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I. INTRODUCTION

On April 14, 2008, the *New York Times* published an article titled *Co-Payments Go Way Up for Drugs With High Prices*.[1] The article focused on the rising cost of prescription drugs, in particular it questioned the development of prescription drug formularies with four or more tiers (i.e., "specialty drug tiers"), which were developed by health insurance companies to control rising costs associated with expensive specialty drugs.[2] The article

1. Gina Kolata, *Co-Payments Go Way Up for Drugs With High Prices*, N.Y. TIMES, Apr. 14, 2008, at A1.

2. *See generally* Bill Walsh, *Strategic Analysis & Intelligence (SAI) Report, The Tier 4 Phenomenon: Shifting the High Cost of Drugs to Consumers*, AARP (Mar. 9, 2009), http://assets.aarp.org/rgcenter/health/tierfour.pdf (showing that historically, health plans used a three-tier structure to determine an insured's copayment amount for specific prescription drugs—typically, a plan would have low cost drugs (such as generics) on Tier 1, preferred brand-name drugs on Tier 2, and non-preferred brand-name drugs on Tier 3). Walsh notes that common practice shows brand-name drugs with a generic equivalent are placed on the third tier to encourage the use of lower cost generic medications. *Id.* at 5-6. Non-preferred brand-name drugs may be placed on a third tier for two other reasons. First, because the medication at issue does not have a greater clinical effectiveness when compared with similar medications for the same health condition placed on the second tier. Second, a medication may be deemed non-preferred by the health insurance plan because the health insurance

recognized the need to control rising costs, but questioned whether the development of such tiers would lead to an increase in the number of persons who could not afford such specialty medications. The *New York Times* article article was not a one-day story; rather, it began a national debate about specialty prescription drugs and whether prescription drug formularies with specialty drug tiers should be prohibited.[3]

The article was the first to expose a nascent trend in prescription drug coverage benefit design – a trend that began in the mid-2000's and continues to grow in popularity among employers and health insurance companies in 2011.[4] Health insurance companies will continue to add specialty drug tiers because of the precipitous rise in the cost of certain specialty drugs, and, more importantly, because employers and health insurance companies are finding that specialty drug tiers are an effective method for controlling rising costs.[5]

The *New York Times* article, however, did not view the evolution of specialty drug tiers as a positive development. Instead, the article asserted that the creation of specialty drug tiers was directly related to a steep rise in the out-of-pocket costs people pay for specialty drugs.[6] Furthermore, it was reported that copayments[7] for specialty drugs could reach "thousands of dollars a month" under prescription drug formularies with specialty drug tiers.[8] Worse yet, these specialty drugs lacked lower-cost generic or brand-

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plan and pharmaceutical company did not reach a mutual agreement on cost sharing, such as a rebate agreement. *See also* Susan E. Cancelosi, *Revisiting Employer Prescription Drug Plans for Medicare-Eligible Retirees in the Medicare Part D Era*, 6 HOUS. J. HEALTH L. & POL'Y 85, 107 (2005) (indicating that plans with four "or more" tiers had a minimal four percent of the market share in 2004). The Cancelosi article shows that the marketplace already has some complex plans (having more than four tiers), but these benefit structures were limited in number in 2005 and appear to be limited as of 2011.

3. Walsh, *supra* note 2, at 5 (noting that specialty drugs are drugs used to treat chronic or complex conditions and typically require special handling and care management).

4. *See* Adam J. Fein, *Big Growth in Four-Tier Drug Benefits*, DRUG CHANNELS (Sept. 14, 2010), http://www.drugchannels.net/2010/09/big-growth-in-four-tier-drug-benefits.html (last visited May 25, 2011); *see also* Jack Hoadley et al., *Medicare Part D 2009 Data Spotlight: Specialty Drug Tiers*, HENRY J. KAISER FAMILY FOUNDATION (June 2009), http://www.kff.org/medicare/upload/7919.pdf (reporting that the vast majority of Medicare Part D enrollees are in plans with specialty drug tiers as of 2009 and that more than half of these beneficiaries were subject to thirty-three percent coinsurance for specialty tier drugs).

5. Kolata, *supra* note 1.

6. *Id.*

7. Mary Crossley, *Discrimination Against the Unhealthy in Insurance*, 54 KAN. L. REV. 73, 125 (2005) (describing cost-sharing mechanisms in health insurance: defining coinsurance as a payment in which a consumer bears an indefinite obligation to pay a percentage of the charges for a service received and copayments as the consumer's obligation to pay a definite dollar amount).

8. Kolata, *supra* note 1.

name alternatives, thereby forcing consumers to face a difficult choice—pay the higher copayment amounts, reduce taking necessary medications, or stop taking medications altogether.[9]

Karen Ignagni, the President of America's Health Insurance Plans, responded to the article. She noted that "[p]rivate insurers began offering [specialty drug] plans in response to employers who were looking for ways to keep costs down."[10] She further noted, "[w]hen people who need [specialty] drugs pay more for them, other subscribers in the [health insurance] plan pay less for their coverage."[11] Dr. James Robinson, a health economist at the University of California at Berkley, strongly disagreed with Ignagni and called the emergence of formularies that target specialty drugs "unfortunate social policy" and "an erosion of the traditional concept of insurance."[12]

The *New York Times* article illustrated a real life example of the hardship a person can suffer when their health insurance company implements a prescription drug formulary that targets certain specialty drugs. Ms. Steinwald, previously diagnosed with multiple sclerosis, was prescribed Copaxone.[13] This particular specialty drug costs about $1900 per month.[14] Before the specialty tier formulary was created, Steinwald's copayment for her Copaxone was only $20 per month (her insurer paid the balance of the drug's actual cost).[15] When her health insurance company moved to a formulary that placed specialty drugs on a fourth benefit tier, Steinwald's monthly copayment increased to $325 a month—meaning her annual out-of-pocket cost jumped to $3900 for one prescription medication.[16]

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9. *Id.* at A17.
10. *Id.*
11. *Id.*
12. *Id.* The "traditional concept of insurance" referred to by Dr. Robinson is "risk spreading." For further discussion on risk spreading, *see* TOM BAKER, INSURANCE LAW AND POLICY 2 (2d ed. 2008) (noting that risk spreading, a core concept in the design of insurance benefits, occurs when an insurer takes on risk of an individual person but then parcels that risk among all people in the insurance pool. The idea is that every person in the group will pay a similar premium cost; however, that cost will be large enough to build a pot of money able to sustain the system when high cost claims are submitted by a small number of people within the larger group).
13. Kolata, *supra* note 1. The article published on April 14, 2008 inferred that Copaxone, a medication used to treat conditions associated with multiple sclerosis, was taken in pill form. However, it was not taken in pill form. Accordingly, the *New York Times* published a correction on April 15, 2008 to clarify that Copaxone is a medication that is administered via an injection—it is not taken orally. Gina Kolata, *Co-Payments Soar for Drugs With High Prices*, N.Y. TIMES, April 15, 2008, http://www.nytimes.com/2008/04/14/us/14drug.html?pagewanted=all (correction appended to online version of article).
14. Kolata, *supra* note 1.
15. *Id.*
16. *Id.*

