



Legislative Budget and Finance Committee

A JOINT COMMITTEE OF THE PENNSYLVANIA GENERAL ASSEMBLY

Offices: Room 400 Finance Building, 613 North Street, Harrisburg

Mailing Address: P.O. Box 8737, Harrisburg, PA 17105-8737

Tel: (717) 783-1600 • Fax: (717) 787-5487 • Web: <http://lbfc.legis.state.pa.us>

SENATORS

ROBERT B. MENSCH

Chairman

JAMES R. BREWSTER

Vice Chairman

DOMINIC PILEGGI

CHRISTINE TARTAGLIONE

KIM WARD

JOHN N. WOZNIAK

Prescription Drug Specialty Tiers in Pennsylvania

REPRESENTATIVES

ROBERT W. GODSHALL

Secretary

PHYLLIS MUNDY

Treasurer

STEPHEN E. BARRAR

JIM CHRISTIANA

DWIGHT EVANS

JAKE WHEATLEY

Conducted Pursuant to
SR 2013-70 and HR 2013-348

EXECUTIVE DIRECTOR

PHILIP R. DURGIN

September 2014

Table of Contents

	<u>Page</u>
Summary and Recommendations	S-1
I. Introduction	1
II. Findings	5
A. Health Insurance and Prescription Drug Coverage Nationwide and in Pennsylvania.....	5
B. Specialty Drug Tiers Have Increasingly Become Part of Prescription Drug Benefit Designs.....	13
C. Specialty Drugs Typically Are Costly to Bring to Market, Produce, and Distribute, and Typically Have High Cost-Sharing	19
D. The High Cost of Drugs in Specialty Tiers and Their Higher Cost- Sharing Requirements Can Adversely Impact Those in Need of Such Life Sustaining Medications	26
E. Almost Half of Those Responding to the LB&FC’s Survey of Consumers Reported Having Insurance Without a Cap on Their Prescription Drug Out-of-Pocket Cost Sharing	37
F. For Those With Limited Income, Certain Public and Private Programs Provide Help With High Specialty Drug Costs.....	41
1. Medicare Part D Program’s Assistance for Those With Low Income .	41
2. Pennsylvania’s Pharmaceutical Assistance Programs and the Medicare “Wrap Around” Program.....	47
3. Medical Assistance in Pennsylvania	50
4. Special Pharmaceutical Benefit Program (SPBP)—Mental Health	54
5. Special Pharmaceutical Benefit Program—HIV/AIDS.....	54
6. Drug Manufacturer Patient Assistance Programs	55
7. The Pennsylvania PACE Patient Assistance Program Clearinghouse (PA-PAP)	57
8. Pennsylvania Prescription Price Finder	60
G. Federal and State Government Proposals and Other Recommended Efforts to Assure Access to Specialty Tier Drugs.....	61
III. Appendices	73
A. Senate Resolution 2013-70	74
B. House Resolution 2013-348	75
C. Glossary of Terms	76

**Table of Contents
(Continued)**

	<u>Page</u>
D. Questionnaire for Major Health Insurers	79
E. Questionnaire for Specialty Drug Consumers in Pennsylvania	83
F. Associations Assisting With Outreach to Consumers of Specialty Tier Drugs	91

Summary and Recommendations

Senate Resolution 2013-70 and House Resolution 2013-348 directed the Legislative Budget & Finance Committee to study prescription drug “specialty tiers” to determine their impact on access and patient care. Drugs on specialty tiers are often used to treat chronic or life-threatening conditions such as hemophilia, multiple sclerosis, hepatitis, cancer, and certain rare conditions. They are often biologics,¹ rather than traditional chemical drugs. Because such drugs are manufactured in living organisms with high sensitivity to change in the manufacturing process, exact replication is almost impossible, and they have no generic equivalents.

Certain specialty drugs may be covered under a beneficiary’s medical insurance benefit, or under a separate outpatient prescription drug benefit. According to Express Scripts’ drug trend report in 2010 and a Milliman analysis based on 2009 and 2010 claims data, about half of all specialty drug spending occurs under a health plan’s medical benefit and the other half under the outpatient prescription drug benefit.

Specialty drugs are also very costly. Often they require the beneficiary to pay a percentage of the drug’s cost (i.e., a coinsurance), rather than a fixed dollar amount (i.e., copayment) for the drug, as a result of their placement on a prescription drug plan’s drug formulary² specialty tier. Typical out-of-pocket costs for a specialty drug with 20 percent cost sharing is in the range of \$1,500 to \$3,000 per prescription, according to one major pharmacy benefit manager.³

We found:

Over half (52 percent) of all Pennsylvanians obtained health care benefits⁴ through their employers in 2012. The remainder receive coverage through Medicare (15 percent), Medicaid (15 percent), other private insurance (6 percent), or are uninsured (11 percent).

¹ Includes products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Appendix C provides a glossary for terms used in this report.

² Formularies are lists of drugs covered by a prescription drug plan. Formularies may group drugs based on their status (e.g., preferred and non-preferred brands, generics, specialty drug, injectable drug, etc.) and may provide for different cost-sharing based on the drug’s formulary status.

³ Pharmacy benefit managers (PBMs) emerged in the late 1970s to manage increasing drug costs. They provide services such as electronic claims processing, formulary development and management, benefit design administration, pharmacy networks, generic substitution, patient services, etc. They adjudicate approximately 80 percent of all prescriptions processed today, with three large PBMs handling around 65 percent of outpatient prescription volume. PBMs are not regulated in Pennsylvania or most states. They provide services to Fortune 500 employers and public purchasers, including Medicare Part D and the Federal Employees Health Benefits Program.

⁴ Health care benefits may include medical, prescription drug, vision, and dental benefits.

Sixty percent of Pennsylvania private sector employers offer health benefit coverage for their employees, with many such plans exempt from state insurance mandates due to the federal Employee Retirement Income Security Act (ERISA).

- Among Pennsylvania private firms offering health benefit coverage overall about one-third self-insure.⁵ Nationwide, when public and private-not-for-profit firms are taken into account, over 60 percent of covered workers receive health benefit coverage through employer self-insured plans.
- Self-insured employers assume risk for the cost of their health plan's claims, are responsible for payment of such claims, typically contract with one or more third-party administrators or insurers to administer services offered through their plans, and are exempt from state insurance laws, including requirements for mandated benefits, premium taxes, and certain consumer protection regulations as a result of ERISA.⁶

Nationwide, nearly all (98 percent) workers in employer-sponsored health plans have a prescription drug benefit, according to the Kaiser Family Foundation's 2013 Employer Health Benefit Survey.

Prescription drug formularies with differing cost sharing tiers have been in use since the mid-1990s, though "specialty drug tiers" only started to proliferate with the introduction of Medicare's voluntary outpatient prescription drug program (Medicare Part D) in 2006. The Medicare Part D program permits (but does not require) Medicare plans to use specialty tiers in their drug formularies. The specialty tiers include drugs with negotiated prices that exceed a Medicare established dollar per month amount (currently \$600).

- In 2006, about two-thirds (63 percent) of all Medicare Part D plans included a specialty tier. By 2013, almost all Medicare Part D (93 percent) and Medicare Advantage prescription drug plans (97.9 percent) had specialty tiers.
- A low percentage (about 12 percent in CY 2011 through CY 2013) of the drugs eligible to be placed on formulary specialty tiers, however, are actually placed on such tiers, and the overall proportion of Medicare beneficiaries that use specialty drugs is very low (under 2 percent in CYs 2011, 2012, and 2013).

Specialty drug tiers are not as common with employer health benefit plans as they are with Medicare Part D plans. Nonetheless, they have been on the rise. In 2004, only 3 percent of workers were in plans with four or more formulary tiers;

⁵ This includes about 15 percent of small private firms (with less than 50 employees) and about two-thirds of large private firms.

⁶ Throughout this report, ERISA refers to the federal Employee Retirement Income Security Act, 29 U.S.C. §1001 et seq.

by 2013, 23 percent were in such plans. Nationwide, covered workers typically had 32 coinsurance rates for drugs on specialty tiers, or flat copayment rates of \$80 in 2013.

A covered worker is more likely to have to pay a portion of the cost of a higher tier drug than for drugs on other lower tiers. Nationwide, in 2013, only 9 percent of covered workers paid a percentage of a drug's cost (i.e., coinsurance) for generic drugs, 21 percent for preferred drugs, and 25 percent for non-preferred drugs. This compares with 48 percent of covered workers paying a percentage of a drug's costs for drugs on higher tiers, such as specialty tiers.

Most covered employees are in plans with general annual out-of-pocket maximums;⁷ but the employee's out-of-pocket costs for prescription drugs is not always counted toward such caps. According to a 2013 national sample of employer health benefit plans,

- 84 percent of those in PPO⁸ plans that offer prescription drug coverage were in plans that did not count prescription drug cost sharing toward the annual out-of-pocket maximum,
- 71 percent of those in HMO⁹ plans were in plans that did not count prescription drug cost sharing toward the annual out-of-pocket maximum,
- 66 percent of those in POS plans¹⁰ were in plans that did not count prescription drug cost sharing toward the annual out-of-pocket maximum, and
- 60 percent of those in HDHP/SO¹¹ were in plans that did not count prescription drug cost sharing toward the annual out-of-pocket maximum.

⁷ An out-of-pocket maximum is the total cost a participant can incur each year for services covered under the out-of-pocket maximum.

⁸ A preferred provider organization (PPO) plan is an indemnity plan where coverage is provided to participants through a network of selected health care providers. The enrollee may go outside the network, but would incur larger costs in the form of higher deductibles, higher coinsurance rates, or non-discounted charges from the provider.

⁹ A health maintenance organization (HMO) is a health care system that assumes the financial risk (both insurance and service risk) associated with providing comprehensive medical services and the responsibility for the delivery in a particular geographic area to HMO members, usually in return for a fixed, prepaid fee.

¹⁰ A point of service plan (POS) is an HMO/PPO hybrid. POS plans resemble HMOs for in-network services. Services received outside of the network are usually reimbursed in a manner similar to conventional indemnity plans.

¹¹ High Deductible Health Plans with Savings Options (HDHP/SO) are a type of consumer-directed health plan. Generally, these plans have low standard insurance premiums but very high deductibles. With the Health Savings Account Option, the beneficiary can contribute tax-free up to \$3,000 for an individual and \$6,250 for a family. Funds left over at the end of the year are rolled over the next year. If an employee changes jobs, the Health Savings account remains with the employee. Some employers may make tax-free contributions to their employee's Health Savings Account.

Almost half (47 percent) of those responding to the LB&FC's survey of consumers using specialty drugs reported their insurance coverage did not limit their annual out-of-pocket prescription drug costs. Only 12 percent reported their drug costs were capped on a per prescription basis.

From national studies, we know high cost sharing for specialty drugs does not reduce unnecessary specialty drug use, but rather shifts the high cost of such drugs onto patients, reduces their adherence to treatment, and creates serious economic hardships.

- Typically, when copayments are doubled for traditional pharmaceuticals, overall spending falls by 30 to 50 percent. When copayments for specialty drugs to treat rheumatoid arthritis are doubled, however, overall spending for the drug declines by only 21 percent, and for cancer drugs, the decline is only 1 percent
- Ten percent of those for whom oral cancer drugs were prescribed did not have the prescription filled within 90 days.
- When cost sharing for an oral cancer drug prescription is greater than \$500, the patient is four times more likely to abandon oral cancer therapy than when cost sharing is \$100 or less.
- When cost sharing for drugs to treat multiple sclerosis is greater than \$200, the patient is 25 percent more likely to abandon the multiple sclerosis drug than when cost sharing is \$100 or less.
- When cost sharing for tumor necrosis factor inhibitors (used to treat various inflammatory diseases) is more than \$500, the patient is 25 percent more likely to abandon such medications than when cost sharing is \$100 or less.
- Patients accounting for the top 20 percent of a commercially insured plans' costs typically expend 5 percent or more of an average household's income on out-of-pocket costs. Elderly patients accounting for the top 20 percent of plans' costs, expend about 20 percent of the average elderly household's income on out-of-pocket costs.
- Privately insured people with out-of-pocket medical expenses exceeding 5 percent of their income are about twice as likely to have difficulty paying their rent and utilities and affording food and face barriers accessing medical care, compared to those with out-of-pocket costs less than five percent of their income.

Many Pennsylvania specialty drug consumers who responded to our survey, including those being treated for cancer, multiple sclerosis, immune deficiency, inflammatory conditions, hemophilia, and other serious conditions, reported the high cost sharing requirements for drugs on specialty tiers affected their access to needed care and/or created serious economic hardships. Almost all (97 percent) of those responding to the LB&FC specialty drug consumer survey reported having health insurance that included coverage for prescription drugs. However, in response to questions concerning access to recommended care:

- over 40 percent delayed filling a prescription,
- over 40 percent reported skipping pills, injections, or dosages,
- over 30 percent chose not to take a particular brand of medication because it was too expensive, even though their doctors thought it was the best medication for their conditions,
- almost 30 percent delayed starting a new medication, and
- 20 percent indicated that they ceased taking the drug because they could no longer afford it.

Concerning economic hardships resulting from their high cost sharing requirements:

- roughly 40 percent reported taking on additional credit card debt,
- over 40 percent reported problems with purchasing food/groceries,
- over 30 percent reported difficulty buying clothes or other needed items for themselves or their family,
- 25 percent reported difficulty making a car payment, and
- 10 percent reported having to declare bankruptcy.

Others reported failing to pay income taxes, having to move in with parents, and having to sell most personal property.

In addition to our survey of specialty drug consumers, LB&FC staff reviewed the cost of common specialty drugs for an average Pennsylvania household, and found:

The average household (with a median income of over \$50,000 and consumer cost sharing at 32 percent for common specialty drugs,¹²) would incur annual out-of-pocket costs of more than 5 percent of the household's median income for all but one common specialty drug.

¹² The typical cost sharing for such drugs reported in the Kaiser Family Foundation's *2013 Employer Health Benefit Survey*.

- Almost 60 percent of such drugs have annual out-of-pocket costs that exceed 20 percent of a Pennsylvania household's median income. Such drugs include, for example, those used to treat cancer (Gleevec and Tarceva), multiple sclerosis (Avonex, Betaseron, Rebif), inflammatory conditions (Enbrel, Humira, and Remicade), Hepatitis C (Pegasys and Sovaldi), and pulmonary hypertension (Letairis and Tracleer).

For those with limited income, certain public and private programs provide help with their high out-of-pocket costs for specialty drugs. In particular,

- *The Medicare Part D Program provides full or partial assistance through its Low Income Subsidy (LIS) program for individuals who:*
 - Qualify for both Medicare and full Medicaid benefits,
 - Qualify for Medicare and full Medicaid benefits while in nursing facilities or receiving home and community-based services,
 - Qualify for partial Medicaid benefits, SSI, or have income below 135 percent of the federal poverty level (\$11,670 for an individual in 2014) and limited resources (\$8,590 for an individual), and
 - Qualify for a partial subsidy as their income is between 135 and 150 percent of the federal poverty level (\$17,505 in 2014 for an individual) and they have limited resources (\$13,300 for an individual).

Those qualifying for Medicare's full low income subsidy have copayments for specialty drugs in the range of \$0.00 to up to \$6.35. Those qualifying for a partial subsidy initially must pay 15 (rather than 25) percent of the cost of the drug, but such amounts are reduced to small copayment amounts (\$2.55-\$6.35) when their annual out-of-pocket threshold is reached (i.e., \$6,690 in 2014). In 2012, approximately 460,000 low income Medicare beneficiaries in Pennsylvania were enrolled in Medicare prescription drug plans and qualified for additional assistance from Medicare for their prescription drug benefit costs.

- *The Pennsylvania Medicaid Fee-for-Service Specialty Pharmacy Drug Program waives Medicaid's minimal copayments (\$1 for a generic drug and \$3 for a brand name drug) for specialty drugs.*
- *The Pennsylvania PACE (the Pharmaceutical Assistance Contract for the Elderly) and PACENET (PACE Needs Enhancement Tier) Program provide considerable assistance to cardholders that require specialty drugs, in particular through the PACE Plus Medicare or "Medicare Wrap Around Program."*
 - *First, PACE and PACENET have less restrictive eligibility criteria than Medicare's. An individual can receive help through Pennsylvania's program with income up to 200 percent (\$23,500) of the federal poverty*

level, rather than 150 percent, and without having to meet Medicare's requirement for limited resources.

- *Second, PACE and PACENET will pay for almost all of a cardholder's share of a specialty drug's cost* under a Medicare Part D plan. The cardholder is only responsible for the relatively small copayments (e.g., \$9.00 for a brand name drug for a PACE cardholder and \$15 for such a drug for a PACENET cardholder) associated with the PACE/PACENET program.
- *Third, PACE and PACENET will pay for medically necessary drugs not on a Medicare Part D plan's formulary.* It will also work with the plan to process a prior authorization on behalf of the member so the drug will be covered by the Part D plan.

In 2013, PACE and PACENET had over 3,200 cardholders (i.e., 1 percent of total cardholders), with over 15,000 specialty drug claims totaling about \$42 million paid on their behalf. Of the specialty drug paid claims total:

- Cardholders were responsible for less than 1 percent (\$268,000),
- PACE and PACENET paid for 25 percent (\$10.5 million), and
- Other third parties (e.g., prescription drug plans) paid all remaining costs (\$31.2 million).

In 2013, six drugs accounted for 60 percent of total program spending for specialty drugs. Three (Revlimid, Gleevec, and Zytiga) of the six drugs are used in the treatment of various forms of cancer and leukemia, two (Enbrel and Humira) are used to treat various inflammatory diseases, and one (Forteo) is used for people who have had a fracture related to osteoporosis, have several risk factors for fracture, or cannot use other osteoporosis treatments.

Pennsylvania also operates a PACE Patient Assistance Program and Clearinghouse (PA-PAP) that assists all adult Pennsylvania residents regardless of age or income to gain access to pharmaceutical manufacturers' pharmacy assistance programs. In 2013, the program assisted over 14,000 persons to receive almost 50,000 medications. Pharmaceutical manufacturer patient assistance programs provide important help. Such help, however, is not usually ongoing. Patients, moreover, can incur significant out-of-pocket costs while waiting to participate and while in such programs.

The federal Affordable Health Care Act¹³ contains an important provision that can help assure affordable access to care, including access to costly specialty drugs. Such provisions, however, do not apply to all plans, and their implementation has been postponed. The act limits total out-of-pocket cost sharing for all “essential benefits,” including prescription drug coverage,¹⁴ to \$6,350 for an individual and \$12,700 for a family in 2014. The existing legislation, however, does not apply to plans that have been “grandfathered” under the act.

The federal departments (Health and Human Services, Labor, and Treasury) responsible for the administration of the Affordable Health Care Act, moreover, postponed implementation of such requirements scheduled to take effect in 2014. Based on the implementing agencies’ decision, a health plan is able to maintain separate out-of-pocket limits for medical and prescription drug benefits in 2014. An individual consumer, therefore, may be required to pay \$6,350 for doctors’ and hospital care, and an additional \$6,350 for prescription drug coverage when such coverage is administered separately from the medical benefit coverage. If such a stand-alone prescription drug plan does not have an out-of-pocket plan limit (and as noted above, most do not), the plan sponsor is not required to establish a limit for 2014. Consumer out-of-pocket costs for prescription drug coverage, therefore, may be unlimited until such time as the Affordable Health Care Act’s out-of-pocket provisions are fully implemented.

Several proposals have been offered at the federal level to help assure access to and affordability of specialty tier drugs. Most notably:

- *The Patients’ Access to Treatment Act of 2013* would limit copayments, coinsurance, or other cost sharing requirements for specialty tier drugs to the dollar amount (or equivalent) of cost sharing requirements for non-preferred brand drug tiers. The proposed legislation also provides that there be no more than a 10 percent difference in total dollar cost sharing between tiers.

One national consulting firm estimated that a plan now using copayments for specialty tier drugs would experience only a \$0.37 average monthly premium increase as a result of the proposed legislation; and a plan using coinsurance would see a \$7.78 increase. Alternatively, to offset the premium increases, a \$6.00 increase in the copayment for non-preferred tiers, a \$0.75 increase in copayments for preferred drugs, or a \$0.50 increase in

¹³ Throughout this report, the federal Affordable Health Care Act refers to the Patient Protection and Affordable Care Act, Pub. L. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, and further amended by the Department of Defense and Full-Year Continuing Appropriation Act, Pub. L. 112-10.

¹⁴ Other items and services in an essential benefit package include: emergency services; hospitalization; maternity and newborn care; mental health and substance abuse disorder services, including behavior health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventative and wellness services and chronic disease management; and pediatric services, including oral and vision care.

copayments for generic drugs would generate plan savings equal to the amount plans might lose by lowering the copayments for specialty drugs.

Fifteen states have acted to improve access and affordability of drugs on specialty tiers, including, for example:

- Alaska, Arkansas, Louisiana, New Mexico, Oklahoma, Texas, and Virginia, which require some form of beneficiary notice concerning changes related to specialty drug availability and/or cost sharing requirements;
- Maine and Vermont, which adopted annual caps on prescription drug costs (\$3,500 and \$1,250 individual/\$2,500 family respectively) if such caps did not already exist in a health benefit plan; and
- Delaware and Maryland, which adopted per prescription caps on certain specialty drugs.

Other interested groups have also offered suggestions to begin to address access and affordability concerns, though they vary in their recommended approaches.

- *Advocacy groups* recommended the elimination of specialty tiers.
- *The American Medical Association* believes cost sharing arrangements for prescription drugs should encourage judicious use of health care resources, rather than simply shifting costs to patients, and that such arrangements should be based on the unit cost of the medication, availability of therapeutic alternatives, medical conditions being treated, personal income, and other factors known to affect patient compliance and health outcomes.
- *Academy of Managed Care Pharmacy* views the problem as the high drug costs established by drug manufacturers and the absence of general or therapeutic alternatives for such drugs, which makes it difficult for plans to negotiate favorable prices from manufacturers. It opposes arbitrarily reduced cost sharing, as it does not lower the overall cost of the prescription drug.
- *A Major Pharmacy Benefit Manager (PBM)* notes that employers often develop their own formularies for their prescription drug benefit rather than relying on the PBM's standard formularies. As a result, there is often considerable variation in plan sponsors' drug benefit designs. The PBM, therefore, encourages employers to develop formularies that enable individual needs be met when clinically justified by the patient's physician.

- *PhRMA* emphasizes that developing new and important pharmaceutical agents is costly (often over \$1.2 billion per drug), time-consuming, risky, and requiring substantial up-front investment; and that new therapeutic advancements have increased survival and, in some cases, resulted in new treatments. It, therefore, opposes efforts to set prescription drug prices. It recommends the Medicare Part D program assure that a therapeutic alternative in the class be available to patients as a preferred tier before a medicine may be placed in a specialty tier and allow beneficiaries to appeal specialty tier cost sharing by demonstrating a medical need for the drug, as occurs with other tiers. It also recommends that the federal Department of Health and Human Services (HHS) reject plans submitted under the Affordable Health Care Act that structure drug coverage in a way that patients with chronic and severe illnesses are subject to very high out-of-pocket costs.
- *Health Policy Researchers* recommend the federal government be allowed to enter into binding arbitration with pharmaceutical manufacturers to establish prices for unique, clinically important drugs with significant therapeutic advantages and no real competition or clinical alternatives.

The recent Food and Drug Administration approval of the drug Sovadi to treat Hepatitis C has highlighted the difficulties in establishing prices for new unique drugs with significant therapeutic advantages and no real competition. Sovadi has been priced by its manufacturer at \$1,000 per pill, or an estimated \$84,000 for a 12-week treatment regimen, and has a reported 95 percent “cure rate.” Its price was set based on the cost of prior, and less effective, treatment regimens (e.g., liver transplants and other drugs, etc.) Payers are especially concerned about the high price of this drug as 3 million Americans may have the Hepatitis C virus.

Even public payers, such as Medicaid and the Veteran’s Administration, which receive manufacturer rebates and discounts for all brand drug purchases (23.1 percent and 44 percent) are concerned about this drug’s high price on their budgets. Some estimate this one drug alone could increase Medicare Part D spending and premiums from 3 to 8 percent, depending upon the number seeking treatment.

Sovadi highlights the key role the federal government has in addressing drug pricing. It also highlights the limited flexibility available to states in their efforts to assure affordable access to clinically important drugs.

Nonetheless, absent prompt federal action to assure implementation of out-of-pocket maximums provided for in the Affordable Health Care Act, to extend such requirements to all plans, and to attempt to assure reasonable pricing for unique,

therapeutically significant drugs, such as certain specialty tier drugs, some states have taken certain limited measures to assist some, if not all, specialty drug consumers.

Recommendations:

- 1. At the federal level, the Commonwealth of Pennsylvania should advocate for change in federal policy to help assure access to affordable life sustaining specialty drugs.** Federal policy changes are critical to address this issue. While states may have limited ability to address the issue directly, they are in a position to advocate on behalf of their citizens and state interest at the national level.

Pennsylvania should highlight the need for federal policy changes to assure access to affordable life sustaining specialty drugs through its leadership role in national organizations such as the National Governors' Association and the National Council of State Legislatures, and state Medicaid directors and state pharmaceutical assistance programs for the elderly groups. Such state advocacy would highlight the need for greater consumer protections for those with serious illnesses and in need of high cost drugs. They should address the major budgetary issues that will arise for states and other public and private payers, absent federal policy changes, as unique, clinically significant drugs that are without clinical alternative or competitors come onto the market. They should also address the need for greater consumer education related to formularies and the implication of formularies when choosing a prescription drug plan.

