Prohibiting Specialty Tiers in Prescription Drug Formularies

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Introduction

AS THE CONSUMER COST OF PHARMACEUTICAL DRUGS CONTINUES TO RISE,

a number commercial health insurance plans have responded by creating a new cost sharing mechanism in their drug plans. New and high cost treatments are being placed on 'specialty tiers' within drug plan formularies. These 'specialty drugs' treat or slow the progression of life threatening diseases and chronic conditions such as HIV/AIDS, cancer, and multiple sclerosis. Because many of these drugs are biologic treatments or must be administered or monitored by a physician, they carry very high costs. Unlike most pharmaceutical drugs that are dispensed with set dollar amount co-payments, drugs on specialty tiers are assigned coinsurance rates where the patient pays a percentage of the drug cost. From a patient perspective the difference between paying a co-payment and paying the coinsurance rate for a medication could be hundreds of dollars a month. For example, common medications to treat multiple sclerosis can cost $3,000 or more a month. Currently a person with health insurance might pay a $55 co-payment for this medication. But, if their drug plan had specialty tiering and charged a 25% to 33% in coinsurance, the same medication would cost between $750 and $990 a month.

As a cost sharing strategy, specialty tiers are problematic for a number of reasons. First, they violate the basic principal of insurance whereby individuals and employers purchase health insurance plans so that they are protected from the risk of needing to pay for highly expensive medical treatments. Second, specialty tier coinsurance rates can change unpredictably. This makes it impossible for patients to anticipate and budget for health care costs. It also impedes them from having informed discussions with their doctors about containing the cost of their treatment. Third, where the practice of specialty tiering is allowed, researchers find that the out-of-pocket costs for medications are high enough to prohibit people from complying with the treatment protocols prescribed by their doctors. They may also force people to choose between paying for basic living expenses or taking their medications. This is bad for both health outcomes and health care costs in general. As patients forgo treatment because of cost concerns their health deteriorates, often necessitating more expensive emergency care. Finally, some proponents of specialty tiering argue that such cost sharing arrangements keep health care costs down overall by encouraging users of very expensive medications to choose less expensive or generic drugs. However, there are no generic alternatives available for the biologic treatments that make up the vast majority of drugs placed on specialty tiers.

The drugs that insurance plans commonly categorize as specialty drugs are used to treat diseases and conditions that affect almost 4 million people in New York State and their families. This report presents information supporting a bill that would prohibit the practice of specialty tiering within the state. Enacting this legislation will have no cost to the state's financial plan and impose no new costs to insurance plans while protecting affordable access to prescription drugs for millions of New Yorkers. In this fiscal climate the state can't afford to leave the health, earning, and spending potential of millions of New Yorkers unprotected from soaring drug prices.

Frank Ridzi is 60 years old and lives in Albany with his wife and two of their five children. He was diagnosed with multiple sclerosis in 1998 when he had a symptomatic episode that paralyzed his left side. After a few months, Frank recovered and regained his mobility. He has been taking Copaxone since 2002 and now feels that his multiple sclerosis is under control. In 2003, Frank retired from a 35-year career working for Verizon as an Area Operations Manager and went on to work part-time as a youth minister at St. Jude Church in Wynantskill. Today, Frank no longer works but stays active by cycling, running, and volunteering with his church, local Boy Scout troop, and with the National Multiple Sclerosis society.

As a retiree, Frank has health insurance through United Health Care and with his Acredo prescription drug benefits his medication costs $20 every three months in co-payments. Although his wife Linda still works, he is on a fixed income. If his insurance plan were allowed to move his medication to a specialty tier, the $800 a month coinsurance payments for his Copaxone would, "mean a lot of tough decisions, especially in this economy where costs are increasing and income is not." Frank says a choice would have to stop taking his medication and sacrifice his mobility or have his family sacrifice their standard of living. Frank is sure that without his medication his multiple sclerosis would be not be controlled and he would lose his ability to function normally. He says, "this legislation is important to me because if we go to specialty tiering I would not be able to treat my MS and I have no doubt that I would be more disabled and more crippled without the treatments that are available today."

