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WAGING WAR ON SPECIALTY PHARMACEUTICAL TIERING IN PHARMACY BENEFIT DESIGN

By Chad Brooker*

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INTRODUCTION

Specialty pharmaceuticals (hereinafter “specialty drugs”), also known as biologics,¹ are an increasingly prevalent and important consideration for health insurers. By the end of 2009, over six hundred specialty drugs were known to be in development.² Demonstrating this development trend, the FDA approved twice as many specialty drugs

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¹ See *FDA 101 Regulating Biologic Products*, FOOD AND DRUG ADMIN. (2008), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048341.htm> (last visited Dec. 4, 2013). A “biologic drug” is one that is made from a living organism. *Id.* “Biotechnology” refers to the application of biological techniques to research and develop new products such as proteins, hormones, vaccines, monoclonal antibodies, and gene therapy. *Id.*

² Brian Schilling, *Purchasing High Performance Specialty Drug Costs Poised to Skyrocket but Many Employers Have Yet to Take Note*, THE COMMONWEALTH FUND (Apr. 11, 2012), <http://www.commonwealthfund.org/Newsletters/Purchasing-High-Performance/2012/April-11-2012/Featured-Articles/Specialty-Drug-Costs-Poised-to-Skyrocket.aspx>.

(fourteen) in 2010 as it did traditional pharmaceuticals.³ That number increased in 2011 when the FDA approved eighteen new specialty drugs.⁴ Furthermore, manufacturers are increasingly investing more research and development funds in specialty drugs due to the robust profit margins on specialty drugs.⁵ Since specialty drugs typically address chronic illnesses, patients may use these drugs for a long period of time, providing manufacturers with a continuous supply of returning customers. Consequently, specialty drugs have “been described as ‘jackpot’ drugs for manufacturers.”⁶

The high cost of specialty pharmaceuticals is the result of the culmination of a number of factors. First, the development costs of producing specialty drugs are high because scientists must rely on molecular and cellular technologies, which are often derived from living organisms or other biological mediums rather than the chemical processes used to make traditional pharmaceuticals.⁷ However, this unique development process is also why specialty drugs typically yield significant therapeutic results with fewer side effects.⁸ Furthermore, specialty drugs often require complex handling, such as refrigeration and attention to their limited shelf life, and many require complex administration, such as intravenous delivery, which makes them even more expensive.⁹ Finally, few specialty drugs have therapeutic or generic equivalents, due to existing patents and the fact that generics are difficult to manufacture given the complexity of their replication and production.¹⁰ This creates very limited or non-existent market competition, allowing pharmaceutical companies to charge exceedingly high rates for specialty drugs while continuing to raise prices year after year.¹¹

The trend towards increased reliance on specialty pharmaceuticals would not raise such an important concern if specialty drugs did not represent the most expensive segment of pharmaceuticals not only for insurers, but also for consumers through cost-sharing measures. In 2000, only one specialty drug was on the list of the top ten selling drugs.¹² In 2010, three of the top ten selling drugs were specialty pharmaceutical products.¹³ Individuals within the pharmaceutical industry predict that by 2016, seven of the top

³ Leah Perry, *2012 Drug Pipeline: Researchers, Industry Experts Remain Optimistic*, DRUG TOPICS (Jan. 15, 2012), <http://drugtopics.modernmedicine.com/drugtopics/Modern+Medicine+Now/2012-Drug-Pipeline-Researchers-industry-experts-re/ArticleStandard/Article/detail/756729>.

⁴ *Id.*

⁵ Shilling, *supra* note 2.

⁶ *Id.*

⁷ *See supra* note 1.

⁸ *Id.*; *see also* Perry, *supra* note 3.

⁹ Adam J. Fein, *7 Reasons Why Specialty Drug Dispensing Will Boom*, SPECIALTY PHARMACY TIMES (May 29, 2012), <http://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2012/June-2012/7-Reasons-Why-Specialty-Drug-Dispensing-Will-Boom>.

¹⁰ *See supra* note 1; *see also* Perry, *supra* note 3.

¹¹ *Specialty Drug Benefit Report*, PHARMACY BENEFIT MANAGEMENT INSTITUTE (2013), *available at* <http://www.specialtydrugbenefitreport.com> (last accessed Dec. 4, 2013).

¹² 2000 Drug Trend Report, EXPRESS SCRIPTS (2000), *available at* <http://www.drugtrendreport.com/docs/DTR-2000.pdf>; *see also* Schilling, *supra* note 2.

¹³ Fein, *supra* note 9.

ten selling drugs will be classified as specialty pharmaceutical products.¹⁴ According to the Pharmacy Benefit Management Institute's 2012 report, insurance plans report that the average monthly cost of a specialty drug is at least \$2,000.¹⁵ Tretinoin, a specialty drug that can help manage some complications of leukemia, costs \$6,800 a month.¹⁶ The most expensive cancer specialty treatments can cost upwards of \$750,000 per year for a single patient.¹⁷ A 2011 AARP study reported that the average annual cost for a patient who was taking just one specialty drug was \$34,550.¹⁸ Specialty drugs do not typically face competition from generics or other drugs, so manufacturers have not hesitated to raise the prices of such drugs annually.¹⁹ As the prevalence and costs of these drug regimens increases (with a seventeen percent increase in average cost in 2011 and a twenty percent average increase in 2012), insurance plans have sought to control their spending on specialty drugs through a number of formulary policies, as well as increased cost-sharing.²⁰

Insurers have reacted to the large and increasing costs of pharmaceuticals, attributed in part to the high costs of specialty drugs, by shifting some of the burden of these costs back onto the insurance policy beneficiaries.²¹ The most common method of achieving this is through the creation of specialty tiers. Tiering generally refers to a health plan placing a drug on a formulary or preferred drug list, which classifies drugs as generic (tier one), preferred brand (tier two), or non-preferred brand (tier three) pharmaceuticals.²² The idea of paying differing amounts of money for different types of prescription drugs is not a new concept. Employers and insurers have long used tiers to set the amount that patients pay for generic drugs, brand-name products, and non-preferred brand-name drugs. A large majority of beneficiaries in employer-sponsored

¹⁴ *Id.*

¹⁵ *Specialty Drug Benefit Report*, *supra* note 11; *see also The Growing Cost of Specialty Pharmacy—Is it Sustainable?*, AM. J. OF MANAGED CARE, <http://www.ajmc.com/payer-perspectives/0213/The-Growing-Cost-of-Specialty-Pharmacy-Is-it-Sustainable> (last visited Dec. 21, 2013).

¹⁶ *See Specialty Drug Benefit Report*, *supra* note 11.

¹⁷ Schilling, *supra* note 2; *see also* 2012 Drug Trend Report, EXPRESS SCRIPTS (2013), <http://www.drugtrendreport.com/docs/DTR-FullPDF-1029.pdf>.

¹⁸ Susan Dentzer, *Slowing the Impact: The Role of Specialty Pharmacy in Managing Progressive and Chronic Diseases*, UNITED HEALTH GRP. (April 2011), <http://www.unitedhealthgroup.com/news/rel2011/Specialty-Pharmacy-WP-Diseases.pdf>.

¹⁹ Schilling, *supra* note 2.

²⁰ *See Specialty Drug Benefit Report*, *supra* note 11; *see also* 2012 Drug Trend Report, *supra* note 17.

²¹ Mari Edlin, *Specialty Tier Falls Out of Favor Because of Access Issues*, FORMULARY J. (Jan 1, 2012), <http://formularyjournal.modernmedicine.com/news/specialty-tier-falls-out-favor-because-access-issues> (“In Medicare, 100% of Part D enrollees in Medicare Advantage-Prescription Drug Plans (MA-PDPs) and 94% in Medicare stand-alone Prescription Drug Plans (PDPs) are in plans with a specialty tier. The median coinsurance for specialty drugs under PDPs—those costing at least \$600 per month—increased from 25% in 2006 to 30%, while MA-PDPs showed a change of 25% to 33%. About half of PDPs charge a 33% coinsurance, while more than three-fourths of MA-PDPs do.”).

²² National Patient Advocate Foundation. *White Paper: Specialty Tiers* (May 2013), http://www.npaf.org/files/5%207%2013%20Specialty%20Tiers%20White%20Paper%20Final_0.pdf.

health care plans have a tiered cost-sharing structure for prescription drug coverage.²³ Given that cost-sharing generally increases with higher tiers, these types of insurance policies have helped increase the use of generic drugs, which are generally cheapest and on which insurers receive the largest discounts.²⁴

Under a traditional three-tier prescription drug formulary, a beneficiary is given a choice between more and less expensive equivalent medications for the same disease or health condition. Thus, a beneficiary who is prescribed a tier three drug can decide that he or she does not want to pay the higher copayment and find a chemically equivalent drug at a lower cost on tiers one or two. As such, three-tier plans are said to achieve the following:

(1) they provide a tool to discourage beneficiaries from making choices that lead to utilization of higher-cost drugs (i.e., discourage moral hazards); (2) they reduce demand for brand-name drugs that was exacerbated by drug company advertising; (3) they move away from undifferentiated drug copayments and help control costs; (4) they offer beneficiaries a choice of medications for a particular disease or condition that vary in cost but not in effectiveness; and (5) because they lower a health insurance company's overall cost to provide insurance, they allow the health insurance company to increase the number of persons who can access insurance benefits and/or lower insurance costs for the individuals already in the insurance pool.²⁵

However, unlike the first three tiers, specialty drugs appearing on specialty drug tiers (i.e., tiers four and higher) often do not have generic or lower-cost brand-name equivalents.²⁶

Specialty tiers—tiers four and beyond—began to expand in 2006 once the strategy was adopted by Medicare Part D.²⁷ With Medicare leading the movement, an increasing number of private plans have created a fourth (or higher) tier of drug cost-sharing that is used for specialty or lifestyle drugs.²⁸ Today, about eighty-five percent of Medicare drug plans include such tiers.²⁹ As the prevalence of specialty pharmaceutical regimens

²³ Gary Claxto et al., *Employer Health Benefits: 2012 Summary of Findings*, THE KAISER FAMILY FOUNDATION & HEALTH RESEARCH AND EDUCATION FUND, 4 (Sept. 11, 2012), <http://kaiserfamilyfoundation.files.wordpress.com/2013/03/8345-employer-health-benefits-annual-survey-full-report-0912.pdf> (“Over three-quarters (78%) of covered workers are in plans with three or more tiers of cost-sharing, a figure that has increased tremendously in the past decade.”).

