

June 22, 2015

Senator Orrin Hatch, Chair
Senator Ron Wyden, Ranking Member
U.S. Senate Committee on Finance

Senator Johnny Isakson, Co-Chair
Senator Mark Warner, Co-Chair
Chronic Care Working Group

Dear Senators Hatch, Wyden, Isakson, and Warner:

The Arthritis Foundation, on behalf of the more than 53 million adults and children in the U.S. living with arthritis, welcomes the opportunity to provide comments to the Finance Committee Chronic Care Working Group. Arthritis is a serious, debilitating chronic condition that affects 53 million adults and 300,000 children in the United States. Osteoarthritis (OA) is the most common form of arthritis, affecting 27 million Americans. Arthritis prevalence increases with age: 50% of Americans over 65 have some form of arthritis, and the prevalence rises as seniors age.¹ For example, by age 85, 1 in 2 seniors is at risk for developing OA of the knee.²

Coordinated care is particularly important for people with arthritis, as co-morbidities are very common. Nearly half of people with arthritis also have at least one co-morbid condition: 24% also have heart disease, 19% have chronic respiratory conditions, and 16% have diabetes.³ Adults with arthritis also have higher risk factors for other chronic conditions. For example, 53% have high blood pressure, 47% have high cholesterol, and 36% are obese.⁴ These co-morbidities are complicated by the fact that nearly half of people with arthritis report arthritis-related physical limitations. In fact, arthritis is the most common cause of disability in the U.S., and people with arthritis report significantly lower quality of life than people without arthritis. For example, adults with arthritis report 2-4 times as many unhealthy days in a month than people without arthritis.⁵ A CDC report released last month shows that arthritis had a worse impact on social participation and work limitations than any other chronic condition.⁶

Arthritis and co-morbidities are extremely costly. There was a 27% increase in arthritis-related health costs between 1997-2005,⁷ which is attributable to the increase in co-morbid conditions among people with arthritis. Currently, OA and rheumatoid arthritis (RA) alone cost \$156 billion a year in direct and indirect expenses. Arthritis results in approximately 1 million hospitalizations annually with a primary diagnosis of arthritis, and 78 million ambulatory care

¹ Centers for Disease Control and Prevention. National Health Interview Survey 2010-2012.

² Murphy L¹, Schwartz TA, Helmick CG, Renner JB, Tudor G, Koch G, Dragomir A, Kalsbeek WD, Luta G, Jordan JM. "Lifetime Risk of Symptomatic Knee Osteoarthritis." *Arthritis Rheum.* 2008 Sep 15;59(9): 1207-13.

³ Centers for Disease Control and Prevention. National Health Interview Survey 2007.

⁴ Ibid.

⁵ Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System 2009.

⁶ Centers for Disease Control and Prevention. Impact of Arthritis and Multiple Chronic Conditions on Selected Life Domains — United States, 2013. *Morbidity and Mortality Weekly Report* June 5, 2015 / 64(21);578-582

⁷ Cisternas MG, Murphy LB, Yelin EH, Foreman AJ, Pasta DJ, Helmick CG. Trends in Medical Care Expenditures of US Adults with Arthritis and Other Rheumatic Conditions 1997 to 2005. *J Rheumatol.* 2009;36(11):2531-8.

visits with a primary diagnosis of arthritis and related disease.⁸ There are approximately 500,000 knee replacements and 250,000 hip replacements primarily related to arthritis every year. The average cost of a total knee replacement ranges from \$20,000 to \$40,000, totaling upwards of \$20 billion a year.

Given the complexity of arthritis, the high rates of co-morbid chronic conditions, and high costs to Medicare, there is a great need to explore better care coordination methods, access issues, and cost of care issues among people with arthritis.

Below are some recommendations as you develop a strategy to improve chronic care delivery in the Medicare population.

Protect seniors from high out-of-pocket costs. Medicare Part D has helped millions of Medicare beneficiaries afford the drugs they need to remain healthy. The implementation of Part D has coincided with a steady trend in specialty medication utilization for complex diseases like RA. To help control the costs of these often expensive medications, Part D plans began putting these drugs into specialty tiers and charging co-insurance rather than fixed co-pays. In 2015, for the first time all Part D plans have specialty tiers.