- 2. The Pennsylvania General Assembly may wish to consider "stop gap" measures as certain other states have done.** A typical Pennsylvania household would expend more than 20 percent of its annual income on out-of-pocket costs for about two-thirds of the drugs commonly found on formulary specialty tiers that are used to treat serious and life-threatening conditions. They, moreover, would likely not qualify for assistance from federal and state programs available to those with lower incomes. Until such time as the federal government fully implements provisions of the Affordable Health Care Act related to out-of-pocket maximums for prescription drugs, Pennsylvania should consider requirements for annual out-of-pocket limits that include prescription drugs in plans that do not already include such limits. As an alternative, it should also consider per prescription out-of-pocket cost sharing limits for certain life sustaining specialty drugs for plans that do not already limit such out-of-pocket costs and require consumers to pay a percentage of the drug's cost for drugs on specialty tiers. Such "stop gap" measures will help some. Their overall impact may be limited, however, as they would not apply to health plans that already have out-of-pocket cost sharing limits that

include prescription drugs, plans that do not utilize formularies with a specialty tiers, plans that do not require consumers to pay a percentage of a drug's costs for drugs on a specialty tier. They, moreover, would not apply to self-insured employer plans (i.e., ERISA) of which there are many.

- 3. Commonwealth agencies should continue to undertake steps to educate consumers about Pennsylvania's Medicare Part D Wrap Around Program and its Patient Assistance Program and its Clearinghouse to assist Pennsylvania residents of all ages and income about pharmacy manufacturer assistance programs.** Through the PACE program, the Commonwealth provides important additional support to its citizens that are not available in most states. The importance of such programs is often only understood when an immediate need arises. For this reason, continuous educational efforts about the important benefits provided through this program should be undertaken. In particular, Pennsylvania's PACE program may wish to routinely engage the Pennsylvania Medical Society to acquaint physicians with the state's Medicare Part D Wrap Around Program and the services available through the Pennsylvania PACE Patient Assistance Program Clearinghouse.

I. Introduction

Senate Resolution 2013-70 (Appendix A) and House Resolution 2013-348 (Appendix B) directs the Legislative Budget & Finance Committee (LB&FC) to study prescription drug “specialty tiers” to determine their impact on access and patient care. Drugs on specialty tiers are often used to treat chronic or life-threatening conditions such as hemophilia, multiple sclerosis, hepatitis, cancer, and certain rare conditions. They may involve complex treatment regimes that include ongoing monitoring and patient education, require special handling (particularly temperature-controlled storage and shipping), include biologicals (see the Glossary of Terms in Appendix C) that require injection or infusion, and have limited or exclusive distribution. Drugs on specialty tiers can also be very costly and often require the beneficiary to pay a percentage of the drug’s cost (i.e., a coinsurance) rather than a fixed dollar amount (i.e., copayment).

Study Scope and Objectives

Specifically, this study seeks to:

1. Explain health and prescription drug plan “specialty tiers” and their implications for insured consumers.
2. Identify the unique features of specialty pharmaceuticals and key features that differentiate them from traditional drugs.
3. Identify the extent to which “specialty tiers” are used by major medical plans in Pennsylvania, in particular in commercial plans for small businesses.
4. Identify health care consumers with conditions requiring specialty pharmaceuticals for life sustaining and medically necessary care, and the implications of “specialty tiers” for their access to essential care.
5. Identify options to assure access to specialty pharmaceuticals that have been proposed and are being pursued at the state and federal level.

To explain health and prescription drug plan “specialty tiers,” we reviewed national literature on health and pharmacy benefit plan design options and their use of formulary “tiering,” which essentially means that the amount an insured will pay out-of-pocket for a drug will depend on the drug’s formulary status placement. We reviewed other options to manage prescription drug utilization and cost. We also reviewed information on the extent to which changes in benefit design have

been adopted by public and commercial plans in recent years, in particular use of benefit designs that include specialty tiers. Further, we reviewed national research concerning the effect of prescription drug cost sharing on access to recommended medical treatment, compliance with recommended drug treatment, and the economic impact of high cost sharing for those with significant medical conditions.

To identify the unique features of specialty pharmaceuticals and key features that differentiate them from traditional drugs, we also relied on published national literature and reports. Such reports include, for example, the work of the American Pharmacists Association and several United States Government Accountability Office (GAO) studies.

To identify the extent to which “specialty tiers” are used by major health insurers in Pennsylvania, in particular commercial plans for small businesses, we surveyed major Pennsylvania health insurers. See Appendix D for a copy of our survey of major Pennsylvania health insurers. With the exception of commercial insurers, all major Pennsylvania insurers responded to our survey and provided significant information for our work. As completion of the survey required provision of company confidential and proprietary information, and the commercial sector did not provide information for the study, we have not included the reported information within the report. Such information has not been included to assure we did not disclose proprietary information for one major industry sector (i.e., the “Blues” and non-profits), but not the other (i.e., the “commercials”).

Pharmacy benefit managers (PBMs) have a major role in provision of outpatient prescription drug benefits for government and non-government employers and insurers and typically use tiered drug formularies to help plan sponsors manage their prescription drug costs. We, therefore, spoke with representatives of one of the nation’s largest pharmacy benefit managers (PBMs), including the company’s senior director of government affairs and the company’s chief pharmacist. They shared information on their company’s formulary development process, the role of their clients (e.g., major public and private employers, insurers, etc.) in the development of custom formularies, and how they provide access to non-formulary medications. In addition, they shared information on specialty tier drugs, including their costs and cost sharing requirements, and their thinking about the use of caps to limit cost sharing for such drugs. We did not attempt to survey PBMs as they are not subject to state regulation in Pennsylvania or most other states.

To identify health care consumers with conditions requiring specialty pharmaceuticals for life sustaining and medically necessary care and the implications of “specialty tiers” for their access to essential care, we reviewed the national literature and spoke with professionals involved in providing or assisting them to access such care, including specialty physicians and staff involved in the operation of Pennsylvania’s PACE Patient Assistance Program and Clearinghouse. We also

designed an online consumer survey for patients and their families to share their experiences with specialty tiers. Such experiences included their total and out-of-pocket costs, the impact of such costs on their adherence to recommended treatment, the economic impact of drug costs on their households, and assistance programs in which they may participate. See Appendix E for a copy of our survey of consumers.

We were able to reach out to patients requiring high cost drugs and their families with the assistance of a coalition of Pennsylvania associations assisting and advocating for persons with hemophilia, transplants, cancer, and other chronic and rare diseases. Such associations shared information about the survey with their members and key providers. (Appendix F provides a list of the associations that assisted in our efforts to obtain direct consumer input for our work.)

Medical specialty societies that work closely with the Pennsylvania Medical Society also assisted our work. Several specialty societies made their members aware of our consumer survey, and they in turn shared information with patients on how they might participate in the survey and share their experiences. In particular, the Pennsylvania Allergy and Asthma Association, the Academy of Dermatology and Dermatologic Surgery, the Society of Gastroenterology, and the Society of Oncology & Hematology assisted our consumer outreach efforts and shared valuable insights about issues related to specialty drugs and specialty tiers for their patients.

To identify options to assure access to specialty pharmaceuticals that have been proposed and are being pursued at the state and federal level, we reviewed studies and legislation proposed and adopted in other states. We also reviewed national studies and bills that have been introduced at the federal level to resolve some of the issues that have been identified with federal health insurance programs' use of specialty drug tiers and reviewed positions taken by patient advocacy groups, the American Medical Association, pharmacy benefit managers, and pharmaceutical manufacturers.

In addition, we met with and obtained input from key state agency staff that manage programs providing access to specialty tier pharmaceuticals. In Pennsylvania, for example, the PACE/PACENET programs provide a wrap-around benefit for Medicare Part D prescription drug coverage. As a result, PACE/PACENET covers certain out-of-pocket costs for beneficiaries requiring specialty drugs. PACE also operates a clearinghouse to assist those not eligible for PACE/PACENET to obtain medically necessary drugs.

Acknowledgements

LB&FC staff completed this study with consultation and assistance from the American Lung Association of the Mid-Atlantic, the Arthritis Foundation, the

American Liver Foundation, the Pennsylvania Medical Society, the National Nursing Centers Consortium, the Lupus Foundation of America, Philadelphia Tri-State Chapter, the National Hemophilia Foundation's Delaware Valley Chapter, the Leukemia & Lymphoma Society, and the Immune Deficiency Foundation. In particular, we thank Ann Rogers from the National Hemophilia Foundation's Delaware Valley Chapter for her assistance with our consumer survey and providing access to information from other states.

We thank the major health insurers. We also thank Terri Cathers, Pharm.D., Director of Pharmacy, Department of Public Welfare, Office of Medical Assistance Programs, and Tom Snedden, the Executive Director of the PACE/PACENET program and his key staff for their valuable assistance throughout the study.

Important Note

This report was developed by Legislative Budget and Finance Committee staff. The release of this report should not be construed as indicating that the Committee members endorse all the report's findings and recommendations.

Any questions or comments regarding the contents of this report should be directed to Philip R. Durgin, Executive Director, Legislative Budget and Finance Committee, P.O. Box 8737, Harrisburg, Pennsylvania 17105-8737.

II. Findings

A. Health Insurance and Prescription Drug Coverage Nationwide and in Pennsylvania

Employer-sponsored health insurance is the primary source for health insurance coverage in the United States and in Pennsylvania. As shown in Table 1, more than one-half of all Pennsylvanians receive health insurance through an employer.¹

Table 1

Health Insurance Coverage of the Total Population in 2012						
	<u>Employer</u>	<u>Other Private</u>	<u>Medicaid</u>	<u>Medicare</u>	<u>Other Public</u> ^a	<u>Uninsured</u>
United States...	48%	5%	16%	14%	1%	15%
Pennsylvania...	52	6	15	15	NSD	11

^a Includes those covered under the military or Veterans Administration.

Sources: Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimates based on the Census Bureau's March 2012 and 2013 Current Population Survey (CPS: Annual Social and Economic Supplements).

Pennsylvania not only has a higher share of its population receiving health insurance coverage through employers than nationwide, but is also among the top five states² with employers offering coverage and workers eligible for such coverage. Table 2 shows for private sector employers in Pennsylvania and nationwide, the percentage of employers offering employer-sponsored insurance, workers in firms that offer health insurance, workers eligible for coverage in establishments that offer coverage, and workers eligible for coverage that take up coverage.

Table 2

Private Sector Employer-Sponsored Health Insurance Availability and Take-Up in 2010-11 (All Firm Sizes)				
	<u>Employers Offering</u>	<u>Percentage of Workers in Firms Offering Coverage</u>	<u>Percentage of Workers Eligible for Coverage in Firms Offering Coverage</u>	<u>Percentage of Eligible Workers That Take-up Coverage</u>
United States.....	52.4%	85.9%	78.1%	76.3%
Pennsylvania.....	59.5	89.9	79.5	77.8

Sources: State Health Access Data Assistance Center, 2013. "State-Level Trends in Employer-Sponsored Health Insurance," SHADAC Report Minneapolis, MN: University of Minnesota and data from the Agency for Healthcare Research and Quality, Center for Cost and Financing Studies, Medical Expenditure Panel Survey-Insurance Component, 2010 and 2011.

¹ Includes both employees and their dependents.

² Hawaii, the District of Columbia, Massachusetts, and Rhode Island are also among the top five states for employers offering coverage and workers eligible for such coverage.

A substantial number of employers that offer health insurance coverage in Pennsylvania and nationwide are self-insured. Such employers assume risk for the cost of health plans' claims and are responsible for payment for such claims. As shown in Table 3, employers in larger firms (i.e., with 50 or more employees) are more likely to self-insure than smaller firms with fewer employees over which to spread their risk.

Table 3

Among Private Firms Offering Coverage, Percentage That Self-Insure by Firm Size in 2010-2011

	<u>All Firm Sizes</u>	<u>Employees: Less Than 50</u>	<u>Employees: 50 or More</u>
United States	36.4%	12.3%	63.8%
Pennsylvania	34.9	12.8	63.3

Sources: State Health Access Data Assistance Center, 2013. "State-Level Trends in Employer-Sponsored Health Insurance." SHADAC Report. Minneapolis, MN: University of Minnesota and Agency for Healthcare Research and Quality, Center for Cost and Financing Studies. Medical Expenditure Panel Survey-Insurance Component, 2010-2011.

Table 3 only provides information on private firms. Annually, however, the Kaiser Family Foundation conducts a nationwide survey of a sample of firms, including private and public and private-not-for profit firms, about their provision of health benefits for their employees. According to its latest survey (2013),³ nationwide 61 percent of covered workers that receive health care through their employers receive such coverage through self-funded plans. As with the Agency for Healthcare Research and Quality data (shown in Table 3), larger firms are more likely than smaller to be self-funded.

The extent to which employers provide health insurance for employees through self-funded plans is important because different rules apply to such plans. While such plans typically contract with one or more third-party administrators or insurers to administer services offered through the plan, Federal law (the Employee Retirement Income Security Act of 1974, or ERISA) exempts self-funded plans from state insurance laws, including reserve requirements, mandated benefits, premium taxes, and certain consumer protection regulations. Under the federal Affordable Health Care Act, moreover, self-funded plans are not required to comply with certain of its requirements. (See Finding G for additional information on such requirements.)

³The Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits, 2013 Annual Survey*.

Most Employer-Sponsored Health Benefits Now Include Prescription Drug Benefits

The first employer-sponsored prescription drug benefit was established as a result of union negotiations with companies in the auto industry. By the late 1970s, most employer-sponsored health plans included prescription drug benefits. At the time, prescription drug coverage was typically part of the overall health plan coverage and not viewed as a separate or “stand alone” benefit. As such, prescription drug coverage was included under the same deductibles and coinsurance as general medical benefits.

Nearly all (98 percent) covered workers in employer-sponsored health plans have a prescription drug benefit, according to Kaiser’s 2013 Employer Health Benefits Survey. Employers may provide for such benefits through a health insurer or they may elect to “carve out” the prescription drug benefit and arrange for provision of the benefit through other arrangements,⁴ such as through pharmacy benefit management (PBMs) firms. Employers and plan sponsors often hire PBMs to design and administer plans for prescription drug benefits, including plan formularies. PBMs are often selected for their industry knowledge, and their negotiating power (given their large patient base) to secure rebates and discounts from drug manufacturers and pharmacies.⁵

Employee Costs for Employer-Sponsored Health Insurance Have Increased Dramatically

National health expenditures have moderated substantially since 2003. As shown in Exhibit 1, from the late 1990s to 2002, national health expenditures were increasing on average annually from 5.5 to 9.7 percent, but since then have increased at a much slower pace. As shown in Exhibit 2, prescription drugs experienced the largest overall change, with such spending increasing only 0.4 percent from 2011 to 2012—substantially down from the first half of 2000 when annual increases were 10 percent or more.

Despite more moderate increases in health care expenditures, health insurance premiums have continued to rise sharply and at a much faster rate than workers’ earnings or overall inflation. As shown in Exhibit 3, moreover, since 2009, the increase in workers’ contribution to premiums has surpassed the increase in the premiums themselves.

⁴ In addition to pharmacy benefits, vision, behavioral health, and dental benefits are common health benefit “carve outs.”

⁵ Pharmacy benefit managers (PBMs) also provide electronic claims processing, pharmacy networks, generic substitution and patient services. They adjudicate approximately 80 percent of all prescriptions processed today, with three large PBMs handling around 65 percent of outpatient prescription volume. PBMs are not regulated in Pennsylvania or most states.

Exhibit 1

Average Annual Percentage Change in National Health Expenditures, 1960-2011

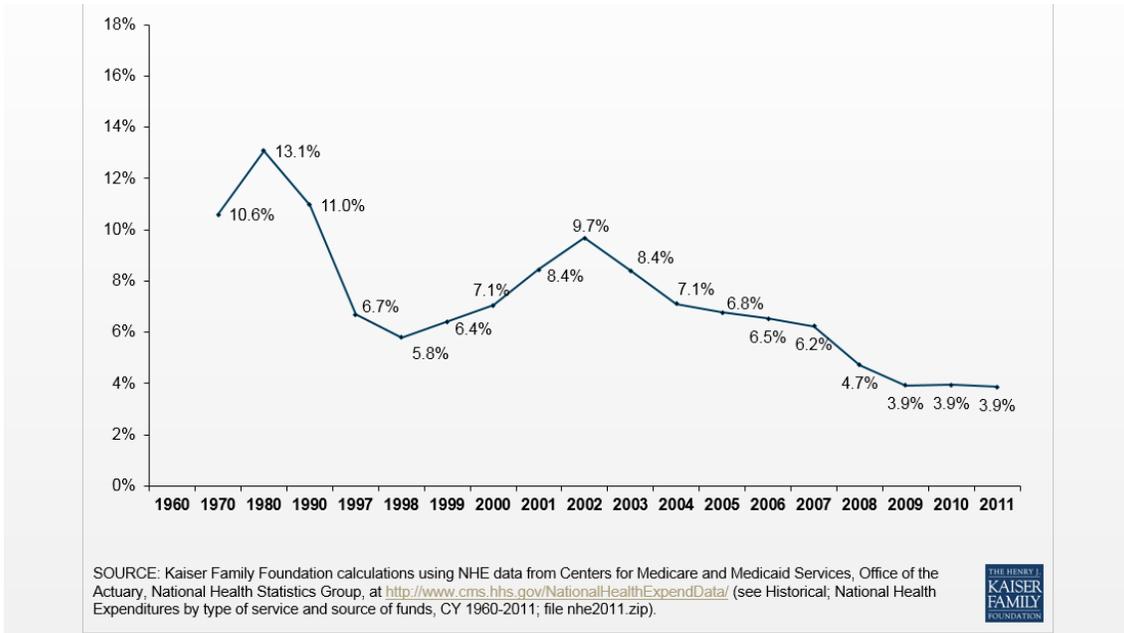


Exhibit 2

Average Annual Percentage Change in National Spending for Selected Health Services, 2002-2012

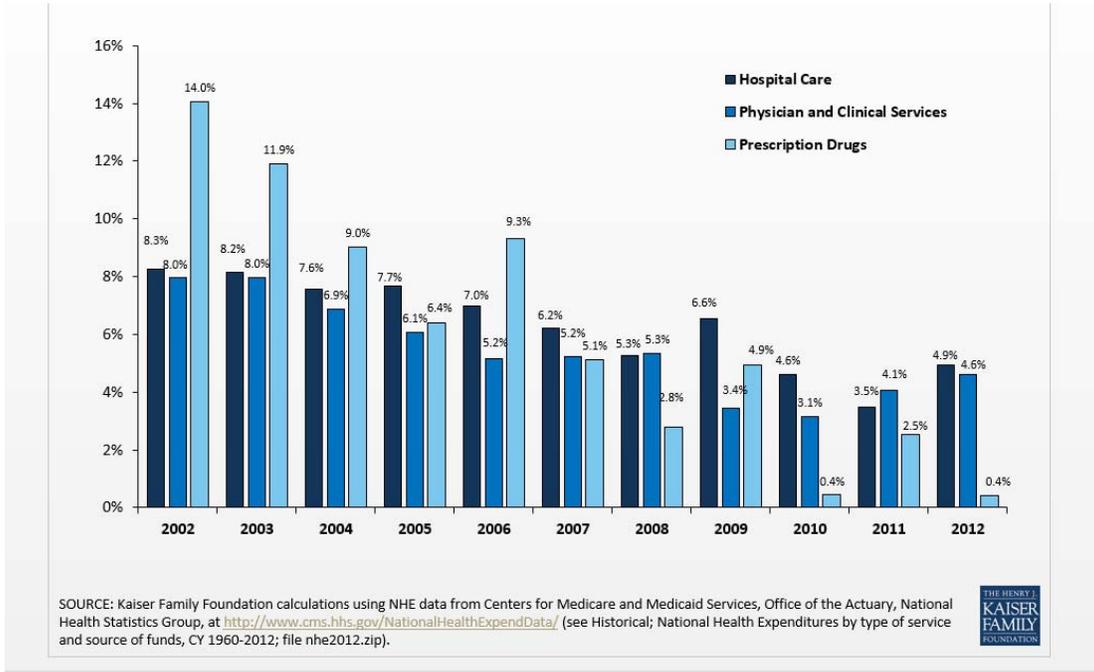
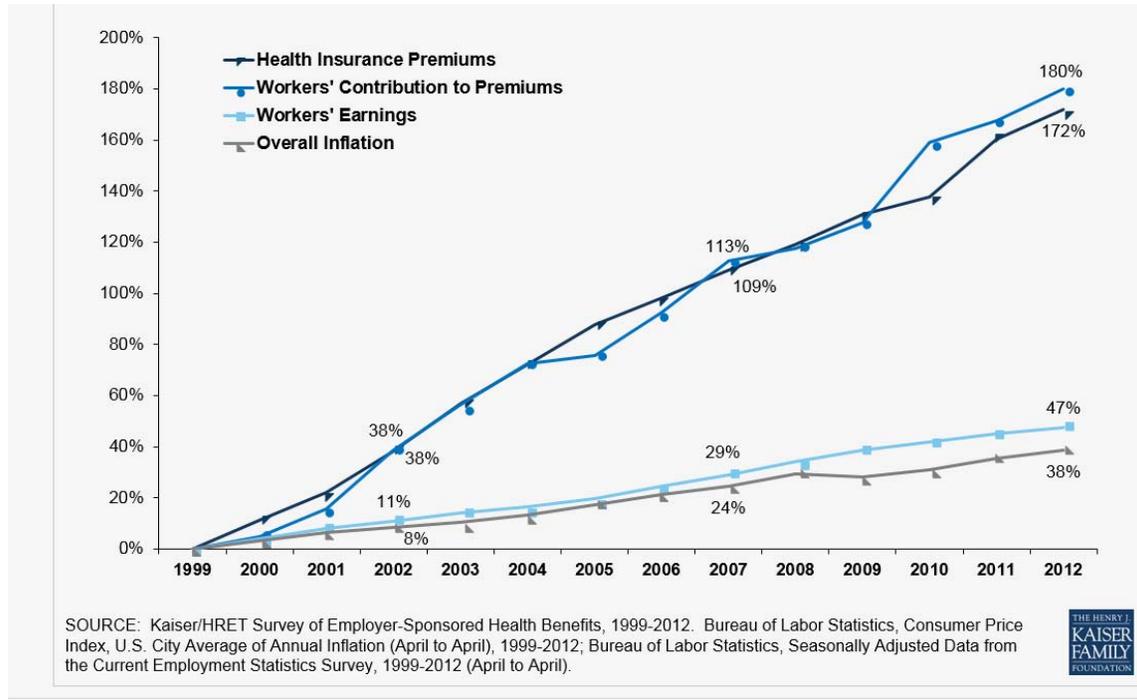


Exhibit 3

Cumulative Increases in Health Insurance Premiums, Workers' Contributions to Premiums, Inflation, and Workers' Earnings, 1999-2012



In addition to contributing to premiums, covered employees incur other costs for their health care. Covered employees' health care costs may include:

- an annual deductible,
- copayments (i.e., a fixed payment amount for service),
- coinsurance (i.e., a percentage of the cost of the service),
- out-of-pocket payments up to an annual out-of-pocket maximum, and
- costs associated with non-covered and out-of-network care.

Contribution to Premiums: The average annual premium for all employer-sponsored health insurance was \$5,884 for single coverage and \$16,351 for family coverage according to the 2013 Kaiser Employer Health Benefits Annual Survey. On average, covered workers contributed 18 percent of the premium for single coverage and 29 percent of the premium for family coverage in 2013, or \$999 for single coverage and \$4,565 for family coverage.

Annual Deductible: Over 75 percent of employees enrolled in an employer-sponsored health insurance plan in 2013 were required to meet an annual deductible⁶ before services were reimbursed by the plan. The average general annual health plan deductible for single coverage in 2013 was \$1,135, with 38 percent of such covered workers in plans with a deductible of \$1,000 or more and another 15 percent in plans with \$2,000 or more.

For family coverage for plans with an aggregate general annual deductible, the amount of the deductible varied by type of plan, with such deductibles ranging from \$1,743 (for an HMO) to \$4,079 for High Deductible Health Plans with Savings Options (HDHP/SO).⁷ Among covered workers with an aggregate general health plan deductible for family coverage (excluding HDHP/SO plans), between 27 percent (HMO) and 33 percent (PPO) are in plans with a \$1,000 to \$2,000 deductible and from 29 percent (PPO) to 65 percent (POS) are in plans with deductibles of \$2,000 or more.

Some plans have a different type of family deductible and require each family member to meet a separate per person deductible amount before the plan covers expenses for that member. Most of these types of plans consider the deductible met for all family members if a set number of family members each reach their separate deductible amount. Such plans may also require each family member to meet a separate per person deductible until the combined spending for the family reaches a specified dollar amount.

Some plans also require the worker to meet a service specific deductible (such as for hospital admissions or outpatient surgery) in addition to the general annual deductible. These deductibles often vary by the size of the firm with employees of larger firms generally having a lower deductible than employees of smaller firms.

Copayments and Coinsurance: Employer-sponsored health insurance plans also often have copayment or coinsurance requirements. In the 2013 Employer Health Benefit Annual Survey, only 6 percent of covered workers were in plans without cost sharing for in-network primary care physician or specialty care visits. Copayments accounted for about three-quarters of such cost sharing in 2013, with

⁶ A deductible is a fixed dollar amount which an insured person pays before the insurer starts to make payments for covered medical services. Plans may have both per individual and family deductibles. Some services, however, may be available outside of the deductible requirement. A plan, for example, may be designed to pay for certain preventative services and/or physician office visits before the deductible requirement is met.

⁷ High Deductible Health Plans with Savings Options are a type of consumer-directed health plan authorized in 2003 by the Medicare Modernization Act (Pub. L. 108-173). Generally, these plans have low standard insurance premiums (i.e., \$1,000 to \$2,000 per year), but very high deductibles. Federal rules require consumer-directed health plans to have deductibles of at least \$1,200 for an individual and \$2,400 for family coverage in 2012. Such plans cap out-of-pocket costs at \$6,050 for an individual and \$12,100 for a family. With the Health Savings Account Option, the beneficiary can contribute tax-free up to \$3,000 for an individual and \$6,250 for a family. Funds left over at the end of the year are rolled over into the next year. If an employee changes jobs, the Health Savings Account remains with the employee. Some employers may make tax-free contributions to their employee's Health Savings Account.

coinsurance accounting for about 20 percent of such cost sharing. The average copayment was \$23 for an in-network primary physician visit and \$35 for specialty care, with coinsurance rates of just under 20 percent for such visits.