²⁴ Julie Appleby, *Specialty Drugs Offer Hope, But Can Carry Big Price Tags*, USA TODAY, Aug. 8, 2011, <http://usatoday30.usatoday.com/money/industries/health/drugs/story/2011/08/Specialty-drugs-offer-hope-but-can-carry-big-price-tags/50090368/1>.

²⁵ Joseph J. Hylak-Reinholtz & Jay R. Naftzger, *Is It Time to Shed A “Tier” for Four-Tier Prescription Drug Formularies? Specialty Drug Tiers May Violate HIPAA’s Anti-Discrimination Provisions and Statutory Goals*, 32 N. ILL. U. L. REV., 33, 42 (2011).

²⁶ Bill Walsh, *The Tier 4 Phenomenon: Shifting the High Cost of Drugs to Consumers*, AMER. ASSN. OF RETIRED PERSONS (Mar. 9, 2009), <http://assets.aarp.org/rgcenter/health/tierfour.pdf>.

²⁷ Julie Appleby, *Workers Squeezed as Employers Pass Along High Costs of Specialty Drugs*, KAISER HEALTH NEWS (Aug. 22, 2011), <http://www.kaiserhealthnews.org/stories/2011/august/22/workers-squeezed-as-employers-pass-along-high-costs-of-specialty-drugs.aspx>.

²⁸ *Id.*

²⁹ *Id.*

has grown, the popularity of specialty plans has grown accordingly.³⁰ Many payors see specialty tiers as an essential element that allows a higher percentage of the drug spending burden to be carried by those who are utilizing higher cost products, allowing beneficiaries who are not using such drugs to maintain lower premiums and cost-sharing.³¹ Specialty tiers can either use a coinsurance or a copay cost-sharing scheme. Under a coinsurance scheme, the beneficiary will pay a certain percentage of the costs of the drug and the insurance company will pick up the remainder of the cost. Commonly, coinsurance rates for the specialty tiers range from twenty-eight to fifty percent.³² As such, coinsurance is a burden for beneficiaries in that the costs of specialty drugs are very expensive and a requirement to pay a sizable percentage of that cost can amount to several hundred or thousands of dollars per month in cost-sharing. Among plans with four or more tiers, in 2012, fifty-five percent of those plans used only a copay—often about \$100 per prescription per month—and thirty-six percent of plans used only coinsurance, percentage based cost-sharing—the average percentage was thirty-two percent.³³

The insurance industry defends the creation of four-tiered plans, but the use of such plans has been met with severe criticism. Patient advocates argue that four-tier plans are unjust because insurance is supposed to spread the risk in an equitable fashion among all insured beneficiaries.³⁴ However, specialty tiers target those with chronic illness who may have very limited therapeutic options, “forcing many to choose between basic necessities and their medications.”³⁵ On the other hand, insurance industry advocates argue that the use of specialty drugs has risen dramatically and having a tiered system helps to control the costs of premiums for all beneficiaries.³⁶ Karen Ignagni, the President of America’s Health Insurance Plans, noted that “[p]rivate insurers began offering [specialty drug] plans in response to employers who were looking for ways to keep costs down.”³⁷ She further noted, “[w]hen people who need [specialty] drugs pay more for them, other subscribers in the plan pay less for their coverage.”³⁸

The prevalence of fourth tier plans varies dramatically across health care markets. Four-tier designs are much less prevalent in markets characterized by historically high levels of unionized labor where the corporate benefits structures have been slow to disfavor

³⁰ Gary Claxto et al., *supra* note 23, at 149 (“Fourteen percent of covered workers are in a plan that has four or more tiers of cost-sharing for prescription drugs—up from 3% in 2005. For covered workers in plans with three or more cost-sharing tiers, 55% face a copayment for fourth-tier drugs and 36% face coinsurance. The average copayment for a fourth-tier drug is \$79 and the average coinsurance is 32%.”).

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ See National Patient Advocate Foundation, *supra* note 22.

³⁵ Kris McFalls, *An Update on Specialty Tier Legislation*, FFF ENTERS. (Oct. 7, 2011), http://www.fffenterprises.com/News/Article_2011-10-07.aspx.

³⁶ Gina Kolata, *Co-Payments Soar for Drugs with High Prices*, N.Y. TIMES, Apr. 14 2008, http://www.nytimes.com/2008/04/14/us/14drug.html?pagewanted=all&_r=0.

³⁷ *Id.*

³⁸ *Id.*

valuable fringe benefit schemes.³⁹ Four-tier penetration also varies greatly by market segment: “the smaller an employer, the greater the price-consciousness and likelihood of adopting a four-tier design. Finally, differences among health plan and employer philosophies and strategies are key in four-tier adoption.”⁴⁰ There is also a difference among insurance companies in adoption of the four-tier design. For example, Aetna and WellPoint have widely adopted four-tier designs.⁴¹ In contrast, Cigna, does not offer four-tier pharmacy benefits in its fully insured product line; however, upon request from self-insured employers, it can provide these insurance products.⁴² More recently, state legislatures have played an important role in affecting the prevalence of four-tiered plans as they seek to alleviate the cost-sharing burden on health insurance beneficiaries.⁴³

I. THE COST-SHARING BURDEN OF SPECIALTY TIERS

Specialty drugs have represented the fastest growing segment of health insurance prescription drug spending for much of the last decade.⁴⁴ This trend should concern private health insurance payors because specialty pharmaceuticals are very expensive and most are too new, complex, or expensive to produce to experience competition from other branded drugs or generics (biosimilars).⁴⁵ While specialty drugs are only used by a small percentage of the population—potentially as low as two percent⁴⁶—specialty drugs accounted for approximately twenty-four percent of total drug expenditures in 2011 and thirty percent of the \$325.7 billion in drug expenditures in 2012.⁴⁷ Moreover,

³⁹ Ha Tu & Divya Samuel, *Limited Options to Manage Specialty Drug Spending*, HSC RESEARCH BRIEF (Apr. 2012), <http://www.hschange.com/CONTENT/1286>.

⁴⁰ *Id.*

⁴¹ *Id.* (“[A]bout half of their small-to-mid-sized group members were covered by such designs as of 2011.”).

⁴² *Id.* (“[C]laiming concerns about affordability and patient adherence . . .”).

⁴³ New York, California, Connecticut, Delaware, Hawaii, Maryland, Massachusetts, New Mexico, Rhode Island, Vermont, Washington, Illinois, Indiana, Nebraska, Pennsylvania, Virginia, Louisiana, Florida, West Virginia, Alaska, Kansas, Mississippi, Maine, and Wisconsin all have previously introduced legislation regarding the use of specialty tiers in their state. However, only seven states have actually passed laws relating to tiering, and only ten states have active bills. Author research. See also Andrew Pollack, *States Seek to Curb Patients Bills for Costly Drugs*, N.Y. TIMES, A1, Apr. 13, 2012, http://www.nytimes.com/2012/04/13/health/states-seek-to-curb-exorbitant-drug-costs-incurred-by-patients.html?pagewanted=all&_r=0.

⁴⁴ See Specialty Drug Benefit Report, *supra* note 11.

⁴⁵ Biosimilars are generic versions of biologics that must prove that they are “biosimilar” and “interchangeable” with biologic reference products (the branded drugs) in order to be approved for sale in the consumer market. While the Biologics Price Competition and Innovation Act (part of the ACA) will help to create an abbreviated approval process for biosimilars so that they may gain easier and quicker FDA approval as long as they meet the Agency’s standards for safety and efficacy. *Biosimilars*, FOOD AND DRUG ADMIN. (July 10, 2012), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>.

⁴⁶ Ira Studin, *4 Payer Trends to Control Specialty Pharmacy Costs*, MANAGED CARE (May 2012), http://www.managedcaremag.com/archives/1205/1205.sp_trends.html.