Shortly after the *New York Times* story was published, Senate Democratic leader Malcolm A. Smith and other members of the New York State Senate Democratic Conference announced the introduction of legislation that, if enacted, would prevent health insurers from establishing prescription drug formularies that target specialty drugs.[17] The Democratic Conference voiced their opposition to specialty drug tiers and asserted that specialty tier pricing would "unfairly shift the burden to consumers."[18] Senator Smith added that the caucus would "do all [it could] to make sure that health care remains accessible and affordable."[19] The New York Department of Insurance, in response to Senator Smith's announcement, added that the state agency had yet to approve any specialty tier formularies and that none were being utilized in the State of New York.[20]

Despite the forceful stance taken at the press conference in 2008, it took New York nearly three more years to pass a law prohibiting specialty drug tiers. In October 2010, Governor David Patterson signed into law legislation sponsored by New York Assembly Member Micah Z. Kellner (D-Manhattan) and State Senator Tom Duane (D-New York) that will prevent health insurance companies from raising the out-of-pocket cost to consumers of more expensive medications.[21] New York's ban on specialty drug tiers received national attention because it was the first time a state law prohibited such practices. As a result, similar efforts have been introduced in several other states, including Arizona, California, Connecticut, Hawaii, Kansas, Maryland, Massachusetts, Nebraska, New Mexico, Pennsylvania, Rhode Island, Vermont, Virginia, and Washington.[22]

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17. *Senate Democrats Move to Ban Tier 4 Prescription Drug Pricing Plan*, LONG ISL. NEWS, Apr. 23, 2009, *available at* http://www.newsli.com/2008/04/23/senate-democrats-move-to-ban-tier-4-prescription-drug-pricing-plan/.

18. *Id.*

19. *Id.*

20. *Id.*

21. *See* 2010 N.Y. Laws 536 (signed into law on October 1, 2010).

22. *See, e.g.*, Arizona, S.B. 1594, 2011 Leg., 1st Sess. (Ariz. 2011); California, A.B. 310, 2011 Leg., 2011-12 Reg. Sess. (Cal. 2011); Connecticut, H.B. 1084, 2011 Leg., Jan. Sess. (Conn. 2011); Hawaii, S.C.R. 93, 26th Leg., Reg. Sess. (Haw. 2011); Kansas, H.B. 2136, 2011 Leg., 2011-12 Sess. (Kan. 2011); Maryland, H.B. 251, 429th Gen. Assemb., 2011 Sess. (Md. 2011) and S.B. 709, 429th Gen. Assemb., 2011 Sess. (Md. 2011); Massachusetts, S. 455, 187th Gen. Ct., 2011 Sess. (Mass. 2011); Nebraska, L.B. 322, 102 Leg., 1st Sess. (Neb. 2011); New Mexico, S.B. 536, 50th Leg., 1st Sess. (N.M. 2011); Pennsylvania (On May 9, 2011, Rep. Mike Vereb announced a plan to introduce legislation banning specialty drug tiers and called for colleagues to join his effort by sending a letter to all members of the state house. *See* Memorandum from Rep. Michael A. Vereb, Republican Leadership Caucus Sec'y, to All Pennsylvania House Members on Proposed Legislation—Specialty Tiers (May 9, 2011), http://www.legis.state.pa.us/WU01/LI/CSM/2011/0/8318.pdf); Rhode Island, H. 5568, 2011 Leg., Jan. Sess. (R.I. 2011); Vermont, H. 202, 2011-12 Leg. Sess. (Vt. 2011), and S.B. 57, 2011-12 Leg. Sess. (Vt. 2011); Virginia, H.J. 579, 2011 Sess. (Va. 2011); and Washington, H.B. 1876, 2011-12 Reg. Sess. (Wash. 2011).

Despite New York's new law and the efforts underway in thirteen other states,[23] specialty drug tiers may already be unlawful under the anti-discrimination provisions in the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).[24] HIPAA, as informed by its legislative history and the Final Rule implementing the law, rejects benefit limitations based upon an individual's health status.[25] Applied to specialty drug tiers, the question is whether specialty drug tiers that, by definition, group together a limited number of people with specifically identifiable medical conditions or diseases, with the knowing intent to charge the members of that particular group higher copayments for their specialty drugs, improperly discriminate under HIPAA based on health status. The answer, although not clear, is found in the HIPAA's statutory language, legislative history, and commentary provided in the Final Rules.[26]

This Article will analyze whether specialty drug tiers violate HIPAA. This is a question of first impression—no federal or state court decision provides an answer. Part II of this Article provides relevant background material. We begin with a discussion about the development of prescription drug coverage in the United States and the emergence of drug tiers as a cost-saving mechanism.

In Part III of this Article, we begin with an historical overview of accepted discrimination and risk classification within insurance. Next, we discuss HIPAA's statutory language, legislative history, and key parts of the Final Rule implementing the law. We also address the impact of national health care reform under the Patient Protection and Affordable Care Act ("Affordable Care Act").[27] Based on the foregoing, we will argue that HIPAA, its statutory history, and the relevant federal regulations demonstrate that specialty drug tiers violate HIPAA's anti-discrimination provisions, yet we acknowledge that reasonable minds could differ on that conclusion. Therefore, we note that courts, regulators, and legislators may have to ask and answer certain questions. What is good public policy? Should courts or regulators act or leave the question unresolved and wait for Congress to act? Generally, statutes regulating the business of insurance do not

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23. In Virginia, H.J. 579 does not propose a ban on specialty drug tiers; rather, the measure directs the Joint Commission on Health Care to study the impacts of cost sharing, coinsurance, and specialty tier pricing for prescription medications. *See* H.J. 579, 2011 Sess. (Va. 2011).

24. 29 U.S.C. § 1182(a) (2006).

25. *See id.*

26. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75,014 (Dec. 13, 2006) (to be codified at 45 C.F.R. pt. 146).

27. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); Health Care and Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) [collectively referred to as the Affordable Care Act].

prevent all discrimination, only unfair discrimination.[28] If specialty tier formularies do not violate HIPAA's anti-discrimination provisions specifically, are these benefit structures still wholly inconsistent with the overall legislative intent of HIPAA—to improve the portability and continuity of health coverage for all insured Americans?[29] To conclude this Part, we argue that specialty drug tiers should be universally rejected because such drug plans not only violate HIPAA, but are inconsistent with HIPAA's broader goals of ensuring that Americans continue to have access to affordable health insurance benefits and repudiating discrimination on the basis of an insured's health status. Additionally, such drug tiers fail to satisfy the basic principles of insurance, do not further the same salutary social goals as traditional prescription drug formularies (i.e., formularies with three tiers), and adversely affect patient access to specialty drugs.