Frank Ridzi
Albany, NY

A.8278-b/S.5000-b

An Act to Prohibit Specialty Tiers in Prescription Drug Formularies

Table 1) Cost of common specialty therapies as a percentage of 2009 median NYS income

MEDICATION	DISEASE OR CONDITION	MONTHLY COST	25% COINSURANCE	33% COINSURANCE	ANNUAL OOP COST AT 25% (33%)	% OF MEDIAN NYS INCOME
Gleevec	Cancer	$3,750	$937	$1,237	$11,244 ($14,844)	**24% (32%)**
Fuzeon	HIV	$2,570	$642	$848	$7,704 ($10,176)	**16% (22%)**
Avonex	Multiple Sclerosis	$2,380	$527	$696	$6324 ($8,352)	**14% (18%)**
Humira	Rheumatoid Arthritis/ Chron's Disease/ Psoriasis	$1,500	$375	$495	$4,500 ($5,940)	**10% (13%)**

Monthly costs of medications are based on NYS average prices (2009). % of Median Income is based on a median income of $46,523 for NYS single earners (2009) http://www.justice.gov/ust/eo/bapcpa/20090315/bci_data/median_income_table.htm.

The bill, sponsored by Assembly Member Micah Kellner and State Senator Thomas Duane, protects insured New Yorkers from having to choose between unsustainably high out-of-pocket pharmaceutical expenses and their health. It does so by prohibiting health insurance companies from imposing drug tiers based on expense or disease category and charging cost-sharing percentages for prescription medications that save lives and slow the progression of disabling chronic diseases.

Currently no state-regulated commercial health insurance plans in New York State use specialty tiers, but the practice continues to grow nationally. In 2004, only 3% of commercial health insurance plans included a specialty tier[1]. But by 2009, almost 17.5% of commercial health plans included one[2]. Although the New York State Insurance Department has not authorized health plans to include specialty tiers in their prescription drug formularies, there are currently no state laws or regulations that would prohibit the department from doing so.

We know from states where pharmaceutical benefit specialty tiering is practiced that the costs of life-saving drugs are out of reach for working people with insurance. By protecting the ability of insured New Yorkers with chronic diseases and life-threatening diseases to afford their medications, the state will also avoid the losses associated with lost wages, unemployment, medical debt, and secondary outcomes on families, neighborhoods, and the larger state economy—all while having no impact to the state financial plan.

1 Kaiser Family Foundation and Health Research and Educational Trust. (2004). Employer Health Benefits: 2004 Annual Survey. Menlo Park and Chicago.

2 Pharmacy Benefit Management Institute. (2009). 2009-2010 prescription Drug Benefit Cost and Plan Design Report. USA.

WHO IS AFFECTED?

The people who would be protected under A.8278-a/S.5000-a are by and large working people who are currently insured.

In the midst of the current fiscal crisis, New York cannot afford to leave the health and financial stability of almost 4 million residents unprotected. If between 10 and 32% of a household income is dedicated to paying for medications to save a life or slow the progress of a debilitating disease, there will be negative consequences to that household's ability to cover basic expenses like food, transportation, and housing—and little left for participating in the broader consumer economy.

Table 2) NYS prevalence[1] of some of the conditions treated with specialty drugs.

Note: *Kidney disease (which affects millions of New Yorkers), Anemia, and Neutropenia, among other diseases and conditions, are also treated with biologics. Prevalence data for these conditions was unavailable.*

DISEASE OR CONDITION (Year of Estimate)	NYS PREVALENCE
Breast Cancer (2006)	163,700
Colorectal Cancer (2006)	75,400
Leukemia (2006)	15,300
Non-Hodgkins Lymphoma (2006)	11,600
Mulitple Sclerosis (2008)	64,000
Rheumatoid Arthritis (2008)	1,169,418
Hemophilia (1998)	1,160
HIV/AIDS (2007)	120,000
Cystic Fibrosis (2008)	1,617
Chron's Disease, Ulcerative Colitis (2007)	39,175, 46,387
Hepatitis B & C (2008)	72,123
Diabetes (2004)	1,578,000
Psoriasis (2005)	428,787
TOTAL	**3,786,667**

