What is the problem?
An alarming trend in today’s health insurance market is the practice of moving vital medications into specialty tiers that utilize high patient cost-sharing methods. Specialty tiers commonly require patients to pay a percentage of the cost of the drug (co-insurance) that can range from 25% to 50% or higher, costing a patient hundreds, even thousands of dollars, per month out-of-pocket for a single medication.

Specialty tiers and co-insurance are placing medically-necessary treatments out of reach of average insured Americans. Failure to adhere to a treatment plan because of lack of access to medications can lead to worsening disease, increased rates of disability, loss of function, productivity and independence, and rising health care costs as more patients forego treatment. Non-adherence to medication regimens not only have a direct impact on health and disease progression - it contributes direct annual costs 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.¹

Why should we support the Patients’ Access to Treatments Act? What will the legislation do?
A patient’s financial responsibility or cost-sharing for a prescription medication should not be so large that it inappropriately restricts or interferes with medically-necessary use of medications.

The bipartisan Patients’ Access to Treatments Act, introduced by Representatives David McKinley (R-WV) and Lois Capps (D-CA), would rein in high cost-sharing for specialty medications, enabling more patients with chronic, disabling, and life threatening conditions to access and afford the treatments they need.

PATA would limit cost-sharing requirements applicable to medications in a specialty drug tier (typically Tier IV or higher) to the dollar amount applicable to drugs in a non-preferred brand drug tier (typically Tier III).

Who would be helped by PATA?
PATA helps patients with chronic, life-threatening, and disabling conditions who rely on so-called specialty drugs. Specialty drugs lack a consensus definition but are generally costly, complicated to develop, require special handling and administration, and/or ongoing clinical

assessment. The average monthly cost for many of these medications can be anywhere from $800 to $3000 or more.²

The majority of specialty medications are biologics, which have no generic or less expensive equivalents. Affected patients include those with certain types of cancers like leukemia and lymphoma, rheumatoid arthritis, psoriatic arthritis, lupus, HIV, primary immunodeficiency diseases, hemophilia, Crohn’s disease, and other chronic, complex, and sometimes rare diseases and conditions.

Patients with chronic and complex diseases and conditions and their families would be directly impacted and benefit from the legislation. Limiting excessive out-of-pocket cost-sharing helps prevent complications and increased medication adherence. For example, a recent Health Affairs study found that for rheumatoid arthritis biologic medications, the abandonment rate increased once out-of-pocket costs reached $250 a month, and began to significantly increase when costs reached $500 a month. By the time out-of-pocket costs reach $2,000, the abandonment rate is over 50%.³ In addition, all Americans would benefit from the limiting of excessive cost-sharing, as no one is immune from becoming ill with a chronic disease.

Wouldn’t state laws protect people from high cost-sharing practices??
In many cases, federal pre-emption rules would nullify state law. The Employee Retirement Income Security Act (ERISA) governs employer-sponsored plans, which cover 149 million Americans. ERISA pre-emption rules nullify state laws with regard to self-insured employer plans. Over half of employer based plans are self-insured and exempt from state laws⁴ meaning that any state law(s) with limits on specialty tier cost-sharing would not apply to the people with self-insured employer plans. Federal legislation is necessary to provide out-of-pocket cost protections to employees in self-insured employer plans. PATA would amend Title XXVII of the Public Health Service Act.

How does PATA interact with existing or future state laws that create patient safeguards for prescription drug cost-sharing?
Patients would benefit from the most protective safeguard, whether the most protective safeguard arises under state law or PATA. PATA would establish a federal limitation on patient cost-sharing requirements for specialty tier drugs. If state law establishes a separate cap on patient cost-sharing that is more protective than PATA, then the state law provision would remain in force. However, if state law is silent or if state law establishes a cap that results in greater patient cost-sharing than PATA, then patients would be protected by the limits under PATA.