⁴⁷ *The Growing Cost of Specialty Pharmacy—Is it Sustainable?*, *supra* note 15. In 2010, total national health expenditures were \$2.59 trillion dollars with retail prescription drugs accounting for 10% of that amount or \$250 billion. Martin A.B. et al., *Growth In US Health Spending Remained*

specialty drugs are anticipated to account for forty-five percent of total drug expenditures by 2017—up from a mere eight percent in 2006.⁴⁸ To put this in perspective, with current plan utilization rates, a moderately sized plan of one million members will be approaching one billion dollars in specialty drug spending annually.⁴⁹ Of these costs, almost fifty percent of which will be oncology related—cancer biologic costs increased 22.3 percent in 2012 alone.⁵⁰ If annual trends of twenty percent growth for spending on specialty drugs continue, that number will again double in less than four years.⁵¹ The damaging potential of this growth has been muted due to the overall downward shift in drug costs in recent years as generic usage has increased; for example, in 2012, traditional drug spending actually decreased while specialty drug spending increased by 18.4 percent.⁵² Reacting to this trend, insurance companies have developed prescription drug formularies with four or more tiers (hereinafter “specialty tiers”), in order to control the rising costs associated with expensive specialty drugs by sharing a greater amount of those costs with their patients.⁵³ While increased specialty drug cost-sharing is certainly warranted, the strain that it places on patients can create negative health and personal externalities.⁵⁴ As such, further effort should be exerted to reduce the burden on those patients who depend on these drugs and who often lack alternative treatment options.⁵⁵

The key feature of specialty drug tiers is a drastically increased cost-sharing component, with the consumer paying a larger amount of the cost for expensive drugs. Such cost-sharing can take the form of much higher copayments, where the consumers pay a certain defined price for a drug in that category or coinsurance, where the consumer pays a percentage of the actual cost of the drug. The practice of cost-sharing has been widely criticized by politicians and patients who cite examples of destructive cost-sharing which could force a person to decide between a certain medication and other personal or familial necessities.⁵⁶ Because most specialty drugs are used to treat chronic

Slow in 2010; Health Share of Gross Domestic Product Was Unchanged from 2009, HEALTH AFFAIRS (2012). In 2012, total drug expenditures had risen to \$325.7 billion and specialty drug expenditures accounted for \$99 billion of that number. Katie Thomas, *U.S. Drug Costs Dropped in 2012, but Rises Loom*, N.Y. TIMES, Mar. 18, 2013, <http://www.nytimes.com/2013/03/19/business/use-of-generics-produces-an-unusual-drop-in-drug-spending.html?pagewanted=all>; *Understanding Specialty Pharmacy Management and Cost Control*, PHARMACEUTICAL STRATEGIES GROUP (June 2010), http://www.psgconsults.com/Understanding_Specialty_Pharmacy_Management_and_Cost_Control_FINAL.pdf.

⁴⁸ *The Growing Cost of Specialty Pharmacy—Is it Sustainable?*, *supra* note 15; see also 2012 DRUG TREND REPORT, *supra* note 20; Kim, Yoona A., et al, *Retrospective Evaluation of the Impact of Copayment Increases for Specialty Medications on Adherence and Persistence in an Integrated Health Maintenance Organization System* (Nov. 5, 2011).

⁴⁹ Artemetrx, *Specialty Drug Trend Across the Medical and Pharmacy Benefit* (2013), http://www.artemetrx.com/docs/ARTEMETRX_Specialty_Trend_Report.pdf

⁵⁰ *Id.*; see also *The Growing Cost of Specialty Pharmacy—Is it Sustainable?*, *supra* note 15.

⁵¹ *Id.* According to the Express Scripts, 2012 Drug Trend Report, specialty trend (cost rate change + utilization rate change) rose 18.4% in 2012. 2012 Drug Trend Report, *supra* note 17.

⁵² *Id.*; Katie Thomas, *supra* note 47.

⁵³ See Kim, Yoona A., et al, *supra* note 48.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Pollack, *supra* note 43.

diseases such as cancer, rheumatoid arthritis, multiple sclerosis, and inherited disorders, the long-term costs to both the insurers and the patients raises serious concerns.

Spurred by patients and patient advocates, lawmakers in at least twenty states from Maine to Hawaii, have introduced legislation that would either ban specialty tiers or limit aggregate out-of-pocket payments by consumers for expensive specialty tier drugs.⁵⁷ New York State passed the first such law, in 2010, prohibiting the use of specialty tiers across the board for beneficiaries of plans offered in the state.⁵⁸ Pharmaceutical companies—that would benefit from such legislation because high copayments discourage patients from taking medications sold by pharmaceutical companies—have been helping the state legislatures craft such specialty tier limiting legislation.⁵⁹ Some companies, like Pfizer, have even drafted entire bills and have provided them to state legislatures, according to legislators and patient advocates.⁶⁰ Insurance companies are pushing back, arguing that reducing payments by users of expensive drugs would raise premiums for everyone else.⁶¹

State legislators must carefully consider the potential that their attempted protective measures—that ban specialty tiers or limit aggregate out-of-pocket payments by consumers for expensive specialty tier drugs—will be limited in effect by the Employee Retirement Income Security Act of 1974 (ERISA).⁶² ERISA preemption applies to nullify state insurance laws that apply to self-insured ERISA plans.⁶³ As an ode to the traditional areas of state regulation, as evidenced by the McCarran Ferguson Act,⁶⁴ state laws directed at the business of insurance are saved from preemption by § 514 of ERISA,⁶⁵ also known as the “insurance savings clause.” However, self-insured plans, where the employer funds the plan and takes on the risk in the plan, are not “deemed” to be in the business of insurance due to the “Deemer Clause,” which is also part of § 514 of ERISA.⁶⁶ As such, only insured health benefit plans must comply with state insurance

⁵⁷ *Id.*

⁵⁸ *See id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² Employee Retirement Income Security Act of 1974 (ERISA), Pub. L. No. 93-406, 88 Stat. 829 (codified as amended in scattered sections of 5 U.S.C., 18 U.S.C., 26 U.S.C., 29 U.S.C., and 42 U.S.C.) (1974).

⁶³ *Id.* § 514.

⁶⁴ McCarran-Ferguson Act, 15 U.S.C. §§ 1011-1015 (1976) (“Congress hereby declares that the continued regulation and taxation by the several States of the business of insurance is in the public interest, and that silence on the part of the Congress shall not be construed to impose any barrier to the regulation or taxation of such business by the several States. [§2.] (a) The business of insurance, and every person engaged therein, shall be subject to the laws of the several States which relate to the regulation or taxation of such business. (b) No Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance, or which imposes a fee or tax upon such business, unless such Act specifically relates to the business of insurance.”). ERISA carved out an area of federal preemption with respect to such traditional state governance.

⁶⁵ ERISA, 29 U.S.C. § 514(b)(2)(A).

⁶⁶ ERISA, 29 U.S.C. § 514(b)(2)(B).

mandates, and state laws seeking to limit specialty drug cost-sharing are similarly limited to only insured plans.⁶⁷ Considering that more than half of Americans with employer sponsored plans have self-insured plans, such laws alone cannot totally solve the concern of high specialty drug cost-sharing.⁶⁸ However, this potential limitation should not discourage state efforts to pass such cost-sharing legislation.

State tier limiting legislation is significantly augmented by the out-of-pocket limits on prescription drug spending that are created by the Affordable Care Act (ACA),⁶⁹ which will, as of January 1, 2014, apply to both insured and self-insured plans having plan years starting on or after January 1, 2014.⁷⁰ Some insurers have indicated that state laws limiting specialty cost-sharing are unnecessary because of the ACA, however, backers of such legislation argue that the state bills would serve as an important supplement to the federal law. While the ACA serves to alleviate some of the cost-sharing concerns for patients as well as the discrepancies between insured and self-insured plans, the cost-sharing limits may remain burdensome for some families.⁷¹ The ACA reduces the burden on those individuals who are paying the most for their pharmaceuticals, but there will still be a role for states to further assist those who depend on specialty pharmaceuticals from almost assuredly reaching the ACA's maximum cost-sharing limits (\$6,350 in 2014 for an individual plan or \$12,700 for a family plan) which can be very financially burdensome considering that these payments are in addition to premium costs.⁷²

⁶⁷ See e.g., *American Medical Security v. Bartlett*, 111 F.3d 358 (4th Cir. 1997).

⁶⁸ Paul Fronstin, *Self-Insured Health Plans: State Variation and Recent Trends by Firm Size*, EMPLOYEE BENEFIT RESEARCH INST. (Nov. 2012). In 2011, 58.5% of workers with employer-provided health coverage were in self-insured plans. *Id.*

⁶⁹ Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-48, § 2702, 124 Stat. 119, 318-19 (2010).

⁷⁰ *Id.* The ACA applies to both insured and self-insured plans since the legislation made amendments to the Public Health Service Act (PHSA) as well as the Internal Revenue Code sections as they apply to ERISA in order to reach all non-grandfathered plans, whether insured or self-insured. ACA § 1301; ACA § 1201 (adding § 2707(b) (applying cost-sharing limits to “group health plans” which had been defined to encompass self-funded plans) to the PHSA.); and ACA § 1302(c).

⁷¹ See *infra* Section V.

⁷² The ACA cost-sharing limits for 2014 were pegged to the High Deductible Health Plan (HDHP) deductible minimums for 2014 which are set year by the Internal Revenue Service (IRS). For 2015 and beyond, the cost-sharing limits will be set through a uniform percentage increase that will be decided by the premium adjustment percentage which is set by CMS in their yearly Benefit and Payment Parameters rulemaking. See ACA, Pub. L. No. 111-48, § 1302(c)(1), 124 Stat. 119, 47-48 (2010). It should be noted that there are diminished cost-sharing limits for those who are at or below 250% of the FPL. Limits for those individuals are set at fractions of the OOP limits set for that given year. They are as follows: enrollees with a household modified adjusted gross income (MAGI) between 100% and 150% of the FPL will be eligible for plans with a 2/3 reduction in the maximum annual limitation on OOP cost-sharing; enrollees with household MAGI between 150% and 200% of the FPL will be eligible for a different set of plans at the respective AV level required by the ACA for such subset that also has a 2/3 reduction in the standard maximum annual limitation on OOP cost-sharing; enrollees with household MAGI between 200% and 250% of the FPL will be eligible for a different set of plans at the respective AV level required by the ACA for such subset that also has a 1/2 reduction in the standard maximum annual limitation on OOP cost-sharing. The FPL for 2014 is \$11,490 for an individual and requires the addition of \$4,020 for each additional person. (i.e., a couple is \$15,510). See 2014 Notice of Benefit and Payment Parameters, 78 Fed. Reg. 15410 (March 11, 2013).