1 Breast Cancer, Colorectal Cancer, Leukemia, and Non-Hodgkins Lymphoma data taken from http://www.health.state.ny.us/statistics/cancer/registry/pdf/table8.pdf (2006).
Combined estimates of people affected by Multiple Sclerosis given by the three NYS MS Society chapters in their 2008 annual reports.
No state level data available for Rheumatoid Arthritis; figure is calculated based on National Health Institute prevalence figure of 0.06% with US Census 2008 population estimate for NYS (19,490,297).
Hemophilia data taken from http://www.wadsworth.org/labcert/blood_tissue/hemo/hemo1.pdf.
HIV/AIDS data taken from: http://www.health.state.ny.us/diseases/aids/statistics/annual/2007/2007-12_annual_surveillance_report.pdf.
Cystic Fibrosis data taken from: http://www.cff.org/UploadedFiles/research/ClinicalResearch/2008-Patient-Registry-Report.pdf.
No state level data available for Chron's Disease; figure calculated based on 0.00201% prevalence of Chron's Disease in the US population as estimated in "The Prevalence and Geographic Distribution of Crohn's Disease and Ulcerative Colitis in the United States," *Clinical Gastroenterology and Hepatology*, 2007 with US census 2008 population estimate for NYS.
Hepatitis B & C data based on NYS Hepatitis B registry data (9,002) and Hepatitis C registry data (63,121) (http://www.nyhealth.gov/diseases/communicable/hepatitis/docs/chronic_hepatitis_b_and_c_annual_surveillance_report_2008.pdf).
Diabetes data includes both diagnosed and undiagnosed cases and is taken from: http://www.health.state.ny.us/statistics/diseases/conditions/diabetes/docs/1997-2004_surveillance_report.pdf.
Based on 2.2% prevalence estimate for Psoriasis given by National Psoriasis Foundation (http://www.psoriasis.org/netcommunity/learn_statistics).

National Trends

ACROSS THE COUNTRY HEALTH CARE COSTS ARE GROWING.

Between 2000 and 2007 health expenditures grew 89% in the United States with prescription drugs representing about 10% of the total spent[1]. Since 2000, increases in health care premiums have outpaced inflation and changes in worker earnings. As wages have grown 2-4%[2] annually health care premiums have grown 5-14%. With prices ranging from $5,000 to $300,000 a year, specialty drugs are already some of the most expensive on the market. Last year their prices rose at three times the rate of inflation[3]. These trends are concerning to citizens and policy makers because they have serious and negative consequences for families' health and finances. For example, a recent survey from the Kaiser Family Foundation found that 53% of families have cut back on health care because of cost concerns and 19% said that they experienced serious financial problems because of family medical bills[4].

One way that insurance plans have responded to increasing health care costs is by implementing specialty tiers in their drug formularies and shifting more of the burden of treatment costs back onto sick patients. Specialty tiering is allowed in Medicare Part D and in states such as California, Maryland, Minnesota, Nebraska, and Wisconsin. Studies from these contexts provide evidence of the negative impact of specialty tiering on people, employers, and states. Readers should keep in mind that Medicare Part D is a drug plan that is part of the federal Medicare system, but is offered and administered through private health insurers. Insurers offering Medicare Part D drug plans are legally required to provide a specified minimum of coverage but are otherwise free to design their drug formularies. Enacting A.8278-b/S.5000-b will not restrict Medicare Part D providers from using specialty tiers in their drug coverage plans.

The number of insurance plans and prescription drug providers using specialty tiers is increasing. This trend can be observed among both Medicare Part D providers and private insurance plans. Between 2006 and 2008 the number of Medicare Part D prescription drug plans using specialty tiers has almost doubled[5]. A similar trend exists in the private sector. In 2004 only 3% of workers faced 4-tier prescription drug plans[6]. By 2009 17.5% of employers are using 4-tier drug plans with either high co-payments or coinsurance for this category of medications[7].

Where specialty tiers are coinsured, these rates are also increasing. Coinsurance on specialty tiers had generally been held to 25%. However, in an effort to reduce deductibles many prescription drug providers have increased coinsurance rates. Between 2006 and 2008 the number of Medicare Part D prescription drug plans using coinsurance rates of 33% for specialty tiers has increased more than five-fold[8]. In 2009, Humana, the second largest provider of Medicare drug plans increased the coinsurance on specialty medications from 25% to 43%[9].

1 The Kaiser Family Foundation. Health care costs: A primer. March, 2009.
2 Ibid.
3 Walsh B. The Tier 4 phenomenon: Shifting the High Cost of Drugs to Consumer. AARP. March, 2009.
4 The Kaiser Family Foundation. Health care costs: A primer. March, 2009.

