

Specialty-Tier Prescription Drugs

Report to the General Assembly

Prepared by the Delaware Health Care Commission

March 15, 2012

Introduction

On September 14, 2011, Governor Jack Markell signed Senate Bill 137 (“SB 137”) directing the Delaware Health Care Commission to “conduct a study for specialty-tier prescription drugs to determine the impact on access and patient care”. SB 137 required the Commission to report its findings to the General Assembly by March 15, 2012.

The Commission convened public meetings in December 2011 and February 2012 for the purpose of gathering information related to the use of specialty-tier drug pricing. In addition to information gathered during public meetings, the Commission gathered information related to prescription drug costs approaches taken at the state and federal level to address this national issue, and actual and potential impact on patients, health care providers, employers and other stakeholders.

Background

In Delaware and in the nation, health care costs are rising. Health care spending in the U.S. has increased by an average of 6.8% annually over the last decade, reaching \$2.6 trillion in 2010, at 17.9% of the nation’s Gross Domestic Product (GDP), and projected to reach \$2.7 trillion in 2011. The State of Delaware now spends \$1.2 billion in state and federal taxpayer dollars on health care each year. Across all payers, health care expenditures for Delawareans reached \$7.5 billion in 2009. In 2009 and 2010, health care expenditures grew at a rate of 3.8% and 3.9% respectively, the two slowest rates in the 51 year history of the National Health Expenditure Accounts. Even an annual increase of 3.9% per year, however, would translate into total health care expenditures in Delaware of \$8.5 billion in 2012.

The cost of health care is much more than a single number. The cost of health care nationally and in Delaware is the complex result of actions, reactions and sometimes inaction in a system designed to pay for services rather than improved outcomes and better health for Delawareans. Our health care system is at a critical juncture with escalating costs, disappointing outcomes and increasing safety concerns, as well as demographic, population health and economic shifts that place an ever-increasing burden on the system itself and the taxpayers, businesses and public institutions that support it.

While health care cost drivers are very complex, we are making significant progress in examining this area. For example, we know that the cost of preventable lifestyle-related illness in Delaware is more than \$900 million each year and we know that detecting many cancers at an earlier stage improves survival and significantly reduces cost of care. We also know that Delaware’s investment in the health care technology infrastructure provided by the Delaware Health Information Network (“DHIN”) is already reducing the incidence of high cost tests and will provide a critical foundation for new health care delivery models such as patient centered medical homes and accountable care organizations. These models can support higher quality, better coordinated care, improved outcomes and reduced costs.

One cost which several states have recently begun to address is that of prescription drugs. The cost of prescription medications is a critical driver of overall health care costs with pharmaceuticals accounting for 10.0% of the total U.S. health care expenditures. As with the overall cost of health care, the cost of prescription drugs is complex and related to the larger health care system. For example, there are methods to reduce the cost of medications such as rebates paid by drug companies to health insurers. These rebates are not typically included in estimates of prescription drug costs. Nationally, Medicaid spending for brand-name drugs actually increased at a lower rate than the inflation rate from 2005-2009 when rebates were included in cost calculations.

When affordable, available and used appropriately, prescription drugs, such as those to manage diabetes, have the potential to improve quality and length of life and productivity as well as to reduce use of other components of the health care system. Recently, actions have been taken in several states to address the affordability of particularly

expensive prescription drugs known as “specialty” drugs. The impact of those actions on cost of and access to specific medications is the subject of this report.

What are specialty-tier medications?

Specialty-tier medications are high cost drugs for which patients may be required by their insurance plan to pay a proportion of the total charge for the drug, referred to as co-insurance, rather than fixed amount, referred to as a co-payment. Insurance plans can include this requirement in the medical and/or pharmacy benefit. These medications generally target very specific medical conditions and may require special handling or application. Each insurance plan develops its own list of specialty-tier drugs. Changes to that list can occur at any point in the plan year. This means that rather than pay a \$10 co-pay to fill a prescription, a patient is instead required to pay a percent, such as 25%, of the total cost of the prescription. It should be noted that co-insurance is typically calculated based on the amount drug companies charge. Because health plans routinely negotiate with drug companies to receive rebates for individual drugs, the actual cost the insurer pays for the drug may be significantly lower than the amount charged initially. As a result, patients may pay a significantly higher percentage of the actual cost of a drug.