States should take note, however, that while the ACA has assisted their efforts in protecting citizens from high costs of specialty drugs, the ACA also stated that the state may face increased costs if they seek to limit cost-sharing further than the ACA mandates through state legislation.⁷³ The ACA requires states that pass laws, after December 31, 2011, that act to strengthen or add to the benefits required to be covered as Essential Health Benefits (EHB) than what appeared in their benchmark plans, as chosen by the state in accordance with the ACA, must defray any additional costs, to the beneficiary or the carrier, in relation to those increased coverage requirements; this has been deemed the “make-whole requirement.”⁷⁴ While some states have argued that cost-sharing limitations are not an additional benefit but a constraint on plan design—which escapes this “make-whole requirement”—the precarious position of many state budgets could make this risk too much to bear—causing specialty drug related legislative efforts to disappear.⁷⁵ Even with this risk in mind, states have continued to legislate to create tighter restrictions on patient cost-sharing (although with diminished success rates), but they have placed language in the bills that would protect the state, by invalidating the law, should they be required to defray the associated costs.⁷⁶ However, a careful reading of the rules related to such cost-sharing laws show that state specialty drug out-of-pocket limits reduction laws should escape cost defrayment requirements set forth in the ACA.⁷⁷ As such, states should seek to further protect their residents from excessive cost-sharing, with respect to specialty drugs, by passing legislation similar to the legislation that has been enacted in New York, or legislation which sets diminished caps on specialty cost-sharing.

II. STATES REACT TO SPECIALTY TIERS

To protect consumers and address the increasingly expensive cost of specialty pharmaceuticals, legislators from states across the country have introduced or passed

⁷³ See ACA, Pub. L. 111-48, 24 Stat. 119 (2010); Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. 70,643, 70,647 (Nov. 26, 2012) (“[T]he Affordable Care Act explicitly permits a state to require QHPs to offer benefits in addition to EHB, but requires the state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional benefits. We propose that state-required benefits enacted on or before December 31, 2011 (even if not effective until a later date) may be considered EHB, which would obviate the requirement for the state to pay for these state-required benefits.”). The final rule, issued on February 25, 2013 maintains these provisions and subjects to the defrayment requirement for at least the 2014 and 2015 plan years. *Id.*; Final Rule, 78 Fed. Reg. 12,834, 12,837-8 (February 25, 2013).

⁷⁴ *Id.* (“In this proposed rule, we interpret state-required benefits to be specific to the care, treatment, and services that a state requires issuers to offer to its enrollees. Therefore, state rules related to provider types, cost-sharing, or reimbursement methods would not fall under our interpretation of state-required benefits. Even though plans must comply with those state requirements, there would be no federal obligation for states to defray the costs associated with those requirements.”).

⁷⁵ See *id.*

⁷⁶ See e.g., Assemb. B. 310, 2011–12 Leg., Reg. Sess. (Cal. 2012) (containing provisions that would make the requirements of the bill inoperative if the Director of the DMHC or the Insurance Commissioner determines that the requirements would result in the “assumption by the state of additional costs pursuant to [the requirements of the ACA]”).

⁷⁷ See ACA, Pub. L. No. 111-48, 124 Stat. 119 (2010); Standards Related to Essential Health Benefits, *supra* note 69, at 70,647.

legislation that seeks to limit the ability of insurers to take advantage of tiering options.⁷⁸ While few states have been able to pass such legislation, several active legislative initiatives remain in place today.⁷⁹ States have used various mechanisms to protect individual or household finances against cost-sharing mechanisms, the strongest of which is the complete ban of specialty tiers. Even more common are out-of-pocket maximums, which typically take the form of annual limits on the out-of-pocket (OOP) cost-sharing required by individuals or families.⁸⁰

As recognition of the serious problem that specialty drug cost-sharing tiers pose for many of those who depend on those medications, eight states⁸¹ have sought a complete ban on any plan design that contains over a three-tiered pharmacy benefit, effectively forbidding specialty tiers. Currently, New York is the only state to have legislation that places a complete ban on specialty tiers.⁸² An additional nine states⁸³ have sought to impose caps on the OOP expenditures allowed for pharmaceuticals in health insurance plans or to link pharmaceutical OOP payments to the overall plan deductible. These laws have been popular proposals from state legislatures, given that they still allow increased member cost-sharing for high-cost pharmaceuticals, in accord with insurance company interests, while protecting beneficiaries from exceedingly high drug costs.⁸⁴ The second largest number of states have approved, or are currently considering legislation that calls for state insurance departments to undertake studies to obtain more information on the prevalence and effect of specialty tiers, seeking to use the findings to craft further limiting legislation.⁸⁵ Often accompanying these studies is a moratorium on the

⁷⁸ Standards Related to Essential Health Benefits, *supra* note 69, at 70,653 (proposing that a plan may exceed the annual deductible limit if it cannot reasonably reach a metal tier).

⁷⁹ The seven states which have passed laws related to specialty tiering include Alaska, New York, Delaware, Vermont, Florida, Maine, and Louisiana. Author research.

⁸⁰ Of the ten states with active bills, six states (Delaware, Nebraska, Pennsylvania, California, Rhode Island, and Massachusetts) have bills that only lower the cost-sharing limits. Author calculation. *See infra* notes 100-106, 119.

⁸¹ New York, Delaware, and Vermont have passed and signed into law bans on specialty tiers for at least certain indications. Only New York has a complete and unlimited ban on specialty tiers. Legislative efforts to enact bans are ongoing in Kansas, Pennsylvania, California, and Massachusetts. Mississippi's legislature considered a complete ban with the same wording as New York in 2012, but it died in committee. Author research.

⁸² *See* Pollack, *supra* note 43.

⁸³ The states and their provisions are as follows: Delaware, bill, total drug OOP limitation to \$100 per month; Maine, law, \$3,500 per year OOP maximum; Vermont, law, deductible limitation to \$2,000 per person per year, \$4,000 per family per year; Nebraska, bill, specialty tier cannot exceed 500% of OOP cost of lowest tier; Pennsylvania, bill, deductible limitation of \$1,000 per person, \$2,000 per family; California, bill, total drug OOP cannot exceed \$150 per month and another bill matching federal deductible limits \$2,000 per person, \$4,000 per family, California, vetoed by gov, oral cancer cost-sharing equal to all other cancer drug delivery methods; Rhode Island, bill, specialty tier cannot exceed 500% of OOP cost of lowest tier and deductible limitation of \$1,000 per person, \$2,000 per family; Massachusetts, bill, specialty tier cannot exceed 500% of OOP cost of lowest tier; Louisiana, law, oral cancer cost-sharing equal to all other cancer drug delivery methods. Author research. *See infra* notes 101-113, 119.

⁸⁴ *See e.g.*, Pollack, *supra* note 43.

⁸⁵ *See e.g.*, S.B. 137, 146th Gen. Assemb., Reg. Sess. (Del. 2011).

approvals of plans with a four-tiered structure until the results of the study have been analyzed.⁸⁶

The insurance savings clause of § 514(b)(2)(A) of ERISA grants states the ability to make such blanket restrictions and limitations on insurance plans.⁸⁷ Section 514 of ERISA states that “[e]xcept as provided in subparagraph (B) [the “Deemer Clause”], nothing in this subchapter will be construed to exempt or relieve any person from any law of any State which regulates insurance”⁸⁸ Effectively, this provision grants state insurance departments the freedom to regulate plans that operate and/or are offered in that state as long as the plans are insured plans.⁸⁹ Accordingly, the savings clause creates an exception to the general rule that ERISA preempts state laws that relate to employee benefit plans.⁹⁰ The purpose of this allowance is to permit states to retain powers over an area of regulation and an industry which they commonly have had purview.⁹¹ The allowance of additive state regulations of health insurance plans is advantageous for beneficiaries in those states which have sought to add increased beneficiary protections. Such regulations, however, can create a patchwork of state regulation that can and do place a burden on compliance measures for insurance companies that must account for this multiplicity of laws given that they operate in multiple states.⁹² The avoidance of such a situation was a prime consideration in the enactment of ERISA.⁹³ Given the popularity of specialty pharmaceuticals by pharmaceutical companies and the

⁸⁶ *Id.*

⁸⁷ *See* ERISA, Pub. L. 93–406, 29 U.S.C. § 514 (b)(2)(A) (providing the construction and application of various exemptions found within the subchapter of the statute); *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 722, 733–47 (1985) (considering a Massachusetts mental health benefit mandate for group health policies; holding that while the mandate “relate[d] to” employee benefit plans, the law regulated the terms of an insurance contract; and ultimately exempting the law from pre-emption under the savings clause). In this defining case regarding ERISA’s “savings clause,” the Court, in coming to its conclusion, applied a three-prong test to determine whether an activity or practice constitutes the “business of insurance.” *Id.* at 743 (requiring that the activity in question must spread risk, the relationship between insured and insurer must be an integral part of the activity, and it must be limited to entities in the traditional insurance industry (*citing* *Union Labor Life Ins. Co. v. Pirineo*, 458 U.S. 119, 127–30 (1982))). Under this test, the Court concluded that the Massachusetts mandate and mandated benefits, in general, met all three criteria, and thus ruled that mandated benefit laws are exempt from pre-emption. *Id.* at 743, 759; *see* William Pierron & Paul Fronstin, *ERISA Pre-emption: Implications for Health Reform and Coverage*, EMP. BENEFIT RESEARCH INST. 1, 8 (Feb. 2008), http://www.ebri.org/pdf/briefspdf/EBRI_IB_02a-20082.pdf. (distinguishing between plans that are insured and “uninsured,” or self-insured, because the Deemer Clause would immunize an uninsured plan from state-mandated benefit laws).

⁸⁸ *See* ERISA, Pub. L. 93–406, § 514.

⁸⁹ *Id.*; *see also* William Pierron & Paul Fronstin, *supra* note 87.