5 Hargrave E, Hoadley J, Merrell K, Cubanski J. Medicare part D 2008 data spotlight: specialty tiers. The Henry J Kaiser Family Foundation; 2007 December.
6 Kaiser Family Foundation and Health Research and Educational Trust. Employer health benefits: 2004 annual survey. Menlo Park and Chicago, 2004.
7 The Pharmacy Benefit Management Institute. 2009-2010 prescription drug benefit cost and plan design report. Scottsdale, 2009.
8 Hargrave E, Hoadley J, Merrell K, Cubanski J. Medicare part D 2008 data spotlight: specialty tiers. The Henry J Kaiser Family Foundation; 2007 December.
9 Walsh B. The Tier 4 phenomenon: Shifting the High Cost of Drugs to Consumer. AARP. March, 2009.

Kenneth Bandler
White Plains, NY

Kenneth Bandler grew up in New York City and now lives in White Plains with his wife and daughter. He was diagnosed with multiple sclerosis in 1990. Since starting treatment in 2003, Ken takes three injections a week of Rebif to manage his disease.

Even though the drug costs between $25,000 and $31,000 a year, his health insurer, United Health Care, requires a minimal co-payment for a monthly supply. If his medication was subject to specialty tiering coinsurance it would cost his family between $700 and $800 a month. Both Kenneth and his wife are gainfully employed, and would do their best to find a way to afford any increased costs for his medication. There really is little choice, as the medication is essential to manage this chronic disease. But, doing so would make a dent in his family income, and he would have to consider what sacrifices to make.

Kenneth knows other people with MS who, due to their economic situations, have been forced to make the very difficult decisions to either cut back or forego their treatment. This legislation is important to Ken because, "as MS patients who must be on medication we are trapped. We have to take medication to manage the disease but economically this can become a burden. A change in the current situation would add to that burden."

Placing pharmaceutical drugs on specialty tiers increases out-of-pocket costs for patients and has negative impacts on health outcomes and health care costs overall.

When severely ill people face financial problems because of their medical bills they are four to five times as likely to delay or avoid medical care as compared to people not facing such financial challenges[10]. Numerous studies demonstrate that high out-of-pocket costs lead to decreases in adherence to medical treatment, especially for lower-income groups who are more likely to experience chronic illness[11]. This decreased adherence to medical treatments ultimately leads to increased medical costs for employers and insurers as patients forgoing treatment end up with worsening health and in need of emergency care and other high cost treatments[12].

10 Ibid.
11 Ibid.
12 Ibid.

Other Strategies to Contain Consumer Costs

Researchers examining the impact of cost sharing insurance strategies on health outcomes and health care costs find that coinsurance does little to reduce overall health care spending and has negative impacts on patients' treatment compliance and health outcomes. Instead they suggest focusing on managing drug utilization so that high cost specialty treatments are only administered to people who will benefit most from them and capping annual out-of-pocket costs. In practice managing drug utilization means minimizing off-label uses and uses not supported by peer-reviewed studies. Utilization management may also require prior authorization and/or step therapies to ensure that specialty drugs are not used when lower cost and equally effective treatments are available. Other utilization management strategies aim to reduce waste and streamline treatment delivery and patient monitoring[1].

In addition to utilization management strategies employers, pharmacy benefit managers, and states have taken other steps to address rising pharmaceutical drug costs. Cost containment strategies used by pharmacy benefit managers include physician counter-detailing and direct-to-consumer counter-detailing whereby doctors and patients are encouraged to consider generic alternatives and lower-cost treatments when they are available[2]. Given that right now there are no generic alternatives for biologic treatments this is not likely to be an effective strategy. But as they become available in the future this may be a useful alternative to specialty tiering. This is important to consider when weighing the utility of specialty tiering and counter-detailing cost containment strategies. When patients are discouraged from using high-cost drugs for which there are low cost alternatives it is unlikely that there will be adverse affects to health. However when no such alternatives exist, as is the case with many specialty drugs, there is a greater risk of adversely affecting health outcomes for patients who cannot afford the high costs of these medications[3].

Research aimed at containing medical costs for employers suggests a combined strategy of using co-insurance to share the costs of specialty drugs and capping out-of-pocket costs. By using a 20% coinsurance rate with a $1,000 out-of-pocket limit, employer costs remained the same with employee costs increasing very slightly and most importantly with health plans adequately protecting workers with the most expensive illnesses to treat from these medical expenses[4]. Workers that are high cost users of health care plan benefits tend to try to stay employed and enrolled in their current insurance plans as long as possible for fear of difficulty finding other employment and health coverage with their preexisting conditions. Thus employers and insurers have an interest in ensuring that these individuals receive the treatments they need to maintain their health and effectiveness on the job[5].

