Position Statement:
Excessive Cost Sharing (Specialty Tiers) for High-Cost Medications Represent a Barrier to Patient Access

The Arthritis Foundation is alarmed about the negative effects that excessive co-payments or co-insurance for high-cost medications have on access to appropriate therapy for people with arthritis. Some commercial health insurance policies and the Medicare Part D program use "specialty tiers" which utilize high patient cost-sharing methods for certain expensive medications. High patient cost sharing compromises access to biologic therapies that have proven to reduce disability and maintain function for certain inflammatory forms of arthritis. The Arthritis Foundation strongly recommends that both federal and commercial insurance plans cap out-of-pocket costs at affordable levels to insure access and affordability and prohibit the discriminatory practice of "specialty-tiers" or high cost sharing methods for these critical therapies.

What is the Problem?

- In response to increasing costs, many insurance plans that cover prescription drugs have instituted a tiered payment system for medications. The tiers are often labeled 'generic,' 'preferred,' and 'non-preferred' and each have a set cost-sharing amount. For example, $10 for generic, $30 for preferred and $60 for non-preferred. Several plans now include a fourth and fifth, 'specialty tier' which requires enrollees to pay a *percentage* of the cost of the most expensive medications on these tiers as opposed to a fixed amount. In commercial private plans, cost-sharing varies from 20-50%. In the Medicare Part D program, cost sharing can be anywhere from 25 to 33 percent of the actual cost of the medication. The yearly costs for these medications ranges from $12,000--S48, 000 (1). The cost sharing amounts result in skyrocketing amounts ranging from several hundred dollars a month for a single medication to the thousands. This practice is simply unacceptable and discriminates against patients with chronic conditions.

- Biologic medications, including arthritis disease-modifying therapies, are increasingly among the medications relegated to specialty tiers which use a high-cost sharing formula. It is important to note that there are currently no generic alternatives available for biologics used to treat arthritis. Subsequently, many people with arthritis may stop taking their prescribed medication or skip doses because they simply cannot afford it -- even though they have health insurance and a prescription drug plan. The tiered cost-sharing structure places a significant financial burden upon people with rheumatoid arthritis, psoriatic arthritis and other forms of inflammatory arthritis. High cost-sharing is also used for those with other chronic illnesses such as multiple sclerosis, cancer, psoriatic arthritis, Crohn's disease, hemophilia and lupus.

Co-insurance for prescription drugs is a rising and alarming trend.

Medicare Part D

- For 2009, The Kaiser Family Foundation reported that 87 percent of stand-alone Medicare Part D prescription drug plans and 98 percent of Medicare Advantage Prescription Drug plans had specialty tiers. More than half of plans with a specialty tier charged a 33 percent out-of-pocket cost before they reached the donut hole, where they then have to pay the full cost of the drug. Under Medicare guidelines, only drugs costing more than $600 per month in 2009 can be placed on specialty tiers (2).

- In a 2009 study, Polinski and colleagues reported that for those with rheumatoid arthritis out-of-pocket costs exceeded $4,000 annually in 2006 in all cost-sharing schemes under Medicare Part D. Medicare Part D covers those age 65 and older and those on Social Security Disability. The authors note that the majority of costs for specialty biologic medications are shifted to beneficiaries, which may place these medications out of the beneficiary's financial reach. (3).

Commercial Insurance

- The Kaiser Family Foundation reports that in 2009, over three-quarters (78%) of workers with prescription drug coverage were in plans with four tiers of drug coverage. In 2000, only 27% of workers with prescription drug coverage had a plan with four tiers of coverage (4)

- Wolfe and Michaud in a 2009 study noted that 43.6% of patients with rheumatoid arthritis reported problems paying medical bills after insurance. The out-of-pocket burden for those under age 65 was more of a problem for those with lower household income, more severe disease and no insurance (5).

- Goldman and colleagues completed a study that analyzed the change in members' utilization given a change in their cost-sharing for specialty drugs, including rheumatoid arthritis. The study included pharmacy and medical claims from 55 health plans offered by 15 large employers with 1.5 million beneficiaries in 2003 and 2004. The study showed that doubling the co-pay (which is a fixed amount much less than co-insurance) resulted in a 21% reduction in use among people with rheumatoid arthritis (6). These policies encourage the practice of non-adherence which leads to poor health outcomes for people with rheumatoid arthritis.