⁹⁰ *Contra American Medical Security v. Bartlett*, 111 F.3d 358 (4th Cir. 1997); *see infra* note 119 (explaining the 4th Circuit’s decision).

⁹¹ *See* McCarran-Ferguson Act, 15 U.S.C. §§ 1011-1015 (1976).

⁹² Such was the purpose of ERISA § 514. *See* *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 11 (1987) (finding Congress’s concern with a “patchwork scheme of regulation [that] would introduce considerable inefficiencies in benefit programs . . .”).

⁹³ *See e.g.*, *Siskind v. Sperry Ret. Program*, 47 F.3d 498, 503, 505 (2d Cir. 1995) (observing that the purpose of ERISA is to provide regulatory consistency and minimize financial and administrative burdens on employers), *abrogated by Janese v. Fay*, 692 F.3d 221 (2d Cir. 2012).

effectiveness of such drugs, however, state actions may be a critical element of reducing the consumer burdens of healthcare, given that federal legislation that could apply such restrictions to all states, that goes beyond the limitations imposed by the ACA, seems not to be feasible.⁹⁴

A. State Prohibitions of Four-Tiered Plans

It took New York lawmakers over a year and a half, but in 2010, the passage of Senate Bill 5000B⁹⁵ marked the first of many state efforts to restrict or limit specialty tier cost-sharing.⁹⁶ The New York legislation was a heavily supported bill in that it never received less than a two-to-one yes-to-no vote margin in any of its committee reviews, and it eventually passed the New York Senate by a vote of fifty-five to one, with Senator Thomas O'Mara being the lone nay vote.⁹⁷ The wave of nationwide support for a similar ban in other states, however, has not had the success for which many patient advocates had originally hoped.⁹⁸ Currently, New York is the only state to have a law that across the board eliminates specialty tiers without constraints or time limitations.⁹⁹ Following in the way of New York legislature by placing complete restrictions on the use of tier four and higher cost-sharing by insured health plans when offered in that state under the control of that state's insurance department are Vermont,¹⁰⁰ whose term limited ban expired on July 1, 2013, and, to a lesser extent, Delaware,¹⁰¹ which only bans four and higher tiered plans as they apply to oral cancer drugs. Both states' plans, however, are limited

⁹⁴ See e.g., Patients' Access to Treatments Act of 2013, H.R. 460, 113th Cong. (Feb. 4, 2013) (GovTrack has the bill as having an eleven percent chance of moving past the House Energy and Commerce Committee and only a three percent chance of passage).

⁹⁵ Tier IV Prescription Drugs, 2010 Sess. Law News of N.Y. Ch. 536 (S. 5000-B) (McKinney); (providing that no health care plan or insurance policy that provides prescription drug coverage and for which cost-sharing, deductibles, or co-insurance obligations are determined by category of prescription drugs shall impose cost-sharing, deductibles, or co-insurance obligations for any prescription drug exceeding the dollar amount of cost-sharing deductibles or co-insurance obligations for any other prescription drug provided under such coverage for non-preferred brand drugs or their equivalents).

⁹⁶ See *infra* part III(B).

⁹⁷ See S. 5000-2009, Reg. Sess. (N.Y. 2009) (pertaining to the elimination of cost-sharing, deductibles and co-payments for certain prescription drugs).

⁹⁸ See National Patient Advocate Foundation, *supra* note 22.

⁹⁹ Pollack, *supra* note 43.

¹⁰⁰ See S.B. 104, 2011 Leg., Reg. Sess. (Vt. 2011) ("Prior to July 1, 2012, no health insurer or pharmacy benefit manager shall utilize a cost-sharing structure for prescription drugs that imposes on a consumer for any drug a greater co-payment, deductible, coinsurance, or other cost-sharing requirement than that which applies for a nonpreferred brand-name drug.").

¹⁰¹ See The Delaware Cancer Treatment Access Act, H.B. 265, 146th Gen. Assemb. Reg. Sess. (Del. 2011) (providing that individual and group health plans in Delaware that provide major medical and prescription drug coverage will be barred from charging cancer patients higher copayments, coinsurance, or deductibles for oral chemotherapy drugs, which are in the specialty tier, than for intravenous therapies, which are covered under medical benefit which does not have specialty tiers).

in either scope or longevity. Several other states, including Kansas,¹⁰² Massachusetts,¹⁰³ California,¹⁰⁴ Pennsylvania,¹⁰⁵ and Mississippi,¹⁰⁶ have pending legislation that seek to place complete restrictions on four or higher tier cost-sharing in plans. Currently, Mississippi is the only state where its legislature passed a complete, unrestricted ban but the Governor vetoed the bill.¹⁰⁷

Surprisingly, the New York State law was passed even though there was never an issue in New York with specialty tiers.¹⁰⁸ The New York State Insurance Department never authorized a commercial health insurance plan that contained specialty tiers before the introduction of this legislation, although there had never been an official law in New York regarding this practice until New York Senate Bill 5000's introduction.¹⁰⁹ A memorandum in opposition to the legislation, from the law firm of Hinman Straub P.C. written on behalf of Blue Cross and Blue Shield Plans of New York, stated that Senate Bill 5000-B was redundant and unnecessary because no private health insurance plan that contained specialty tiers previously had been approved by the State Insurance Commissioner.¹¹⁰ Because the New York legislation did not attempt to prevent a practice that was already in place, advocates neither expected nor confronted a forceful opposition

¹⁰² See H.B. 2136, 84th Gen. Assemb., Reg. Sess. (Kan. 2011) (“It shall be an unlawful discriminatory practice . . . [f]or any employer, labor organization, insurer, health maintenance organization or other entity to limit health care coverage such that cost-sharing, deductibles or coinsurance obligations for any prescription medication exceeds the dollar amount of cost-sharing, deductibles or coinsurance obligations for any category of non-preferred brand medication or its equivalent, or brand medication if there is no non-preferred brand medication category.”).

¹⁰³ See S.B. 455, 187th Gen. Assemb., Reg. Sess. (Mass. 2012) (providing that an insurer shall not create specialty tiers that require payment of a percentage cost of prescription drugs).

¹⁰⁴ See Assemb. B. 310, 2011–12 Leg., Reg. Sess. (Cal. 2012) (“A health insurance policy issued, amended, or renewed on or after January 1, 2012, that covers outpatient prescription drugs shall not require coinsurance as a basis for cost-sharing with the insured for outpatient prescription drugs shall not require coinsurance as a basis for cost-sharing with the insured for outpatient prescription drug benefits.”).

¹⁰⁵ See H.B. 1609, 2011 Leg., Reg. Sess. (Pa. 2012) (“An insurer shall not create specialty tiers that require payment of a percentage cost of prescription drugs.”).

¹⁰⁶ See H.B. 1319, 2012 Leg., Reg. Sess. (Miss. 2012) (“A health care service plan contract issued, amended, or renewed on or after January 1, 2013, that covers prescription medicine shall not create specialty tiers that require payment of a percentage cost of prescription drugs.”). This bill has been reintroduced but previously died in committee on March 6, 2012. *Id.*

¹⁰⁷ See *id.* (pertaining to all health care service plans issued, amended, or renewed on or after January 1, 2013).

¹⁰⁸ See Haley Gillet et al., *Regulating the Specialty Tier in Georgia*, GA. TECH. PUB. POL’Y TASK FORCE 2012, 24 (2012), http://www.advocatesforresponsiblecare.org/uploads/GRC_Specialty_Tier_GA_Tech_Final_Report_Regulating_the_Specialty_Tier.pdf.

¹⁰⁹ See *id.* (observing that an important element was that this bill did not incur any costs on New York State; rather, no additional state oversight was necessary to regulate and monitor the elimination of drug formularies containing a specialty tier because they had never been approved by the Insurance Department).

¹¹⁰ Memorandum from Hinman Straub P.C. Legislative Counsel for the Blue Cross and Blue Shield Plans (Apr. 15, 2010), <http://www.nysblues.org/pdf/A8278AS5000A.pdf>.

from the insurance industry.¹¹¹ The insurance industry was only mildly opposed and did not employ any massive campaign in resistance to the New York legislation.¹¹²

According to New York Senate Bill 5000, cost-sharing policies in general create negative health outcomes because they decrease the utilization of drugs, which may lead to increased hospitalizations to address the consequences of foregoing treatment.¹¹³ With the degree of cost-sharing in specialty tiers, the legislature found these detrimental effects to be uncontainable.¹¹⁴ In its legislative findings, Senate Bill 5000-B indicates that “[t]he cost-sharing, deductibles and co-insurance obligations for certain drugs are becoming cost prohibitive for persons trying to overcome serious and often life-threatening diseases and conditions such as cancer, multiple sclerosis, rheumatoid arthritis, hepatitis C, hemophilia and psoriasis.”¹¹⁵ As an attempt to avoid such limitations on patient care, § 3216 of New York State’s insurance law was amended by adding paragraph 27, which provides that “[n]o policy delivered or issued for delivery in this state which provides coverage for prescription drugs and for which cost-sharing, deductibles or coinsurance obligations are determined by category of prescription drugs shall impose cost-sharing, deductibles or co-insurance obligations for any prescription drug that exceeds the dollar amount of cost-sharing, deductibles or co-insurance obligations for non-preferred brand drugs or its equivalent (or brand drugs if there is no non-preferred brand drug category).”¹¹⁶ The effect of this amendment is to limit the maximum cost-sharing to the level required for non-preferred brand name drugs, typically referred to as tier three pharmaceuticals.¹¹⁷

B. Cost-Sharing Limits Falling Short of Prohibitions

While many states have entertained bills that seek to limit specialty drug cost-sharing, many others have resisted such proposals in order to avoid drawing the ire of insurers in the state, or, for fear that such measures would increase premiums for all beneficiaries—regardless of whether they use drugs covered in the specialty tier.¹¹⁸ Thirteen states either have passed laws or currently have proposed legislation that would place caps on

¹¹¹ Gillet et al., *supra* note 108, at 26.