1 Opdycke, RC, Ellis JJ, Kirking DM. Specialty drug whitepaper. Center for medication use policy and economics, University of Michigan College of Pharmacy; 2007.
2 Malkin J, Goldman D, Joyce G. 2004. The changing face of pharmacy benefit design. Health Affairs 23(1): 194-199.
3 Ibid.
4 Hodge B, Martin M. 2008. Benefit design critical to protecting out-of-pocket costs for employees. American Journal of Managed Care. 14(8S): 246-251.
5 Wiley V, Kopenski F, Lawless G. 2008. Beyond the myths: Finding benefit design solutions that address the true costs of high healthcare

The National Congress of State Legislatures' 2008 and 2009 annual reports on prescription drug state legislation highlight measure that states are taking to contain pharmaceutical drug costs[67]. Examples of these strategies include commissioning cost comparison studies of orally administered and injection chemotherapy drugs (NM 2009), providing funds to subsidize pharmaceutical drugs costs to seniors (MA 2009), requiring greater transparency of drug formularies (TX 2009), investigating the potential cost savings from pooled purchasing of common preferred drugs (IA 2008), identifying opportunities for providing drugs through section 340B (ME 2008), mandating education for prescribers about cost effective utilization of prescription drugs and banning pharmaceutical company gifts to doctors (MA 2008), and requiring health insurance companies to have open pharmacy networks (WA 2008).

In contrast to the pharmaceutical drug cost containment strategies described above, A.8278-b/S.5000-b is an immediate and cost neutral route to keeping specialty drugs affordable for New Yorkers. Without A.8278-b/S.5000-b New Yorkers will see specialty tiering in their health plans and experience the same negative outcomes of this insurance practice that have been observed in other states and among New York's Medicare Part D users. Patients will put off or limit their medical treatment because of concerns about cost. The adverse effects of this will fall most heavily on low and moderate income New Yorkers for whom prescription drug costs will be prohibitive even with insurance. This will exacerbate income-based health disparities and limit the ability technological advances in the treatment of chronic and life threatening diseases have to realize their potential to improve public health. In addition, rising medical costs for consumers and employers will have negative secondary impacts on households and the state economy.

The recent passage of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act will help 32 million Americans gain access to health insurance but will have little impact on people in New York State who are currently insured. As this federal legislation helps more people secure health insurance it becomes increasingly important for states to regulate insurance practices to ensure that they adequately protect people from exorbitant out-of-pocket medical costs. When people with chronic conditions gain health insurance and access to needed medications they may be able to reenter the workforce and contribute to the state economy. In contrast, forcing people to choose between working but still being unable to afford their medications and basic living expenses, or not working and relying on publicly funded programs to cover their health care needs is socially unconscionable and costly to the state.

Relevant to this discussion of specialty tier formularies in New York State, the national health reform legislation establishes a regulatory pathway for bringing generic biologic medications (called biosimilars) to market more quickly. As biosimilars become available they will significantly reduce treatment costs for patients, employers, and insurance companies. Passing A.8278-b/S.5000-b will maintain the status quo in New York and prevent biologic drugs being placed out of reach because of their costs before biosimilars can make lower cost treatment alternatives available for the almost 4 million New Yorkers that could benefit from such medical advances.

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use. American Journal of Managed Care. 14(8S): 252-263.

6 National Congress of State Legislatures. Prescription drug 2009 Enacted state laws.

7 National Congress of State Legislatures. 2008 Prescription Drug State Legislation.

Support for A.8278-b/S.5000-b

National opinion polls demostrate broad public support for using regulation to protect consumers from escalating drug prices. For example, a recent representative national survey shows that most Americans find the high cost of prescription drugs problematic and support increasing legislation that regulates drug costs.

Key findings include[1]:

• 79% of Americans say that the cost of prescription drugs is unreasonable.

• 58% of Americans do not trust pharmaceutical companies to price their drugs fairly.

• 64% of Americans say that there is not enough regulation when it comes to limiting the price of prescription drugs.

• When presented with the argument that regulating drug prices could lead to less research and development on new drugs, 48% of Americans say there should still be more regulation in this area.