Annual Out-of-Pocket Maximum: Most covered employees are in plans with general annual out-of-pocket maximums.⁸ Only 12 percent of covered employees with single coverage and 12 percent with family coverage are in plans without such maximums. Among covered workers with single coverage 71 percent are in plans with general annual out-of-pocket maximums of \$2,000 or more. For those with family coverage, 88 percent are in plans with aggregate annual out-of-pocket maximums of \$2,500 or more. For those with family coverage and separate per person out-of-pocket maximums, 73 percent are in plans with separate per person out-of-pocket maximums of \$2,000 or more.

While annual out-of-pocket maximums serve to limit employee health care costs, not all employee out-of-pocket costs count toward such limits. Employee share of premium costs, for example, are not included; and often plans do not count the annual plan deductible toward the annual out-of-pocket maximum limit. Forty-five percent of the HMOs, 34 percent of the PPOs, 16 percent of the POSs, and 17 percent of the HDHP/SO plans did not count the plan's general annual plan deductible toward its annual out-of-pocket maximum.

Employee costs for certain services, moreover, may not be counted toward the out-of-pocket maximum. Typically, prescription drug costs are among those services not counted toward the out-of-pocket maximum. In the 2013 Kaiser Employer Health Benefit survey:

- 71 percent of those in HMO plans that offer prescription drug coverage were in plans that did not count prescription drug cost sharing toward the annual out-of-pocket maximum,
- 84 percent of those in PPO plans that offer prescription drug coverage were in plans that did not count prescription drug cost sharing toward the annual out-of-pocket maximum,
- 66 percent of those in POS plans that offer prescription drug coverage were in plans that did not count prescription drug cost sharing toward the annual out-of-pocket maximum, and
- 60 percent of those in HDHP/SO plans that offer prescription drug coverage were in plans that did not count prescription drug cost sharing toward the annual out-of-pocket maximum.

⁸ An out-of-pocket limit is the maximum amount of cost sharing a participant must pay each year for services covered under the out-of-pocket maximum.

As discussed in Finding G, the federal Affordable Health Care Act includes a provision for annual out-of-pocket maximum limits that include prescription drug costs. The implementation of this provision, however, has been postponed by the federal agencies responsible for administration of the Act.

Non-Covered and Out-of-Network Care: Employees are also typically responsible for costs for services not included in their employer's plan benefits and for costs of care delivered by providers outside of the plan's network of providers. Such costs can be substantial.

B. Specialty Drug Tiers Have Increasingly Become Part of Prescription Drug Benefit Designs

As noted in Finding A, since the late 1970s, most employer health benefits have included a prescription drug benefit. Around the mid-1990s, when pharmaceutical companies began advertising specific brand name drugs for specific conditions and patients started requesting specific brand name drugs from their physicians, employers and health plan administrators became concerned about their rising prescription drug costs. They also started to consider various ways to avoid unnecessary increases in their pharmaceutical drug costs.

Prescription Drug Formularies With Differing Cost Sharing Tiers Have Been in Use Since the Mid-1990s

As part of their strategies to contain their prescription drug costs, private insurers and health plan administrators began to “carve out” prescription drugs from other health plan benefits and to develop formularies for use with such benefits. Formularies are lists of drugs that include preferred and non-preferred brands and generics, and they can be closed or open. Typically, with a closed formulary, the plan will only cover drugs listed on the plan formulary. Open formularies have no restrictions as to which Federal Drug Administration (FDA) approved drugs are included on its drug list. Not all drugs listed on a formulary, however, may be available to a covered employee or beneficiary. As part of strategies to avoid unnecessary costs, a plan’s formulary may also include specific requirements that must be met (e.g., prior authorization, step therapy or the demonstrated failure of other drugs, quantity limits, etc.) before the plan will contribute toward the cost of the drug.

Private insurers and health plan administrators also looked for ways to influence covered employees’ behavior and make them aware of prescription drug costs. One way they accomplished this was through the introduction of different cost sharing tiers for drugs on their formularies.

The model that was initially introduced typically included at most three cost sharing tiers: one for generic drugs, a second for preferred brand name drugs, and a third for non-preferred drugs. Such models included varying fixed copayment amounts that increased based on the cost of the drug to the plan. In such formulary cost-sharing models, generic drugs had the lowest copayments; and brand name drugs without generic substitutes had copayments higher than generic drugs, but lower than non-preferred brand name drugs with available generic substitutes.

Over time, the number of formulary tiers has increased. As shown in Exhibit 4, it is not unusual for a prescription drug plan formulary to have more than three tiers, including tiers for which there is no employee cost sharing.

Examples of Prescription Drug Plan Tiers

- No Charge Generics
- Preferred Generics
- Nonpreferred Generics
- Preferred Brands
- Nonpreferred Brands
- Specialty Drugs
- Injectable Drugs

Source: Developed by LBFC staff.

Specialty Drugs

As shown in Exhibit 4, one of the “newer” tiers is a tier for “specialty drugs.” Currently, no standard definition exists for a specialty drug. Health plans and Pharmacy Benefit Managers (PBMs),¹ which often use or own specialty pharmacies, have their own criteria, definitions and drug lists (or, at the request of an employer, may have criteria developed for a specific employer). In general, specialty drugs do not have generic or lower cost brand name equivalents and include some of the most expensive medications available. Typically, they treat a range of complex diseases or health conditions such as cancers, multiple sclerosis, hepatitis, AIDS, and hemophilia. As shown in Exhibit 5, key organizations and states have varying definitions for “specialty drugs.”

As would be expected based on the conditions specialty drugs are used to treat, they are utilized by only a small percentage of those with prescription drug coverage. Due to their higher cost, however, they account for a larger portion of plan total drug costs. According to CuraScript’s 2009 Specialty Drug Trend Report, for example, fewer than 1 percent of their members nationwide utilized specialty drugs; yet specialty medications accounted for more than 12 percent of total costs. Health plans and pharmacy benefit managers are concerned that as new specialty drugs come to market to treat more common conditions, health expenditures for prescription drugs will increase dramatically in coming years.

In view of the conditions they are used to treat and the requirements for their administration, some specialty drugs, in particular, are available under a beneficiary’s medical benefit (dispensed in physician offices and hospital outpatient

¹ Pharmacy Benefit Managers (PBMs) are third party administrators responsible for managing prescription plans for most people with outpatient prescription drug coverage.

Selected Definitions of Specialty Drugs and Specialty Tiers

Academy of Managed Care Pharmacy's Format for Formulary Submissions ^a

Specialty Drugs: Drugs that require a difficult or unusual process of delivery to the patient (preparation, handling, storage, inventory, distribution, federally required Risk Evaluation or Mitigation Strategies (REMS) program, data collection, or administration); or drugs that require patient management prior to or following administration (monitoring, disease or therapeutic support systems).

Medicare Prescription Drug Benefits—Part D ^b

Specialty Tier: A formulary tier exempt from tiered cost-sharing exceptions. To ensure plans sponsors are not substantially discouraging enrollment by specific patient populations reliant on high cost and unique items, only specialty tiers within formularies and benefit designs that comply with the following are approved by the Centers for Medicare and Medicaid Services:

- Only one tier is designated a specialty tier exempt from cost-sharing exceptions.
- Cost-sharing is limited to 25 percent after the deductible and before the initial coverage limit (or an actuarially equivalent for sponsors with decreased or no deductible [i.e., 55 percent of the stand-alone plans in 2013] under alternative prescription drug coverage designs).
- Only Part D drugs with negotiated prices that exceed a Medicare established dollar-per-month amount (currently, \$600) may be placed in the specialty tier.
- If not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must ensure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment.

Delaware ^c

Specialty Drug Tier: A tier of cost sharing designed for specialty drugs [see Maryland definition below] that imposes a cost-sharing obligation for specialty drugs that exceeds the amount for non-specialty drugs and such a cost sharing amount is based on coinsurance.

Maryland ^d

Specialty Drug: A prescription drug that:

- Is prescribed for an individual with a complex or chronic medical condition (i.e., a physical, behavioral, or development mental condition that may have no known cure, is progressive, or can be debilitating or fatal if left untreated or undertreated, including multiple sclerosis, hepatitis C, and rheumatoid arthritis) or a rare medical condition (i.e., a disease or condition that affects fewer than 200,000 individuals in the United States, or approximately 1 in 1,500 individuals worldwide, including cystic fibrosis, hemophilia, and multiple myeloma).
- Costs \$600 or more for up to a 30-day supply.
- Is not typically stocked at retail pharmacies.
- Requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or requires enhanced patient education, management or support, beyond those required for traditional dispensing before or after administration of the drug.

^a AMCP Format for Formulary Submissions v 3.1, p.34 (December 2012).

^b Medicare Prescription Drug Benefit Manual, Chapter 6—Part D Drugs and Formulary Requirements.

^c Delaware Senate Substitute No 1 for Senate Bill 35, effective January 1, 2014.

^d Chapter 422 (HB 761) enacted May 5, 2014.

Source: Developed by LBFC staff.

settings) rather than a separate “carved out” pharmacy benefit. Oral and self-injectable specialty drugs, moreover, may be covered under both the medical and pharmaceutical benefits of health plans.

Medicare Part B, Medicare’s voluntary outpatient insurance program, for example, generally covers drugs and biologicals administered under a physician’s direct supervision in physician offices and in hospital outpatient departments. Such drugs include infused drugs, certain vaccines, blood clotting factors for hemophilia patients, injectable drugs, and immunosuppressive drugs for transplant patients. Medicare also pays for some drugs, such as drugs used to treat cancer, orphan drugs (which are used to treat rare diseases), and some drugs administered in a hospital outpatient setting. Under Medicare Part B, the Medicare program pays 80 percent of the cost of these drugs and the patient is responsible for Part B’s 20 percent coinsurance, which may be paid on behalf of the beneficiary by Medicare supplemental insurance if the beneficiary has such coverage.

Estimates differ as to the proportion of specialty drug costs incurred under medical benefits and under prescription drug benefits. A sizeable portion of current specialty drug costs, however, appear to occur under the medical benefit rather than the outpatient prescription drug benefit. According to Express Scripts’ drug trend report² in 2010, approximately 47 percent of U.S. specialty drug spending occurred in the medical benefit. Similarly, in a study based on 2009 and 2010 claims data,³ Milliman, Inc. reported that approximately 50 percent of total specialty drug costs were paid as a medical benefit and 50 percent were paid as an outpatient pharmacy benefit.

Specialty Drug Tiers

The increase in the number of plans with specialty drug tiers in their prescription drug formularies accelerated with the introduction of the Medicare voluntary outpatient prescription drug benefit (Medicare Part D) program in 2006, and the program’s allowance for specialty tiers. When the Medicare Part D program started, 63 percent of all Part D plans included a specialty tier. By calendar year 2013, almost all stand-alone Medicare Part D prescription drug plans (93.0 percent in CY 2013) and Medicare Advantage prescription drug plans (97.9 percent in CY 2013) used specialty tiers.

As shown in Exhibit 5, within Medicare’s outpatient prescription drug program, plans may adopt coinsurance for drugs on designated specialty tiers, but it cannot exceed 25 percent (or the actuarial equivalent) of a plan’s negotiated cost for

² Express Scripts, *2011 Pharmacy Trend Report*, April 2012.

³ Milliman, Inc., *Milliman Specialty Medical Drug 2010 Commercial Benchmark Study*, November 26, 2012.

the drug. Finding G provides additional information on Medicare's prescription drug plans and the extent to which those enrolled in such plans utilize specialty drugs.

In recent years, employer-sponsored health plans have also seen a substantial increase in the number of plans with four or more tiers. In 2013, the vast majority (92 percent) of covered workers were in plans that used a tiered cost sharing formulary for prescription drug benefits, according to Kaiser's 2013 Employer Health Benefit Annual Survey. Not all such plans, however, included fourth tiers (which often include "specialty drugs"). Twenty-three percent of covered workers were in plans with four or more tiers in 2013. In 2004, however, only 3 percent of such workers were in plans with four or more tiers.

Specialty and Higher Tiers Have Higher Cost Sharing

Typically, covered workers in plans with four or more tiers have higher cost sharing for drugs on the fourth formulary tier than for drugs on other tiers. They are more likely to pay for a percentage of the drug's costs (i.e., a coinsurance) than to pay a fixed amount regardless of the drug's cost (i.e., a copayment). As shown in Table 4, 48 percent of covered workers had coinsurance costs for fourth tier drugs compared with only 9 percent of covered workers having such cost-sharing for first-tier or generic drugs. The average copayment for a drug on the fourth tier was \$80 in 2013, and only \$10 for a drug on the first tier, as shown in Table 5. Table 5 also shows that employee cost-sharing tends to increase as the cost to the plan for the drug increases.

Table 4

**Distribution of Covered Workers by Type of Cost Sharing for Prescription Drugs,
by Drug Tier**

	<u>Copayment</u>	<u>Coinsurance</u>	<u>Plan Pays Entire Cost After Any Deductible</u>	<u>Some Other Amount</u>
1st Tier (Generic Drugs) ^a	89%	9%	2%	<1%
2nd Tier (Preferred Drugs) ^b	76	21	1	1
3 rd Tier (Nonpreferred Drugs) ^c	71	25	2	2
4 th Tier ^d	39	48	1	11

^a Drug products no longer covered by patent protection that may be produced and/or distributed by multiple drug companies.

^b Drugs included on a formulary or preferred drug list (e.g., a brand-named drug) without a generic substitution.

^c Drugs not included on a formulary or preferred drug list, such as a brand-named drug with a generic substitution. Some brand-name drugs may be classified as non-preferred and placed on a separate tier for other reasons. This may occur because the medication does not have a greater clinical effectiveness when compared with similar medications for the same health condition placed on a lower tier. A medication may also be deemed non-preferred by the health insurance plan because the health insurance plan and pharmaceutical company did not reach a mutual agreement on cost sharing, such as a rebate agreement.

^d New types of cost sharing arrangements that typically build additional layers of higher copayments or coinsurance for specifically identified types of drugs, such as biologics.

Source: The Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits 2013 Annual Survey*.

Table 5

**Average Copayments and Average Coinsurance by Tiers for
Employer Covered Workers in 2013**

	<u>Average Copayment</u>	<u>Average Coinsurance</u>
1 st Tier.....	\$10	16%
2 nd Tier.....	29	25
3 rd Tier	52	38
4 th Tier.....	80	32

Source: The Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits 2013 Annual Survey*.

C. Specialty Drugs Typically Are Costly to Bring to Market, Produce, and Distribute, and Typically Have High Cost Sharing

All drugs, in particular specialty drugs, are costly to bring to market. Specialty drugs often have production and distribution requirements that differ from those for conventional drugs. Their high costs, moreover, can result in significant cost sharing for individuals when the design of their health benefits provides for cost sharing based on the cost of the pharmaceutical, as occurs when cost sharing is based on coinsurance, and there are no limits on such cost sharing. For those with prescription drug coverage, many common specialty drugs can cost more than 20 percent of a Pennsylvania household's annual median income when cost sharing is based on coinsurance.

United States Food and Drug Administration Requirements for Drug Approval

The development of a new drug is a long, complex process. All new drugs, specialty as well as non-specialty, must be approved by the Food and Drug Administration (FDA) to ensure the drug is safe and effective before it can be offered to the public in the United States. Drugs are approved based on laboratory findings that are likely to predict clinical benefit. Exhibit 6 outlines key steps in the FDA approval process for drugs that make it to the clinical testing phase.

Certain drugs that have the potential to provide innovative clinical outcomes for serious and life threatening illnesses that lack current treatment can also be approved through the FDA's streamlined approval process. Drugs approved using the accelerated approval process are required to complete post market studies and report the results of those studies to the FDA.

The pharmaceutical development process is not only complex, it is also risky and extremely costly. The risk of failure can occur at each step in the process. As a result, thousands of new possible drugs are screened in the laboratory each year, but only relatively few eventually receive FDA approval after 10 to 15 years of testing.

FDA Approval Process for Drugs Reaching the Clinical Testing Phase

First Phase: Can take over three years to complete and includes an FDA review of the preclinical testing results to determine if the compound is safe enough for human testing.

Second, Third, and Fourth Phase: Require clinical trials, including:

- 20-80 healthy volunteers who are used to establish a drug's safety and profile. (about 1 year)
- 100-300 patient volunteers who are used to assess the drug's effectiveness. (about 2 years)
- 1,000-3,000 patients in clinics and hospitals who are monitored carefully to determine drug effectiveness and identify adverse reactions. (about 3 years)

Fifth Phase: Company submits an application (usually about 100,000 pages) to the FDA for approval, a process that can take up to two and a half years.

Following FDA Approval: After final approval and the drug becomes available for physicians to prescribe, the drug company continues to report cases of adverse reactions and other clinical data to the FDA.

Source: Developed by LB&FC staff from Annual Mandated Health Insurance Services Evaluation 2010, Maryland Health Care Commission.

For most drugs, not just specialty drugs, the FDA's formal approval process costs over \$350 million. The average cost to yield a single FDA approved drug, however, increases to over \$1.2 billion when the costs of drugs that fail to gain FDA approval are factored in.¹

Typically, the cost to develop certain specialty drugs—biologics²—is more costly than that for traditional chemical drugs. The average cost to develop a new chemical drug is \$802 million, compared to the \$1.2 billion average cost to develop a new biologic. Biotherapeutic drugs that reach the clinical testing phase, moreover, are less likely to gain final FDA approval—about 4 percent for biotherapeutic drugs, compared with 14 percent for traditional chemical drugs, according to the International Federation of Pharmaceutical Manufacturers & Associations.

The reason biologics are more costly to produce than traditional chemical drugs is that chemical drugs are based on small molecules that may consist of dozens of atoms. Biologics are based on large molecules that may consist of millions of atoms. While small molecule drugs are made using commonly known chemical pro-

¹ Pharmaceutical companies can invest considerable resources in drugs that enter into trials but do not obtain FDA approval. In 2012, for example, one drug proposed for use in the treatment of depression (sponsored by AstraZeneca and Targacept) that entered into trials but did not obtain FDA approval had a development cost write-off of over \$500 million. A second drug to treat heart disease following an acute coronary syndrome (sponsored by Roche) that did not obtain FDA approval had development costs of over \$250 million. A third drug to treat mild-to-moderate Alzheimer's disease (sponsored by Johnson & Johnson with Pfizer) that did not obtain FDA approval had a development cost of \$700 million.

²Include products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

cesses, biologics are often protein-based drugs using biological processes inside human organisms. Thus, the process for manufacturing biologics is more complex and more expensive than the chemical methods for making small molecule drugs, and results in higher production costs.

Drug Pricing in the United States

To encourage innovation and provide incentives for research and development of new drugs, pharmaceutical developers and manufacturers in the United States are provided with certain protections for their “intellectual property” under various federal laws. They can obtain:

- *Patents*³ that may cover a drug’s composition, its manufacturing process, method of use, or a combination of these, which typically have a 20 year term (from the date of filing).⁴
- *Data exclusivity* upon FDA approval of the drug, which prohibits another company from relying on the innovator company’s data (i.e., typically, the clinical trial data) in filings with the FDA to demonstrate safety and effectiveness.
- *Market exclusivity* upon FDA approval of the drug, which requires the FDA to refuse to approve another drug for commercialization during a period of time after the innovator drug has been approved to treat a particular condition.

The time frame for exclusivity varies depending on the drug, according to the FDA. Exclusivity for:

- orphan drugs is 7 years,
- new chemical drugs is 5 years,
- “other” exclusivity is 3 years for a change if certain criteria are met,⁵
- pediatric exclusivity adds 6 months to existing patents/exclusivity,
- Patent Challenge is 180 days (applies in certain cases with generic drugs),⁶ and
- Biologics is 12 years.

³ From the U.S. Patent and Trade Office.

⁴ As the drug may not have been approved by the FDA at the time the patent application was filed, and as there is a provision in federal law that takes into account certain amounts of the time for FDA approval of the drug, the average patent protection for a chemical drug once approved by the FDA is about 11 to 13 years.

⁵ For example, if a company receives approval of a drug including a previously approved active ingredient, it may receive three additional years of exclusivity if the application includes new clinical investigations showing new dosage strength, dosage form, route of administration, indication, dosage schedule, patient population, or drug-release profile.

⁶A generic drug manufacturer pursuing accelerated approval must certify in its application that its product will not infringe on any existing patents, either because the relevant patents are expired or because they are invalid. The original patent holder can respond by suing to gain a 30-month stay on the generic’s application. If the brand-name company loses its suit, the generic company receives 180 days of market exclusivity following FDA approval.

Such exclusivity, while encouraging research and development of new medicines, also allows manufacturers considerable flexibility in setting prices for new drugs.

The price of biological products is also increased as a result of their not having generic equivalents. As biologics are highly complex molecules, manufactured in living organisms with a high sensitivity to change in the manufacturing process, exact replication is almost impossible. The FDA, therefore, does not consider biologics as having “generic” equivalents. The FDA, however, recognizes “biosimilar” or “follow-on biologics” as imitators of biologic drugs.

To encourage the development of “biosimilars” or “follow-on biologics,” the Affordable Health Care Act directed the FDA to create an accelerated approval process for biosimilars and “interchangeable” biological products. This provision in the Affordable Health Care Act, however, has been characterized as providing for a biosimilar market with no concrete means to implement it.

In 2012, the FDA issued guidance documents to facilitate biosimilar approval. According to such guidance, the FDA will consider a “follow-on biologic” “biosimilar” if it is “highly similar” to the original product and there are “no clinically meaningful differences” between the original product and the “follow-on biologic” in terms of safety, surety and potency of the product. For this to occur, the biosimilar’s structure must produce the same immune response in the body as the original product. Slight differences in the biosimilar product’s structure, however, may have a dramatically different effect in the body. The biosimilar, moreover, must be able to be interchangeable, i.e., safely substituted for the original product during the course of treatment.

Unfortunately, with today’s state of scientific development, only clinical trials can inform whether structural variations in biologics result in changes in safety and efficacy. As a result, costly and time-consuming clinical trials are required to determine if a “follow-on biologic” will have the same particular immune response as the original product and if there is any diminished safety or efficacy as a result of alternating or switching between use of the original product and the “follow-on biologic.” The FDA, moreover, has indicated that it does not believe technology is evolved enough to truly establish interchangeability. As a result, the FDA will consider such issues on a case-by-case basis, and there is considerable uncertainty associated with the called for “expedited” approval process.

Patient advocates and payers hope that the introduction of these “follow-on” versions of biologics will force prices down in the same way that generic drugs compete with traditional brand-name drugs. Many experts believe that even once approved, biosimilars will offer cost savings, but not of the magnitude seen with small-molecule generics. Others are concerned that patients will be switched, with or

without their knowledge, to “biosimilars,” which may not achieve the same results as the original drug.

Special Handling and Administration

Specialty pharmaceuticals also have higher costs because their distribution may require specialized shipping and temperature-controlled storing and handling. Handling requirements for specialty drugs can be complicated and may include a need for special mixing or compounding, refrigeration, or special lab work.

As a result, specialty drugs are often distributed through special channels. A class of providers, known as specialty pharmacies, exists to distribute and/or dispense these drugs. Such pharmacies can be owned by stand-alone companies, pharmaceutical benefit managers (PBMs), or large pharmacy chains. Drug manufacturers may also control the distribution of specialty products due to production limits and special handling requirements for the drug, some of which may be required as part of the FDA approval process.

The distribution channels may also be limited because of the drug administration requirements. Some specialty drugs must be administered by a clinician.

Patient Monitoring

Patients often need intensive education and follow-up care to manage their specialty drug use as well as their complex health conditions. Dosage, adherence, and side effects require careful monitoring to ensure effectiveness and patient safety. In some cases, the Food and Drug Administration (FDA) has mandated specific strategies to control and monitor their use.

High Cost Sharing

Increasingly, specialty pharmaceuticals have come to be defined as those drugs exceeding a certain cost threshold, such as \$600 per month, which may place such drugs on higher formulary cost sharing tiers. Medicare has elected to use this threshold for Medicare Part D since 2006. Commercial health plans and pharmacy benefit managers may also consider the cost of a drug in determining if a drug is placed on a specialty drug tier. According to the CuraScript⁷ 2010 Specialty Drug Trend Report, the monthly cost for a specialty drug prescription averages over \$2,000. A major pharmacy benefit manager, moreover, has reported the typical out-of-pocket cost for a specialty drug with 20 percent cost sharing is in the range of \$1,500 to \$3,000 per prescription.

⁷ CuraScript is an industry leader for specialty medications and related services. CuraScript and Express Scripts publish an annual Drug Trend Report.

Prescription drug benefit designs, such as Medicare Part D's prescription drug program, and benefit designs for health plans offered through insurance exchanges under the Affordable Health Care Act,⁸ promote cost sharing for higher tier drugs by providing for covered individuals to pay a percentage of the cost of a drug. LB&FC staff reviewed the costs of common specialty drugs to consider what cost-sharing for such drugs would require as a portion of a typical Pennsylvania household's annual income.

To consider such costs, we identified common specialty drugs reported in the national studies and on the Pennsylvania Medical Assistance Program's specialty drug formulary. We identified such drug costs typically for a 30-day supply of the drug or a treatment regime (e.g., 12-24 weeks of therapy) based on the Pennsylvania Pharmaceutical Assistance Program's Average Wholesale Price. Hemophilia products, which are often on specialty drug formularies, were not included in our analysis as their costs are not able to be quantified based on a 30-day supply or treatment regime. Dose and duration for such products are very patient specific and take into account specific issues such as weight, severity and location of bleed, and current clotting factor levels.

Table 6 shows the cost of our list of common specialty drugs as a percentage of 2012 median income for Pennsylvania households. For example, a household with a member who is prescribed Gleevec, a specialty drug often used in the treatment of cancer, would find that the average wholesale price for a 30-day supply was \$2,723. Based on the average coinsurance rate of 32 percent⁹ for specialty tier drugs, the coinsurance would be \$871 per month, or \$10,457 annually. This represents over 20 percent of the median annual income of a Pennsylvania household in 2012.¹⁰ According to a DXR¹¹ survey, the average wholesale price of Gleevec increased by 158 percent between 2007 and 2014.