¹¹² *See id.* (reasoning that the legislation would maintain the status quo).

¹¹³ *See e.g.*, Kris McFalls, *supra* note 35 (comparing how various states have passed legislation to ban specialty tiers but eventually opining that such legislation will not apply to self-funded plans under ERISA).

¹¹⁴ *See* Tier IV Prescription Drugs, 2010 Sess. Law News of N.Y. Ch. 536 (S.B. 5000-B) (McKinney) (explaining that such drugs are usually produced in smaller quantities than are other drugs and are unavailable as less expensive generic drugs).

¹¹⁵ *See id.* (asserting that it is in the public interest to provide assistance to patients to afford necessary prescription drugs and that the “extraordinary disparity in cost-sharing, deductible and co-insurance burdens imposed on patients whose life and health depend on these drugs constitutes serious and unjustified discrimination based on their disease or disability”).

¹¹⁶ *See id.* (intending to provide patients a more affordable access to essential prescription drugs).

¹¹⁷ *See* Tier IV Prescription Drugs, 2010 Sess. Law News of N.Y. Ch. 536 (S. 5000-B) (McKinney) (“No policy . . . shall impose cost-sharing, deductibles or co-insurance obligations for any prescription drug that exceeds the dollar amount of cost-sharing, deductibles or co-insurance obligations for non-preferred brand drugs or its equivalent.”).

¹¹⁸ *See supra* notes 100-106 (listing the enacted legislation and active bills).

specialty drug spending,¹¹⁹ create moratoriums on the creation of new tier four benefit structures,¹²⁰ or directed state insurance departments to explore specialty cost-sharing limitations.¹²¹ The most common of these measures is a limitation on the extent of cost-sharing such that the difference between the lowest and the higher cost-sharing amounts among all tiers cannot exceed 500%.¹²² This effectively eliminates coinsurance and instead replaces it with a limited copayment feature. Seeing as drugs in the first tier can have OOP amounts as low as five dollars, the ability of insurance companies to attain

¹¹⁹ Several states have enacted laws that limit cost-sharing: Maine, Louisiana, and Vermont. *See* Me. Rev. Stat. tit. 24-A, § 4317-A (2012) (“[F]or all benefits provided under a health plan, the carrier shall establish a separate out-of-pocket limit not to exceed \$3,500 per year for prescription drugs subject to coinsurance provided under a health plan to the extent not inconsistent with the federal Affordable Care Act.”); H.B. 693 2012 Leg., Reg. Sess. (La. 2012) (requiring parity for orally administered anti-cancer medications with intravenously administered or injected anti-cancer medications); H.B. 559, Reg. Sess. (Vt. 2012) (establishing an annual out-of-pocket limit for prescription drugs at two thousand dollars per individual and four thousand dollars per family); Del. Gen. Stat. Ch. 33 §3364 (S.B. 35, 147th General Assembly) (De. 2013) (indicating that a health plan that provides coverage for prescription drugs shall not have cost-sharing of more than \$100 per month for up to a 30-day supply of any single drug, and cannot charge more than \$200 per enrollee per month in the aggregate for covered pharmaceuticals).

Various bills that limit cost-sharing exist in other states, too. *See e.g.*, S.B. 455, Reg. Sess. (Mass. 2012) (providing no cost-sharing more than five-hundred percent of the least expensive drug category); Legis. B. 322, 102d Leg. 1st Reg. Sess. (Neb. 2012); S.B. 252, 146th Gen. Assemb., 2d Reg. Sess. (Del. 2011) (stating that any required copayment or coinsurance that applies to covered drugs cannot exceed \$100 per month for up to a thirty-day supply of any single drug, whereby such required copayment or coinsurance does not exceed, in the aggregate for all covered drugs, \$200 per month per enrollee). “An insurer shall not create specialty tiers that require payment of a percentage cost of prescription drugs” that cost more than 500% of the lowest price prescription drug. H.B. 1609, 2012 Leg. Reg. Sess. (Pa. 2012) (no plan can create a specialty tier and maximum copay cannot exceed lowest by 500%). *See* Assemb. B. 310 (stating that “health insurance policies . . . shall not require an insured to pay a copayment for outpatient prescription drugs in excess of one hundred fifty dollars (\$150) for a one-month supply of a prescription, or its equivalent for a prescription for a longer period, as adjusted for inflation”).

A more recently introduced bill, which created a limit on out-of-pocket expenses at the level set by the federal OOP limit, died in the appropriations committee on August 16, 2012. *See* Assemb. B. 1800, 2012 Leg. Gen. Sess. (Cal. 2012); *see also* H.B. 7573, 2012 Leg. Reg. Sess. (R.I. 2012) (providing that no tiers shall be created where the maximum cost-sharing exceeds the lowest in the plan by 500% or more).

¹²⁰ Currently, both Florida and Delaware have such laws. *See* H.B. 1003, 115th Leg. 2d Reg. Sess. (Fla. 2013) (creating specialty tier prescription drug moratorium for a year until July 1, 2014, and requiring a report to the Governor and Legislature as to cost-sharing effects.); S.B. 137, 146th Gen. Assemb., Reg. Sess. (Del. 2011) (creating a moratorium on health insurance providers that charge higher cost-sharing for different classification of prescription drugs until the Legislature enacts legislation to limit such higher cost-sharing is not needed, and moreover requiring that by March 15, 2012, the Delaware Healthcare Commission submit to the General Assembly a report that summarizes the impact of specialty cost-sharing).

¹²¹ States who have enacted such requirements include: Florida (*See supra*, note 119), Delaware (*See supra*, note 119), and there is a bill in Illinois to extend the period, by a year, to deliver their previously required report which would be due under the bill on November 30, 2013. 2011 IL H.R. 1310 (NS), 2011 Illinois House Resolution No. 1361, Illinois Ninety-Seventh General Assembly (Jan. 6, 2013).

¹²² *See supra*, note 119.

any real assistance in covering the excessive costs of specialty drugs is severely limited. Many other states have targeted or enacted numerical limits as a way to ensure that cost-sharing in the specialty tier cannot rise above a certain set amount.¹²³ This strategy is much more feasible and yet remains highly effective in that it would allow a cost-sharing amount to be imposed relative to the cost of specialty pharmaceuticals, allowing the beneficiary to share in some, albeit small, amount of the cost of the specialty drugs they use. This structure would not cause as much upward pressure on the cost-sharing for other drug categories, while still limiting the total costs to those beneficiaries who depend on such specialty drugs.

Pharmaceutical companies have been active in lobbying for state legislatures to introduce legislation that limits cost-sharing.¹²⁴ For instance, legislators in Maine have reported in-depth discussions with Pfizer, and some pharmaceutical companies have even supplied draft bills that may be introduced by state legislatures.¹²⁵ Pharmaceutical companies seek such limits as this creates a wider market for their drugs and helps to insure the patient will actually fill their prescriptions for specialty pharmaceuticals and not be deterred from doing so based on high costs.¹²⁶ Noncompliance to a drug regimen is one of the more damaging externalities of high cost-sharing, not only for pharmaceutical companies but also for health care more generally. However, the country's largest health insurance companies have been more active and have effectively ended reform movements in some states.¹²⁷ The incentives for insurance companies to oppose such reforms are obvious as the loss of specialty tier cost-sharing greatly affects not only their bottom line but also the risk pool of their health insurance plans.¹²⁸

III. WHY SECTION 514 OF ERISA HAS LIMITING EFFECTS ON STATE EFFORTS

State legislative attempts to limit specialty pharmaceutical cost-sharing are severely limited by ERISA's express preemption of state laws that "relate to" employee benefit plans and which are not saved under the insurance savings clause.¹²⁹ Some experts and advocates have argued that the preemption provision in § 514 of ERISA is overly restrictive in that it "prevents state and local governments from regulating employment-based health plans," limiting the potential for comprehensive health insurance reform to start at the state or local level where such legislation is often more easily legislated.¹³⁰ For instance, in accordance with ERISA, state specialty tier laws cannot impact self-funded employee health plans which are under the sole purview of ERISA and federal

¹²³ *Id.*

¹²⁴ Pollack, *supra* note 43.

¹²⁵ *Id.*

¹²⁶ See National Patient Advocate Foundation, *supra* note 22.

¹²⁷ See Pollack, *supra* note 43.

¹²⁸ See e.g., 2012 Drug Trend Report, *supra* note 17 (showing the emergence of specialty drugs as the most lucrative of all pharmaceuticals).

¹²⁹ See ERISA, 29 U.S.C. §§ 514(b)(2)(A), (B).

¹³⁰ William Pierron & Paul Fronstin, *ERISA Pre-emption: Implications for Health Reform and Coverage*, 8 EBRI Issue Brief no. 314, 38 (Feb. 2008), http://www.ebri.org/pdf/briefspdf/EBRI_IB_02a-20082.pdf.

regulations.¹³¹ This is arguably detrimental considering that over half of all employees with health insurance coverage are enrolled in self-funded employer sponsored plans.¹³²

Under the “insurance savings clause” of ERISA, all state laws that govern the business of insurance, such as limitations on cost-sharing, are exempt from ERISA preemption as they apply to insured plans—as established in § 514 of ERISA.¹³³ All insured employee benefit plans are deemed to be included under the umbrella of the insurance savings clause, and as such, state insurance law mandates apply to these plans—as long as they are additive to ERISA mandates.¹³⁴ Conversely, ERISA’s “Deemer Clause” declares that self-funded plans¹³⁵ are not deemed to be in the business of insurance; and are therefore exclusively under the purview of ERISA, and federal mandates that amend ERISA, such as the ACA.¹³⁶ As such, these plans do not have to comply with state mandates that require more than federal minimum coverage and plan design requirements.¹³⁷

The insured/self-insured split is the result of congressional intent that ERISA provide a legal framework for the uniform provision of benefits by employers doing business anywhere in the country.¹³⁸ This uniformity allows multistate companies that self-insure to offer consistent benefit packages wherever they happen to be located. The result of which is ease of administration and lower expenses to ensure plan compliance.¹³⁹ For self-insured plans, freedom from state benefit mandates also allows plan sponsors to design benefit packages that meet the needs and desires of their employees, as well as to

¹³¹ See *supra* notes 64–67.