Numerous national and state organizations support this legislation, including:

Cystic Fibrosis Foundation

Crohn's and Colitis Foundation of America

New York State Hemophilia Advocacy Coalition

The Mary M. Gooley Hemophilia Center

Lupus Agencies of New York State

National Psoriasis Foundation

New York Multiple Sclerosis Coalition Action Network

American Autoimmune Related Diseases Association

Sjogren's Syndrome Foundation

Scleroderma Foundation

The Arthritis Foundation

New York State Rheumatology Society

National Kidney Foundation

Leukemia and Lymphoma Society

New York State Breast Cancer Network

New Yorkers for Accessible Health Coverage

The League of Women Voters

There is also broad support for A.8278-b/S.5000-b within the New York State legislature. The bill is sponsored by Assembly Member Kellner and co-sponsored by Assembly Members Gottfried, Reilly, Koon, Jacobs, Cymbrowitz, Cook, Lancman, Rosenthal, Boyland, Espaillat, Gunther, Benedetto, Jaffee, Meng, Cahill, Lopez, Galef, Hooper, Spano, Castro, Burling, Glick, McDonough, McEneny, Perry, Schimel, Sweeney, Thiele, Titone, and Weisenberg.

In the Senate the bill is sponsored by Senator Duane and co-sponsored by Senators Espada, Krueger, Monserrate, Montgomery, Vlesky, Dilan, Perkins, and Thompson.

In addition, the New York State Department of Insurance has reviewed the bill and raised no opposition.

1 USA Today, Kaiser Family Foundation, and the Harvard School of Public Health. The public on prescription drugs and pharmaceutical companies. 2008 March.

Robin D'Andrea lives in Riverhead, Long Island with her husband and two-year-old daughter. She knows first hand how devastating co-insurance on specialty drugs can be. Robin has been living with multiple sclerosis for 14 years and takes Copaxone daily to slow the progression of the disease. Copaxone is a biologic drug that is injected and costs about $2,800 a month without insurance.

For most of these 14 years, Robin's medication was covered by her health insurance and she paid a $25 monthly co-payment. However, when her husband's employer began purchasing employee health coverage through Blue Cross Blue Shield of Alabama, Robin's medication was subject to a 30% co-insurance rate. Because the employer is based outside of New York, our insurance regulations do not protect Robin's family. The switch meant that her Copaxone now would cost $789 a month.

Robin was forced to stop taking her medication for two years until she was able to find a federal program to subsidize its cost. Even still, program eligibility is based on income and Robin's husband had to take a pay cut for their family to qualify. In those two years without medication, Robin's multiple sclerosis progressed rapidly. She now has pain and weakness in her legs and suffered a temporary lost her vision. Before this interruption to her treatment Robin had not experienced these symptoms.

Robin stresses that without health insurance and the federal subsidy there is no way her family could afford their basic living expenses and her medication. "This legislation is important because people are being put in a position where we have to choose between our healthcare and life expenses like food and housing," says Robin. Without MS medications, patients "will end up with life long disabilities that society will end up paying for anyway. It makes more sense to keep these drugs affordable."

Robin D'Andrea
Long Isand, NY

Myths & Realities

Some employers, health insurance companies, and pharmaceutical benefit managers oppose this legislation. The next section of this report examines the myths opponents have mobilized and responds to their underlying arguments.

Myth: The bill is unconstitutional because it regulates self-insured ERISA plans.

Reality: Self-insured plans or other plans subject to ERISA will not be affected by this bill.

Myth: This bill limits the ability of insurers to set up lower-cost tiers.

Reality: To date, the New York State Insurance Department has never received applications for lower-cost tiers. If in the future insurance companies wish to create lower-cost tiers state policy could be amended to allow them to do so.

Myth: This bill will limit health plan innovation.

Reality: Here 'innovation' means allowing insurance companies to shift the burden of escalating drug costs to consumers so that they can continue to improve their profitability. Health insurance companies are making record dividends despite the current financial climate. Covering these medications has clearly not threatened their solvency and profitability.

Myth: Legislation that may restrict profits on specialty drugs will reduce incentives for pharmaceutical research and development.

Reality: This legislation does not restrict the profitability of pharmaceutical drug companies. Rather, it restricts the ability of insurers and drug providers to use some relatively new cost containment tools that have been shown to negatively impact treatment compliance and health outcomes for people with life threatening conditions and chronic diseases.

Myth: Specialty tiers have successfully demonstrated reduction in costs to insurers and drug providers and these savings are passed on to consumers in the form of lower deductibles. Patients who need more expensive medications should pay more for them.