Most of the specialty drugs included in Table 6 have an annual out-of-pocket cost that would be more than 5 percent of the median household income in Pennsylvania. Almost 60 percent of the drugs, however, have annual out-of-pocket costs that exceed 20 percent of the median household income in Pennsylvania. Without insurance coverage with out-of-pocket limits, most average families would be challenged to afford such medications.

⁸Findings F and G provide additional information on the benefit designs for such federal program plans.

⁹Thirty-two percent is the average coinsurance for fourth tier formulary drugs reported in the Kaiser Family Foundation 2013 Employer Health Benefit Survey.

¹⁰ According to the American Community Survey conducted by the U.S. Department of Commerce, the median household income in Pennsylvania was \$51,230 in 2012.

¹¹ DRX is a provider of technology solutions for web-based prescription drug comparison as well as Medicare health plan comparison and enrollment services and provides web-based healthcare comparison tools, technology, and data to a broad range of clients in the healthcare industry.

Table 6

Cost of Common Specialty Drugs as a Percentage of 2012 Median PA Income

Medication	Disease or Condition	Monthly Cost ^a	32% Coinsurance	Annual OOP	% Median PA Income ^b
Gleevec	Cancer	\$2,723	\$871	\$10,457	20.4%
Lupron Depot	Cancer	\$688	\$220	\$2,643	5.2%
Tarceva	Cancer	\$7,454	\$2,385	\$28,625	55.9%
Avonex	Multiple Sclerosis	\$5,454	\$1,745	\$20,943	40.9%
Betaseron	Multiple Sclerosis	\$6,240	\$1,997	\$23,962	46.8%
Rebif	Multiple Sclerosis	\$5,804	\$1,857	\$22,286	43.5%
Enbrel	RA/Inflammatory Conditions	\$12,127	\$3,881	\$46,568	90.9%
Humira	RA/Inflammatory Conditions	\$6,006	\$1,922	\$23,064	45.0%
Remicade	RA/Inflammatory Conditions	\$4,247	\$1,359	\$16,310	31.8%
Ribavirin	Hepatitis C	\$1,244	\$398	\$4,776	9.3%
Pegasys	Hepatitis C	\$3,702	\$1,185	\$14,216	27.7%
Sovaldi	Hepatitis C	\$26,544	\$8,494	\$101,929	199.0%
Aranesp	Anemia/Blood Cell Deficiency	\$6,175	\$1,976	\$23,711	46.3%
Epogen	Anemia/Blood Cell Deficiency	\$165	\$53	\$635	1.2%
Procrit	Anemia/Blood Cell Deficiency	\$1,947	\$623	\$7,476	14.6%
Genotropin	Growth Deficiency	\$1,290	\$413	\$4,953	9.7%
Humatrope	Growth Deficiency	\$1,281	\$410	\$4,919	9.6%
Norditropin	Growth Deficiency	\$5,617	\$1,797	\$21,569	42.1%
Letairis	Pulmonary Hypertension	\$8,272	\$2,647	\$31,764	62.0%
Tracleer	Pulmonary Hypertension	\$4,230	\$1,354	\$16,243	31.7%
Revatio	Pulmonary Hypertension	\$441	\$141	\$1,693	3.3%
Xolair	Respiratory Conditions	\$932	\$298	\$3,580	7.0%
Pulmozyme	Respiratory Conditions	\$932	\$298	\$3,580	7.0%
TOBI Podhaler	Respiratory Conditions	\$8,012	\$2,564	\$30,767	60.1%
Atripla	Immune Deficiency	\$2,402	\$769	\$9,224	18.0%
Truvada	Immune Deficiency	\$1,540	\$493	\$5,913	11.5%
Norvir tabs	Immune Deficiency	\$3,703	\$1,185	\$14,220	27.8%

^a All Average Wholesale Price.

^b \$51,230 in 2012 according to the American Community Survey conducted by the US Department of Commerce.

Source: Developed by Legislative Budget & Finance Committee staff.

D. The High Cost of Drugs in Specialty Tiers and Their Higher Cost-Sharing Requirements Can Adversely Impact Those in Need of Such Life Sustaining Medications

Access to affordable, high quality prescription drug coverage is essential, in particular, for those with chronic health care needs, those with severe illnesses, and those in need of life sustaining medications. Lack of access to such coverage can create significant economic hardships, in particular, for those with chronic health care conditions and those with severe illnesses. In addition to economic hardship, absence of such access, may reduce the likelihood of individuals going to a doctor, filling a prescription, and adhering to the recommended treatment regime.

The importance of access to affordable, high quality coverage is clearly illustrated in longitudinal data for Pennsylvanians who participate in the PACE/PACENET program. It is also underscored by responses to our survey of specialty drug consumers and in national studies.

Access to Medication Improves With Affordable High Level Prescription Drug Coverage

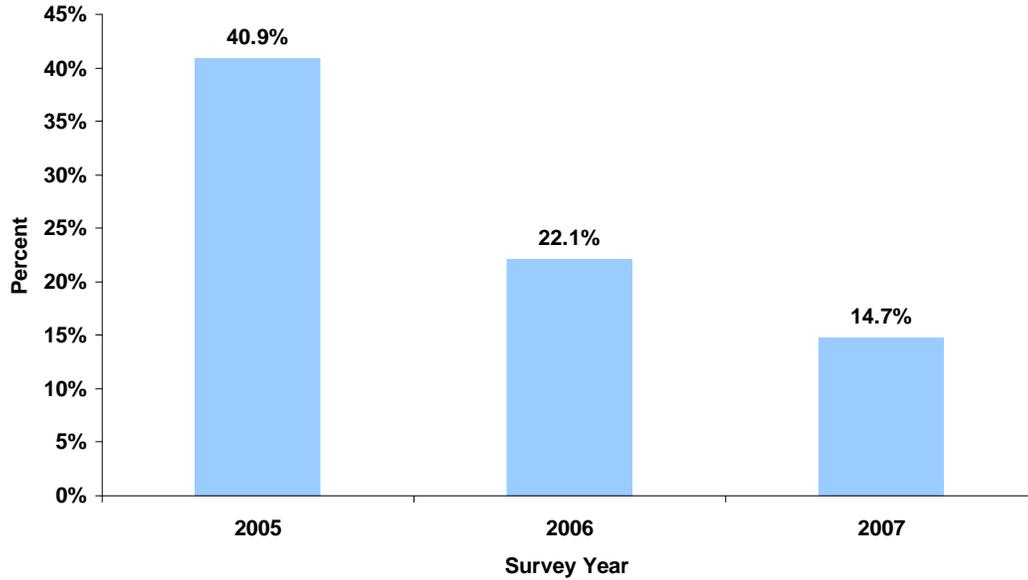
Access to medication improves when affordable, high level prescription drug coverage is available. The PACE/PACENET program routinely surveys cardholders as part of its new enrollment and cardholder renewal application processes. As a result, program cardholder surveys offer a window into what happens as a result of access to affordable coverage. As shown in Exhibit 7, following their enrollment in PACE/PACENET, new enrollees in 2005 were substantially less likely to report not filling a prescription due to cost, skipping doses to make a prescription last longer, or avoiding seeing a doctor because of concerns about medication costs.

PACE/PACENET Survey on Health and Well-Being

Percentage of Cardholders Who Report Ever Not Filling a Prescription Due to Cost

Sample: Cohort of New Enrollees in 2005 Who Also Responded to Surveys in 2006 and 2007

(N=3,093)



Percentage of Cardholders Who Report Skipping Doses to Make Prescription Last Longer

Sample: Cohort of New Enrollees in 2005

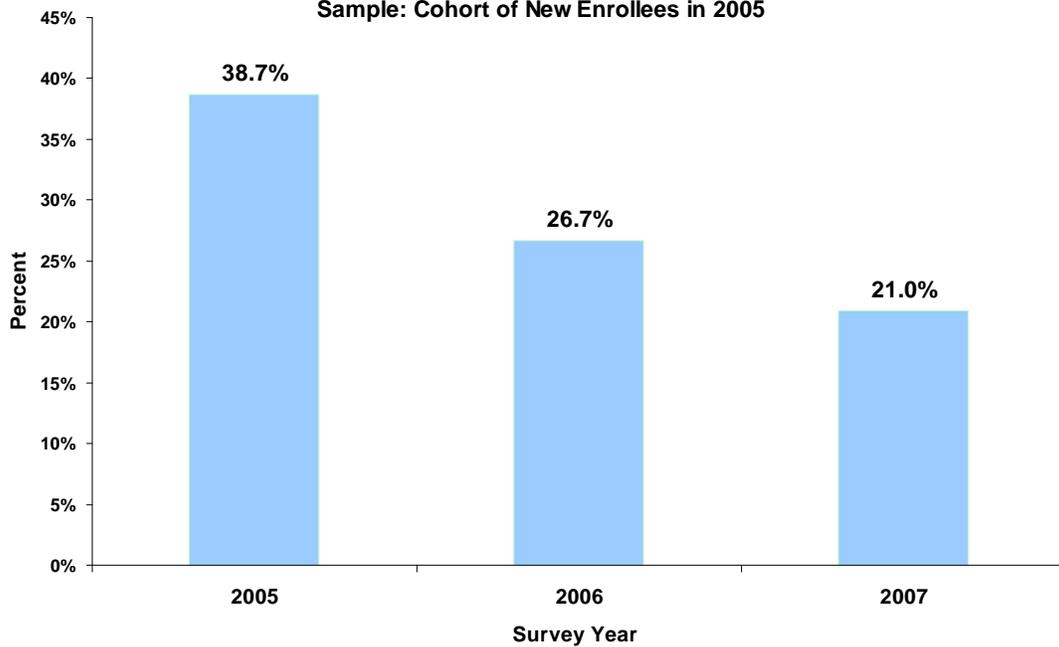
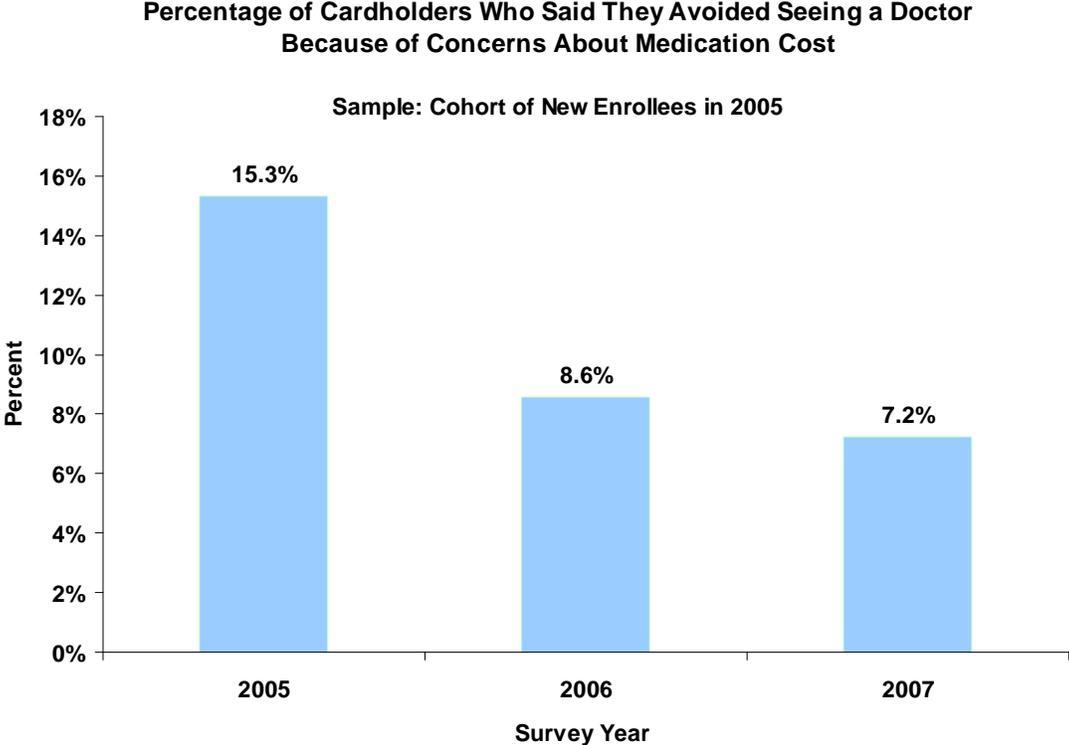


Exhibit 7 (Continued)



Source: PACE/PACENET Survey on Health and Well-Being: Statewide Survey of Older Pennsylvanians, January 2011.

Even with the access to prescription drugs and the substantial cost savings the PACE/PACENET program provides, some of its cardholders still encounter problems with the cost of their medications. In the 2012 PACE/PACENET survey, for example:

- 5.5 percent of PACE and 7.7 percent of PACENET cardholders reported they avoided seeing a doctor at least once because of concerns about medication costs,
- 13.3 percent of PACE and 13.1 percent of PACENET cardholders received help paying for their prescription from friends or family,
- 15.3 percent of PACE and 22.0 percent of PACENET cardholders skipped doses of medicine to make their prescriptions last longer, and
- 20.2 percent of PACE and 26.2 percent of PACENET cardholders spent less on other basic needs to pay for their prescription.

Despite Having Prescription Drug Coverage, Many Specialty Drug Consumers Have Major Problems Related to Their Drugs' Costs

Almost all (97 percent) of those responding to the LB&FC's specialty drug consumer survey reported having health insurance that includes coverage for prescription drugs, including 28 percent who reported having a high deductible/catastrophic plan. Many, however, reported significant problems due to their specialty drug costs. About 40 percent of those responding to the survey answered the question: "Have you ever done any of the following to save money on your specialty tier medication?" Of those,

- over 40 percent reported skipping pills, injections or dosages;
- over 40 percent delayed filling their prescription;
- over 30 percent chose not to take a particular brand of medication because it was too expensive, even though their doctors felt it was the best medication for their conditions; and
- almost 30 percent delayed starting a new medication.

Our consumer survey also asked those responding if they had taken specialty drugs in the past and were no longer, and the reasons they were not currently taking the specialty medication. Of those reporting they were no longer taking a specialty drug, 20 percent indicated they had ceased taking the drug as they could no longer afford it. One oncologist with whom we spoke also confirmed there are cancer patients unable to obtain medically required medications as they can no longer afford their high costs.

High Out-of-Pocket Cost Sharing Can Result in Treatment Abandonment

Research has shown that those using specialty drugs often have limited alternatives. Like those in our survey, some are unable to pursue recommended treatment and fill specialty drugs that have been prescribed by their physicians. Streeter and her colleagues,¹ for example, analyzed a nationally representative pharmacy claims database with Medicare and commercial insurance beneficiaries for whom oral cancer therapy was recommended between 2007 and 2009. They found that 10 percent of those for whom such therapy had been prescribed did not have the prescription filled within 90 days. High cost sharing, high prescription activity in the previous month, lower income, and Medicare coverage were associated with higher therapy abandonment rates. Those with cost sharing greater than \$500 were four times more likely to abandon oral cancer therapy than those with cost sharing of \$100 or less.

Gleason and his colleagues² found similar results when considering patient abandonment of high costs medication therapy involving tumor necrosis factor (TNF) inhibitors and biologic agents used to treat multiple sclerosis. The unadjusted abandonment rate for those with out-of-pocket expenses of \$100 or less was 5.7 percent, increasing to more than 25 percent with out-of-pocket expenses of \$200 or more for multiple sclerosis medication. For TNF, the abandonment rate was 4.7 percent for those with out-of-pocket expenses of \$100 or less, increasing to more than 25 percent with out-of-pocket expenses of more than \$500.

Conwell and her colleagues³ conducted structured interviews with nurses and social workers from National Cancer Institute designated centers, teaching hospitals, comprehensive cancer treatment centers at community hospitals, and private physician practices to understand how the Medicare Part D coverage gap (a.k.a. the “doughnut hole”) affects Medicare beneficiaries’ access to oral anticancer targeted therapies. They reported that once such therapies are prescribed, patients’ immediate concerns are about costs, followed by the drug’s potential side effects and benefits. Typically, after seeking to obtain financial assistance, beneficiaries will attempt to pay out-of-pocket costs by withdrawing money from savings or retirement accounts, assuming debt, lowering living expenses, and declining targeted therapy when copayments become too high after they enter their insurance coverage gap.

¹Streeter, S.B. et al, Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions, *Journal of Oncology Practice*, Vol. 7, Issue 3 S, 2011.

² Gleason, P.P. et al, Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications, *Journal of Managed Care Pharmacy*, Vol. 15, No. 8., 2009.

³ Conwell, L.J. et al, Promising Therapies, Prohibitive Costs: a Qualitative Assessment of the Effects of the Medicare Part D Doughnut Hole on Access to Costly Cancer Medications, *Community Oncology*, Vol. 8, Number 3, 2011.

Increased Cost Sharing for Specialty Drug Products Does Not Reduce Unnecessary Use, but Transfers a Greater Share of Their Cost to Patients

Cost sharing is considered a way to manage drug costs and to reduce unnecessary drug use (e.g., use of antibiotics to treat a viral infection, patient requests for a drug when life-style changes would be as effective, patient request for a prescription drug advertised to the public when other less expensive drugs are available and as effective, or patient use of a brand name drug when safe and effective generic alternatives are available.) Specialty drug use by the severely disabled, however, is largely insensitive to cost sharing levels. As those that do not forgo treatment entirely, elect to pay the high out-of-pocket costs, increased cost sharing for specialty drugs merely transfers a greater share of such drug costs onto patients.

Researchers from the University of Pittsburgh and Harvard University,⁴ for example, examined prescription drug use in a random sample of two groups of Medicare beneficiaries both before and after they reached Medicare's prescription drug coverage gap (a.k.a. "doughnut hole"). One group of Medicare beneficiaries experienced no coverage gap as they had employer group coverage that continued to provide coverage after the Medicare coverage gap was reached. The second group of Medicare beneficiaries had no coverage or only some generic coverage after reaching the "doughnut hole."

The University of Pittsburgh and Harvard researchers found that those lacking coverage in the "doughnut hole" reduced their drug use by 14 percent (about 0.7 prescriptions per month) compared with beneficiaries with coverage in the gap. When they examined data for the most seriously ill beneficiaries (i.e., those who reached both the coverage gap and the catastrophic coverage phase), however, they found no reduction in the number of filled prescriptions occurred as a result of reaching the coverage gap. This severely ill group filled an average of seven prescriptions a month both before and after reaching the coverage gap.

Goldman and his colleagues⁵ specifically examined patients with employer-sponsored health insurance⁶ and conditions treated with specialty drugs, including cancer, kidney disease, rheumatoid arthritis, and multiple sclerosis, to consider how use of specialty drugs responds to cost sharing. In the study, patients with these conditions were considerably more expensive than average plan beneficiaries, with average annual medical plan spending ranging from \$19,321 (in 2003-04 dollars) for those with rheumatoid arthritis to \$31,218 for those with kidney disease, compared with \$6,038 for the overall average beneficiary. Average out-of-pocket costs were also considerably greater than for the average beneficiary. While the typical plan

⁴ Zhang, Y. et al, The Effects of the Coverage Gap on Drug Spending: A Closer Look at Medicare Part D. *Health Affairs*, 28(2); 317-325, 2009.

⁵ Goldman, D.P. et al, Benefit Design and Specialty Drug Use, *Health Affairs*, 25(5), 1319-1331, 2006.

⁶ Fifty-five health plans offered by fifteen large employers in 2003 and 2004 and covering approximately 1.5 million beneficiaries continuously enrolled in a plan for an entire year.

beneficiary had average out-of-pocket costs of \$1,687, such costs ranged from \$3,301 for those with multiple sclerosis to \$8,878 for those with kidney disease.

Such average out-of-pocket costs, however, understate the out-of-pocket costs incurred by many. More than 10 percent of the patients with cancer had out-of-pocket spending that exceeded \$18,500 per year, and 5 percent had costs that exceeded \$35,600 per year. Similar patterns emerged for those with kidney disease. For those with rheumatoid arthritis, more than 10 percent had out-of-pocket costs of about \$9,000, and 5 percent more than \$17,000 per year. For patients with multiple sclerosis, more than 10 percent had out-of-pocket costs of just over \$5,000 per year, and 5 percent more than \$9,000 per year.

Typically, with traditional pharmaceuticals, when copayments are doubled, overall spending for traditional drugs falls by 30 to 50 percent. Goldman and his colleagues, however, found that such decline did not occur once a patient initiated a specialty drug. When copayments for specialty drugs to treat rheumatoid arthritis were doubled, overall spending for the drug declined by only 21 percent. For cancer drugs, moreover, overall spending was reduced by only 1 percent.

Significant Economic Consequences Can Occur as a Result of the Burden of Out-of-Pocket Medical Expenses

Most of those responding to our survey reported having health insurance with coverage for prescription drugs. However, about 40 percent of those responding also provided information about difficulties they encounter because of the cost of their medications.

- over 40 percent reported problems with purchasing food/groceries,
- roughly 40 percent reported taking on additional credit card debt,
- over 30 percent reported difficulty buying clothes or other needed items for themselves or their family,
- 25 percent reported difficulty making a car payment, and
- 10 percent had to declare bankruptcy.

Others identified a variety of difficulties, including going without medications, failing to pay income taxes, having to move in with parents, and having to sell personal property except for a bed, computer, and clothing. Such findings are consistent with results reported in national surveys.

The 2012 National Health Interview Survey (NHIS) data found that 20 percent of non-elderly adults reported difficulty paying medical bills in the previous year. According to the survey's data, the vast majority of non-elderly adults with medical debt (70 percent) are insured, with people with employer-sponsored health

insurance accounting for the largest share (54 percent) of non-elderly with medical debt.

National survey data also confirm the burden high out-of-pocket costs (OOP) place on those requiring health care. In 2014, for example, researchers from the Henry J. Kaiser Family Foundation's Program for the Study of Health Reform and Private Insurance and the Georgetown University Health Policy Institute's Center on Health Insurance Reform reported:⁷

Our analysis of the Survey of Income and Program Participation (SIPP)⁸ finds that privately insured people with out-of-pocket medical expenses that exceed five percent of their income are about twice as likely to have difficulty paying their rent and utilities, affording food, and face barriers accessing medical care, compared to those with OOP cost less than five percent of their income.

The researchers also reported that unaffordable medical debt among those with insurance primarily results from cost sharing for care covered by their insurance.

In addition to economic deprivation, medical debt has other serious consequences, including damaged credit, which creates difficulty in qualifying for mortgages, auto loans, and other consumer credit at affordable interest rates. Medical debt can also result in depletion of long term assets, emotional stress, housing instability (including missed mortgage or rent payments, property tax liens, eviction, rental applications denied, and in extreme circumstances, homelessness), and bankruptcy.

In 2007, medical bills were the leading cause of personal bankruptcy in the United States, contributing to over 60 percent of personal bankruptcies. Contrast this with 1981, when only 8 percent of families experienced personal bankruptcy as a result of serious medical problems.

Of the medical bankruptcies in 2007, over 90 percent had medical debts of 10 percent or more of pre-tax family income. The remainder had lost significant income due to illness or had mortgaged a home to pay medical bills. Those declaring medical bankruptcy, moreover, were well educated, owned homes, and had middle income occupations, according to Harvard researchers.⁹

⁷ Kaiser Family Foundation, *Medical Debt Among People with Health Insurance*, January 2014.

⁸ The U.S. Census Bureau sponsors the SIPP survey. The survey collects data related to types of income, labor force participation, social program participation and eligibility, and general demographic characteristics. It is used to estimate future costs and coverage for government programs and provide statistics on the distribution of income and measures of well-being in the U.S.

⁹ Himmelstein, D, Thorne, D., Warren, E., and S. Woolhandler, Medical Bankruptcy in the United States, 2007: Results of a National Study, *The American Journal of Medicine*, 2009.

Based on interviews with a sample of 2007 medical bankruptcies, Harvard researchers reported that at the onset of illness about 80 percent were insured, including 60 percent with private insurance as their primary coverage.¹⁰ By the time of bankruptcy, private coverage had dropped to about 55 percent, with Medicare and Medicaid coverage increasing (from about 10 to 16.4 percent and from about 5 percent to 9.9 percent respectively).

The Harvard researchers' work also provided a window into the significant out-of-pocket medical costs incurred by families forced into medical bankruptcy. Out-of-pocket medical costs averaged:

- \$17,943 for all medically bankrupt families,
- \$26,971 for uninsured patients,
- \$22,568 for patients who initially had private coverage but lost it,
- \$14,633 for those eventually reverting to Medicaid,
- \$12,021 for those with Medicare, and
- \$6,544 for those with Veterans Affairs/military coverage.

In this study, non-stroke neurologic illnesses such as multiple sclerosis had the highest associated out-of-pocket costs (\$34,167). Other diagnoses with some of the highest out-of-pocket costs included diabetes, injuries, stroke, mental illness, and heart disease.

In the Harvard researchers' study, prescription drug out-of-pocket expenses were second only to hospital bills. Hospital bills accounted for the largest out-of-pocket costs (48.0 percent), followed by prescription drugs (18.6 percent), doctors' bills (15.1 percent), and premiums (4.1 percent). For about one-third of the patients, however, prescription drugs were the largest out-of-pocket expense.

The Economic Burden of High Out-of-Pocket Costs Is Typically Greatest for Those With Chronic Conditions and Severe Illnesses

The burden of persistently high out-of-pocket health care costs is heaviest for those with chronic conditions and severe illnesses. Based on analysis of Medical Expenditure Panel Survey data from 2001 through 2005,¹¹ Commonwealth Fund¹² researchers found that nearly 40 percent of non-elderly adults with three or more

¹⁰ Ten percent had Medicare, about 5 percent Medicaid, and 2 percent had Veterans Affairs/military coverage.

¹¹ The U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality's Medical Expenditure Panel Survey collects data from a nationally representative sample of families and individuals on specific health services that Americans use, how frequently they use them, the cost of these services, and how they are paid. It also collects data on the cost, scope, and breadth of health insurance held by and available to U.S. workers.