Specialty tier cost-sharing requirements can translate to hundreds and even thousands of dollars in out-of-pocket costs each month for beneficiaries. Studies show that higher cost-sharing results in reduced medication adherence. For example, a recent Health Affairs study found that when out-of-pocket costs reach \$150-\$200 a month for anti-inflammatory biologics, new therapy abandonment rates double.⁹ Forgoing medication can be devastating for RA patients, since these drugs can actually halt the progress of this degenerative disease. Failure to adhere to medications can lead to worsening disease, increased rates of disability, and loss of function that contributes to direct annual costs of over \$100 billion to the U.S. health care system.¹⁰

The Arthritis Foundation has two recommendations to help mitigate the adverse financial effects to Medicare beneficiaries who depend on specialty drugs.

1. The Medicare definition of a specialty drug is any drug over \$600. This number has not been updated in 5 years, even though the average specialty drug cost is over \$1,000. The 2016 Methodological Changes and Call Letter on Part D does not update this definition. We recommend that the Working Group analyze the specialty drug and cost-sharing trends over the last ten years to determine a more reasonable definition of specialty drug that accounts for current market prices.
2. Out-of-pocket costs for specialty drugs can be stabilized by limiting cost-sharing in specialty tiers. The Patients' Access to Treatment Act (PATA), introduced in the House

⁸ Centers for Disease Control and Prevention. 2001-2005 National Hospital Ambulatory Medical Care Survey.

⁹ Starner, Catherine; G. Caleb Alexander; Kevin Bowen; Yang Qiu; Peter Wickersham; and Patrick Gleason. "Specialty Drug Coupons Lower Out-Of-Pocket Costs and May Improve Adherence at the Risk of Increasing Premiums." *Health Affairs*. Oct 2014 33:10, pgs 1761-1769.

¹⁰ IMS Institute for Healthcare Informatics. "Avoidable Costs in U.S. Health: The \$200 Billion Opportunity From Using Medications More Responsibly." June 2013.

by Reps David McKinley (R-WV) and Lois Capps (D-CA), would limit specialty tier cost-sharing to the non-preferred brand drug tier (usually tier 3). While this bill only applies to the private insurance market, the objectives of the bill are applicable to public insurance markets, and we recommend the Working Group use PATA as a model for beneficiary cost-sharing protections.

Strengthen the appeals process. A consistent, reliable and transparent appeals process is a critical component of Medicare Part D. The process itself should be timely and transparent, and there should be great emphasis on consumer education. Currently, there are concerns among patient groups and CMS surrounding non-compliance with the exceptions and appeals requirements for Part D, which include ensuring enrollees receive accurate and clear information related to their denials. Further, less than 17% of Part D coverage denials are appealed for redetermination. This may be due in part to a lack of awareness by beneficiaries about the appeals process. For example, pharmacy notices currently do not include personalized information on why a prescription was not filled, which misses a key opportunity to educate patients on the ability to file an appeal.

The 2016 Methodological Changes and Call Letter on Part D moves towards a stronger appeals process by requiring more information about denials in coverage denial notices, and improving information about denials at the point-of-sale. CMS is exploring other policies such as developing an appeals tracking system to better determine whether plans are providing adequate access to Part D drugs, and triggering an appeal for a denial at the point-of-sale. However, there are other issues in the appeals process that merit attention, such as specialty tier drug exclusions from appeals requirements. The fact that all Medicare Part D plans have specialty tiers for the first time in 2015 means that any Medicare beneficiary who relies on specialty medications could be denied an important tool to help them access the drugs they need.

The Arthritis Foundation has two recommendations to address the Medicare Part D appeals process:

1. The Working Group and the Committee should monitor the implementation of the 2016 Medicare rule to ensure that the new denials and appeals policies are appropriately implemented, and accelerate the development of policies that will better track appeals and help beneficiaries file appeals.
2. The Working Group and the Committee should consider S. 1488, the Part D Beneficiary Appeals Fairness Act, introduced by Senators Nelson (D-FL) and Susan Collins (R-ME), which would allow tiering exceptions to apply to all drug tiers, including specialty tiers.