Reality: The purpose of health insurance is to redistribute the financial burden of risk so that when illnesses present themselves they can be treated in a humane and cost effective manner. There is strong evidence that higher medication costs negatively impact patient compliance, deteriorate health outcomes, and lead to increased health care spending in the long run. There are also broad economic impacts when patients spend hundreds or thousands of dollars a month on mediations. These include mortgage delinquency, housing insecurity, and food insecurity.

Myth: There are many health insurance and pharmaceutical drug plans available. Consumers should bear the responsibility of understanding the terms of these plans and select one that meets their needs.

Reality: People can't be expected to predict when they will present symptoms for and become diagnosed with chronic and life threatening diseases like multiple sclerosis and cancer. By relying on consumers to educate themselves and select plans that best cover the medications they need, policymakers will enable selection effects to have negative financial implications for insurers and drug providers that protect their beneficiaries from the high cost of specialty drugs. If most of the patients who need specialty drugs buy into the few plans that cover them, these plans will likely go out of business.

Conclusion

At present New York State does not allow specialty tiering in the prescription drug formularies of private health insurance providers. Enacting A.8278-b/S.5000-b will preserve the status quo and prohibit health insurance plans from adopting specialty tier and cost sharing formularies that put life saving treatments financially out of reach for people with serious diseases. This bill is fiscally prudent in contrast to other legislative pharmaceutical cost containment measures such as capping out-of-pocket medical costs or subsidizing specialty drugs.

In New York there is broad support for this legislation within the state government and from advocacy groups. This legislation builds on New York's tradition of recognizing that there are costs to people's lives and the economy of the state associated with not providing access to health care. Programs like Family Health Plus and Healthy New York have positioned New York as a national leader in providing access to health care for those who are working but can't afford health insurance. Almost four million New Yorkers and their loved ones would be protected from the immediate and secondary impacts of sudden, unpredictable, and unsustainable medical costs. Most of those that will benefit from this bill are working and insured through their employers. This bill enables people with life threatening and chronic diseases to afford the medications that help keep them healthy enough to work, contribute to their families, and the state. It does so without any additional cost the state and sets an example for other states currently considering specialty tiering.

Glossary

Biologic treatments: Therapeutic treatments produced through recombinant DNA technology or other biological processes.

Biosimilar treatments: Generic alternatives to biologic treatments. Unlike generic equivalents to small molecular treatments that can be approved based on bioequivalence data, biosimilars are required to have their clinical and manufacturing processes reviewed and approved, slowing their entry into the pharmaceutical marketplace.

Coinsurance: A cost sharing insurance strategy where beneficiaries pay a percentage of the cost of a medication.

Co-payment: A cost sharing strategy where beneficiaries pay a flat fee for a medication.

Deductible: The portion of an insurance claim that is not covered by the insurance provider.

Drug formulary: A list of prescription drugs that an insurance policy or drug plan will pay for. The formulary's purpose is to contain costs by specifying what drugs a plan will pay for and sometimes by using cost incentives to encourage patients and doctors to choose less expensive drug treatments.

ERISA: The Employee Retirement Income Support Act of 1974. This federal law sets minimum standards for most voluntarily established pension and health plans to protect individuals covered by these plans.

Medicare Part D: A federal program subsidizing the cost of prescription drugs for Medicare beneficiaries but administered through private health insurance companies. Thus drug formularies under Medicare Part D vary within and between states depending on the terms set by the company administering the plan. Because Medicare Part D is a federal drug plan it is not restricted state insurance regulations although states. In New York State the Elderly Pharmaceutical Insurance Coverage (EPIC) Program helps seniors with Medicare Part D cover the out-of-pocket costs for their prescription drugs.

Specialty drug: Injectable, infused, oral, or inhaled medications that treat or slow the progression of life threatening diseases and chronic conditions such as HIV/AIDS, cancer, and multiple sclerosis. Because many of these drugs are biologic treatments and/or must be administered or monitored by a physician they carry very high costs.

Tiers: Drug formularies usually group medications in to tiers that specify out-of-pocket costs to patients. Typically formularies have three tiers where the first tier has the lowest out-of-pocket cost and includes generic drugs, a second tier may specify a higher cost for preferred brand name drugs, and a third tier will apply the highest out-of-pocket cost to brand name drugs that are not preferred because they have lower cost treatments that are equally effective or are still considered to be experimental.