¹² The Commonwealth Fund supports independent research on health care issues to help achieve its mission of promoting a high performance health care system.

chronic conditions had out-of-pocket costs and insurance premiums that exceeded 5 percent or more of their income for two consecutive years. This compared with 20 percent of those with one chronic condition and 14 percent for those with no chronic condition.

Prescription drug costs, moreover, were found to be the single largest contributor to the high financial out-of-pocket costs for those with chronic conditions. Such costs accounted for 55 percent of the out-of-pocket costs (excluding premiums) for those with two or more chronic conditions and 36 percent for those with one chronic condition. For those with no chronic condition, other costs (i.e., dental care, vision care, home health, and other medical equipment) accounted for the largest share (38 percent) of their out-of-pocket costs.¹³

The burden of high out-of-pocket costs is even greater for those with severe illnesses, such as cancer, non-Hodgkin's lymphoma, chronic kidney disease, rheumatoid arthritis, multiple sclerosis, and hepatitis C, than it is for those with chronic illnesses, such as a cerebrovascular accident, coronary artery disease, COPD, diabetes mellitus, and asthma. Willey *et al*, using a managed care database (from July 2000 through August 2004) representing over 25 million members, examined the cost, both to the commercial plan and the patient, for three groups—those with severe illness, those with chronic disease, and a group representative of the plan's population.¹⁴ Severely ill patients in the study represented less than 1 percent (0.8 percent) of the study populations, but their cumulative health care needs were almost 10 times higher than for the general plan participant (\$3,075 in average annualized costs compared with \$29,273 in 2005 dollars), and more than three times higher than for those with chronic illnesses (\$8,225 in averaged annualized costs compared with \$29,273).

Similar differences occurred when only patient out-of-pocket costs were considered. Those with severe illnesses incurred average annualized out-of-pocket costs that were almost twice those of individuals with chronic illnesses (\$2,077 compared with \$1,195 in 2005 dollars), and almost four times those of plan members as a whole (\$2,077 compared with \$570).¹⁵ The study also found that while the costs of biologic medications and pharmacy medications were significant overall, such costs were not the primary cost drivers for severely ill individuals.¹⁶ Medical service costs, including hospitalization and ambulatory care, accounted for over three-quarters of total plan costs for the severely ill.

¹³ Cunningham, P. *Issue Brief, Chronic Burdens: The Persistently High Out-of-Pocket Health Care Expenses Faced by Many Americans with Chronic Conditions*, Commonwealth Fund pub. 1301, Vol 63, July 2009.

¹⁴ Willey, V., et al, Costs of Severely Ill Members and Specialty Medication Use in A Commercially Insured Population, *Health Affairs*, Vol. 27 no.3., May 2008.

¹⁵ Willey, V. *et al*, Beyond the Myths: Finding Benefit Design Solutions that Address the True Costs of High Health Care Use, *The American Journal of Managed Care*, Vol. 14, No. 8, July 2008.

¹⁶ Biologics represented 6.6 percent of the costs paid by the health plan for all patients, and less than one third of total pharmacy costs. Less than half of patients in the top out-of-pocket bracket, moreover, used biologic medications.

Willey *et al.* further noted that patients accounting for the top 20 percent of the commercially insured plans' costs were expending 5 percent or more of an average household's income on out-of-pocket health care costs. For the elderly, the impact is even greater. Elderly patients accounting for the top 20 percent of plans' costs were expending between 17 to 20 percent of the average elderly household's income on out-of-pocket cost.

Based on the high proportion of family income spent on out-of-pocket health care costs for those with chronic conditions and severe illnesses, Willey and his colleagues concurred with a prior conclusion of the federal Agency for Health Research and Quality:

...Increasing OOP [out-of-pocket] expenditures might lead to higher overall health care costs....[as] High OOP burdens are associated with delaying or forgoing medical care for financial reasons—behavior that can have severe consequences for those in poor health.

E. Almost Half of Those Responding to the LB&FC’s Survey of Consumers Reported Having Insurance Without a Cap on Their Prescription Drug Out-of-Pocket Cost Sharing

To identify how specialty drug tiers impact consumers who require specialty drugs to treat their medical condition, we designed an online consumer survey for patients and their families to share their experiences with specialty tiers. Such experiences included their total and out-of-pocket cost, the impact of such costs on their adherence to recommended treatment, the economic impact of drug costs on their households, and assistance programs in which they may participate. (See Appendix E for a copy of our survey of consumers.)

In Finding D we have provided detailed information about the economic hardships and problems with treatment adherence experienced by Pennsylvania specialty drug consumers. As noted in Finding D, such experiences tend to mirror those reported in national research studies.

Geographic Location

We received responses from over 375 individuals dealing with conditions that can require specialty tier drugs. The respondents were from all across the Commonwealth. As shown in Table 7, the most responses came from residents of south-western (31 percent) and southeastern (22 percent) Pennsylvania.

Table 7

Survey Respondents by Region		
<u>Region</u>	<u>Number of Responses</u>	<u>Percentage of Responses</u>
Northeast	67	19.0%
Northwest	22	6.2
North Central	15	4.2
Southeast	79	22.4
Southwest	111	31.4
South Central	<u>59</u>	16.7
Total	353 ^a	

^a Twenty-four respondents did not identify the region where they reside.

Source: Developed by LB&FC staff.

Household Income and Composition

Among our survey respondents, over 30 percent had household income less than \$50,000 per year, while 25 percent had household income of more than \$100,000 per year. Forty-two percent of the respondents reported having at least

one child in the household. Sixteen percent of the households included only one adult.¹

Seventy-two percent of those responding to our survey (266) lived in households in which someone was currently taking a specialty tier medication. Those responding were being treated for many different medical conditions. The most often cited was treatment for multiple sclerosis, followed by cancer, immune deficiency, inflammatory conditions such as rheumatoid arthritis, and hemophilia.

Prescription Drug Out-of-Pocket Cost Sharing Caps

Almost 97 percent of those responding to our questionnaire indicated that they have health insurance that includes prescription drug coverage. Over 70 percent of those who had some type of health insurance reported having private health insurance, either through an employer or purchased individually. About 28 percent of those with insurance have a high deductible or catastrophic health insurance plan.

About half of those responding to our consumer survey told us their insurance had limits on their out-of-pocket costs for prescription drugs (53 percent), with the remainder (47 percent) indicating their insurance placed no limits on their out-of-pocket prescription drug costs. Most of the reported out-of-pocket cost sharing limits (70 percent) took the form of an annual cap on overall out-of-pocket expenditures. About 12 percent of those reporting out-of-pocket cost sharing limits, however, reported such limits were applied on a per prescription basis. As noted in Finding G, several states have adopted legislation providing for annual or per prescription cost sharing limits for certain specialty drugs.

Almost 60 percent of our respondents reported paying a flat copayment amount per prescription for specialty tier medications. The flat copayment amount varied greatly, ranging from \$0 to over \$600 per prescription refill. Forty percent of the respondents reported paying a percentage of the drug cost (coinsurance). Rates for coinsurance also varied considerably, ranging from 10 percent to 60 percent of the drug's cost. Exhibit 8 shows some of the comments the respondents provided related to the cost they must pay for their medication.

Prior Notice of Prescription Drug Cost Sharing Changes

We also asked the consumers we surveyed if their insurance company had changed its requirements for prescription drug cost sharing and to tell us how they learned about such changes. About 45 percent of our respondents told us their insurance company had made changes to their prescription drug copayment or coinsurance requirements.

¹ Three of the 55 single adult households also included at least one child.

Exhibit 8

Consumer Comments Related to the Cost of Specialty Tier Drugs

- For people with multiple diseases out-of-pocket costs can be extreme. My out-of-pocket for 3 specialty tier drugs is over \$250 [a] mo[nth], plus I take 5 other non-tier meds.
- I've had chemo twice in the past four years. I am hoping to take advantage of the new drugs currently being introduced to the market. My concern is that I will not be able to do so because the looming costs of these specialty drugs. It's "will I die because I can't afford the cost of the drugs"? Unfortunately others hold my life in their hands for financial reasons.
- I never realized before how much these medications could cost. I hope my husband's employer continues to offer the wonderful health coverage we would have. The medication retail cost per month is 122% of his take home pay. No, that is not a typo. The medication is more than the take home pay.
- We meet the out-of-pocket maximum for our family in the first month of each New Year. This always places a financial burden on our family. Moving hemophilia factor replacement into a specialty tier would increase the cost to our family significantly. We cannot afford to pay the expected costs for this medication and would need to go on public assistance to ensure our children receive the medication they need to live a normal life.
- If I did not receive help paying for my Avonex^a I would be forced to discontinue therapy because we would not be able to afford the cost of the medication on top of all of the other medications we must pay for on a monthly basis.
- The second hardest part of dealing with MS is the cost of the medications. Particularly the specialty tier ones.
- Would just like to say, people think you make enough to cover these expenses when they see your middle class income. But when you have a child and spouse who also need medicine on a monthly basis and you have medical bills in addition to your prescription bills, and you are not expecting to have this type of diagnosis and you were fine financially before this all happened and you have no control of what needs to be done in order to maintain your health and keep your job in order to financially try to meet the obligations you already incurred prior to all this it is a snowball effect and just goes downhill. I don't live in a fancy home. My home is worth less than 100k. I don't drive a fancy car. We were hit hard with the economy and while we are both educated, we lost an income for many months and had to survive on credit cards. We made too much money with one income to qualify for state assistance. It seems to me that you help those who don't try to make it and those of us who keep plugging on and try to make it are overlooked because on paper we look ok. WE ARE NOT OK.
- I am having difficulty paying the copay for my infusion along with all the copays for my other drugs, many of which are third tier. If my obligation changes from a copay to a percentage, it would be up to \$2,000 per month which I could not pay and would then die. Not easy for a 44 year old.
- As a family our son's medical costs has greatly impacted our financial situation. If his medication is put on a specialty tier it would drastically effect his ability to remain on treatment and ultimately his overall health.
- The drugs are usually necessary to sustain life. Higher copays and coinsurance do nothing to rein in usage. They just incur financial pain on the patients.
- My medication would cost over \$5,000/month if I had to pay it out of pocket. If it wasn't covered through insurance, not only could I not afford it, but neither could almost anyone!
- My family had to find a way to pay more than \$30,000 in medical bills when you are only making \$35,000. How are you supposed to do that?
- I do not believe these medications should be priced so high forcing people to forgo taking the medication or causing financial hardship. Many of these medications are life sustaining.

^a A biologic used in the treatment of relapsing forms of multiple sclerosis to slow the accumulation of physical disability.

Source: Developed by LB&FC staff from survey responses.

Almost 40 percent of those who experienced changes in their cost sharing responsibilities reported finding out about them at the pharmacy counter when they went to refill a prescription. Thirty-one percent received prior notice from their insurance company, and 17 percent received notice from their employer.

Of those receiving prior notice, almost half received notification less than 30 days before the cost increase went into effect. As noted in Finding G, several states have adopted legislation requiring prior notice of changes (typically 60 to 90 days) to cost sharing and formulary changes for specialty drugs. The Affordable Health Care Act, moreover, requires 60-days advance notice for benefit changes that occur within the year a health plan is in effect. While this provision does not apply specifically to formulary changes, such changes are typically posted and available from insurers though formal notice is not provided, according to one major insurer with whom we spoke.

Patient Assistance Program Participation

We also asked consumers if they received any help in paying for specialty tier medication from a patient or prescription assistance program. One-third of the respondents who answered the question said that they did receive some type of assistance. This assistance came from various sources, including programs run by drug manufacturers, non-profit groups, government agencies, and pharmacy distributors. Finding F provides additional information on some of the pharmacy assistance programs in which survey respondents reported participating.

F. For Those With Limited Income, Certain Public and Private Programs Provide Help With High Specialty Drug Costs

Several public programs assist with out-of-pocket costs for high cost drugs, including those on drug formulary specialty tiers. They include the federal Medicare and Medicaid programs, and several select state programs.

Medicare¹ Part D Program's Assistance for Those With Low Income

Since 2006, Medicare, the federal health insurance program for the elderly and disabled, has offered a voluntary outpatient prescription drug benefit known as Medicare Part D. With Medicare Part D, Medicare beneficiaries may enroll and obtain prescription drug coverage through stand-alone prescription drug plans (PDP)² or Medicare Advantage private managed care plans (MA-PD) that offer a prescription drug benefit. All who enroll in Medicare Part D for outpatient prescription drug coverage have their monthly premium partially subsidized by Medicare for “standard coverage.”³

Exhibit 9 depicts Medicare Part D's 2014 “standard” coverage benefit. As shown in Exhibit 9, Medicare beneficiaries with “standard” prescription drug coverage may incur considerable out-of-pocket costs, including:

¹ The federal Medicare program is highly complex, consisting of several distinct and different parts. Medicare's Hospital Insurance benefit is known as Part A, and covers hospitalization and post-acute care services. It is the only Medicare benefit financed through a mandatory payroll tax (2.9 percent split between employers and employees, with an additional tax on wages over \$200,000 for single filers and \$250,000 for married filers). Medicare Part B is part of Medicare's Supplementary Medical Insurance benefit and covers outpatient hospital services and ambulatory care and certain home health care. Medicare Part C is the Medicare Advantage program which contracts with private managed care plans to offer Part A and Part B services. Part D is a part of Medicare's Supplementary Medical Insurance benefit and covers outpatient pharmaceuticals. Medicare Part D differs substantially from Medicare Parts A and B. When enacting Medicare Part D, Congress elected to provide beneficiaries in traditional Medicare with a choice of competing prescription drug plans rather than a single government administered program as Medicare does with hospital and physician services. It also decided against administrative pricing of services such as Medicare applies to almost all other services and instead provided for prices to be set in negotiations between prescription drug plans (PDPs) and drug manufacturers relying on private PDPs modeled on commercial pharmacy benefit managers. As a consequence, absent benefit standardization, Medicare Part D plans have considerable flexibility in their pharmaceutical benefit designs. Congress also elected to provide for cost sharing between beneficiaries and plans based on explicit ten-year forecast spending limits for the Part D program. As such, while Medicare Part D offers certain catastrophic coverage, it runs counter to insurance principles that emphasize protection against larger risks over smaller ones.

² PDPs are mostly owned by pharmacy benefit management (PBMs) companies or health insurance companies.

³ Medicare provides plans with a subsidy for each Medicare enrollee that averages 74.5 percent of “standard coverage.” The subsidy takes the form of a direct subsidy to plans and individual reinsurance where Medicare subsidizes 80 percent of drug spending above the established annual out-of-pocket threshold. Medicare Part D plans may also offer “enhanced” plans, or “enhanced” coverage with the beneficiary responsible for all added costs above those for the “standard” benefit or “standard” coverage.

- an annual deductible (\$310 in 2014),⁴
- 25 percent of the costs of drugs during the initial coverage period (\$635),
- over \$3,600 in discounted drug costs during the coverage gap (a.k.a. “doughnut hole”), and
- 5 percent of drug costs after reaching the catastrophic coverage period.

Certain low income individuals enrolled in Medicare Part D receive additional help with their prescription drug costs. Such individuals include:

1. Individuals with both Medicare and full Medicaid⁵ benefits.
2. Individuals with Medicare and full Medicaid benefits in nursing homes and Home and Community Based Services.
3. Individuals eligible for one of the four Medicare Savings Programs,⁶ SSI, or who apply with income at or below 135 percent of poverty (\$11,670 in 2014) and limited resources (\$8,580 for an individual).⁷
4. Individuals with income below 150 percent of poverty (\$17,505 in 2014) and resources below \$13,300.

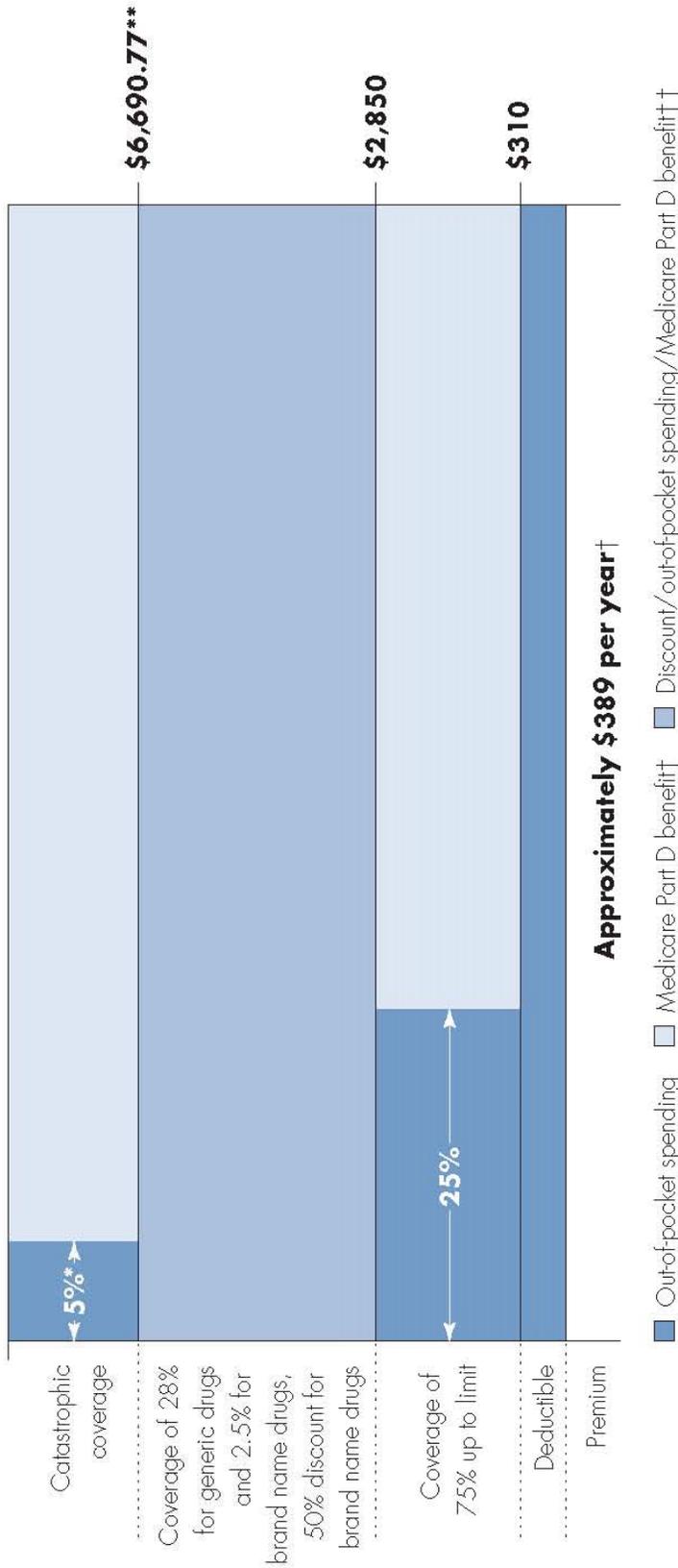
⁴ Medicare Part D plans can also provide plans that are an “actuarial equivalent” to the “standard benefit” plan. In general, actuarial equivalent plans provide the same actuarial value as the defined standard benefit but with a different benefit structure. For example, a plan may use tiered copayments rather than 25 percent coinsurance or have no deductible but use cost sharing requirements that are equivalent to or higher than 25 percent. In 2013, 3 percent of the plans provided the defined standard benefit, 47 percent provided actuarially equivalent benefits, and 50 percent provided enhanced benefits (for which the beneficiary is responsible for all costs above the standard benefit). In 2013, only 45 percent of the Medicare Part D prescription drug plans utilized the standard deductible. The remainder have no (45 percent) or reduced (9 percent) deductibles.

⁵ Some Medicare beneficiaries with Medicaid coverage do not receive “full” Medicaid benefits, and only qualify for help with certain Medicare costs. For example, through four Medicare Savings Programs, Medicare beneficiaries with limited incomes and resources can receive Medicaid assistance to pay for Medicare premiums, deductibles, coinsurance, and copayments. Medicaid pays for Medicare Part A and Part B premiums, deductibles, coinsurance, and copayments for a Qualified Medicare Beneficiary (QMB—with income less than \$993 monthly). It also pays for Part B premiums for a Specified Low-Income Medicare Beneficiary (SLMB)—with monthly income less than \$1,187, a Qualified Individual (QI—with monthly income less than \$1,333) and a Qualified Disabled & Working Individual (QDWI—with monthly income less than \$3,975).

⁶ See footnote 5 above for information on the four Medicare Savings Programs.

⁷ The value of an individual’s life insurance policy, real estate that is the beneficiary’s primary residence, and \$1,500 for burial expenses are excluded from resource limit calculations.

Medicare Part D Standard Drug Benefit in 2014



Note: Benefit structure applicable to an enrollee who has no supplementary drug coverage.

* Cost sharing above the out-of-pocket (OOP) threshold is the greater of either 5 percent coinsurance or a copay of \$2.55 for generic drugs, or \$6.35 for brand name drugs.

**Equivalent to \$4,550 in OOP spending: \$310 (deductible) + \$635 (25% cost sharing on \$2,540) + \$3,605 (72% cost sharing for generic drugs, 47.5% cost sharing for brand name drugs, and 50% manufacturer discount for brand name drugs in the "coverage gap"). The amount of total covered drug spending at which a beneficiary meets the annual OOP threshold depends on the mix of brand name and generic drugs that the individual fills during the coverage gap. The estimated amount of total drug expenses at the annual OOP threshold for 2014 (\$6,690.77) is for an individual, not receiving Part D's low-income subsidy (LIS), who has no other sources of supplemental coverage.

† There is a base beneficiary premium of \$389 per year, which is 25.5% of expected Medicare Part D benefits per person, but the actual premiums that beneficiaries pay vary by plan. Federal subsidies pay for the remainder of covered Part D benefits.

†† In 2014, cost sharing for drugs filled during the coverage gap will be 72% for generic drugs (the remaining 28% will be picked up by the Part D benefit) and about 47.5% for brand name drugs. The actual cost sharing amount for brand name drugs will depend on the amount of dispensing fee charged by a plan since the 2.5% covered by the Part D benefit applies to both the ingredient cost and the dispensing fee, while the 50% manufacturer discount applies only to the ingredient cost.

Source: MedPAC, Part D Payment System, Payment Basics Revised October 2013.

In 2012, approximately 460,000 low income Medicare beneficiaries in Pennsylvania were enrolled in Medicare prescription drug plans and qualified for additional assistance from Medicare for their prescription drug benefit costs. Some of these beneficiaries qualify for a full subsidy. Others qualify for a partial subsidy.

Added Help for a Low Income Full Subsidy Beneficiary: Medicare refers to beneficiaries who are dual eligible (#1 above),⁸ receive full Medicaid institutional or community-based long term care (#2), qualify for one of the four Medicare Savings Programs or SSI, or have income below 135 percent of poverty and limited resources (#3) as full subsidy individuals. Such individuals are subject to certain out-of-pocket costs, but through the Medicare low income subsidy, their out-of-pocket costs for prescription drug coverage are substantially reduced. Such reductions include:

- A 100 percent subsidy of the monthly premium for standard or basic prescription drug coverage in their region.⁹ (As shown in Exhibit 9, approximately \$389 annually.)
- Elimination of the annual deductible. (\$310 annually)
- Elimination of the coverage gap. (Costs from \$2,850 to \$6,690.)
- Elimination of cost sharing above the annual out-of-pocket threshold. (5 percent of cost incurred during the catastrophic coverage period)
- Waiver of any late enrollment penalty.

Added Help for a Low Income Partial Subsidy Beneficiary: Medicare refers to beneficiaries with income between 135 and 150 percent of the federal poverty level and limited resources as partial subsidy individuals. Like full subsidy individuals, they are not exposed to the coverage gap or late enrollment penalties. They must, however, pay a portion of their monthly premium,¹⁰ and they incur a reduced annual deductible (\$63 compared to \$310). They must also pay the coinsurance for drugs in the initial coverage period, but their coinsurance is reduced from 25 percent (see Exhibit 9) to 15 percent.

⁸ States help pay for Medicare Part D drug benefits for individuals eligible for both Medicare and Medicaid. Prior to implementation of Medicare Part D, dual eligibles had their drug benefit covered entirely by state Medicaid programs. The federal legislation creating Medicare Part D shifted such drug benefit coverage from Medicaid to Medicare for “dual eligible” individuals but required states to continue making certain payments to the federal government for their Medicare Part D drug benefits. Each state has a state-specific Per Capita Expenditure that is adjusted annually, and must be paid toward drug benefit costs for its “dual eligible” beneficiaries. In 2013-14, the Pennsylvania Department of Public Welfare paid approximately \$130 on average monthly for approximately 340,000 individuals, for an annual total of about \$530 million.

⁹ If the low income beneficiary elects to enroll in an “enhanced” prescription drug plan, the beneficiary is responsible for the monthly premium costs above the “standard” or basic coverage benefit.

¹⁰ Those with income above 135 percent but at or below 140 percent pay 25 percent of the premium; those with income above 140 percent but at or below 145 percent pay 50 percent; and those with income above 145 percent but below 150 percent pay 75 percent.

With the exception of full-subsidy dual eligible individuals in institutions and home and community based services (# 2 above), both full subsidy and partial subsidy beneficiaries are responsible for certain drug copays. Such copays, however, are capped and well below those that may be incurred by Medicare beneficiaries who do not qualify for the low-income subsidy. As shown in Table 8, such copays vary by a beneficiary's income level, where a drug is placed on a plan's formulary,¹¹ and whether the cost is incurred during the initial coverage or the catastrophic coverage period.