In Part IV of this Article, we conclude that legislators and regulators should promote the public policy used to pass HIPAA into law and exercise their authority to end the proliferation of specialty tier drug plans.

II. BACKGROUND ON PRESCRIPTION DRUG COVERAGE IN THE UNITED STATES AND THE EMERGENCE OF SPECIALTY DRUG TIERS

A. PRESCRIPTION DRUG BENEFITS IN HEALTH INSURANCE

The cost of prescription drugs has been a national problem since the 1960s.[30] During that decade, relatively few private health insurance plans offered prescription drug coverage.[31] In 1965, Congress enacted Medicare and Medicaid, but only Medicaid included a prescription drug benefit.[32] When a health insurance company offered prescription drug coverage, coverage was minimal.[33] The typical plan imposed many limits—such as coinsurance, high deductibles, and low annual maximums—making the coverage little help to the insured population.[34]

In 1967, the first employer-sponsored prescription drug benefit was established as a result of negotiations between the United Auto Workers

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28. Deborah S. Hellman, *Is Actuarially Fair Insurance Pricing Actually Fair? A Case Study in Insuring Battered Women*, 32 HARV. C.R.-C.L. L. REV. 355 (1997).

29. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75,014 (Dec. 13, 2006) (to be codified at 45 C.F.R. pt. 146).

30. Cancelosi, *supra* note 2, at 105.

31. *Id.*

32. *Id.*; *see also Medicare: A National Treasure for Forty Years*, MED. RTS. CENTER (July 2005), http://www.medicarerights.org/pdf/Medicare_A_National_Treasure.pdf (last visited Oct. 25, 2011).

33. Cancelosi, *supra* note 2, at 105.

34. *Id.*

(UAW) union and General Motors, Chrysler, and Ford.[35] By the late 1970s, most employer-sponsored health plans included a prescription drug benefit.[36] However, prescription drug coverage was typically part of the overall plan and not viewed as a separate benefit, subjecting prescription drug costs to the same deductibles and co-insurance as the plan's general medical benefits.[37] By 2004, most employer-sponsored prescription drug benefit plans included cost-saving mechanisms, such as prescription drug formularies.[38]

B. PRESCRIPTION DRUG BENEFIT TIERS

1. The Development of the Traditional Three-Tier Prescription Drug Formulary

Historically, a treating physician exclusively determined what prescription drugs were necessary to treat a disorder; thus, patients were without sufficient knowledge of specific drugs to have any input into the specific drug-prescribing decision.[39] Around the mid-1990s, consumers started to demand specific brand-name drugs from their health care providers.[40] The increased demand for brand-name drugs was attributed to a "tremendous increase" in advertising by drug manufacturers.[41] Health plan administrators, alarmed by the rise in brand-name utilization, looked for new ways to influence the behavior of health insurance beneficiaries in order to counter the impact that advertising was having on patient behavior, and to reign in the rapidly growing costs associated with prescription drug benefit plans.[42]

Health plan administrators established the modern model for copayments, placing a varying copayment amount that a health insurance beneficiary must pay for a particular prescription, which would increase based on the cost of the drug and whether it had a generic equivalent. Previously, most beneficiaries paid a standard five dollar charge for any prescription

35. *Id.* at 106.
36. *Id.*
37. *Id.*
38. Cancelosi, *supra* note 2, at 106.
39. The development of the learned intermediary rule that insulated drug companies from tort liability if their drug caused harm was a reflection of this knowledge disparity. *See, e.g.*, Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 199-205 (2004).
40. Cancelosi, *supra* note 2, at 111.
41. *Id.*
42. *Id.* at 107.

medication, without regard to the type or cost of the particular drug.[43] In addition to copayments, health plans began to develop formularies[44] that separated prescription drugs into different tiers. The goal of the new formularies was to achieve cost savings by charging beneficiaries more for prescription drugs placed on a higher-level tier and thereby encourage the use of lower-cost generic medications.[45]

A three-tier prescription drug formulary became the most common structure. Generally, three-tier formularies separate prescription drugs as follows: Tier 1 includes low-cost generic medications, Tier 2 includes brand-name drugs without generic substitutes, and Tier 3 includes brand-name drugs with generic substitutes.[46] In regard to costs, Tier 1 drugs have "the lowest copayments ($10 or less)" and generally include only generic drugs.[47] Tier 2 drugs have "higher copayments ($15 or more)" and include "'preferred'" brand-name drugs.[48] Tier 3 drugs have "the highest copayments ($25 or more)" and include "non-preferred" brand-name drugs.[49] Preferred drugs are usually prescription medications for which a generic equivalent is not available but still have a lower cost because the health insurance company previously negotiated favorable rebate agreements with drug manufacturers (rebate agreements, in theory, reduce the cost of drugs for insureds but benefit a drug manufacturer by securing increased market share within a specific insurance pool).[50]

According to one observer, the goal of "incentive-based formularies [was] to encourage people to choose lower-cost prescription drugs, thereby creating cost savings for the health plan."[51] The main assumption underlying the early three-tier structures was that consumers had a choice between medications for the same disease or health condition; that is, a chemically

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43. Cindy Parks Thomas, *Incentive-Based Formularies*, 349 NEW ENG. J. MED. 2186 (2003).

44. *See Health Resources and Services Administration Glossary of Pharmacy-Related Terms*, U.S. DEP'T OF HEALTH & HUM. SERVS, http://www.hrsa.gov/opa/glossary.htm (last visited Apr. 24, 2009) (defining a "formulary" as "a preferred list of drug products that typically limits the number of drugs available within a therapeutic class for purposes of drug purchasing, dispensing and/or reimbursement. A government body, third-party insurer or health plan, or an institution may compile a formulary. Some institutions or health plans develop closed (i.e. restricted) formularies where only those drug products listed can be dispensed in that institution or reimbursed by the health plan. Other formularies may have no restrictions (open formulary) or may have certain restrictions such as higher patient cost-sharing requirements for off-formulary drugs.").

45. *Id.*

46. Cancelosi, *supra* note 2.

47. *Id.*

48. *Id.*

49. Thomas, *supra* note 43, at 2187.

50. *Id.*

51. *Id.* at 2186.

equivalent, lower-cost choice (most likely a generic drug) was available in place of a higher-cost, brand-name medication.[52] Moreover, the creation of three-tier plans was consistent with the insurance industry's long-standing objective to minimize moral hazards.[53] Insurance companies, therefore, find that it is reasonable to create programs that encourage consumers to make more-informed, cost-conscious choices. In the prescription drug context, policies that discourage beneficiaries from choosing higher-cost brand-name drugs over a generic equivalent minimize moral hazards in health insurance.