¹³² Pierron & Fronstin, *supra* note 130; Carolyn Johnson, *Bill Aims to Stop Specialty Tier Prescription Drug Costs*, ABC NEWS SAN FRANCISCO, Feb. 9, 2011, <http://abclocal.go.com/kgof/story?section=news/health&id=7950299>. It is important to note that an increasing number of such self-funded plans do feature stop-loss protections that seek to limit the potential losses of the corporation offering the coverage. As long as the stop-loss is not set at too low a number, such plans will still be considered to be “deemed” saved from state regulation by ERISA preemption. See *American Medical Security v. Bartlett*, 111 F.3d 358 (4th Cir. 1997) (holding that ERISA preempted a Maryland insurance regulation which sought to regulate and require the coverage of certain state mandated benefits if the self-funded health insurance plan had a stop-loss insurance policy with an attachment point below \$10,000).

¹³³ See ERISA, at § 514 (stating any state law that governs an area that is also governed by ERISA is preempted and the state law will be invalid to those plans. The Federal coverage requirements had not covered contraceptives or many other female preventative treatments or products until ERISA was amended as part of ACA).

¹³⁴ *Id.*

¹³⁵ Insured plans involve the employer contracting with an insurance company to cover the risk associated with having a health plan. Self-funded plans are those employee welfare plans where the entity establishing the plan assumes all of the risk associated with paying out and distributing claims as in accordance with the plan. Since they do not involve insurance companies, which are under the purview of states, self-funded plans cannot be regulated by states. See *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers*, 514 U.S. 645 (1995).

¹³⁶ *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 722, 743, 759 (1985) (one of the factors of the “Deemer Clause” (section 514(B) of ERISA) application is whether the employer has spread the risk of coverage to an insurance company).

¹³⁷ See ERISA, 29 U.S.C. §§ 524(b)(2)(A), (B).

¹³⁸ See *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 11 (1987).

¹³⁹ Pierron & Fronstin, *supra* note 130, at 7.

effectively promote wellness and control health costs.¹⁴⁰ Such unique needs, as well as the risk that these employers have assumed in their self-insured plans, are some of the primary reasons why they are allowed to largely escape state insurance regulations.¹⁴¹

Due to ERISA, state legislation limiting specialty tiering, even if passed in all fifty states, will not apply to self-funded plans.¹⁴² Federal legislation—such as the reform measures enacted in the ACA—is needed to address ERISA-governed plans, particularly to attain a universal application of limits. Given the number of beneficiaries in self-insured employer plans, the federal reform approach would have a much larger influence on the market.¹⁴³ Such a federal measure was introduced in the U.S. House of Representatives on February 4, 2013 by Representative David McKinley. The Patients’ Access to Treatments Act of 2013,¹⁴⁴ “amend[s] title XXVII of the Public Health Service Act to limit co-payment, coinsurance, or other cost-sharing requirements applicable to prescription drugs in a specialty drug tier to the dollar amount (or its equivalent) of such requirements applicable to prescription drugs in a non-preferred brand drug tier, and for other purposes.”¹⁴⁵ This bill is similar to the law enacted in New York in that it effectively bans the usage of specialty tiers by setting the maximum pharmaceutical cost-sharing, which is equal to the rate for non-preferred brand drugs—traditionally the third tier.¹⁴⁶ With eighty-five co-sponsors across both parties (sixty-seven Democrats and eighteen Republicans) there appears to be support for such a bill; however, it will require much more support to transverse the current state of federal politics.¹⁴⁷ While such a measure is assuredly gaining the ire of health insurance advocates, such a measure would prove beneficial to those states that have been wrestling with this issue for a number of years.¹⁴⁸ This bill could essentially solve both the state legislative backlog and the insured/self-insured dichotomy in one legislative act. Since this is a reintroduced bill, however, it is hard to overlook its past failures, especially with all of the recent burdens placed on insurers by the ACA.¹⁴⁹

¹⁴⁰ See generally Pierron & Fronstin, *supra* note 130.

¹⁴¹ *Id.*; see also *Fort Halifax Packing*, 482 U.S. at 11.

¹⁴² Pierron & Fronstin, *supra* note 130.

¹⁴³ *Id.* (indicating that, in 2011, 58.5% of all workers with health insurance coverage were in employer funded self-insured plans).

¹⁴⁴ Patients’ Access to Treatments Act of 2013, H.R. 460, 113th Cong. (Feb. 4, 2013). This bill was a re-introduction of H.R. 4209 (112th Cong.) (Mar 19, 2012); *H.R. 460: Patients’ Access to Treatments Act of 2013*, GOVTRACK.US (2013), <http://www.govtrack.us/congress/bills/113/hr460> (last visited Dec. 22, 2013).

¹⁴⁵ *H.R. 460: Patients’ Access to Treatments Act of 2013*, GOVTRACK.US (2013), <http://www.govtrack.us/congress/bills/113/hr460> (last visited Dec. 22, 2013).

¹⁴⁶ Patients’ Access to Treatments Act of 2013, H.R. 460, 113th Cong. (Feb. 4, 2013).

¹⁴⁷ *H.R. 460: Patients’ Access to Treatments Act of 2013*, GOVTRACK.US (2013), <http://www.govtrack.us/congress/bills/113/hr460> (last visited Dec. 4, 2013).

¹⁴⁸ See Pollack, *supra* note 43; see also National Patient Advocate Foundation, *supra* note 22.

¹⁴⁹ See *H.R. 460: Patients’ Access to Treatments Act of 2013*, *supra* note 147 (GovTrack lists the bill as having an eleven percent chance of moving past the House Energy and Commerce Committee and only a three percent chance of passage).

IV. WILL THE AFFORDABLE CARE ACT MAKE STATE ACTION ON SPECIALTY TIERS LESS PALATABLE?

While the ACA creates a cost-sharing limit that will apply to all health benefit plans, further state out-of-pocket (OOP) restrictions are necessary because the ACA limits remain prohibitively high for some of the beneficiaries that are most in need.¹⁵⁰ However, some states fear that any increased benefits may trigger an ACA requirement that would require states to defray the extra costs of offering such increased benefits.¹⁵¹ The cost-sharing limits set forth in the ACA are pegged to the OOP limits for high-deductible health plans (HDHPs).¹⁵² The cost-sharing limits for HDHPs in 2014 are \$6,350 for an individual or \$12,700 for “family” coverage.¹⁵³ This amount is corrected for inflation and generally increases yearly—the 2013 HDHP limit was \$6,250 for an individual and \$12,500 for “family” coverage.¹⁵⁴ While the restrictions this places on cost-sharing will surely limit the high coinsurance rates that some beneficiaries are required to pay, given their health conditions and the prices for the pharmaceuticals on which they depend, for many Americans these capped amounts can still be extremely burdensome or even cost prohibitive for those on fixed incomes who may not be able to access federal or state health benefits.¹⁵⁵ And the affordability does not appear to be improving for the 2015 benefit year, as Centers for Medicare and Medicaid Services (CMS) on November 26, 2013 issued its proposed 2015 Notice of Benefit and Payment Parameters rule, in which it calls for the OOP limits to be raised by four times the amount the Internal Revenue Service (IRS) raised the HDHP rates for 2014; CMS proposed that the 2015 maximum annual limitation on cost-sharing be \$6,750 for self-only coverage and \$13,500 for “family” coverage.¹⁵⁶ As such, there may be an even greater need now for states to act to reduce the burden on beneficiaries who depend on specialty drugs.

As state legislators consider laws that would prohibit or limit cost-sharing, the ACA has created a wrinkle that may cause budget conscious state governments to think twice about enacting such legislation. It is still unknown if legislation that places limits on

¹⁵⁰ FAQs About Affordable Care Act Implementation Part XII, UNITED STATES DEPARTMENT OF LABOR, (Feb. 20, 2013), <http://www.dol.gov/ebsa/faqs/faq-aca12.html>. Public Health Service (PHS) Act § 2707(b), as added by the Affordable Care Act, provides that a group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under §§ 1302(c)(1) and (c)(2) of the Affordable Care Act. Section 1302(c)(1) limits out-of-pocket maximums and § 1302(c)(2) limits deductibles for employer-sponsored plans.

¹⁵¹ See Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-48, § 2702, 124 Stat. 119, 318-19 (2010).

¹⁵² *Id.* at § 1302(c)(1); see also *supra* note 72 (outlining lower limits applicable to those with incomes under 400% of the Federal Poverty Level).

¹⁵³ 2014 HSA/HDHP Limits Announced, BUCK CONSULTANTS (May 6, 2013), available at <http://www.buckconsultants.com/portals/0/publications/fyi/2013/FYI-2013-0506-2014-HSA-HDHP-limits-announced.pdf>.

¹⁵⁴ See e.g., IRS Announces 2013 HSA Contribution Limits & HDHP Minimum Deductibles & Out-of-Pocket Maximums, CLS PARTNERS (May 7, 2012), <http://www.clspartners.com/post.php?id=42>.

¹⁵⁵ Kim, Yoona A., *supra* note 48.