Table 8

2014 Maximum Medicare Part D Copayments for Low Income Subsidy Individuals

	Up to Out-of-Pocket Threshold ^a - Generic/Preferred Multi-Source Drug ^b	Up to Out-of-Pocket Threshold- Other Drug	Above Out-of-Pocket Threshold- Generic/Preferred Multi-Source Drug	Above Out-of-Pocket Threshold- Other Drug
Full Subsidy—Institutionalized or Receiving Home and Community Based Services	\$0	\$0	\$0	\$0
Full Subsidy—Dual Eligible- Income up to or at 100 percent of Poverty	\$1.20	\$3.60	\$0	\$0
Full Subsidy Dual Eligible—Income Over 100 percent of Poverty	\$2.55	\$6.35	\$0	\$0
Full Subsidy—SSI, Medicare Savings Program, or Individual with Income at or below 135 percent of Poverty	\$2.55	\$6.35	\$0	\$0
Partial Subsidy—Individual with Income below 150 percent of Poverty	15 percent coinsurance	15 percent coinsurance	\$2.55	\$6.35

^a All Medicare cost sharing subsidy payments made by the federal government on behalf of Medicare low income subsidy individuals are counted toward the cost of the beneficiary's annual out-of-pocket threshold—i.e., the point when a beneficiary enters the catastrophic coverage phase. All payments made by State Pharmaceutical Programs on behalf of Medicare low income subsidy individuals also count toward the cost of the beneficiary's annual out-of-pocket threshold.

^b A preferred drug is a covered Part D drug on a plan's formulary for which beneficiary cost sharing is lower than for a non-preferred drug on the plan's formulary. A preferred multi-source drug is both a preferred drug and a multi-source drug, with one version of the drug placed on the plan's formulary with lower cost sharing than for a non-preferred drug.

Source: Developed by Legislative Budget & Finance Committee staff from the Center for Medicare and Medicaid Services February 21, 2014, *2015 Call Letter*, Table III-I. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy.

¹¹ A Medicare Part D plan's list of prescription drugs covered by the plan. Many plans place drugs on their formularies on different tiers with different out-of-pocket cost sharing associated with each tier.

Medicare Low Income Subsidy Beneficiaries' and Specialty Drugs: In 2010, the U.S. Government Accountability Office (GAO) reviewed Medicare beneficiary cost sharing for high cost drugs eligible for specialty tier placement in Medicare Part D plans. It found that:

Specialty-tier-eligible drugs accounted for about 10 percent, or \$5.6 billion, of the \$54.4 billion in total prescription drug spending [includes spending by Medicare, the plans, and beneficiaries] under [Medicare Part D]...plans in 2007. Additionally, even though only 41 percent of prescriptions for nonspecialty tier-eligible drugs filled under [Medicare Part D]...plans in 2007 were for LIS [low income subsidy] beneficiaries, more than 75 percent of prescriptions for specialty-tier-eligible drugs were for LIS beneficiaries. Prescriptions for LIS beneficiaries accounted for about 70 percent, or about \$4.0 billion, of the \$5.6 billion spent on specialty tier-eligible drugs under [Medicare Part D]...plans that year.¹²

The GAO also reported that 55 percent of beneficiaries who used at least one specialty tier drug reached the annual catastrophic coverage threshold where Medicare pays for a great share of the drug's costs. As a result, the GAO found that for low income subsidy beneficiaries:

- Medicare paid for 79 percent of the specialty tier-eligible drug spending,
- the plans for 21 percent, and
- low income beneficiaries for less than 1 percent.

For beneficiaries not eligible for the low income subsidy, Medicare paid 42 percent of specialty drug costs, the plans 38 percent, and the beneficiary 20 percent.

While Medicare's assistance with out-of-pocket prescription drug costs is limited to individuals with income below 150 percent of poverty (\$17,505 for an individual in 2014) and resources below \$13,300, the Commonwealth administers several programs that provide help for those with somewhat higher incomes and resources that may require use of drugs on specialty tiers. Such programs include:

- the Pennsylvania Pharmaceutical Assistance Program,
- certain Medicaid programs designed to assist severely disabled children and disabled adults who are employed,
- state assistance for certain specific high cost drugs, and
- support in accessing pharmaceutical companies' patient assistance offerings.

¹² GAO-10-242 *Medicare Part D Specialty Tier-Eligible Drugs*, p.13.

Pennsylvania’s Pharmaceutical Assistance Programs and the Medicare “Wrap Around” Program

Pennsylvania has a long history of helping state residents who are 65 and older and do not qualify for Medicaid to pay for their prescription medications. To provide such assistance, in 1983, the Pennsylvania General Assembly first created the PACE (Pharmaceutical Assistance Contract for the Elderly) program; and later, in 1996, the PACENET (PACE Needs Enhancement Tier) Program. With the advent of Medicare Part D drug coverage in 2006, the General Assembly further created PACE Plus Medicare to allow cardholders who elect to enroll in Medicare Part D to take advantage of both PACE and Medicare Part D.

PACE/PACENET Programs’ Eligibility and Cost Sharing Requirements: The PACE and PACENET programs have no asset-related eligibility requirements, and their income eligibility thresholds are higher than those for Medicare’s low income assistance program. To qualify for help with prescription medication costs through PACE, an eligible Pennsylvania resident 65 and older can have annual income up to 124 percent of the poverty level (\$14,500 in 2014); and for help through PACENET, an individual can have income up to 200 percent of the poverty level (i.e., between \$14,501 and \$23,500 in 2014).

The only out-of-pocket costs for those who qualify for PACE are \$6.00 copays for a 30-day supply of covered generic drugs and \$9.00 copays for brand drug, including drugs on specialty tiers. PACENET cardholders are subject to slightly higher copays (\$8.00 copays for a 30-day supply of covered generic drugs and \$15 copays for a brand drug, including drugs on specialty tiers), and are responsible for a monthly premium (i.e., \$34 in 2014) if they use their coverage.

PACE Plus Medicare—the Medicare Wrap Around Program: PACE and PACENET members may enroll in Medicare Part D plans for prescription drug coverage. In 2012, PACE/PACENET had over 320,000 cardholders, with 85 percent of such cardholders enrolled in PACE/PACENET and Medicare Part D prescription drug plans.¹³

Just as there are certain differences between the benefits of PACE and PACENET cardholders in the state’s “regular” pharmaceutical assistance program, there are cardholder differences with the Medicare wrap around program. When a PACE cardholder enrolls in a Medicare Part D prescription plan, the state program pays the Part D premiums up to Medicare’s regional benchmark premium (\$35.50

¹³ Of those enrolled in PACE/PACENET but not in Medicare Part D plans, over 40 percent had no pharmacy claim during the year.

monthly in 2014) if the member enrolls in one of the plans that has a signed partnership agreement with the program.¹⁴

When a PACENET cardholder enrolls in a Medicare Part D plan, and enrolls in a plan that does not have an agreement with PACE, the cardholder is responsible for paying the Part D plan's monthly premium amount directly to the plan. If, however, the PACENET cardholder enrolls in a plan with an agreement with the PACE program and the cardholder's monthly drug costs are lower than the monthly premium, the PACENET member only pays the pharmacy the cardholder's cost for the prescription—effectively receiving a reduced monthly premium.

The only required out-of-pocket costs¹⁵ for prescription drugs for PACE and PACENET cardholders enrolled in Medicare Part D plans with partnership agreements with PACE¹⁶ are the relatively small copays described above.¹⁷ The PACE Medicare wrap around program pays for all other Medicare required out-of-pocket costs, including the Part D plan's:

- deductible,
- coinsurance and plan copay amounts above those of PACE/PACENET during the initial coverage period,
- beneficiary costs in the coverage gap period (a.k.a. the “doughnut hole”), and
- coinsurance in the catastrophic coverage period.

The program also pays for drugs not on the Medicare Part D plan's formulary, or works directly with the plan to process a prior authorization on behalf of the member so the drug will be covered by the Part D plan.

When PACE and PACENET members qualify for Medicare's low income subsidy assistance, the state program enrolls such members in Medicare's low income subsidy assistance program. Medicare then covers the subsidy costs rather than the PACE/PACENET program. Most (approximately 70 percent) PACE/PACENET

¹⁴ If the PACE cardholder enrolls in a plan with a partnership agreement and a higher premium than Medicare's regional benchmark premium, the cardholder must pay the difference.

¹⁵ PACE and PACENET cardholders, however, may voluntarily incur additional out-of-pocket costs if they chose to enroll in Part D plans that do not have partnership agreements with PACE, or if they elect to enroll in a plan with a monthly premium higher than the regional benchmark plan (\$34 monthly in 2014).

¹⁶ In 2014, PACE/PACENET had partnership agreements with 25 plans, including Geisinger, Independence Blue Cross, Highmark, UPMC, WellCare, United Health Care, HealthAmerica, Coventry, Capital Blue Cross, Cigna, and SilverScript. Three of the partnership plans (WellCARE, Cigna, and SilverScript) have premiums at or below Medicare's regional benchmark premium.

¹⁷ PACENET cardholders enrolled in non-partner plans are responsible for their plan's deductible.

cardholders enrolled in Part D plans, however, do not qualify for the Medicare low income subsidy.¹⁸

Specialty Drug Use by PACE/PACENET Cardholders: In 2013, PACE Preferred Partner Plans had over 3,200 cardholders (i.e., 1 percent of total PACE/PACENET cardholders) with over 15,000 specialty drug paid claims. The total paid claim amount for such specialty drugs was about \$42 million. Of PACE's total 2013 specialty drug costs:

- PACE/PACENET cardholders were responsible for less than 1 percent (\$268,000),
- the PACE program for 25 percent (\$10.5 million), and
- other third parties all remaining costs (\$31.2 million).

In 2013, six specialty drugs accounted for almost 60 percent of the total PACE/PACENET specialty drug paid claim amount. Three (i.e., Revlimid, Gleevec, and Zytiga), of the six drugs are used to treat various forms of cancer and leukemia, two (Enbrel and Humira) various inflammatory diseases (i.e., rheumatoid arthritis, plaque psoriasis, Crohn's disease, ulcerative colitis, psoriatic arthritis, and juvenile idiopathic arthritis), and one (Forteo) fractures related to osteoporosis in people who have several risk factors for fracture, or cannot use other osteoporosis treatments.

In 2013, the drug with the highest total paid claim amount was Revlimid, which is used to treat multiple myeloma (a cancer of the blood), and has significantly improved overall survival with myeloma. The average total (i.e., insurers, the state program, and PACE/PACENET cardholders) paid claim cost for one cardholder using this drug was about \$55,000. All but less than a fraction of 1 percent of such costs were paid by third parties and the state PACE/PACENET program. If such a drug were to be paid for by an average patient without Medicare Part D and without PACE coverage, the average patient costs per year would be over \$160,000.

The PACE Medicare wrap around program clearly fills an important gap for PACE/PACENET cardholders who must use specialty drugs. Of the PACE/PACENET cardholders using specialty drugs in 2013, three-quarters of those were enrolled in Medicare Part D but did not qualify for Medicare's low income subsidy for their prescription drug coverage and out-of-pocket costs. Such cardholders, moreover, accounted for about 90 percent of the total paid claim amount for PACE/PACENET cardholders enrolled in Medicare Part D.

¹⁸While the total count of Pennsylvanians enrolled in Medicare's low income assistance subsidy program was about 460,000, in 2012, only about 87,000 PACE/PACENET cardholders enrolled in Medicare Part D plans qualified for Medicare's low income assistance subsidy. The difference is accounted for by persons 65 years of age and older who are eligible for Medicaid and those under 65 years of age who are disabled who qualify for Medicaid and are enrolled in Medicare Part D. Such individuals do not qualify for PACE/PACENET, though they do qualify for Medicare's low income subsidy assistance program.

Not all PACE/PACENET cardholders who use specialty drugs are enrolled in Medicare Part D. Twelve percent of the PACE/PACENET cardholders that used specialty drugs are not enrolled in Medicare Part D, and they account for 12 percent of the specialty drug total paid claim amount for PACE/PACENET specialty drug users. Three cancer treatment drugs (Revlimid, Gleevec, and Zytiga) account for 40 percent of total specialty drug claim amounts for this group of cardholders.

Currently, the PACE/PACENET program serves only Pennsylvania residents who are 65 years and older. It does not, however, serve adults with disabilities who qualify for Social Security Disability Insurance but must wait 24 months before they qualify to receive health benefits through Medicare. It also does not serve Pennsylvania residents who are enrolled in the Department of Public Welfare's Medical Assistance Program.

Medical Assistance in Pennsylvania

In Pennsylvania, the Department of Public Welfare's (DPW) Medical Assistance Program provides medical coverage, including prescription drug coverage of specialty tier drugs. While such assistance is typically available for those with income below or near the poverty level and very limited assets, DPW's Medical Assistance Program offers certain programs designed to assist seriously disabled children and adults with chronic health problems and income and resources levels that may be higher than Medicaid's standard requirements, and has programs specifically for those requiring specialty pharmaceuticals.

Department of Public Welfare's Medical Assistance for Workers With Disabilities (MAWD)

Currently,¹⁹ Pennsylvania through the Medical Assistance for Workers with Disabilities (MAWD) program provides opportunity for disabled individuals between 16 and 65 years of age with chronic health problems who are working and have income and assets higher than those in the standard Medical Assistance program to "buy into" Medicaid. The cost for such coverage is a monthly premium equal to 5 percent of the individual's countable income.

Individuals who participate in the MAWD program qualify for Medical Assistance benefits that include prescription drug coverage. Those residing in counties with the HealthChoices program²⁰ are enrolled in Medicaid managed care plans, except for those with other insurance such as Medicare or private insurance. Those

¹⁹ The MAWD program was to be eliminated effective January 1, 2015, under the proposed Healthy Pennsylvania (PA) Initiative, but the federal Department of Health and Human Services did not approve its elimination in the PA Initiative it approved in August 2014.

²⁰ HealthChoices is a mandatory managed care Medical Assistance program that serves more than two million Medical Assistance (MA) consumers.

with other insurance, receive services through their primary insurer with the Medical Assistance fee-for-service programs effectively serving as their secondary or supplemental insurance.

Compared to typical Medical Assistance Programs, MAWD has high income and resource limits. As a consequence middle-income individuals with chronic health problems may qualify for the program with:

- “countable” income²¹ at or below 250 percent of the poverty level and
- “countable” resources²² equal to or less than \$10,000.

Currently, over 35,000 individuals are enrolled in this program on average monthly.

Department of Public Welfare Medical Assistance for Children Under 18 With a Severe Disability

Pennsylvania’s Medical Assistance program also has special eligibility qualifications for children under 18 with a severe disability. In Pennsylvania, children who are 18 years of age or younger, who meet federal Social Security Administration disability standards, and do not financially qualify for Medical Assistance under any other Medical Assistance eligibility category, may qualify for the Category PH-95, or the “Loophole” program. Under this program, the income and assets of the family (i.e., the parent and child) do not count when determining a child’s financial eligibility for Medical Assistance,²³ and the child need not require an institutional level of care to qualify under the disability standards.²⁴

The Social Security Administration’s *Listing of Impairments for Children* includes a range of impairments where treatment may require specialty pharmaceuticals. The list includes, for example, hematological disorders (e.g., inherited coagulation disorders), digestive system disorders (e.g., Crohn’s disease, chronic liver

²¹ “Countable income” does not include the first \$65 of earned income, half of the remaining earned income, and the costs of any impairment-related work expenses and transportation costs.

²² “Countable resources” do not include retirement savings, a home, one vehicle, and personal items such as furniture and clothing.

²³ At age 18, parental income and resources no longer counts when determining eligibility for SSI. “Special Needs” Trusts, moreover, can be established for severely disabled individuals over age 18.

²⁴ Pennsylvania is the only state in the United States that does not require an institutional level of care to qualify under the program’s disability standard, according to the Department of Public Welfare.

disease including hepatitis and liver transplantation), skin disorders, immune system disorders, and various forms of cancer.²⁵

Children who are eligible for Medical Assistance in this way qualify for the full range of Medicaid Assistance benefits, including prescription drugs and specialty pharmaceuticals. They are enrolled in Medicaid managed care plans for their medical and pharmaceutical coverage. If, however, the child has available insurance coverage under their parent's health plan, the Medical Assistance program may elect to pay the child's portion of the employer insurance premium (if applicable) and enroll the child in the Medical Assistance Health Insurance Premium Payment (HIPP) program.²⁶ Children with such coverage are served by the family's employer-sponsored insurance as the primary insurer, and the Medicaid fee-for-service program, as a secondary insurer. Families of children with income above 200 percent of poverty who participate in this program may be subject to a small copayment for certain medical services. As discussed below, however, such copayments may be waived for specialty and certain other drugs.

Department of Public Welfare's Medical Assistance Fee-for-Service Specialty Pharmacy Drug Program

In 2009, the Department of Public Welfare received a federal waiver that allowed the state to require beneficiaries in 42 counties to obtain specialty drugs through two contracted specialty pharmacies.²⁷ The Department's Medical Assistance Fee-for-Service Specialty Pharmacy Drug Program defined specialty drugs as oral and injectable medications that:

- Are used to treat chronic and life-threatening diseases.
- Require clinical monitoring.
- Are expensive.
- Require temperature control or other specialized handling.

Specialty drugs required to be provided under the contract included, for example, drug classes related to oncology, hemophilia, hepatitis B and C, immune deficiencies, inflammatory conditions, multiple sclerosis, osteoarthritis, osteoporosis,

²⁵ A complete listing of the Social Security childhood listing of impairments and standards may be found at <http://www.socialsecurity.gov/disability/professionals/bluebook/ChildhoodListings.htm>.

²⁶ The Health Insurance Premium Payment Program is a program developed to help families who have at least one person enrolled in Medical Assistance to pay for private insurance through an employer. The program reviews the medical insurance available through the employer to determine the amount of the premium and policy benefits and if the Medical Assistance costs for the benefits are greater than the cost of the employer insurance. If Medical Assistance costs are greater than the employer insurer costs, the Medical Assistance participant is enrolled in the employer health insurance. The employer's health insurance coverage then provides primary medical coverage, with the Medical Assistance fee-for-service program providing secondary or supplemental coverage.

²⁷ Medical Assistance consumers with other third party coverage, including Medicare, were excluded from the program, unless the insurer did not cover the specific specialty drug required by the consumer.

and chronic renal failure. Medical Assistance consumers participating in the program incur no copays for such drugs.²⁸

As part of the program, contractors are required to provide specialty drugs and related supplies to beneficiaries at physician offices, clinics, treatment centers or their homes. They are also required to provide training on drug administration and storage, arrange for a nurse when a prescriber determines a specialty drug must be administered by a nurse, to staff a 24/7 call center to respond to consumer questions, and provide a dedicated nurse case manager to work closely with the specialty pharmacists.

The Department's contract includes performance measures to assess the contract specialty pharmacies. It also monitors for accurate dispensing, timely delivery of specialty drugs, treatment outcomes, and call center performance.

The program is designed to provide quality care and to help contain specialty drug costs. According to Department of Public Welfare data, its specialty medications accounted for just over 12 percent of total pharmacy expenditures in the fee-for-service program compared with over 20 percent in Medicaid programs nationally. The Department's Fee-for-Service Specialty Drug Program expenditures also compared favorably with those of HealthChoices Medicaid managed care plans. From March to July 2013, HealthChoices plans expended \$3,391 per member per month for each member on specialty drugs, compared with \$2,208 in the Specialty Drug Program. During the same period, the Specialty Pharmacy Program spent \$3,387 per member per month for hemophilia factor products, compared with \$15,933 for the managed care organizations. In part, such differences were due to the ability of the state Medicaid program to negotiate individual specialty drug prices and drug manufacturer rebates available to the state program.

When the Medical Assistance Fee-for-Service Specialty Pharmacy Drug Program started in 2009, it operated in the 42 counties that were not included in HealthChoices, and provided services for Medical Assistance recipients excluded from enrollment in managed care. With the expansion of HealthChoices statewide,²⁹ the number of Medical Assistance consumers participating in the program has been reduced. In January 2013, the program served almost 2,000 Medical Assistance consumers using specialty drugs. By June 2013, that number had dropped to fewer than 400.

²⁸ Medical Assistance typically has a \$1 copay for each prescription and prescription refill of a generic drug and \$3 for each prescription and prescription refill for a brand name drug. The program, however, does not have copayments for certain individuals, such as persons younger than 18 years old, pregnant women, residents of long-term care facilities, and individuals receiving hospice care. Adult medical assistance consumers, moreover, are not subject to a copayment for specific drugs used to treat high blood pressure, cancer, diabetes, epilepsy, heart disease, HIV/AIDS, and psychosis.

²⁹ Prior to 2001, HealthChoices was available in 19 of Pennsylvania's 67 counties. It became available statewide in 2013 after expansion into 13 counties in 2012 and 22 counties in 2013.

Special Pharmaceutical Benefit Program (SPBP)—Mental Health

The Department of Public Welfare also offers a state-funded special pharmaceutical benefit for individuals with schizophrenia who are residents of Pennsylvania, do not qualify for Medical Assistance, and do not respond to other “first-line” therapies. The program provides atypical antipsychotic medications³⁰ for such individuals when provided by physician/physician groups, outpatient psychiatric clinics, and psychiatric partial hospitalization clinics enrolled in the Medicaid program. An individual with income up to \$35,000 can qualify for the program.

Special Pharmaceutical Benefit Program—HIV/AIDS

The Pennsylvania Department of Health provides pharmaceutical assistance and specific lab services to individuals with a diagnosis of HIV/AIDS who are not eligible for pharmacy services through the Medical Assistance program. To qualify for the program, along with a diagnosis of HIV/AIDS, an individual must be a resident of Pennsylvania and have gross annual income of less than or equal to 500 percent of poverty (\$58,350 in 2014).

This program serves as a payer of last resort, with other third-party resources used first before payment is made by the state program. The program also has agreements with certain Medicare Part D plans. It will automatically enroll an SPBP client and cover all premium, copay, and deductible costs for all Medicare Part D plans with partnership agreements with the program. With non-partnering plans with an agreement with the program, the program will pay the SPBP client’s premiums up to the costs associated with a partnering plan, copays, and deductibles. For all other Medicare Part D plans that are without program agreements, the SPBP client is responsible for the Medicare Part D plan’s premium, however, the program will cover all copays and deductibles.

Through certain other Department of Health programs, assistance with medications may also be available to Pennsylvania residents with rare diseases who do not qualify for Medical Assistance. Such programs include the Department’s Chronic Renal Disease, Cystic Fibrosis, Spina Bifida, Metabolic conditions, and Phenylketonuria programs.

Several persons using specialty drugs who responded to the LB&FC survey provided information indicating they participated in some of these state assistance programs, including the Medical Assistance Program for Workers with Disabilities, and programs where Medical Assistance serves as the secondary insurer responsible for high deductibles and coinsurance.

³⁰ Such drugs include: Abilify, Clozaril, Clozapine, Geodon, Invega, Risperdal, Risperidone, Seroquel, and Zyprexa.

Drug Manufacturer Patient Assistance Programs

Patients who do not qualify for public programs may be able to obtain help with prescription costs through non-profit copayment foundations. Such foundations often receive support from drug manufactures. Exhibit 10 provides a list of some copayment assistance organizations and their eligibility requirements developed by the Medicare Rights Center.

At times, pharmaceutical companies also directly provide assistance with the costs of brand-name drugs for qualified individuals. Some of the brand-name drugs with coupon and voucher programs are for specialty drugs, and others are not.

In 2010-11, there were approximately 400 brand-name drugs with copay card or voucher programs, according to the IMS Institute for Healthcare Informatics. Typically, coupons and vouchers help reduce a patient's copay from a non-preferred brand copay level to a more affordable level. They are designed to address patients' economic concerns, and from the manufacturer's perspective, ensure patients start and remain with their medications. In recent years, patient use of copay coupons and vouchers from pharmaceutical companies has increased, though such use represents less than 5 percent of dispensed brand prescriptions.

As noted in Finding E, just over one-third of the respondents to our survey indicated they receive help through patient assistance programs, with a large proportion (over 30 percent of those who report receiving assistance) indicating the assistance program helped pay for their copayments. At least 10 of the respondents identified the copay assistance foundations and funds from which they received assistance (e.g., Chronic Disease Fund, the Leukemia & Lymphoma Society), and at least another 15 identified the specific pharmaceutical drug company from which they received help.

Some indicated they received assistance as part of a clinical trial. One such individual receiving a cancer treatment medication costing \$8,000 per month noted the drug would be available free-of-charge only for the duration of the clinical trial. This individual further noted: "It is a medication one takes for life."

Exhibit 10

Examples of Copayment Assistance Foundations and Other Copayment Assistance Programs

Program	Benefits	Eligibility
CancerCare Copayment Assistance Foundation	Provides copay assistance for prescribed oral and intravenous medication.	Must meet certain cancer diagnosis and treatment criteria and have limited income (i.e., up to 400 percent of the federal poverty level).
Caring Voice Coalition	May help pay for some prescription drug costs.	Must be diagnosed with specific conditions, e.g., Huntington's disease.
Chronic Disease Fund	Offers patient financial assistance to provide copay assistance for certain drugs as long as the drug plan covers the drug and the patient cannot afford the plan's copays.	Must be diagnosed with specific conditions, e.g., multiple sclerosis and rheumatoid arthritis. Also must participate in a therapy management program to maintain eligibility.
The HealthWell Foundation	Helps pay drug copays if you have insurance or helps pay monthly premium if you are eligible for insurance and the drug is covered on the insurance plan's drug formulary.	Helps with specific diseases, e.g. Hodgkin's Disease.
The Leukemia & Lymphoma Society	Copay Assistance program helps pay for treatment related copays, private health insurance copays and premiums. Can also help pay for Medicare Part B, Part D, Medigap, and private plan premiums and copays.	Must reside in the U.S. and qualify both financially (i.e., income within 500 percent of the federal poverty level) and medically (i.e., must have prescription drug coverage, a doctor must certify the diagnosis, drugs, and/or doctors' visits are used to treat a covered cancer).
National Organization for Rare Disorders (NORD)	Helps obtain prescriptions, and helps pay for premiums and copayments.	Must have certain rare diseases, e.g. Multiple Sclerosis and Parkinson's Disease.
Patient Advocate Foundation's Copay Relief	Pays for deductibles and full copays for prescriptions covered by insurance plans and taken to treat certain medical conditions.	Must have financial need and be diagnosed and taking medications for specific conditions (e.g., macular degeneration).
Patient Services Incorporated (PSI)	Helps those with specific conditions pay prescription copayments regardless of income.	Copayment assistance for drugs that treat certain medical conditions, e.g., hemophilia and multiple myeloma.