Nevertheless, it is imperative to note that 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 3 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 1 or 2. Three-tier plans, therefore, have at least the following salutary effects: (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.[54]

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52. A generic drug is "a medication whose active ingredients, safety, dosage, quality, and strength are identical to that of its brand-name counterparts . . . [y]ou can expect the generic drug to produce the same effects as the comparable brand-name drug." *See Glossary of Terms and Acronyms*, PARAMOUNT HEALTH CARE (Aug. 8, 2011), http://www.paramounthealthcare.com/documents/employers/Glossary-of-Terms.pdf.

53. *See* BAKER, *supra* note 12, at 4 (describing that "in the insurance context . . . 'moral hazard' typically is used to refer to the theoretical tendency for insurance to reduce incentives (1) to protect against loss or (2) to minimize the cost of a loss."). As an example, the author explains that moral hazard is "leaving a car door unlocked, comfortable in the knowledge that if the car is stolen the insurance company will pay." *Id.* Likewise, in a health insurance context, the same would be true when an insured does not care about the type or amount of drugs prescribed or the cost difference between a generic and brand-name equivalent medication because the insurance company covers the bulk of the cost. *See id.* Formulary tiers were designed to combat moral hazard in the insured's decision when choosing medications. *See id.*

54. Thomas, *supra* note 43, at 2187 (noting that incentive-based formularies slowed the growth of pharmaceutical expenditures, highlighting one example where an insurer saw thirty percent savings in overall drug expenditures by moving to a three-tier plan).

Despite the noted advantages, three-tier formularies have not avoided criticism. Early critics of three-tier plans argued that "incentive-based formularies [could] affect access to care and the quality of care."[55] These critics asked an important question: Should cost be the only factor driving the design of prescription drug formularies, or should the scope of the analysis include other factors, such as health outcomes and the total impact on the cost of medical services?[56] This question becomes even more relevant now—when health insurance companies continue to add new tiers that target specialty drugs. From a cost control view, when a beneficiary pays more for specialty drugs, the insurance company is able to lower its risk and increase the likelihood that the company will remain viable for all beneficiaries in the insurance pool. On the other hand, placing extreme cost control measures on specialty drugs could discourage use of prescription drugs and possibly lead to bad health outcomes for specific beneficiaries. In this scenario, the ultimate effect on the health insurance company may increase costs even further due to hospitalizations, prolonged treatment courses, et cetera, that could have been avoided by making specialty drugs accessible to plan beneficiaries.

2. Specialty Drug Tiers

Prescription drugs are often expensive, and historically, proposals aimed at controlling costs have been accepted. For example, drugs commonly placed on Tier 3 of a three-tier formulary are brand-name drugs for which an acceptable and equivalent generic, or lower-cost brand-name, medication is available.[57] Schemes to encourage the use of the lower-cost generics made sense in an era experiencing rapidly rising prescription drug prices and unchecked consumerism. Three-tier formularies properly encouraged consumers to choose generics over brand-name drugs and avoid moral hazard by ending consumer indifference to costs related to the type and amount of drugs prescribed by their treating physician. Although price constraints were used, consumers still had several choices for their specific disease or condition and were ensured access to necessary prescription drugs. The strategy also worked to counter advertising efforts by pharmaceutical companies that were promoting higher-cost, brand-name drugs.[58]

Health plans and employers, pleased that formularies were successful at modifying beneficiary decision-making and saving money, wanted fur-

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55. *Id.* at 2188.
56. *Id.*
57. Walsh, *supra* note 2, at 6.
58. Cancelosi, *supra* note 2, at 112 (noting a slow-down in direct-to-consumer advertising).

ther refinements to their formularies and additional cost savings.[59] In 2004, 58% of employer-sponsored plans with prescription drug coverage used a three-tier formulary structure.[60] Only 4% of employers offered a plan with four or more tiers.[61] In comparison, a report published by the AARP in March 2009 revealed that, five years later, 10% of health insurance plans offered a prescription drug benefit that placed specialty drugs on a fourth tier.[62] By 2010, an industry analyst studying 2,046 health insurance companies found that 13% of employer-sponsored plans had four or more tiers in their prescription drug formulary.[63]

Unlike the first three tiers, specialty drugs appearing on specialty drug tiers (i.e., Tiers 4 and higher) do not have generic or lower-cost brand-name equivalents and represent some of the most expensive medications in the marketplace.[64] Biological drugs—those derived from living organisms and which are commonly injectable—make up the majority of drugs placed on specialty drug tiers.[65] The AARP analysis found that "the average annual price of the most widely used biologic drugs on a fourth tier exceeds $20,000."[66] As the *New York Times* article highlighted, many Americans "may have to spend more for a drug than they pay for their mortgages, more, in some cases, than their monthly incomes."[67]

Prescription drug formularies with specialty drug tiers are significantly different than the traditional three-tier formularies. Specialty drug tiers do not include drugs with lower-cost generic equivalents; instead, these higher-level tiers focus on unique medications that do not have generic equivalents. Specialty drug tiers accomplish nothing more than a blatant cost-shift to beneficiaries—thereby placing a much more severe financial burden on limited groups of persons within an insurance pool. Because a less expensive alternative drug is not available on Tiers 1, 2, or 3, specialty drug tiers cannot alter consumer behavior and fail to address moral hazard concerns.

Specialty drug tiers are additionally distinguishable from lower tiers because they disproportionately burden the sickest and most physically and emotionally vulnerable members within an insurance pool (targeting a limited group of persons with higher-cost health conditions). The majority of specialty medications address a limited range of complex diseases or health

59. Crossley, *supra* note 7.
60. Cancelosi, *supra* note 2.
61. *Id.*
62. Walsh, *supra* note 2, at 8.
63. *See* Adam J. Fein, *Big Growth in Four-Tier Drug Benefits*, DRUG CHANNELS (Sept. 14, 2010), http://www.drugchannels.net/2010/09/big-growth-in-four-tier-drug-benefits.html.
64. Walsh, *supra* note 2, at 5.
65. *Id.* at 8.
66. *Id.*
67. Kolata, *supra* note 1.

conditions—mostly cancer, AIDS, rheumatoid arthritis, hemophilia, and multiple sclerosis.[68] Targeting specific high-cost medications that address a narrow set of health conditions, and subsequently charging higher copayments via specialty drug tiers, walks a razor-thin line between socially acceptable, facially neutral insurance risk classifiers and unacceptable discrimination based on immutable characteristics of insured beneficiaries. For the reasons that follow, we find that specialty drug tiers are improper, and legislators, regulators, and courts should move aggressively to prohibit specialty drug tiers.

