthritis are protected from mid-year cost-sharing changes for particular benefits, as a change in cost-sharing can threaten access to needed medications and services. We applaud CMS for addressing this issue in the proposed rule. However, there are other mid-year changes that can cause severe disruptions in disease management, such as medications being removed from formularies and implementation of utilization management tools. We urge CMS to strengthen this requirement by including a prohibition on plans taking medications off their formularies, changing co-pay amounts, and implementing utilization management tools mid-year.

Cost-sharing requirements

We agree with CMS's proposal to add language clarifying that the annual limitation on cost-sharing applies to non-calendar year plans to ensure that cost-sharing applies to one 12 month annual limit per plan year.

We also agree that the annual limitation on cost-sharing should apply per person, regardless of whether they have self-only or family coverage. For many families, a person with arthritis may very well be the only person in the family requiring on-going, expensive care that may exceed out-of-pocket limits. It wouldn't make sense for this person to be required to reach the family out-of-pocket limit rather than the individual out-of-pocket limit if he or she is the only one in the family requiring care. Because of the complexity and cost of some arthritis drugs, there are patients who will meet their annual limitation on cost-sharing within the first few months of the calendar year, which places an extreme financial burden on those individuals. While it may be outside the scope of CMS to address this problem, we encourage CMS to consider these types of complications in future cost-sharing policy discussions.

Network Adequacy Standards

Network adequacy is a critical issue for people with arthritis, as this chronic disease often requires regular, consistent access to health care providers. Preserving the patient-provider relationship and the ability of patients to see the physician best suited to manage their disease is of the utmost importance to the Arthritis Foundation. We recommend that the following criteria be met to ensure network adequacy:

- i.** Plans must ensure access to care in a way that does not negatively impact an enrollee's health.
- ii.** Plans must ensure a sufficient number of geographically accessible health care providers for the number of enrollees in a given region.
- iii.** Plans must ensure a minimum level of access to care based on clinical appropriateness, the nature of the specialty, and the urgency of care.
- iv.** Plans must ensure a network that includes sufficient health care providers in each area of specialty practice to meet the needs of the enrollee population.
- v.** An insurance plan that is unable to provide sufficient access to required providers must ensure that an enrollee may obtain a covered benefit at no greater cost to the person than if the benefit were obtained from participating providers.
- vi.** Plans must ensure the ability to select specialty practice health care providers within a reasonable travel time and distance – taking into account the conditions for provider access in rural areas.
- vii.** Plans must ensure a sufficient range of services.
- viii.** Plans must not exclude any type of health care provider as a class.

We agree with CMS that a 30-day transition period is important for enrollees in new health plans to find physicians in-network. We recommend CMS strengthen this policy to allow for a transition

period any time a provider is removed from a plan's network, and to extend it for patients who cannot find a provider in-network.

We applaud CMS's commitment to improving the transparency of provider networks available within health plans, and requiring directories to be updated at least once a month. Provider directories are an important tool for patients to compare and assess health plans. We recommend that directories be required to include information on whether physicians are accepting new patients, as this is crucial information for determining the adequacy of a provider network. Requiring these directories to be machine-readable will also help enrollees to more readily access the information. Directories should be available to both members and non-members so prospective enrollees have the most up-to-date and detailed information possible to choose the plan that will work best for them.

Again, thank you for the opportunity to comment on the HHS Notice of Benefit and Payment Parameters for 2016. We look forward to future opportunities to work with you as you finalize and implement this rule. If you have any questions or if we can be of assistance in any way, please contact Sandie Preiss, Vice President of Advocacy and Access, at 202-887-2910 or spreiss@arthritis.org.

Sincerely,

A handwritten signature in cursive script that reads "Sandie G. Preiss".

Vice President, Advocacy and Access
Arthritis Foundation