Source: 2013 Medicare Rights Center website (www.medicareinteractive.org).

The Pennsylvania PACE Patient Assistance Program Clearinghouse (PA - PAP)

As shown above in Exhibit 10, the criteria for eligibility for assistance from a pharmaceutical assistance program vary. Exhibit 11 further illustrates the high degree of variability for direct assistance from drug manufacturers across manufacturers. Exhibit 11 provides a list of specialty drugs used by PACE/PACENET cardholders in CY 2013 and some of the varying manufacturer requirements to qualify for assistance. As shown in Exhibit 11, about 40 percent of the specialty drugs have coupon cards available, and 30 percent of such drugs require a case review to potentially qualify for assistance.

Exhibit 11 also shows that several manufacturers limit their direct assistance only to individuals without insurance coverage, or provide assistance to those with commercial coverage but not federal or state insurance coverage.³¹ Each manufacturer, moreover, has its own company-specific eligibility requirements, application form; review process; wait time, and differ in the amount of medication they will provide.

Given the complexity of the pharmaceutical manufacturers' application processes, in 2001, the PACE program, in conjunction with local Area Agencies on Aging offices, initiated the Pennsylvania Patient Assistance Program Clearinghouse, or PA-PAC.³² The PA-PAC program is open to all adult Pennsylvania residents regardless of age, and accepts applications from individual patients, physician offices, social workers and other agencies.

The PA-PAC program's coordinator helps determine the likelihood of eligibility³³ for a person seeking assistance from manufacturers' medication programs, gathers the information required to complete the pharmacy manufacturer's application, offers guidance and assistance to the patient, and coordinates throughout the process with the patient and the patient's physician. For those who are accepted into a manufacturer's assistance program, the PA-PAC program also assists with the reorder processes. In 2013, over 14,000 persons assisted by the PA-PAC program had received almost 50,000 medications.

³¹ Some manufacturers will provide assistance to certain Medicare Part D beneficiaries. Such beneficiaries include those in the Medicare Part D coverage gap "doughnut hole," Medicare Part D beneficiaries who require a medication not on the prescription plan's formulary, and those who experience high copayments over \$100 per month for a 30-day supply of medication. Drug manufacturer patient assistance programs, however, do not assist those with Medical Assistance prescription drug coverage, those receiving Medicare Part D's Low Income Subsidy (LIS), or Veteran's Administration Prescription Benefits.

³² The program can be reached at 1-800-955-0989.

³³ Typically, the gross household income for manufacturer assistance programs is 200 percent of the federal poverty level, though many manufacturers will consider hardship circumstances outside of their usual guidelines. Drug manufacturers, moreover, do not always publicly disclose their financial eligibility requirements.

Exhibit 11

Patient Assistance Programs for Specialty Drugs Used in the PACE/PACENET Program in 2013

Drug Name	Coupon Available	Patient Assistance Program, With or Without Insurance, Case Review	Patient Assistance Program, With Insurance	Patient Assistance Program, Without Insurance	Patient Assistance Program, Drug Not Covered by Insurance	No Patient Assistance Program, No Discount Card
Actimmune				X		
Actiq						X
Afinitor	X					
Apokyn			X			
Arcalyst						X
Betaseron	X					
Bosulif	X					
Caprelsa			X			
Carimune		X				
Cerezyme			X			
Cometriq		X				
Copaxone	X					
Enbrel	X					
Erivedge	X					
Exjade	X					
Forteo	X					
Gammagard			X			
Gleevec	X					
Humira	X					
Iclusig		X				
Incivek				X		
Increlex						X
Inlyta	X					
Jakafi					X	
Kuvan	X					
Lazanda	X					
Letairis	X					
Leukine				X		
Mekinist				X		
Neupogen		X				
Orfadin				X		
Peg-Intron	X					
Pomalyst		X				

Exhibit 11 (Continued)

Drug Name	Coupon Available	Patient Assistance Program, With or Without Insurance, Case Review	Patient Assistance Program, With Insurance	Patient Assistance Program, Without Insurance	Patient Assistance Program, Drug Not Covered by Insurance	No Patient Assistance Program, No Discount Card
Procrit		X				
Promacta		X				
Provigil						X
Remicade	X					
Revatio	X					
Revlimid		X				
Rituxan	X					
Sabril		X				
Sandostatin		X				
Sandostatin LAR		X				
Somatuline Depot			X			
Sprycel	X					
Stivarga		X				
Sutent	X					
Tafinlar				X		
Tarceva	X					
Targretin		X				
Tasigna	X					
Tracleer	X					
Tykerb					X	
Tysabri		X				
Victrelis	X					
Votrient		X				
VPRIV				X		
Xalkori		X				
Xenazine		X				
Xgeva	X					
Xolair	X					
Xtandi		X				
Zavesca		X				
Zelboraf	X					
Zolinza		X				
Zytiga	X					
Total (n=66)	28	20	5	7	2	4

Note: In addition to the coupon card programs, many manufacturers provide free medication based upon their set of federal poverty income guidelines.

Source: The PACE/PACENET Program.

The PA-PAC program also enrolls participants in available Attorney General Settlement programs. Through such settlements, PA-PAC is able to offer assistance for specific medications to patients ineligible for manufacturer assistance programs. As of the first half of 2014, there were seven Attorney General Settlements available to provide such assistance. An individual qualifying under the Pfizer Settlement, for example, can receive up to \$3,000 in medication assistance, with a \$0 generic copayment and \$15 brand copayment for certain medications.

While providing important assistance, pharmaceutical manufacturer patient assistance programs do not usually provide ongoing help. Many have time-limited assistance (e.g., six months). Patients, moreover, can incur significant out-of-pocket costs while waiting to participate and while in such programs, according to the PACE staff.

Pennsylvania Prescription Price Finder

Pennsylvania also provides a website with tools to help prescription drug cash paying customers compare drug prices for frequently used drugs at various area pharmacies. For those with prescription drug insurance, moreover, the website can be useful if such coverage requires the insured to pay for a percent of the total price of the drug.

Specifically, the site (www.parxpricefinder.com, or 800-835-4080) provides weekly price updates on the price paid by cash paying customers for 300 of the most widely-used prescription medications at pharmacies that participate in the PACE program. In addition to providing price comparisons for particular drugs and store details (e.g., address, telephone numbers, days and hours of operation), the site provides lists of pharmacies that will match lower prices and provides drug education information.

G. Federal and State Government Proposals and Other Recommended Efforts to Assure Access to Specialty Tier Drugs

Nationwide, there is widespread recognition of the challenges in balancing access and affordability presented by specialty drugs. Varying proposals have been and are being offered at the federal and state level, by major health care associations and patient care advocacy groups, and others to address specialty drug access and affordability issues.

Federal Proposals to Improve Access and Affordability

Currently, there are three federal legislative proposals related to specialty tier drugs and specialty drug tiers:

- The Patients' Access to Treatment Act of 2013,¹
- The Part D Beneficiary Appeals Fairness Act,² and
- The Cancer Treatment Parity Act of 2013.³

The Patients' Access to Treatment Act: If enacted, this legislation would apply to commercial health insurers offering individual or group health insurance that provides coverage for prescription drugs and uses a formulary or other tiered cost sharing structures. The legislation would limit copayments, coinsurance, or other cost sharing requirements for specialty drugs to the dollar amount (or equivalent) of cost sharing requirements for non-preferred brand drug tiers.⁴ The legislation also provides that there be no more than a 10 percent difference in total dollar cost sharing between tiers.

Avalere Health⁵ analyzed the impact of the Patients' Access to Treatment Act of 2013 on premiums and cost sharing for commercial plans. It estimated that for the 14 percent of the commercial plans with a specialty tier,⁶ annual premiums would increase on average \$3.00, absent other changes in the benefit design. The impact, however varies based on whether the plan has a copay or coinsurance for the specialty tier. Plans using copays for specialty tier drugs would experience only

¹ H.R. 460—113 Congress, 1st Session.

² S.1365 and H.R. 2827—113 Congress, 1st Session.

³ S.1879—113 Congress, 1st Session.

⁴ In the absence of a non-preferred brand drug tier, the legislative requirement would apply to the preferred brand tier cost sharing requirements. If there are more than one non-preferred brand drug tiers, the legislative requirement applies to the non-preferred brand drug tier with the lowest cost sharing requirements.

⁵ A Washington-based research and analysis firm with pharmaceutical expertise.

⁶ Based on data from the Kaiser/HRET Employer Health Benefits 2012 Annual Survey.

a \$0.37 average premium increase,⁷ while those using coinsurance would see an annual average increase of \$7.78.

Avalere Health also considered what changes in cost sharing amounts would be needed to offset the identified premium increases. It concluded that a \$6.00 increase in the copay on the non-preferred tier would lower total plan costs by the same amount that lowering copays for specialty medications would increase total plan costs. Similarly, it concluded that a \$0.75 increase in copays for preferred drugs would offset the premium increase due to the specialty drug cap, with a \$0.50 increase in copays for generic drugs having a similar effect.⁸

In addition, Avalere concluded it would be unlikely for plans to shift from copays to coinsurance for non-preferred brand tiers, as most non-preferred brand tiers in commercial plans (72 percent) used copays in 2012, and the proposed legislation allows for only a 10 percent dollar value difference in cost sharing on a tier. Plans would not be able to meet the 10 percent dollar difference requirement using a coinsurance when there are large differences between the prices for non-preferred and specialty drugs.⁹

Part D Beneficiary Appeals Fairness Act: As noted in Finding B, currently Medicare Part D beneficiaries can appeal the placement of a drug on a formulary tier with high cost sharing, with the exception of drugs placed on a formulary specialty tier. If enacted, this proposed legislation would allow appeal for such exceptions for drugs placed on specialty tiers. Specifically, the proposed legislation would amend the Social Security Act¹⁰ to prohibit the Secretary of Health and Human Services from allowing a Medicare Part D prescription drug plan to make any formulary tier of a cost sharing structure, including a tier for high cost or unique items, such as specialty drugs, ineligible for lower-cost sharing through an exception process.

Cancer Treatment Parity Act of 2013: Newer specialty drugs now include oral drugs for the treatment of cancer. If enacted, the proposed legislation amends the Employee Retirement Security Act of 1974, the Public Health Service Act, and

⁷ Plans using copay structures experience only a small change in the premium as their copay structure already limits cost sharing exposure for high cost drugs as copay amounts are fixed.

⁸ All premium and cost sharing estimates include a change in overall demand due to changes in out-of-pocket costs.

⁹ If, for example, a non-preferred brand name drug cost \$100 and a specialty drug costs \$1,000, a single coinsurance rate of 25 percent would result in \$25 out-of-pocket cost for the non-preferred brand name drug and a \$250 out-of-pocket cost for the specialty drug. Such a difference would be inconsistent with the proposed legislation's maximum 10 percent difference requirement.

¹⁰ 42 U.S.C. 1395w-104(g)(2).

the Internal Revenue Code of 1986¹¹ to require individual and group health insurance coverage plans to provide coverage for oral anticancer drugs on terms no less favorable than anticancer drugs that require administration by health care providers.

Specifically, the legislation would allow anticancer medications to be subject to annual deductibles, coinsurance, or copayments as long as such cost sharing requirements were the same as those for anticancer medications administered by health care providers. To comply with the legislation, health plans would be prohibited from imposing an increase in out-of-pocket costs for anticancer medications, reclassifying benefits with respect to anticancer medications, or applying more restrictive limitations on prescribed orally-administered anticancer medications or intravenously administered or injectable anticancer medications.¹²

State Efforts to Improve Access and Affordability

Fifteen states have acted to address concerns related to specialty drugs. As shown in Exhibit 12, states vary in the efforts they have taken thus far.

- One state (New York) has enacted legislation prohibiting cost sharing for specialty drugs from exceeding the cost sharing requirement for a non-preferred brand name drug on a drug tier formulary.
- Two states (Pennsylvania and West Virginia) are requiring the issue be studied.
- Five states (Delaware, Maine, Maryland, Nevada, and Vermont) have adopted per prescription or annual out-of-pocket cost sharing caps for at least certain specialty drugs.
- Seven states (Alaska, Arkansas, Louisiana, New Mexico, Oklahoma, Texas, and Virginia) require some form of beneficiary notice concerning changes related to specialty drug availability and/or cost sharing requirements.

¹¹ Employee Retirement Income Security Act of 1974 Amendments –(1) Subpart B of part 7 of sub-title B of title I; Title XXVII of the Public Health Services Act; and Internal Revenue Code of 1986, Subchapter B of chapter 100.

¹² The proposed legislation also calls on the Medicare Payment Advisory Commission to complete an assessment of how the closing of the Medicare Part D doughnut hole (provided for by the Patient Protection and Affordable Health Care Act and the Health Care Education and Reconciliation Act of 2010) affects Medicare coverage of orally administered anticancer medications, including their cost and accessibility.

States Efforts to Address Specialty Drug Tier Issues

Alaska: Requires at least a 90-day advance notice of cost sharing, deductible, or copayment terms applicable to specialty drugs.

Arkansas: Requires a 60-day notice of increased financial responsibility for drug cost.

Delaware: Limits patient copay or coinsurance to \$150 per prescription per month; requires an exception process for non-formulary drugs; and prohibits plans from placing all drugs in a class on a specialty tier.

Louisiana: Requires notice of covered prescription drugs and use of a drug formulary; limits formulary modifications during a plan year; and requires response within 3 business days to requests about specific drugs on a particular formulary.

Maine: Establishes an out-of-pocket expense limit of \$3,500 annually on prescription medications if the health plan does not include prescription drugs subject to coinsurance under the total annual out-of-pocket limit for all plan benefits.

Maryland: Limits copayments or coinsurance for specialty drugs for certain conditions to \$150 for a 30-day supply (with the amount allowed to increase annually); permits plans to designate specialty drug pharmacies for enrollees to obtain such drugs; and treats identification of specialty drugs as a benefit coverage decision subject to complaint filings.

Nevada: Limits combined cost sharing for deductibles, copayments, and coinsurance to no more than \$100 per prescription for orally administered chemotherapy; prohibits orally administered chemotherapy from being more costly than injections or intravenous drugs; and prohibits insurers from meeting previous requirements by decreasing the coverage for chemotherapy.

New Mexico: Requires a 60-day advance written notice of changes in prescription drug coverage when a drug is reclassified to a higher tier, changed from a preferred to non-preferred tier (unless moved to a lower tier), subject to increased cost sharing, removed from formulary, subject to new or modified drug quantity limits, or subject to step-therapy restriction; and prohibits prescription drug tier changes within 120 days of a previous coverage change.

New York: Prohibits health plans with prescription drug coverage that use a tiered formulary from imposing cost sharing (deductibles or coinsurance) that exceeds cost sharing for non-preferred brand drugs or their equivalent.

Oklahoma: Requires at least a 60-day written or electronic advanced notice of any deletions to a plan formulary, and a notice of a need to respond within 3 business days to requests about a particular drug's status on a particular formulary.

Pennsylvania: Requires a study of specialty tier prescription drugs to determine their impact on access and patient care.

Texas: Requires a 60-day advance notice of modification to prescription drug coverage other than at the time of plan renewal and response within 3 business days to an enrollee request for information about a specific drug's inclusion on a particular formulary; allows continuation of a drug until the end of the contracted benefit if the drug has been removed from the plan's formulary; and requires coverage of non-formulary drugs if a physician determines the drug is medically necessary.

Vermont: Requires annual limits on out-of-pocket prescription drug expenditures (\$1,250 per individual and \$2,500 per family) and prohibits health plans and pharmacy benefit managers from imposing annual prescription drug benefit limits.

Virginia: Requires a 30-day advanced notice of a formulary change to a higher cost sharing tier other than at the time of coverage renewal.

West Virginia: Requires a study of the impact of cost sharing, coinsurance, and specialty tiers.

Source: Developed by LB&FC staff from relevant state legislation and resolutions.

Many of the state initiatives are recent and some have not been fully implemented. Delaware's cap on specialty drug costs, for example, only took effect in January 2014, and Maryland's cap will not take effect until October 2014. Virginia's requirements for notice will not become effective until July 2014. It is, therefore, not possible to consider the extent to which such initiatives have been able to improve access and affordability of specialty drugs.

New York was one of the first states to attempt to address issues of access and affordability of specialty drugs by prohibiting specialty tiers with higher cost sharing than occurs with non-preferred brand name tiers. A bill now before the New York State Assembly (A2666), if enacted, would prohibit group health insurance policies from categorizing prescription medications based on specific diseases or cost and from charging a cost sharing percentage for such prescriptions. According to New York officials, the practice of requiring plan enrollees to pay a percentage of a drug's cost has been adopted by some HMOs and Pharmacy Benefit Managers despite the state's earlier legislation.

Other Suggested Actions

In addition to federal and state proposals, various groups have offered suggestions for how to begin to address issues of access and affordability of specialty drugs. Patient advocates, health care providers, pharmacy benefit managers, and major pharmaceutical groups vary in their recommended approaches.

Patient Advocacy Groups: Advocacy groups representing those with conditions most affected by the introduction of specialty tiers, such as the National Multiple Sclerosis Society and the Leukemia & Lymphoma Society, among others, recommend the elimination of specialty tiers in prescription drug coverage formularies and capping patient cost sharing. Such capping approaches are similar to those recently adopted in Delaware and Maryland.

American Medical Association House of Delegates: The American Medical Association's (AMA) Council on Medical Services has considered the challenges presented by specialty drugs on several occasions, including the issues of cost sharing and treatment access and adherence. The AMA has stated that it:

- believes that cost sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients;
- believes that cost sharing requirements should be based on considerations such as: unit cost of medications; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes; and

- supports the development and use of tools and technology that enables physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient’s medical condition.¹³

As such, the AMA’s Council on Medical Services has endorsed value-based insurance benefit designs (VBID),¹⁴ for which specialty drugs are particularly suited.¹⁵ With value-based benefit designs, patient cost sharing requirements are determined based on the clinical value of a health care service treatment. The Council has further recommended that within such designs “consideration should be given to further tailoring cost sharing requirements to patient income and other factors known to impact compliance.”¹⁶

Medicare Access for Patients Rx (MAPRx):¹⁷ MAPRx has taken the position that specialty tiers “create an undue burden on one of the most vulnerable populations—seniors and people affected by life-threatening diseases.” In response to federal guidance for Medicare Part D plans for 2014, MAPRx also recommended the Centers for Medicare and Medicaid Services (CMS) take steps to:

- address beneficiary confusion over cost sharing, in particular at preferred and non-preferred network pharmacies,
- address inappropriate use of prior authorization forms, and
- ensure real-time direct access to systems for claims adjudication and all areas of claims adjustment, appeals, and grievances processing.

Specifically, with respect to specialty drugs, it called for CMS to consider the possibility of discriminatory cost sharing by plans and expressed concern that CMS has not increased the dollar threshold for designation as a specialty eligible drug¹⁸ given the significant increases in drug costs. It further requested CMS to disclose

¹³ AMA Policy H-110.990

¹⁴ According to the AMA, a value based benefit design (VBID) “uses cost sharing as a tool to encourage the use of specific health care services based on their ‘value,’ which is defined as the clinical benefit gained for money spent. The primary goal of VBID is not to lower costs. It is a benefit design strategy that is intended to promote the most efficient and effective use of health care services, and generate better health outcomes for dollars spent. Unlike traditional benefit designs that apply a standard set of cost sharing requirements to all services and all patients, VBID determines coverage and cost sharing rules based on an assessment of the clinical value of individual health care treatments or services.”

¹⁵ CMS Report 1-1-12.

¹⁶ CMS Rep. 2-A-13.

¹⁷ A coalition of beneficiary, patient advocacy, family caregiver, and health professional organizations committed to safeguarding the well-being of patients with chronic diseases and disabilities under Medicare Prescription Drug Coverage.

¹⁸ Medicare Part D Plans may, but are not required to, designate one tier as a specialty tier exempt from tier cost sharing exceptions. Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month threshold established each year by CMS are eligible for placement on a specialty tier. Since Medicare Part D’s inception, the threshold has remained at \$600.

its method for determining the cost threshold for specialty drugs and to better explain how the threshold amount is determined.¹⁹

In April 2014, CMS provided details on how it identifies the annual threshold for eligibility for placement of a drug on a specialty tier.²⁰ It noted it consistently reviews prescription drug event data (PDE) and that for the past three years (CYs 2011, 2012, and 2013) less than 1 percent of the claims exceed \$600 per 30 days.

CMS noted that, while the percentage of prescription drug plans (PDPs) and Medicare Advantage Prescription drug plans (MA-PDs) with specialty tiers is high (97.9 percent of MA-PD and 93.0 percent PDPs in CY 2013), the percentage of drugs that meet the criteria for inclusion in the specialty drug tier has remained stable and low over the past three years (12.8, 11.9, and 12.9 percent in CYs 2011, 2012, and 2013 respectively). In addition, the percentage of formulary drugs actually included in each plan's specialty tier has also remained stable and low (8.1, 8.5, and 8.9 percent in CYs 2011, 2012, and 2013 respectively).

The percentage of specialty drug claims in relation to overall Part D claims, moreover, is very low (less than 1 percent) and has remained stable over the past three years. CMS noted, however, that it has observed an increase in the proportion of expenditures related to specialty drugs, with specialty drugs accounting for 8.51 percent of total expenditures in CY 2011 and increasing to 11.04 percent in CY 2013.

CMS data further confirm that beneficiaries who qualify for the low income subsidy (LIS), and as discussed in Finding F, receive support for their out-of-pocket costs and are substantially more likely to use specialty drugs than are non-LIS beneficiaries. It also confirms that the proportion of overall (1.81, 1.63, and 1.71 percent), LIS (1.19, 1.09, and 1.14 percent), and non-LIS (0.62, 0.54, and 0.57 percent) beneficiaries that use specialty drugs has remained low and stable over the past three calendar years.

Academy of Managed Care Pharmacy:²¹ This professional association views the root cause of the specialty drug problem as the high costs established by drug manufacturers and the absence of generic or therapeutic alternatives for such drugs. The absence of generic or therapeutic alternatives for such drugs makes it difficult for plans to negotiate favorable prices from manufacturers. While concerned about the effect of the high cost of drugs on patients and their families, the

¹⁹ MAPRx March 13, 2013, letter to CMS in response to CMS's draft call letter for Medicare Advantage and Prescription Drug Programs.

²⁰ CMS Medicare Part D Specialty Tier, April 7, 2014.

²¹ AMCP is a national professional association of pharmacies, health care practitioners and others who develop and provide clinical, educational, and business management services for those covered by a managed pharmacy benefit.

association has opposed legislation to cap cost sharing for specialty tier drugs. In response to one state's proposal, the association stated:

Health plans must retain the flexibility to design affordable prescription drug benefits that suit the specific needs of their patient populations.... Arbitrarily reduced cost sharing...does not lower the overall cost of the prescription drug. Instead, it simply shifts those costs back to the health plan and ultimately both the employers who sponsor the plans and the employees who pay increased premiums...²²

A Major Pharmacy Benefit Manager (PBM): A major pharmacy benefit management company representing numerous employers and health insurers has also taken the position that drug companies should be asked to explain the severe increase in their drug prices. The PBM notes that tiered formulary designs are tools used by payers to provide some coverage for expensive drugs, and ways to ensure members are aware of the cost of products so that they prevent inappropriate use.

Very expensive drugs in this PBM's experience typically have beneficiary cost sharing of 20 percent, with typical out-of-pocket costs generally in the range of \$1,500 to \$3,000, with the employer continuing to carry the majority of the drug's costs and the employee paying more than they typically pay for less expensive, non-specialty drugs. Elimination of differences in patient cost sharing between tiers might provide an incentive for employers and health plans to categorically eliminate coverage for certain drugs, raise premiums and out-of-pocket costs for all members, increase cost sharing for all drugs, or some combination of such options, according to the PBM.

This major pharmacy benefit manager also emphasized that employers often develop unique formularies for their prescription drug benefits rather than relying on the manager's standard formularies. As a result, there is often considerable variability in plan sponsors' drug benefit designs. The PBM, therefore, encourages plan sponsors to develop formulary systems that enable individual patient needs be met when clinically justified by the patient's physician. Decisions to cover non-formulary drugs and their administration, however, are ultimately determined by the plan sponsor/employer.

PhRMA:²³ Specifically, with respect to specialty drugs, the association in Congressional testimony recommended:

²² January 31, 2014, letter to the Chairman of the Virginia House Commerce and Labor Committee regarding House Bill 304.

²³ PhRMA is an association representing the country's leading biopharmaceutical research companies. According to the National Science Foundation such companies account for \$1 of every \$5 of industry research and development in the United-States.

...Improvements [in the Medicare Part D Prescription Drug Program] could be considered to ensure that the use of a specialty tier in Part D does not undermine access to needed medicines. In our past comments to CMS [Centers for Medicare and Medicaid Services], we have recommended a more patient-centered approach that would allow patients to appeal specialty tier cost sharing by demonstrating a medical need for the specialty tier drug, as the rules allow for medicines on other tiers. CMS should also assure that a therapeutic alternative in the class be available to patients as a preferred tier before a medicine may be placed in the specialty tier. Taking these steps would ensure that patients needing specialty medicines do not face high barriers to accessing care.²⁴

The association also notes that biopharmaceutical research companies are a leading industry in the United States, and their investment in discovery and development of new medicines have resulted in new medical advances and changed the course of disease and medical care. It notes, for example:

- life expectancy for cancer patients has increased about four years since 1988, with most of that gain attributable to new treatments, including medicine;
- the death rate for cardiovascular disease declined by 33 percent between 1999 and 2009;
- since the approval of antiretroviral treatments in 1995, the HIV/AIDs death rate has dropped by 85 percent; and
- new treatment advances for hepatitis C are expected to halt the progression to end stage liver disease, reduce the need for liver transplantation, and prevent complications from liver cancer.