Why are specialty tiers used?

The primary purpose of specialty tiers is to share the cost of particularly expensive drugs between patients and health insurance plans. Other approaches to controlling and shifting cost include step therapy, which require patients to first try similar but less expensive drugs, and prior authorization, which requires health care providers to justify the medical necessity of these more expensive drugs.

Is the use of specialty tiers an increasing trend?

The increasing trend is the ever-increasing pipeline of the prescription drugs and biologic agents that have a strong potential to fall into a specialty-tier category due to their high cost. The number of drugs being placed on the Medicare Part D specialty tier has increased from 100 in 2006 to 160 in 2008. Specialty-tier drugs were once reserved for patients with rare diseases, but now are often used to treat chronic conditions such as multiple sclerosis, rheumatoid arthritis, and certain cancers. Based on the discussions at the hearings held, it is a fair assumption that we will see an ever increasing array of high cost prescription treatment options, accompanied by all the benefits as well as the cost considerations at issue in this report.

What is the impact when specialty tiers are used?

When specialty-tier pricing is used, consumers absorb a larger proportion of the cost of prescription drugs in the specialty category. The impact of this increase varies depending on the amount of the increase, whether and to what extent use of the drugs eliminates other health care costs (out of pocket costs for the patient, use of other components of the health care system, etc.), and the patient’s financial status. Affordability is a critical determinant of access to health care. When medical care, including prescription medications, is not affordable, patients cannot and do not use it. Cost-related medication non-adherence is well documented in patients with a variety of health conditions including end-stage renal disease, cancer, depression, arthritis and other illnesses. Consequences of lack of adherence to medication regimens are also well documented and vary depending on the health condition. In general, consequences include poorly managed disease and increased complications. For some conditions including multiple sclerosis, these medications most often stop or significantly delay the progression of the disease. For example, they are absolutely essential for salvaging any quality of life for patients with multiple sclerosis. If they become inaccessible due to cost issues, research indicates that patients' ability to function in all areas of life is severely impacted. In certain health conditions (e.g. hemophilia, HIV/AIDS, and cancer), inability to access medications can be life threatening.

A very real impact of specialty tiers is the potential to place certain high-cost prescription drugs out of the reach of some or even much of the population. One example provided was for a hemophilia drug at the cost of \$30,000 per month. With the institution of a co-pay in the 25% range, without a cap, many families would be faced with very significant financial hardship or the simple inability to afford to take the drug. Beyond the individual impact on consumers, potential effects of specialty tiers on the health care system as a whole include increases in Medicaid enrollment as families look to public assistance in the absence of other means of accessing care.

Another consideration is the potential impact on health insurance premiums. Given the potential for significant increase in utilization and prevalence of high cost medications, in the absence of increased cost shifting via mechanisms such as co-insurance, or reductions in other health care spending, health claims may increase and result in higher health insurance premiums for consumers. Under the Medical Loss Ratio requirements in the Affordable Care Act, insurance companies in the individual and small group markets must spend at least 80% of the premium dollars they collect on medical care and quality improvement activities. Insurance companies in the large group market must spend at least 85% of premium dollars in the same areas. If there is a net increase in expenses, there is a risk that premiums will be affected as well.