III. RISK CLASSIFICATION AND DISCRIMINATION IN INSURANCE GENERALLY

A. DISCRIMINATION IN INSURANCE GENERALLY

Discrimination, in the broadest sense, is defined as the treatment or consideration of, or making a distinction in favor of or against, a person or thing based on the group, class, or category to which that person or thing belongs rather than on individual merit.[69] In the insurance context, discrimination occurs every day. For example, insurers charge smokers higher premiums for life insurance than nonsmokers and charge males higher rates for auto insurance than similarly aged females.[70] This practice, known as "risk classification," allows an insurer to charge persons different amounts of money according to predictions concerning how often, and at what cost, each individual will make insurance claims in the future.[71]

Risk classification is certainly discrimination, but in the context of insurance, not all discrimination is wrong, unjustifiable, or illegal. Insurance risk classification is typically justified on economic grounds, that is, discrimination between insured beneficiaries can be justified in order to avoid adverse selection.[72] Adverse selection is a theory asserting that pricing insurance at the same rate for everyone in society, without identifying individuals who are high-risk, encourages only the unhealthy to purchase insurance, making the business of insurance unprofitable and ultimately unavailable to everyone.[73] As a result, defenders of risk classification argue that

68. Walsh, *supra* note 2, at 3.
69. BLACK'S LAW DICTIONARY 534 (9th ed. 2009).
70. BAKER, *supra* note 12, at 705, 707.
71. *Id.* at 705.
72. *Id.*
73. Peter Siegelman, *Adverse Selection in Insurance Markets: An Exaggerated Threat*, 113 YALE L.J. 1223, 1223-24 (2004).

charging different rates for insurance, with price dictated by a person's risk level, is necessary to continue offering everyone affordable insurance.[74]

Further, a practice such as risk-based insurance pricing is deemed fair if it is "actuarially fair."[75] The principle of actuarial fairness mandates that an insurance beneficiary bear a financial responsibility commensurate with his or her specific risk and that "each person's insurance premium should reflect that person's actuarially determined risk—no more and no less."[76] A health insurance market that accepts the actuarial fairness view of insurance, consequently, will favor policies that segment individuals into specific insurance pools based on an assignment of risk no matter how great the financial burden is on those unfortunate enough to be unhealthy.[77] Supporters of risk classification, therefore, assert that assigning appropriate costs for high-risk and low-risk populations is fair.[78] Under a fairness theory, the higher cost for insurance should give high-risk consumers an incentive to alter their behavior or situation in order to remove or mitigate their high-risk classification.[79]

Insurers' attempts to identify risk characteristics, however, can lead to disparate-impact discrimination.[80] Disparate-impact discrimination occurs when a facially neutral practice or policy disproportionately and adversely affects a group of people sharing a similar characteristic.[81] For example, an insurance company sells an identical policy to a man and a woman that excludes coverage for breast cancer.[82] The policy, on its face, treats the man and woman equally in that neither can receive coverage for breast cancer.[83] However, the policy, as applied, affects women in much larger numbers than men and will be found as discriminatory.[84]

The recent trend to place high-cost drugs on specialty drug tiers as a cost-control measure could be viewed as a form of risk classification. A specific tier for specialty medications identifies particular high-cost drugs and places those drugs into a special group (Tier 4 or 5). Rather than charge everyone in the entire insured group a higher premium due to the use of specialty drugs, a prescription drug formulary with a specialty tier charges more only to those insureds that will actually use the specialty drugs. Pro-

74. BAKER, *supra* note 12, at 705.
75. *Id.* at 706.
76. Crossley, *supra* note 7, at 78; *see also* Spencer L. Kimball, *Reverse Sex Discrimination: Manhart*, 1979 AM. B. FOUND. RES. J. 83, 105 (1979).
77. Crossley, *supra* note 7, at 78.
78. BAKER, *supra* note 12, at 706.
79. *Id.*
80. Crossley, *supra* note 7, at 83.
81. *Id.*
82. *Id.*
83. *Id.*
84. *Id.*

ponents argue that the plan based the assignment of a drug to a specialty tier based on the nature and cost of the drug, not any characteristic of any persons in the insured group. Therefore, the use of a specialty tier in a drug benefit program can appear to be facially neutral.

Unquestionably, though, specialty drug tiers have a clear, disparate impact on beneficiaries, and appear to be actuarially unfair and unacceptable discrimination. Health conditions requiring many of the drugs placed on specialty drug tiers are "breakthrough" drugs that treat "cancer, MS, AIDS, [rheumatoid] arthritis[,] [and] kidney disease."[85] Higher copayments that result from placing these drugs on a specialty tier cannot be justified on the contention that mandating a higher copayment may alter the insured's behavior since the beneficiary cannot switch to a lower-cost alternative. Furthermore, it cannot be argued that a person with one of these higher-cost conditions is under the person's control. For example, it is inappropriate to compare a person who is a smoker and, as a result, has higher health care costs due to his or her voluntary choice to start and continue smoking with a person who needs a specialty drug and whose need for such a drug is not attributable to previous or existing behaviors that increase risk. Thus, charging a higher copayment to a person diagnosed with a kidney disease who needs a specialty drug will not alter any aspect of his or her behavior. Moreover, due to the nature of the drugs placed in specialty drug tiers, only the most vulnerable beneficiaries are affected. Specialty drug tiers place a significant burden on the sickest members of the insurance pool, placing unreasonable obstacles on people when the most important task is obtaining potentially life-saving drugs. The facially neutral identifiers, notably cost or drug characteristic, have a disparate impact that has the effect of segregating the insured group based on specific disease states, such as by health status.

If indeed the addition of specialty drug tiers segregates a subgroup of the insured population by health status, the question becomes whether the group identified and discriminated against is a group that is legally protected from discrimination. One group of persons who have been "[n]otably absent" from protection are persons having a similar health status,[86] at least until Congress addressed this concern when it passed HIPAA in 1996.[87]

Congress enacted HIPAA on August 21, 1996.[88] Congress intended to "address the fears that voters would lose their health insurance when they really needed it"[89] and wanted HIPAA to focus "on addressing the security

85. Walsh, *supra* note 2, at 2.

86. Crossley, *supra* note 7, at 108.

87. *Id.* at 113-14.

88. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

89. Crossley, *supra* note 7, at 113.

and portability of health insurance coverage."[90] In addition, Congress wanted to "further reassure insured [Americans that] the law also prohibits group health insurers from discriminating against individual participants on the basis of health status in establishing eligibility rules and setting premiums."[91]

HIPAA prohibits a group health plan or health insurance issuer from discriminating against individual participants on several enumerated health status-related factors.[92] For example, a plan or issuer is not allowed to create plan policies for eligibility, or continued eligibility, based on an individual's health status or medical condition.[93] A plan or issuer, while making an initial coverage determination, cannot reject an application for insurance coverage because the individual applicant, or one of his or her beneficiaries, has AIDS.[94] A plan or issuer is also not allowed to create a policy that says an individual loses coverage if that individual, or a beneficiary of that individual, develops AIDS during the policy year.[95]

HIPAA Section 1182(a)(2) looks beyond eligibility, or continued eligibility, determinations and states that a plan or issuer is not mandated to provide coverage for a particular benefit, nor is the plan prohibited from *limiting* the "amount, level, extent, or nature of the benefits or coverage for similarly situated individuals."[96] The statute does not define the key phrase "similarly situated individuals"; however, the legislative history is informative.[97]

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90. *Id.*

91. *Id.* at 114.