Such advances significantly improve health outcomes and quality of life, but have associated costs. Recently, this issue has come to a head with one of the new drugs for hepatitis C. The drug, Sovaldi, costs \$84,000 for a 12-week course of treatment, or \$1,000 per pill. It, however, “cures” the disease 95 percent of the time. Patients, physicians, and others, however, have questioned the high price of the drug set by the pharmaceutical company.²⁵ In response, the company has indicated that Sovaldi “is priced such that the total regimen cost is equal to that of prior standard of care regimens.” From the perspective of the manufacturer, “the drug

²⁴ Testimony of Richard I Smith before the Senate Special Committee on Aging on the Medicare Prescription Drug Program, May 22, 2013.

²⁵ Reportedly, a pharmacologist at Liverpool University (in the U.K.) indicated in the journal *Clinical Infectious Diseases* that if the drug could be produced in large quantities, the production cost would be no more than \$136 per 12-week treatment regimen.

reduces total treatment costs for the disease and represents ‘a finite cure’ that doesn’t have to be taken chronically, unlike many drugs.”²⁶

Health Policy Researchers:²⁷ To address such issues, some health policy researchers have recommended the federal government be allowed to enter into binding arbitration with pharmaceutical managers to establish prices for unique, clinically important drugs with significant therapeutic advantages and no real competition or clinical alternatives.

The Affordable Care Act²⁸ and Postponed Limits on Out-of-Pocket Costs

The federal Affordable Care Act requires most U.S. citizens and legal residents to have health insurance. For those without coverage through their employer or other sources, it allows for coverage to be obtained through state-based health benefit exchanges with premium and cost sharing credits available to individuals and families with income between 133-400 percent of the federal poverty level.²⁹ It also created separate exchanges through which small businesses can purchase coverage,³⁰ and imposed new regulations on health plans in the exchanges and in the individual and small group markets. While the overall Act is outside of the scope of this study, the Act includes certain provisions relevant to those in need of specialty drugs.

Specifically, the Act requires qualified health plans as of January 1, 2014, to provide an “essential benefit package.” The “essential benefit package” requires

²⁶ Langreth, Robert, Cancer Doctors Join Insurers in U.S. Drug-Cost Revolt, May 7, 2014, accessed May 14, 2014 at <http://mobile.Bloomberg.com/news>.

²⁷ Frank, R. and J. Newhouse, *Mending the Medicare Prescription Drug Benefit: Improving Consumer Choices and Restructuring Purchasing*, The Brookings Institution, April 2007 provides detailed information as to how an arbitration system would work. Other researchers who suggest such an approach be considered include the Kaiser Family Foundation.

²⁸ The Affordable Health Care Act refers to the Patient Protection and Affordable Care Act (enacted March 23, 2010, Pub. L. No. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (enacted March 30, 2010, Pub. L. No.111-152), and further amended by the Department of Defense and Full-Year Continuing Appropriations Act, 2011 (enacted April 15, 2011, Pub. L. No. 112-10).

²⁹ As of April 2014, about 550,000 individuals in Pennsylvania were eligible to enroll in an exchange plan and 318,077 individuals had selected a plan. About 260,000 Pennsylvania enrollees were eligible for financial assistance, with a \$2,322 estimated average premium subsidy per enrollee. The monthly premium for a benchmark silver plan in the federally run exchange was \$84 for an individual plan for a child, \$133 for an individual plan for a 21-year-old, \$139 for an individual plan for a 27-year-old, \$170 for an individual plan for a 40-year-old, and \$297 for an individual plan for a 55-year-old in Allegheny county. In Bucks, Montgomery, Chester, Delaware, and Philadelphia, the monthly premiums for such individual plans were \$149, \$235, \$246, \$300, and \$524 respectively.

³⁰ It also required employers (with the exception of small employers) to pay penalties for employees who receive tax credits for health insurance through an exchange.

provision of items and services in the following categories, including prescription drugs:³¹

- emergency services,
- hospitalization,
- maternity and newborn care,
- mental health and substance abuse disorder services, including behavioral health treatment,
- prescription drugs,
- rehabilitative and habilitative services and devices,
- laboratory services,
- preventive and wellness services and chronic disease management, and
- pediatric services, including oral and vision care.

The “essential benefit package” requirement applies to individual and small group plans both inside and outside of the health exchanges. It does not, however, apply to “grandfathered” group plans.³² In 2013, 35 percent of firms in Northeastern United States³³ offered at least one “grandfathered” plan, and 27 percent of covered workers in the Northeast were in “grandfathered” plans.

The Act also limits cost sharing for such essential benefits for certain plans.³⁴ For such plans, the out-of-pocket costs are not to exceed \$6,350 for an individual and \$12,700 for a family in 2014 and \$6,600 for an individual and \$13,200 for a family in 2015.

In February 2013, however, the federal Departments of Health and Human Services, Labor, and the Treasury determined that for the first year of implementation, it would consider the Affordable Health Care Act’s statutory requirement met

³¹ Under the Act, at least 60 percent of the “actuarial value” of the covered essential health plan benefits are covered by the plan. In other words, the health plan will pay at least 60 percent of the cost of care for a standard population and the standard enrollees will pay the remainder through a combination of deductibles, copays, and coinsurance. The higher the actuarial value of the plan chosen by the enrollee, the less patient cost sharing the plan will have on average. (So called “bronze” plans have a 60 percent actuarial value, “silver” plans a 70 percent value, “gold” plans a 80 percent value, and “platinum” plans a 90 percent value.) The percentage a plan will pay for an individual, however, will generally be different from the plan’s “actuarial value.” The amount an individual will pay will depend upon the services used and the total cost of such services, as well as the specific details of cost sharing that can vary substantially from one plan to another.

³² These are plans that were in place before March 23, 2010. The plan remains “grandfathered” even if the company enrolls new employees in the plan or changes insurance carriers if the benefits and costs to employees stay largely the same.

³³ Pennsylvania is in the Northeast Region. State specific data, however, is not available.

³⁴ The overall out-of-pocket cost sharing annual limit applies to all non-grandfathered health plans, including individual, small group, large group, and self-funded administrative services only plans. A provision limiting the deductible, however, only applies to non-grandfathered, fully-insured small group plans. It does not apply to large group and self-funded plans.

for plans that use multiple providers to administer benefits (e.g., one third-party administrator for major medical coverage, a separate pharmacy benefit manager, and a separate behavioral health organization) if both of the following conditions are satisfied.

- The plan complies with the requirements with respect to its major medical coverage (excluding, for example, prescription drug coverage and pediatric dental coverage).
- To the extent the plan or any health insurance coverage includes an out-of-pocket maximum on coverage that does not consist solely of major medical coverage (for example, if a separate out-of-pocket maximum applies with respect to prescription drug coverage), such out-of-pocket maximum does not exceed the dollar amounts set forth in §1302(c)(1) [i.e., \$6,350 for an individual and \$12,700 for a family in 2014].³⁵

The Departments also advised that:

Separate plan services providers may impose different levels of out-of-pocket limitations and may utilize different methods for crediting participants' expenses against any out-of-pocket maximums. These processes will need to be coordinated...which may require new regular communication between service providers.

As a consequence of the February 2013 federal agencies' determination, a health plan may be able to maintain separate out-of-pocket limits for benefits in 2014. An individual consumer may be required to pay \$6,350 for doctors' and hospital care, and an additional \$6,350 for prescription drug coverage when such coverage is administered by a pharmacy benefit manager.

If such prescription drug plans do not have an out-of-pocket limit, moreover, the pharmacy benefit manager will not have to impose one for 2014. Consumer out-of-pocket costs for such plans therefore, may be unlimited in 2014, and in subsequent years if the further safe harbor extensions are granted to plans by federal agencies.

As noted in Finding A, in the 2013 Kaiser Family Foundation Employer Health Benefit Survey, employees with employer-sponsored health benefits that include prescription drugs typically are in plans that do not count prescription drug cost sharing toward the plan's out-of-pocket maximum. Almost half of those responding to the LB&FC consumer survey, moreover, indicated they had insurance, but such coverage did not include annual out-of-pocket limits (see Finding E).

³⁵ FAQs About Affordable Care Act Implementation (Part XII), February 20, 2013.

III. Appendices

APPENDIX A

PRIOR PRINTER'S NO. 789

PRINTER'S NO. 1505

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE RESOLUTION

No. 70

Session of
2013

INTRODUCED BY MENSCH, ERICKSON, YUDICHAK, VULAKOVICH, GREENLEAF,
BAKER, BREWSTER, DINNIMAN, VOGEL, SOLOBAY, LEACH, McILHINNEY,
HUGHES, BROWNE, ARGALL, SCHWANK, TOMLINSON, STACK AND WASHINGTON,
MARCH 26, 2013

AS AMENDED, OCTOBER 21, 2013

A RESOLUTION

Directing the Legislative Budget and Finance Committee to study the issue of specialty tier prescription drug pricing in Pennsylvania.

WHEREAS, Traditional prescription drug benefit plans include a multitiered drug formulary structure; for example, generic drugs are in the first tier, preferred brand name drugs are in tier two, nonpreferred brand drugs are in tier three and specialty tiers are typically the fourth or greater tier; and

WHEREAS, Specialty tier drugs are commonly prescription drugs used to treat conditions such as hemophilia, human immunodeficiency virus (HIV), hepatitis, multiple sclerosis, lupus, some cancers, rheumatoid arthritis and others; and

WHEREAS, The specialty tier changes the patient's cost from a fixed copayment to a coinsurance as a percent of the cost of the drug; and

WHEREAS, A patient may pay a copayment which is increased with each tier but is a fixed amount for medications on the lower tiers of an insurance formulary; and

WHEREAS, The specialty tiers require the patient to pay a coinsurance or percentage, 20% to 30% or more, of the drug cost; and

WHEREAS, The number of specialty drugs is expected to grow more than 25% per year, both in increased utilization and increased unit cost; therefore be it

RESOLVED, That the Legislative Budget and Finance Committee conduct a study of specialty tier prescription drugs to determine the impact on access and patient care; and be it further

RESOLVED, That the committee report its findings and recommendations to the Senate no later than ~~January 30, 2014~~ JULY 15, 2014.

APPENDIX B

PRIOR PRINTER'S NOS. 1923, 2793

PRINTER'S NO. 3301

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 348 Session of
2013

INTRODUCED BY CHRISTIANA, MILLARD, PICKETT, COHEN, GINGRICH, V. BROWN,
CLYMER, MARSHALL, PASHINSKI AND HESS, JUNE 4, 2013

AS AMENDED, HOUSE OF REPRESENTATIVES, APRIL 2, 2014

A RESOLUTION

Directing the Legislative Budget and Finance Committee to study the issue of specialty tier prescription drug pricing in Pennsylvania.

WHEREAS, Traditional prescription drug benefit plans include a multitiered drug formulary structure; for example, generic drugs are in the first tier, preferred brand name drugs are in tier two, nonpreferred brand drugs are in tier three and specialty tiers are typically the fourth or greater tier; and

WHEREAS, Specialty tier drugs are commonly prescription drugs used to treat conditions such as hemophilia, human immunodeficiency virus (HIV), hepatitis, multiple sclerosis, lupus, some cancers, rheumatoid arthritis and others; and

WHEREAS, The specialty tier changes the patient's cost from a fixed copayment to a coinsurance as a percent of the cost of the drug; and

WHEREAS, A patient may pay a copayment which is increased with each tier but is a fixed amount for medications on the lower tiers of an insurance formulary; and

WHEREAS, The specialty tiers require the patient to pay a coinsurance or percentage, 20% to 30% or more, of the drug cost; and

WHEREAS, The number of specialty drugs is expected to grow more than 25% per year, both in increased utilization and increased unit cost; therefore be it

RESOLVED, That the Legislative Budget and Finance Committee conduct a study of specialty tier prescription drugs to determine the impact on access and patient care; and be it further

RESOLVED, That the committee report its findings and recommendations to the House of Representatives no later than ~~June 30,~~ JULY 15, 2014.

APPENDIX C

Glossary of Terms

Actuarial Equivalent	Used to compare two insurance plans with each other. A measurement in which the payment streams on two, different insurance policies or other plans have the same present value under a given set of actuarial assumptions.
Biologic	A medicinal preparation made from living organisms and their products, such as a serum or vaccine.
Coinsurance	A form of medical cost sharing in a health insurance plan that requires an insured person to pay a stated percentage of medical expenses after the deductible amount, if any, was paid.
Copayment	A form of medical cost sharing in a health insurance plan that requires an insured person to pay a fixed dollar amount when a medical service is received. The insurer is responsible for the rest of the reimbursement. Also referred to as a "co-pay."
Cost Sharing	Health care provider charges which a patient is responsible under the terms of a health plan. Common forms of cost-sharing include deductibles, coinsurance, and co-payments.
Deductible	A specific dollar amount that a health insurance company may require paid out-of-pocket each year before the health insurance plan begins to make payments for claims.
Drug Formulary	A list of prescription medications selected for coverage under a health insurance plan.
ERISA	The Employee Retirement Income Security Act of 1974. The protective laws under ERISA only apply to private employers (non-government) that offer employer-sponsored health insurance coverage and other benefit plans to employees.
High Deductible Health Plan	A type of health insurance plan that, compared to traditional health insurance plans, requires greater out-of-pocket spending, although premiums may be lower.

Appendix C (Continued)

HMO Plan	Health Maintenance Organizations offer a wide range of health care services through a network of providers that contract exclusively with the HMO, or who agree to provide services to members at a pre-negotiated rate. A primary care physician provides most of health care and referrals to HMO specialists as needed.
Medicare Advantage Plan	Medicare Advantage plans are offered by private health insurance companies and provide Medicare Part A and Part B coverage (hospital and medical benefits). Some plans may include routine vision, routine dental, and/or wellness programs. Many include Medicare Part D prescription drug coverage.
Medicare Prescription Drug Plan	Medicare Part D prescription drug coverage, often referred to as Part D, is available to anyone who is also eligible for Original Medicare through a private insurance company that is contracted with Medicare to offer these plans.
Out-of-Pocket Limit	An annual limitation on all cost-sharing for which patients are responsible under a health insurance plan. This limit does not apply to premiums, balance-billed charges from out of network health care providers or services that are not covered by the plan.
Patient Protection and Affordable Care Act	Federal legislation enacted with the goals of increasing the quality and affordability of health insurance, lowering the uninsured rate by expanding public and private insurance coverage, and reducing the costs of healthcare for individuals and the government. It introduced a number of mechanism including mandates, subsidies, and insurance exchanges, intended to increase coverage and affordability. Also known as the Affordable Health Care Act.
Pharmacy Benefit Manager	Administrator of prescription drug programs, responsible for developing and maintaining the formulary, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers.

Appendix C (Continued)

POS Plan	Point of Service plans combine elements of both HMO and PPO plans and may require a primary care physician who will then make referrals to specialists in the health insurance company's network of preferred providers.
PPO Plan	Preferred Provider Organization plans require that medical care be provided by doctors or hospitals on the insurance company's list of preferred providers.
Self-Insured Plan	A plan offered by employers who directly assume the major cost of health insurance for their employees. Some self-insured plans bear the entire risk while others insure against large claims by purchasing stop-loss coverage. Some self-insured employers contract with insurance carriers or third party administrators for claims processing and other administrative services; other self-insured plans are self-administered.
Specialty Drug	High-cost injectable, infused, oral, or inhaled drugs that generally require special storage or handling and close monitoring of the patient's drug therapy.
Specialty Pharmacy	Provides specialized medication for complex, genetic, rare, and chronic health conditions.
Specialty Tier	Prescription drug plans offer different levels of cost sharing for generic, preferred, and non-preferred drugs. A growing number of plans include an additional "specialty" tier for very high cost drugs. CMS established a minimum cost threshold drugs must meet before Medicare plans can place them on a specialty tier: in 2013 the minimum was \$600.

Source: Developed by LB&FC staff.

APPENDIX D

Legislative Budget and Finance Committee
 PO Box 8737
 Harrisburg PA 17105-8737

Phone (717) 783-1600
 Fax (717) 787-5487
 info@lbfc.legis.state.pa.us

Study of Specialty Drugs in Pennsylvania (Senate Resolution 70) Questionnaire for Major Pennsylvania Health Insurers

Market Share

1. What is the extent of your health insurance business in Pennsylvania in Plan Year 2013?
 Please include all policies, contracts, and health benefit plans issued.

_____ Number of Plans
 _____ Number of Members
 \$ _____ Premium Dollars

2. What portion of your business in Pennsylvania is included in each of these four market segments?

	Number of Plans	Number of Members	Premium Dollars
Individual			
Small Group			
Large Group			
Self-funded Large Group			

3. What portion of your business for each of the four market segments provides any level of prescription drug coverage?

	Number of Plans	Number of Members	Premium Dollars
Individual			
Small Group			
Large Group			
Self-funded Large Group			

Formulary Tier Design Characteristics

4. Of your prescription drug coverage plans, what percentage provide a separate tier for specialty drugs?

	Number of Plans	Number of Members	Premium Dollars
Individual			
Small Group			
Large Group			
Self-funded Large Group			

Appendix D (Continued)

Legislative Budget and Finance Committee
 PO Box 8737
 Harrisburg PA 17105-8737

Phone (717) 783-1600
 Fax (717) 787-5487
 info@lbf.c.state.pa.us

5. Of your plans that provide a specialty drug tier, what portion (percentage) has the same cost sharing provisions for the specialty tier as for the other tiers?

	Number of Plans	Number of Members	Premium Dollars
Individual			
Small Group			
Large Group			
Self-funded Large Group			

6. What types of utilization management strategies are used for drugs on the specialty tier?

- Prior authorization requirement
- Step therapy requirement
- Quantity limits
- Other (Please describe) _____

Specialty Tier Characteristics

7. What criteria were used in determining to place a drug on the specialty drug tier? (Check all that apply and rank in order of importance.)

- Price of the drug or biologic.
- Biologic medicine.
- Oral drugs that are complex to manufacture, can be difficult to administer, and may require special patient monitoring.
- Self-injectable drugs that are complex to manufacture, can be difficult to administer, and may require special patient monitoring.
- Physician administered infusions.
- How other drugs in the treatment category are assigned.
- Other (Please identify) _____

8. Do you require members to use a designated specialty pharmacy for specialty drugs?

- Yes No

9. What are the top five specialty medications covered by your prescription benefit?

<u>By Your Cost</u>	<u>By Number of Members Using</u>
1. _____	1. _____
2. _____	2. _____
3. _____	3. _____
4. _____	4. _____
5. _____	5. _____

Appendix D (Continued)

Legislative Budget and Finance Committee
PO Box 8737
Harrisburg PA 17105-8737

Phone (717) 783-1600
Fax (717) 787-5487
info@lbfc.legis.state.pa.us

16. Does your company have a program to help subscribers who have difficulty paying for high cost prescription medication? Yes No

16a. If Yes, please describe this program. _____

16b. If No, does any entity assist members in accessing patient assistance programs?
 Yes No

Please identify this entity. _____

17. Do you have any suggestions on how to address the concerns of your members who use specialty drugs with substantial out-of-pocket costs (i.e. greater than \$2,500 per year)? Possible examples include: encouraging employers to consider alternative benefit designs, encouraging your specialty pharmacy to negotiate lower prices, expecting your specialty pharmacy to help members access patient assistance programs, using an out-of-pocket cap per specialty drug prescription.

Name: _____

Company: _____

Email: _____

Telephone: _____

**The identity of individuals responding to this questionnaire will remain confidential.
Thank you for your assistance and cooperation with this study.**

APPENDIX E

Specialty Drugs in Pennsylvania Questionnaire for Specialty Drug Consumers in Pennsylvania

The identity of individuals responding to this questionnaire will remain confidential. Thank you for your assistance and cooperation with this study.

Use of Drugs on Specialty Tiers

1. Are you, or is someone in your household, currently taking a prescription medication that has an individual retail cost of \$600 or greater per month--sometimes referred to as a "specialty tier medication"?

Yes

No

If Yes, how many such different specialty medications are you taking?

2. If your answer to question 1 was No, and you have taken a specialty tier medication in the past but are not currently taking one, is it because (Check all that apply):

- It wasn't helping me.
- It had too many bad side effects.
- I could no longer afford the medication.
- My doctor put me on a less expensive medication.
- Other (please explain)

3. What type of condition is the specialty medication being used to treat? (Check all that apply.)

- Anemia/Blood Cell Deficiency
- Cancer
- Growth Deficiency
- Hemophilia
- Hepatitis C
- Immune Deficiency
- Inflammatory Conditions/RA
- Multiple Sclerosis
- Pulmonary Hypertension
- Respiratory Conditions
- Transplant
- Dermatologic Conditions
- Other (please identify)

Appendix E (Continued)

4. How do you receive your specialty medication?

- From a retail pharmacy such as CVS or Rite Aid
- From your physician
- From a mail order pharmacy
- From a specific pharmacy designated by your insurance company to provide specialty drugs--sometimes referred to as a "specialty pharmacy"
- Other (please explain)

Insurance Coverage

5. Do you (or the person taking the specialty tier drugs) have health insurance that includes prescription drug coverage?

- Yes
- No

6. If you do not currently have health insurance, what is the reason? (Check any that apply)

- Not available to me at work
- Premiums too expensive
- Out of pocket costs too high
- Applications rejected due to a preexisting condition
- Didn't think I needed it
- Prefer to pay on my own without insurance
- Other (please specify)

7. If you have health insurance, what type of health insurance do you have?

- Private individual or family health insurance through employer
- Private individual or family health insurance plan that was purchased (not through employer)
- Medicaid
- Medicare
- Tricare (military insurance)
- I don't have health insurance that pays for medicines.
- Other (please specify)

Appendix E (Continued)

8. What is the name of your health insurance provider?

- Aetna
- Amerihealth
- Capital BlueCross
- Geisinger
- Highmark
- Keystone
- United Health Care
- UPMC
- Other (please specify)

9. Is your health insurance plan a high deductible/catastrophic plan?

- Yes
- No

Cost Sharing

10. What is your current cost sharing obligation for your specialty tier medication(s)?

- Flat co-pay amount per prescription
 - Percentage of the drug cost (i.e., co-insurance)
- Other (please explain)

11. If you pay a flat co-pay per specialty tier drug, what is that amount? (e.g., \$50/prescription)

12. If you pay a percentage of the drug cost (i.e., co-insurance payment), what is the percentage that you pay per medication?

Appendix E (Continued)

13. How much is your cost for a one month supply for each of your specialty tier drugs?

Specialty tier drug #1 one month supply

Specialty tier drug #1 other than one month supply

Specialty tier drug #2 one month supply

Specialty tier drug #2 other than one month supply

Specialty tier drug #3 one month supply

Specialty tier drug #3 other than one month supply

14. Does your insurance have a limit on the amount you must pay in out-of-pocket costs?

- Yes
- No

15. If your answer to question 14 is Yes, is the limit

- Per prescription
- Per month
- Per year
- Other (please explain)

16. What is the maximum amount you must pay?

Appendix E (Continued)

17. Do you currently receive any help paying for your specialty tier medication from a Patient or Prescription Assistance Program?

- Yes
- No

18. What type of assistance do you receive?

- Program pays the full cost of my medication
- Program pays my co-pay for me
- Program pays my co-insurance payment for me
- Other (please explain)

19. What is the name of the assistance program in which you are enrolled?

Demographic Information

20. How many people currently live in your household?

Adults

Children (17 years old and younger)

21. What is your approximate annual household income?

- \$0 to \$24,999
- \$25,000 to \$49,999
- \$50,000 to \$74,999
- \$75,000 to \$99,999
- \$100,000 to \$124,999
- \$125,000 to \$149,999
- \$150,000 to \$199,999
- \$200,000 or more

Appendix E (Continued)

Area of the State Where You Live

22. In which Pennsylvania region do you live?

- Northeast
- Northwest
- North Central
- Southeast
- Southwest
- South Central

Access and Quality of Care Issues

23. Have you had difficulty with any of the following due to the cost of your specialty tier medication(s)? Please check all that apply.

- Making mortgage or rent payments on time
- Purchasing food/groceries
- Making a car payment
- Buying clothes or other needed items for self or family
- Had to take on additional credit card debt
- Had to declare bankruptcy
- Other (please specify)

24. Have you ever done any of the following to save money on your specialty tier medication(s)? Please check all that apply.

- Skipped pills, injections, or dosages
- Split pills, injections, or dosages
- Delayed filling your prescription
- Delayed starting a new medication
- Chose to not take a particular brand of medication because it was too expensive, even though you or your doctor felt it was the best medication for your condition
- Other (please specify)

Appendix E (Continued)

Benefit Administration Issues

25. Have you ever had problems getting your medicine on time because of a problem with your insurance company? (i.e., your insurance company moving the specialty drug you are taking from a brand drug tier to a specialty tier with a different out-of-pocket cost; requiring prior authorization, requiring step therapy)?

Yes

No

If yes, please explain the problem.

26. Has your current health insurance company ever changed your specialty tier prescription co-pay or co-insurance (i.e., required out-of-pocket expenses)?

Yes - Out-of-pocket expense increased

Yes - Out-of-pocket expense decreased

No

27. How did you first receive notification of the change?

From my pharmacy/when I refilled my prescription

From my employer

From my insurance company

Other (please explain)

28. When did you receive the notification of the change?

Less than 30 days before the cost increase

30 to 60 days before the cost increase

More than 60 days before the cost increase

Appendix E (Continued)

29. Do you have any other comments you would like to make regarding specialty tier drugs in Pennsylvania?

30. Name: (Optional)

31. Telephone: (Optional)

32. Email: (Optional)

The identity of individuals responding to this questionnaire will remain confidential.
Thank you for your assistance and cooperation with this study.

Done

Powered by **SurveyMonkey**

Check out our [sample surveys](#) and create your own now!

APPENDIX F

Associations Assisting With Outreach to Consumers of Specialty Tier Drugs

- American Liver Foundation
- American Lung Association of the Mid-Atlantic
- Arthritis Foundation
- Immune Deficiency Foundation
- Leukemia & Lymphoma Society
- Lupus Foundation of America, Philadelphia Tri-State Chapter
- Multiple Sclerosis Society
- National Hemophilia Foundation, Delaware Valley Chapter
- National Nursing Center Consortium
- Pennsylvania Medical Society
- United Cerebral Palsy
- Western Pennsylvania Chapter National Hemophilia Foundation

Source: Developed by LB&FC staff.