¹⁵⁶ HHS Notice of Benefit and Payment Parameters for 2015, 78 Fed. Reg. 72321, p. 139 (Nov. 26, 2013), http://www.ofr.gov/OFRUpload/OFRData/2013-28610_PI.pdf.

cost-sharing for prescription drugs would create a new mandate subject to the ACA requirement that for coverage provided through the Exchange, the State is required to pay the full cost of any new mandate exceeding the covered services required in that state's Essential Health Benefits (EHB) Package.¹⁵⁷ Section 1311(d)(3)(B) of the ACA, which is more acutely defined in a November 2012 Department of Health and Human Services (HHS) proposed rule (final rule, issued on February 28, 2013, maintains such provisions but does not speak as directly to its application), allows states to create mandated benefits for exchange plans, above and beyond those required elsewhere in the ACA (EHBs), as long as the state defrays the additional costs.¹⁵⁸ Since coverage for prescription drugs is included as one of the ten required EHBs, state laws related to additional pharmaceutical benefits must comply with this requirement.¹⁵⁹ Within the EHB design template, there is a clearly demarcated area for the inclusion of specialty drug tiers.¹⁶⁰ In addition, the actuarial value calculator, which is used to calculate the coverage level for the plan, known as "metal tiers,"¹⁶¹ includes the option of adding a specialty drug tier cost-sharing amount that will be used to calculate the average plan cost to the beneficiary.¹⁶²

The November 2012 rule, however, explicitly states that cost-sharing legislation is not a mandate that will trigger the state to defray costs, allowing states to pass such laws without

¹⁵⁷ ACA, Pub. L. No. 111-48, § 1311 (d)(3)(B), 124 Stat. 119 (2010); *see also* 77 Fed. Reg. 70,643, 70,647 (Nov. 26, 2012). The ACA left states with the requirement that they establish an essential health benefit plan for that state—within certain parameters. Such a plan mirrored a specific existing plan in the state augmented, where required, such that the plan features would be compliant with the ACA. Such existing plans already contained current state mandates that survived ERISA § 514. However, if the state where to add required benefits or plan features above and beyond the ACA requirements after the adoption of an EHB benchmark plan, the state would be required to reimburse the insurance company for the provision of such benefits or plan features where they augmented the EHB or ACA requirements. *Id.*

¹⁵⁸ 77 Fed. Reg. 70,643, 70,647 (Nov. 26, 2012). The defrayment required by the state was suggested in the rule by calculating the additional costs incurred by the plan and spreading that cost across all plan beneficiaries. The state will then pay to the plan on behalf of each beneficiary or to the beneficiary themselves the extra premium costs that the additional benefit(s) creates. *Id.*

¹⁵⁹ *Essential Health Benefits Standards: Ensuring Quality, Affordable Coverage*, CTR. FOR CONSUMER INFO. AND INS. OVERSIGHT (July 2012), <http://cciio.cms.gov/resources/factsheets/ehb-2-20-2013.html>.

¹⁶⁰ *Plans and Benefits Template*, CMS (2012), http://www.serff.com/documents/plan_management_data_templates_plans_benefits_instructions.pdf.

¹⁶¹ A metal tier is a term that corresponds to four of the five possible levels of health insurance coverage (other level is a catastrophic plan) offered on either the federally-facilitated marketplace or on state marketplaces. Each coverage tier relates to a specific actuarial value (AV) which represents the average amount of coverage provided to an average beneficiary with average medical spend. A bronze plan has an AV of 60% (the insurance company will pay for 60% of the average beneficiaries medical spend in a given year), a silver plan has an AV of 70%, a gold plan has an AV of 80%, and a platinum plan has an AV of 90%. Each plan is granted a 2% deference in order to ensure adequate comparison potential between different plan designs.

¹⁶² *See* ACA, Pub. L. No. 111-48, 124 Stat. 119 (2010); Actuarial Value Calculator Methodology, DEPT. OF HEALTH AND HUMAN SERV. (Feb. 25, 2013), <http://cciio.cms.gov/resources/files/av-calculator-methodology.pdf>.

the fear of triggering the defrayment requirement of § 1311(d)(3)(B) of the ACA.¹⁶³ According to the CMS proposed rule, CMS will, “interpret state-required benefits to be specific to the care, treatment, and services that a state requires issuers to offer to its enrollees. Therefore, state rules related to provider types, cost-sharing, or reimbursement methods would not fall under our interpretation of state-required benefits. Even though plans must comply with those state requirements, there would be no federal obligation for states to defray the costs associated with those requirements.”¹⁶⁴ Legislative studies conducted in California¹⁶⁵ and Maryland¹⁶⁶ suggest that a bill that restricts forms of cost-sharing does not create a mandated covered service; rather, it places restrictions on cost-sharing designs that can be used to craft the levels of cost-sharing within the EHB benchmark plan.¹⁶⁷ In an attempt to reduce the risk of a conflicting interpretation, some states considering going forward with specialty tier limiting legislation have included escape provisions in their legislation.¹⁶⁸ For example, a California specialty tier limiting bill includes language that would make the bill inoperative if it were determined that the requirements would result in the assumption by the state of additional costs pursuant to § 1311(d)(3)(B) of the ACA.¹⁶⁹ The use of such language in other states bills should allow them to pursue specialty tier cost-sharing legislation without the risk that such provisions would activate the ACA requirement that would require states to defray costs.

CONCLUSION

Specialty drugs represent a growing concern for both health insurance issuers and beneficiaries given their exceedingly high cost. They are projected to represent almost half of all drug spending by 2017.¹⁷⁰ Payers have sought to reduce specialty drug spending by sharing more of the cost of these drugs with the beneficiaries who depend on them

¹⁶³ ACA, Pub. L. No. 111-48, 124 Stat. 119 (2010); Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. 70,643, 70,647 (Nov. 26, 2012) (in accord with the final rule which appears at 78 Fed. Reg. 12834, 12837-8, <http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>).

¹⁶⁴ *Id.*

¹⁶⁵ Analysis of Assembly Bill 310: Prescription Drugs, CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM (Apr. 14, 2011), <http://escholarship.ucop.edu/uc/item/8w87h8wq>.

¹⁶⁶ 2011 Session Position Paper regarding H.B. 251, MARYLAND HEALTH CARE COMMISSION (2011), <http://dls.state.md.us/data/tabs/wha/Issue-Papers—2012-Legislative-Session-for-web.pdf>.

¹⁶⁷ See *supra* note 165. California argues that AB 310 does not require coverage of additional benefits as it specifically states, that “[n]othing in this section shall be construed to require a [health care service plan/health insurance policy] to provide coverage not otherwise required by law for any prescription drug.” *Id.* The California report also lists several factors that would be considered by the Department of Insurance in deciding whether there was a mandated benefit that would require the state to defray the extra costs to the plans. *Id.* at 23.

¹⁶⁸ For instance, AB 310 contains provisions that would make the requirements of the bill inoperative if the Director of the DMHC or the Insurance Commissioner determines that the requirements would result in the “assumption by the state of additional costs pursuant to Section 1311(d)(3)(B) of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by Section 10104(e) of Title X of that act, relative to benefits required by the state to be offered by qualified plans in the California Health Benefit Exchange that exceed the requirements imposed by federal law.” *id.*

¹⁶⁹ See ACA, Pub. L. No. 111-48, § 1311, 124 Stat. 119 (2010).

¹⁷⁰ Schilling, *supra* note 2; see also 2012 Drug Trend Report, *supra* note 17.

through the creation of specialty drug tiers.¹⁷¹ This has forced some patients to choose between forgoing other needs to pay for their medications or not take their medications at all. While several states have sought to outlaw the use of specialty drug tiers or limit pharmaceutical OOP cost-sharing, only New York has been successful in passing an unlimited prohibition on specialty tiers.¹⁷² There are, however, currently legislative efforts in a quarter of states that seek to either limit or eliminate cost-sharing requirements for beneficiaries who depend on specialty pharmaceuticals for treatment.¹⁷³ While some state legislatures have been concerned that the ACA cost defrayment requirement that applies to new state required benefits that are above and beyond the required benefits in that state's EHB benchmark plan, the November 2012 HHS Essential Health Benefit proposed rule makes it explicit that state laws concerning cost-sharing limitations do not implicate the requirement to defray costs—they merely effect benefit designs, not the number of EHBs.¹⁷⁴ For those states that remained skeptical of this CMS interpretation of the ACA, there is the option of constructing the legislation in such a way that the specialty pharmaceutical cost-sharing limitations would be inoperative should the state be required to defray the costs of such additional benefit features—as has been done in both California and Maryland.¹⁷⁵ Whether such protections are written in, given the CMS interpretation and its appearance in the February EHB final rule, CMS has provided states will an opportunity to limit the burdensome OOP costs that are associated with specialty drugs. Doing so could allow beneficiaries to not have to choose between their medications and basic necessities.¹⁷⁶ While the ACA caps on OOP expenditures go far in reducing the most egregious cases of specialty pharmaceuticals spending, it does not go far enough, and in fact such limits will continue to rise yearly (the limits are slated to rise by \$1,000 for families in 2015), providing less and less protection; states must act to further remove or limit the constraints that specialty tier OOP requirements place on beneficiaries who many times have no other treatment options.¹⁷⁷

¹⁷¹ See Walsh, *supra* note 26.

¹⁷² See Pollack, *supra* note 43.

¹⁷³ See *supra* Section III(B).

¹⁷⁴ Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,647, available at <http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28362.pdf>.

¹⁷⁵ See Analysis of Assembly Bill 310: Prescription Drugs, *supra* note 165.

¹⁷⁶ Kim, Yoona A., *supra* note 48.

¹⁷⁷ See HHS Notice of Benefit and Payment Parameters for 2015, *supra* note 156.