92. 29 U.S.C. § 1182(a)(1) (2006).

93. *Id.*

94. *See* H.R. REP. NO. 104-736, at 186 (1996) (Conf. Rep.), *reprinted in* 1996 U.S.C.C.A.N. 1990, 1999.

95. It is common in government benefits to remove a person from coverage if a certain event occurs. For example, a person who has an income above annual income thresholds is not eligible for state-sponsored pharmacy benefits in Illinois. If a presently eligible beneficiary wins the lottery, making their income exceed the pre-determined income ceiling, the beneficiary loses eligibility for the benefit. Thus, the beneficiaries' continuing eligibility for the benefit ends and coverage is terminated. For a federal example, Social Security disability benefits end during coverage if (1) the person is determined to be no longer disabled or (2) the person gains employment that increases their income above a pre-determined level. In the HIPAA anti-discrimination context, a plan or issuer cannot design a benefit that ends coverage mid-year because of a change in an individual's health status. Unlike government benefits, it is unacceptable under HIPAA to cover an individual on January 1st but remove the individual from coverage one month later when he or she is diagnosed with AIDS.

96. 29 U.S.C. § 1182(a)(2) (2006).

97. Because the statutory language on its face does not explicitly resolve whether specialty tier pharmaceutical benefit plans are discrimination under HIPAA, and because there is no case law adding clarity to the statutory language, a court would likely examine

In the conference agreement, Congress indicated that:

> It is the intent of the conferees that a plan cannot knowingly be designed to exclude individuals and their dependents on the basis of health status. However, generally applicable terms of the plan may have a disparate impact on individual enrollees. For example, a plan may exclude all coverage of a specific condition, or may include a lifetime cap on all benefits, or a lifetime cap on specific benefits. Although individuals with the specific condition would be adversely affected by a lifetime cap on all or specific benefits, . . . such plan characteristics would be permitted as long as they are not directed at individual sick employees or dependents.
>
> The Conference agreement does not require a group health plan or health insurance coverage to provide particular benefits other than those provided under the terms of the plan or coverage. Nor does it prevent any plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage . . . .
>
> It is the intent of the conferees that a plan or coverage cannot single out an individual based on the health status or health status related factors of that individual . . . . For example, the plan or coverage may not deny coverage for prescription drugs to a particular beneficiary or dependent if such coverage is available to other similarly situated individuals covered under the plan or coverage. However, the plan or coverage could deny coverage for prescription drugs to all beneficiaries and dependents. The term "similarly situated" means that a plan or coverage would be permitted to vary benefits available to different groups of employees, such as full-time versus part-time employees . . . in different geographic locations. In addition, a plan or coverage could have different benefit schedules for different collective bargaining units.

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legislative history. *See, e.g.*, Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A., 530 U.S. 1, 6-7 (2000).

> The conference agreement provides that a group health plan and an issuer offering group coverage cannot require a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor relating to the individual or to any individual enrolled under the plan as a dependent of the individual. It does not restrict the amount that an employer may be charged for coverage under a group health plan . . . .
>
> The conferees intend that these provisions preclude insurance companies from denying coverage to employers based on health status and related factors that they have traditionally used. In addition, this provision is meant to prohibit insurers or employers from excluding employees in a group from coverage or charging them higher premiums based on their health status and other related factors that could lead to higher health costs. This does not mean that an entire group cannot be charged more. But it does preclude health plans from singling out individuals in the group for higher premiums or dropping them from coverage altogether.[98]

It is abundantly clear that health insurers are not required to cover all services or medications. As the conference report plainly states, "a plan may exclude *all coverage* of a specific condition, or may include a lifetime cap on all benefits, or a lifetime cap on specific benefits."[99]

The conference report also states that HIPAA does not "prevent any plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage."[100] According to the conference agreement, similarly situated means "that a plan or coverage would be permitted to vary benefits available to different groups of employees, such as full-time versus part time . . . or employees in different geographic locations . . . or coverage could have different benefit schedules for different collective bargaining units."[101]

HIPAA, and its legislative history, does not directly answer the question whether specialty drug tiers violate the anti-discrimination provisions. In fact, the Act seems internally contradictory and raises more questions

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98. H.R. REP. NO. 104-736, at 186-87 (1996) (Conf. Rep.), *reprinted in* 1996 U.S.C.C.A.N. 1990, 1999-2000.

99. *Id.* at 186 (emphasis added).

100. *Id.* at 187.

101. *Id.*

than it provides answers when the anti-discrimination provisions are applied to specialty tier drug plans. For example, if the anti-discrimination provisions allow a plan or coverage to entirely exclude specialty medications, how is it possible that including a financially limited coverage, such as a fourth-tier specialty drug benefit, becomes a violation of the Act? Omitting a drug or service from coverage unquestionably applies equally to every person in the insurance pool; however, once an insurance company decides to add a benefit to a plan or coverage, it must ensure that its benefit structure does not improperly discriminate. If a plan covers 1000 people, and all 1000 people are subjected to the specialty tier formulary structure, it would seem that no discrimination occurred. On the other hand, if a plan covering 1000 people determined, through its actuaries, that ten people on the plan were using a costly medication and subsequently created a specialty tier, the HIPAA anti-discrimination provisions could be violated because the new tier might be seen as a reaction to claims by individual plan beneficiaries. In this hypothetical, the plan created two distinct groups—the first group of ten being those who need the medication and the second group of 990 being those who do not need the medication. Does HIPAA contemplate the grouping of people within a plan or coverage who need specialty medications as one group and those who do not as another group? Are these groups similar to or different than full-time versus part-time employees?

With the statute itself not directly answering the question whether specialty tier plans violate the HIPAA anti-discrimination provisions, and with the legislative history providing some support to both sides of the question, we now turn to the federal regulations and/or subregulatory guidance interpreting HIPAA.

1. Federal Regulations and Other Guidance

The most instructive evidence of Congress's intent on what activities are discriminatory under HIPAA is found in the Commentary to the Final Rule completing HIPAA's implementation.[102] Part 2590 of the rulemaking provides additional guidance on discrimination against participants and beneficiaries based on a health factor.[103] HIPAA provides that benefits provided under a plan or through group health insurance coverage must be uniformly available to all similarly situated individuals.[104] The Final Rule's Commentary, in relation to discrimination as it applies to the application of

102. *See* Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75,014, 75,038-40 (Dec. 13, 2006) (to be codified at 45 C.F.R. pt. 146).