Specific positive and negative consequences of the use of specialty-tier pricing vary by stakeholder group and include:

Specialty-Tier Pricing for Prescription Drugs		
Stakeholder Group	Benefits	Concerns
Health care consumer	May help to control the cost of health care premiums	Purchasers of health insurance (especially those purchasing individual coverage) disproportionately affected by higher premiums and co-insurance
Patient		Restricts access to medications for those unable to pay, disproportionately impacts the sickest patients and leads to worsening illnesses and non-compliance
		Co-insurance is based on the retail cost of drugs, not on actual cost to insurers after rebates. Patients may pay a significantly larger portion of the actual cost of the drug than the co-insurance requirement.
Health care provider	Helps providers include the issue of cost of care in treatment planning discussions with patients	Cost of care discussion competes with messages patients receive in other venues (media, friends, relatives, etc.) about treatment choices
		Complicates treatment planning and limits provider's use of medical judgment to develop an individualized treatment plan

Employer	Medication costs are shared with employees	Lost productivity, higher health care and disability insurance costs as employees' health conditions go unmanaged
Pharmaceutical manufacturer		Lower utilization of prescription drugs decreases revenue
		Inconsistent use of medications complicates analysis of efficacy
Health insurer	Decreased share of costs results in increased revenue.	Unhealthy insured population can result in higher costs (NOTE: MLR requirements set by ACA will negate any impact on insurers)
Public policy	Help health care consumers understand cost of health care	Contrary to principle of equitable sharing of risk and cost
		May disproportionately affect small states
	Allows for preserving and prioritizing resources to help provide specialty tier drugs for those who are most in need of them, where clinically appropriate	Disproportionately affects people with conditions that are typically treated with specialty products, such as rheumatoid arthritis, cancer, hemophilia, HIV/AIDS, or multiple sclerosis. Often, patients with these conditions have no lower-cost options available to treat their disease and may be least able to afford their prescription drug under a co-insurance model
Public health		Limits access to health care for vulnerable and at-risk populations
		Lack of treatment/management for communicable diseases results in increased transmission and higher infectivity (e.g., HIV/AIDS)

Recommendations

The Delaware Health Care Commission is acutely aware of the need to assure access to medications. Delaware cannot allow a situation in which life-saving medications are out of reach for patients in need simply because the drugs are too expensive. The Commission also recognizes that continued increases in health care costs are unsustainable and supports the use of tools to share and manage those costs, as well as incentives to encourage use of cost-effective, well-coordinated preventive health and disease management services. These efforts are critical to reducing the costs that many agree are preventable, and maintaining the capacity to provide critical access to needed drugs.

In order to assure access to prescription drugs while retaining tiered pricing as a tool to encourage healthy behaviors and the most cost-effective use of health care resources, the Delaware Health Care Commission recommends that use of specialty tiers using co-insurance to control costs should only occur when:

- Therapeutically similar drugs are available in lower cost tiers
- Specific measures to assure affordability are in place
- Processes for designating specialty-tier drugs are uniform and transparent to all stakeholder groups, including providing appropriate notice

Potential options to accomplish these recommendations include:

- Legislation restricting the use of co-insurance payment structures for specialty medications.
- Implementation of tiered pricing combined with caps for limiting out of pocket expenses. The inpatient payment structure may be used as a model.
- Creation, implementation, dissemination and ongoing evaluation of disease-specific uniform treatment guidelines/treatment pathways.
- Implementation of statewide programs to share cost and risk (e.g. use of captives or reinsurance programs to bear the high cost risks).

The Delaware Health Care Commission is available to continue to research and explore potential options and recommendations.

During the process of gathering information and developing recommendations related to specialty-tier pricing, the Commission heard a variety of issues and concerns related to the availability, affordability and quality of prescription drugs in general. These include:

- Special issues related to children including:
 - Health conditions and treatments unique to children.
 - The significantly larger proportion of children covered by public insurance programs as compared to the adult population.
 - Economics of developing and marketing drugs for children.
- Factors influencing prescription drug pricing, and actual costs from research and development through consumer use and demand including use of rebates.

- Drug shortages
- “Orphan” drugs, defined as products that treat rare diseases or conditions and affect a very small number of individuals.

While these issues are not directly related to this report, the Commission recognizes that these factors have a significant “upstream” impact on cost, access and quality of health care.

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- | | |
|-------------------------------|---|
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Letters:

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Hamilton, Deborah – Cozen O'Connor
Pando, MD, FACP, Jose Antonio – Private Practice Physician

Rogers, Ann - National Hemophilia Foundation, Delaware Valley Chapter

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