³ 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.
What about Medicare?
PATA would not address the significant specialty tier issue in Medicare Part D. Additional legislation would be needed to limit the excessive cost sharing of specialty tiers for Medicare beneficiaries. Legislation exists that would provide an appeals and exceptions process for Medicare beneficiaries whose treatments are placed in a specialty tier and subject to a co-insurance. In addition, the Centers for Medicare and Medicaid Services should reconsider the long standing $600 threshold for placing prescription medications on the specialty tier.

What about the Affordable Care Act (ACA)? Didn’t it address the issue?
A provision of the ACA did cap total yearly out-of-pocket costs at approximately $6,600 for individuals and $13,200 for families, in 2015. However, if a patient’s medication cost-sharing equals the out-of-pocket maximum in one month, that still represents a significant barrier to access. In addition, these out-of-pocket maximums apply to drugs that covered by the health plan’s formulary. Therefore, if a patient needs a medication that the health plan does not cover, they will pay more than the $6,600 annual out-of-pocket limit.

In addition, the pharmacy benefits within Qualified Health Plans certified for sale through the Exchange proliferate the problem. Benefit design under these plans often have co-insurance rates of up to 50% and in some cases higher. For example, a recent New England Journal of Medicine article used the term “adverse tiering” to describe the placement of all HIV drugs in a certain class in tiers with cost-sharing of at least 30 percent. Adverse tiering, the authors said, “puts substantial and potentially unexpected financial strain on people with chronic conditions.” The article documents evidence of this practice in 12 plans out of 48 exchange plans analyzed from 12 states.

Will PATA increase the overall cost of health insurance? If cost sharing for high-cost medicines is limited, who shoulders the additional costs?
The purpose of health insurance is to spread risk and share health care costs. Specialty tiers do the opposite by passing on the financial burden to the patient with a chronic condition, while healthy patients and the insurance companies pay less. Not only does this run counter to the very purpose of insurance, it is not appropriate for medically-necessary treatments for some conditions to be singled out for co-insurance so excessive that the insured patients cannot afford the treatments they need.

It is likely that as health insurance companies adjust cost-sharing in response to the need to avoid these serious problems with patient access, they will spread the risk and costs among the entire pool of the insured. Because a limited number of people need specialty medications, an analysis of PATA conducted by Avalere Health shows an increase in premiums for the entire pool would be approximately $3.00 per year, a nominal cost.

---

5 Using Drugs to Discriminate, New England Journal of Medicine, January 29, 2015.
What if insurance companies increase cost sharing for Tier III non-preferred brand drugs, rather than spread the cost among the premiums of the entire pool of the insured?
It is possible that insurance companies could choose to increase cost-sharing requirements for non-preferred brand drugs in plans (typically Tier III), rather than spread costs through premiums. Tier III drugs typically have co-payments of $30 to $50, which is much more affordable than specialty tier co-insurance of $600, $800 or more per drug per month. According to Avalere Health, the average increase in cost-sharing for the non-preferred tier would be approximately $6.00.7

What about the high cost of medications?
New medications coming to market are expensive. They are also more highly specialized and beneficial to a specific subset of those with a disease. New treatments are coming to market for diseases that have never had medications specifically designed for that disease. In addition, one medication will not help all.

Many of the newer drugs are biologics that are expensive because of the materials required to create them and then complex manufacturing processes needed to handle development from live organisms. Currently, there are no generic alternatives for biologic treatments. While the ACA created a pathway for the development of biosimilars, and the Food and Drug Administration has a handful of applications for biosimilars, it will be difficult to ensure medications are replicated safely and effectively.

What about Patient Assistance Programs?
Patient Assistance Programs offered by foundations and pharmaceutical companies provide much-needed financial assistance to qualified patients who have difficulty paying the out-of-pocket costs required for their treatments. However, assistance provided by foundations is limited, and available funds often run out before eligible patients can receive assistance. Furthermore, foundations also typically impose income requirements that exclude many patients in need, and some assistance plans are available only to those who lack any insurance.

Additionally, certain Patient Assistance Programs are prohibited under federal regulation from providing direct cost-sharing assistance to many patients including Medicare, Tricare, and other beneficiaries.

(Updated April, 2015)

7 Ibid.