103. *Id.*

104. *Id.*

benefits, provides additional guidance on the meaning of this language.[105] The basic rule shows that benefits provided must be uniformly available to similarly situated individuals, and likewise, restrictions on benefits must also apply uniformly to all similarly situated individuals. The Final Rule Commentary provides:

> [A] plan or issuer *may limit* or exclude *benefits in relation to a specific disease or condition*, *limit* or exclude *benefits for certain types of treatments or drugs*, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but, *only* if the benefit limitation or exclusion applies uniformly to all similarly situated individuals, *and* is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.[106]

The Commentary further provides:

> [A] plan or issuer *may impose* annual, lifetime, or *other limits on benefits* and *may require* satisfaction of a deductible, *copayment*, coinsurance, or other cost-sharing requirement in order to obtain a benefit *if* the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.[107]

At Section 2590.702(b)(2), the Final Rule provides eight examples of situations which are either permitted or violate the non-discrimination provisions of HIPAA.[108] The examples are intended to guide the analysis of future legal questions. Four of the examples provide guidance when determining whether specialty drug tiers are discriminatory:

> *Example 2*. (i) *Facts.* A group health plan has a $2 million lifetime limit on all benefits (and no other lifetime limits) for participants covered under the plan. Participant B files a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a $10,000

105. *Id.*

106. *Id.*at 75,039 (emphasis added).

107. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039 (emphasis added).

108. *Id.*

lifetime limit on benefits for the treatment of AIDS, effective before the beginning of the next plan year.

(ii) *Conclusion.* The facts of this *Example 2* strongly suggest that the plan modification is directed at *B* based on *B*'s claim. Absent outweighing evidence to the contrary, the plan violates this paragraph (b)(2)(i).

. . .

Example 4. (i) *Facts.* A group health plan has a $2,000 lifetime limit for the treatment of temporomandibular joint syndrome (TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4*, the limit does not violate this paragraph (b)(2)(i) because $2,000 of benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries . . . .

Example 5. (i) *Facts.* A group health plan applies a $2 million lifetime limit on all benefits. However, the $2 million lifetime limit is reduced to $10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.

(ii) *Conclusion.* In this *Example 5*, the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals.

Example 6. (i) *Facts.* A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 6*, the exclusion from coverage of drugs not listed on the drug formulary does not

> violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.[109]

From the Act, the conference agreement, and these examples, a three-part formula emerges that can be used to analyze whether a benefit limitation is discriminatory: (1) is the group in question a group of similarly situated individuals; (2) does the benefit limitation apply uniformly to all similarly situated individuals; and (3) is the benefit limitation directed at individual participants or beneficiaries.[110]

2. The Argument in Support of the View That Specialty Drug Tiers Do Not Violate HIPAA's Anti-Discrimination Provisions

(i) What is an Acceptable Grouping of Similarly Situated Individuals Under HIPAA?

The first step in analyzing whether four-tier drug plans violate HIPAA's anti-discrimination provisions is to identify potential groupings of similarly situated individuals. There are three groups to consider here. The first is the group of covered individuals who need the drugs on a specialty tier, the second is the group of covered individuals using the plan's drug benefit at any tier, and the third is the group of all covered participants and beneficiaries, which we will refer to as all enrollees.

Are all of these appropriate groups under HIPAA? The full group of all enrollees is an acceptable group under HIPAA because they have identified themselves based on the need, or the potential need, for the benefits offered under the plan, not any current medical condition. The identifier for the entire group of enrollees is completely neutral; it is the desire for financial security that identifies the group, not health status.

But what about the subgroups of people who need the drugs on a specialty tier and the larger subgroup of all people using the drug benefit at any tier? In the conference agreement, Congress stated that a "plan or coverage may not deny coverage for prescription drugs to a particular beneficiary or dependent if such coverage is available to other similarly situated individuals covered under the plan or coverage."[111] According to the conference

109. *Id.* at 75,039-40.

110. *See id.*

111. H.R. REP. NO. 104-736, at 187 (1996) (Conf. Rep.), *reprinted in* 1996 U.S.C.C.A.N. 1990, 2000.

agreement, similarly situated "means that a plan or coverage would be permitted to vary benefits available to different groups of employees, such as full-time versus part-time employees . . . in different geographic locations . . . [or] have different benefit [structures] for different collective bargaining units."[112] It is noteworthy that Congress viewed similarly situated groups mainly in employment-status terms. That is, Congress chose to draw a distinction between full-time employees and part-time employees, or between different bargaining units. For example, a school has teachers represented by a teachers' union, janitors are represented by the laborers' union, and bus drivers are represented by a transportation workers' union. Congress did not provide any example showing individuals with similar health conditions as a "similarly situated" group.

Nevertheless, those who would advocate that the existence of a specialty tier group does not violate HIPAA would argue that the examples of "similarly situated" groups used by the conference agreement do not limit such groupings to those based on employment status only. Employment status was used as an example because it is a neutral identifier. The people in the employment status groups were not identified based on their health status or medical condition, which HIPAA would not allow. Any identifier which is neutral, which does not use health status or medical condition to identify the group, is acceptable under HIPAA.[113] The group of people who need specialty tier drugs is an appropriate HIPAA grouping because the common identifier is the utilization of the very high-cost drug. Drugs are placed on specialty drug tiers because of their high cost, without regard to the diseases those drugs treat. Whenever a person becomes a member of such group, it is not because of an impermissible identifier such as health status; it is because of a permissible, neutral identifier—cost. Therefore, the argument goes, the specialty tier group is an appropriate grouping within which to measure whether "similarly situated" individuals are treated uniformly.

Similarly, the group of all people using any tier of the drug coverage would be an acceptable grouping because it is simply the need for the particular benefit that identifies the grouping, not the medical condition that requires the drug. To conclude otherwise would be to say there can never be acceptable groupings of "similarly situated" individuals under HIPAA, which, of course, is nonsensical.

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112. *Id.*

113. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039.

(ii) The Benefit Limitation Must Apply Uniformly to Similarly Situated Individuals

According to the Commentary in the Final Rule, a proposal to limit benefits within a plan or coverage will comport with HIPAA as long as benefits are *uniformly available* to all similarly situated individuals.[114] The Final Rule's Commentary, Part 2590.702(b)(2), supports a contention that a specialty tier is permissible under HIPAA.[115] The Commentary provides that "any restriction on a benefit . . . must apply uniformly to all similarly situated individuals and must not be . . . based on any health factor of the participants or beneficiaries."[116] Thus, a benefit plan "may *limit* or exclude benefits in relation to a specific disease or condition, [or] *limit* or exclude *benefits for certain types of treatments or drugs* . . . but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals."[117] Basically, any time a plan or coverage excludes or limits coverage for a specific benefit, the exclusion or limitation must apply equally to every person within the affected grouping of similarly situated individuals.

If the relevant grouping is all persons needing the specialty drugs, then the very high copayments must be applied uniformly to all who are in the group using those specialty drugs. If the relevant grouping of similarly situated individuals is all enrollees, or all enrollees accessing any drug benefit tier, then the very high copayments must be applied uniformly to people from those groups who need the specialty drugs. Because a specialty tier, which imposes higher cost-sharing requirements, is a restriction on a pharmacy benefit that affects every person in a permissible grouping equally, specialty tier drug plans treat similarly situated individuals uniformly.