Ensure a stable transition into Medicare. As previously discussed, arthritis is a complex, chronic disease, and it can take many years to find the right treatment protocol for any given patient. Therefore, it is imperative that patients have the ability to remain on their medications when they transition into Medicare. Unfortunately, many Medicare beneficiaries find that their current drugs are not available on their new formulary when they switch from private insurance

to Medicare Part D, which can cause them to lose access to drugs they rely on to maintain their health. Further, co-pay cards – which many people with arthritis rely on to preserve access to their medications – are not allowed in Medicare Part D. While we understand that there are reasons for federal policies against the use of co-pay cards in government health programs, we remain concerned that the lack of access to co-pay cards limits the mechanisms available to beneficiaries to receive cost-sharing assistance.

We recommend that the Working Group:

1. Design a policy that protects Medicare beneficiaries from non-medical switching when they transition into Medicare or switch Part D plans. At a minimum:
 - a. In circumstances where an insured is changing health insurance plans, the new plan should not require the patient to repeat step therapy when that person is being treated for a medical condition by a prescription drug, provided that the drug is appropriately prescribed and is considered safe and effective for the patient's condition.
 - b. When a health insurance plan changes formulary design, the plan should not limit or exclude coverage for a drug for an insured if the drug previously had been approved for coverage by the plan for a medical condition of the person and the patient's physician continues to prescribe the drug for the medical condition.
2. Analyze the impact of the prohibition of co-pay cards in Part D and consider policies that will expand the availability of cost-sharing assistance to Medicare beneficiaries.

Monitor utilization management techniques for discrimination. As you may know, there have been some challenges with Health Exchange plans discriminating against people with chronic diseases by placing all drugs for a given disease in specialty tiers. Most of the attention to-date has focused on the HIV/AIDS population, but RA is 1 of 4 disease areas CMS will monitor for these types of discriminatory practices among qualified health plans (QHPs), per the 2016 final letter to issuers in the Federally-Facilitated Marketplace.

Several other utilization management techniques have become increasingly common by insurers to control the costs of treating people with chronic conditions like arthritis, including step therapy, and prior authorization. While the Arthritis Foundation does not oppose these techniques, we also believe there should be patient safeguards, and there should be limits placed on them. For example, a patient should not be required to go through a step therapy process twice for the same drug, and prior authorization requests should be completed within 48 hours of submission or receive automatic approval.

We recommend that the Working Group commission a GAO report to assess the prevalence and impact of utilization management techniques like step therapy and prior authorization in Medicare Part D. This would be an important step in determining whether discriminatory practices are occurring and the prevalence of such practices.

Expand telemedicine to the broader Medicare population. Telemedicine holds great promise in increasing access to care among people with chronic conditions. There is no cure for arthritis - when a person is diagnosed, they will require regular, on-going care to manage their disease for the rest of their life. Therefore, having ready access to a health care provider best suited to manage their disease is critical to their health and well-being. CMS allows coverage of remote patient face-to-face, interactive services for beneficiaries who meet certain criteria such as living in rural areas. However, Medicare only reimburses for telehealth services delivered in a medical facility, not the patient's home. We believe people with arthritis could benefit from telehealth services being provided in places beyond medical clinics. Further, it is not just rural beneficiaries who can benefit from telemedicine; people with arthritis who have limited mobility can also greatly benefit from these programs, even if they live in urban areas. We believe that telemedicine policies should be broadened to larger segments of the Medicare population.

We appreciate the focus on tele-medicine in Congress. S. 1549 would help expand access to telehealth emergency support, and telemedicine is addressed in the 21st Century Cures legislation, which supports the efforts of the Energy and Commerce Bipartisan Telemedicine Member Working Group to develop long-term solutions to adopting new technologies into the health care delivery system.

We recommend that the Working Group coordinate with the Bipartisan Telemedicine Member Working Group and others who have introduced telemedicine legislation to design a comprehensive set of Medicare policies that will allow for broader use of telemedicine. Such legislation should consider:

1. Scaling up telemedicine programs to all Medicare beneficiaries with chronic conditions.
2. Providing coverage for home telehealth services.

Again, thank you for the opportunity to provide comments to the Chronic Care Working Group. We look forward to future opportunities to work with you to address the chronic care needs of people with arthritis. Should you have any questions or if we can be of assistance in any way, please contact me at 202-887-2910 or spreiss@arthritis.org.

Sincerely,



Sandie Preiss
Vice President, Advocacy and Access
Arthritis Foundation