The Impact of Non-Adherence

- A 2009 study by some of the same authors concluded that high cost sharing delays the initiation of drug therapy for patients newly diagnosed with chronic disease (7). In rheumatoid arthritis, studies show that most of the joint damage occurs in the first three years of the disease, so any delay increases the risk for lifelong disability.

- Non-adherence to medication regimens contributes direct annual cost of $100 billion to the US health care system. Indirect costs exceed $1.5 billion annually in lost patient earnings and $50 billion in lost productivity (8).

- A *Journal for Managed Care Pharmacy* article found that out-of-pocket expenses greater than $100 for tumor necrosis factor (TNF) blocker medications for rheumatoid arthritis, and greater than $200 for multiple sclerosis therapies, were associated with increased prescription abandonment. (9)

The problem will not be solved by federal health care reform.

While the Patient Protection and Affordable Care Act (PPACA) will reform many aspects of health care, and holds great promise, it will not regulate prescription drug costs for those with commercial insurance or those on Medicare. Health care reform will:

- *Require that prescription drug benefits be an "essential benefit" in health plans sold or renewed in 2014 and beyond,*
- *Prohibit lifetime caps on benefits from September 2010 and beyond, including for prescription drugs,*
- *Prohibit annual caps on insurance benefits in 2014 and beyond, including for prescription drugs.*

- Even with PPACA, however, limited regulations exist to avert trends towards increased cost sharing, co-insurance and specialty tiers.

- Many of these patients must take multiple medications to improve the quality and duration of their lives.

- Insurers may also move a patient's medication into the most expensive categories during the plan year. A patient might select an insurance plan based on the cost of their specific medication, but the insurer is free to move that medication into an expensive fourth or fifth specialty tier later that same year. The patient can only change insurance plans during the annual enrollment period.

Some states are taking action

- In 2010, New York was the first state to pass legislation prohibiting the use of specialty tiers.

- The state of Maryland issued a report in 2010 on a proposal that would regulate specialty tiers. The report concluded that in the absence of separate out-of-pocket limits, state residents would have a significant issue purchasing specialty medications (10).

- In 2011, a number of states (including California, Delaware and Vermont) considered legislation examining specialty tiers. Some bills prohibit specialty tiers, others bills

instruct the state to study the issue and others use various approaches to reduce the annual out-of-pocket limit.

Changes are Necessary

- High cost sharing such as specialty tiers act as a barrier to medication access for patients with chronic, disabling, and life threatening conditions and may result in serious harm and unjustified discrimination based on disease or disability. Cost-sharing for prescription medications should not be so large as to inappropriately restrict or interfere with the proper use of medications, which can lead to negative health outcomes and additional costs to the healthcare system.

- Pharmaceutical companies are prohibited by statute from providing assistance with co-pay coverage for Medicare Part D beneficiaries. Federal law should be changed to allow for pharmaceutical companies to provide assistance with out-of-pocket payments for high cost specialty medications.

- Even with the Affordable Care Act, limited regulations exist to avert trends toward cost-sharing, co-insurance and specialty tiers. Legislation is needed to eliminate or cap high cost-sharing for high-cost specialty medications.

- Commercial insurance plans need to eliminate specialty tiers and cap out-of-pocket costs for high cost specialty medications.

Recommendations for Action

- The Arthritis Foundation will work at both the federal and the state levels to create new laws and regulations that cap out-of-pocket costs for important and often life-changing drugs that currently carry copayments or co-insurance amounts that are too high for most families to afford.

- We cannot solve this problem alone but recognize critical partnerships will be necessary. The Arthritis Foundation will partner with other organizations including other patient advocacy organizations that are facing similar access barriers and professional medical societies that share our concerns about high cost-sharing for expensive specialty medications.

- The Arthritis Foundation will strongly discourage future benefit design to include these discriminatory high cost-sharing tiers. As the federal implementation of health care reform is rolled out and each state decides how to implement health care reform, the Arthritis Foundation will advocate for affordable access to therapy and the prohibition of specialty tiers.

- The Arthritis Foundation will also support legislative efforts to change Medicare Part D and its policies regarding specialty tiers and to revise the Affordable Care Act to incorporate changes that cap out-of-pocket costs for specialty medications.

- The Arthritis Foundation will support legislative efforts to permit manufacturers provide direct patient assistant programs to Medicare beneficiaries.

- The Arthritis Foundation will support state legislative efforts to eliminate the practice of high co-insurance or co-pays for these specialty medications.

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As passed by the Arthritis Foundation Board of Directors, November 19, 2011
For more information, contact Amy Melnick, Vice President, Advocacy, amelnick@arthritis.org