Part 2590.702(b)(2)(D), Example 4, is most analogous to specialty drug tiers, and bolsters the position that such formularies are not problematic:

> *Example 4.* (i) *Facts.* A group health plan has a $2,000 lifetime limit for the treatment of temporomandibular joint syndrome (TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.
>
> (ii) *Conclusion.* In this *Example 4*, the limit does not violate this paragraph (b)(2)(i) because $2,000 of benefits for the treatment of TMJ are available to all similarly situated

114. *Id.*
115. *Id.*
116. *Id.*
117. *Id.* (emphasis added).

> individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.[118]

Example 4 is a key example because it shows that a plan can identify a specific health condition, temporomandibular joint syndrome (TMJ), adopt a limitation on coverage for the condition, and not violate HIPAA's discrimination provisions. There is no violation in Example 4 because every person in the relevant grouping is equally subjected to the $2000 lifetime limit on TMJ coverage. Likewise, creating a specialty tier formulary does not violate HIPAA because every person in the pertinent group of similarly situated individuals is subjected to the same cost-sharing requirements. For example, if a formulary requires a fifty dollar copayment for Aptivus, as long as every person in the insurance pool who is prescribed Aptivus pays the same out-of-pocket copayment of fifty dollars, the plan remains lawful under HIPAA. Moreover, even when an individual with TMJ reaches his or her $2000 lifetime limit, all other coverage continues unaffected. Comparably, a person's overall health care benefit is not affected when a plan places limitations on specialty drugs.

Example 6 provides additional support for the conclusion that specialty drug tiers are consistent with HIPAA because the example demonstrates the government's acceptance of drug formularies at a time when federal policymakers were aware of emerging Specialty tier plans:[119]

> *Example 6.* (i) *Facts.* A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.
>
> (ii) *Conclusion.* In this *Example 6*, the exclusion from coverage of drugs not listed on the drug formulary does not violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uni-

118. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039-40.

119. *Id.* at 75,040.

> formly to all similarly situated individuals and is not directed at individual participants or beneficiaries.[120]

This example shows that formularies are considered to be applied uniformly to all similarly situated individuals and that formularies, in general, are not viewed as discriminatory. This is important for two reasons. First, specialty tier plans (formularies with four or more tiers) have existed since the mid-1990s, well before the final rulemaking was in place, leading to the conclusion that federal policymakers implicitly approved of multiple drug tier structures notwithstanding the complexity of the benefit design.[121] Furthermore, the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, the major federal agency involved with the promulgation of the Final Rule, was intimately involved with the implementation of Medicare Part D, which included provisions endorsing tiered benefit structures.[122] It would be difficult to conclude that an agency supportive of drug formularies in 1996, and supportive of more complex tier structures in 2003 during Medicare Part D, would oppose specialty drug tiers.

Further evidence of the federal government's support, either explicit or implicit, can be found in the myriad of approved contracts that procure health and life insurance benefits for federal employees. The Office of Personnel Management (OPM), which oversees the Federal Employees Health Benefits (FEHB) Program, annually contracts with over 250 private sector firms to provide health and life insurance benefits to over eight million federal government employees.[123] With only a cursory overview of the approved benefit plan contracts available online, one can quickly determine that this federal agency has approved many specialty tier plans that carve out specialty medications and attach higher copayments. For example, the 2009 contract in effect between the OPM and PersonalCare Insurance of Illinois, which provides health care benefits to federal government employees in sixty-five Illinois counties, shows that a plan requiring higher co-

120. *Id.*

121. *See* Donna Young, *Humana Adds Fourth Tier to Drug Benefit Plans*, ONLINE NEWS: AM. SYS. OF HEALTH-SYS. PHARMACISTS, (June 15, 2001), http://www.ashp.org/menu/News/PharmacyNews/NewsArticle.aspx?id=618 (noting that specialty drug tiers equaled about one percent of the market share in 2001, five years before the final HIPAA anti-discrimination rulemaking).

122. Walsh, *supra* note 2, at 7. *See also* 42 U.S.C. § 1395w-104(b)(1)(E) (2006) (providing that Medicare Prescription Drug Plans are not required to accept insurance risk); 42 U.S.C. § 1395w-104(b)(3) (recognizing the existence of "tiered cost-sharing formularies").

123. *Federal Employees Health Benefits Program Handbook*, U.S. OFF. OF PERSONNEL MGMT. (2009), http://www.opm.gov/insure/health/reference/handbook/fehb00.asp.

payments for specialty drugs has government approval.[124] Specifically, the approved plan mandates a copayment of "20% for name brand formulary self administered injectables" and "40% for name brand non-formulary self administered injectibles."[125] The OPM recently commented on the approval of plans with specialty drug tiers, stating that one contractor made a convincing argument that charging a percentage of the cost of these drugs "helped lower the rates for federal employees."[126]

Based on the widespread acceptance of formularies and the reasonable assumption that the federal government does not oppose specialty tier plans—neither at the time HIPAA's Final Rule was promulgated, nor today as evidenced by OIM's endorsement in 2009 contracts—it is reasonable to conclude that specialty tier plans would be found to comport with HIPAA's anti-discrimination provisions.

(iii) The Benefit Limitation is Not Directed at Individual Participants or Beneficiaries

The final prong of the argument in favor of specialty drug tiers is that proposed specialty drug tiers do not violate HIPAA's anti-discrimination because the benefit structure is not directed at individual participants or beneficiaries enrolled in the plan. The Final Rule's Commentary in Part 2590.702(b)(2)(C) provides that "a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries."[127] Therefore, unless proof can be offered during a plan year that an insured was specifically targeted, the ability to challenge the plan ends when the plan adopts a policy term of general applicability effective on the first day of the next policy year.

The United States Department of Labor, Employee Benefits Security Administration, includes frequently asked questions about the HIPAA nondiscrimination requirements on its website.[128] The website notes:

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124. *Official Statement of Benefits of Personal Care Insurance Under Contract with the United States Office of Personnel Management*, U.S. OFF. OF PERSONNEL MGMT., CENTER FOR RETIREMENT & INS. SERVS. 38 (2009), http://www.opm.gov/insure/health/planinfo/2009/brochures/73-257.pdf.

125. *Id.*

126. Kolata, *supra* note 1.

127. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75,014, 75,039 (Dec. 13, 2006) (to be codified at 45 C.F.R. pt. 146).

128. *FAQ's About the HIPAA Nondiscrimination Requirements*, U.S. DEP'T OF LAB. EMP. BENEFITS SEC. ADMIN., http://www.dol.gov/ebsa/faqs/faq_hipaa_ND.html (last visited Nov. 17, 2011) [hereinafter EMP. BENEFITS SEC. ADMIN.].

> Question: Can plans exclude or limit benefits for certain conditions or treatments?
>
> [Answer:] Group health plans may exclude coverage for a specific disease, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination that the benefits are experimental or medically unnecessary - but only if the benefit restriction applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on a health factor they may have. (*Plan amendments that apply to all individuals in a group of similarly situated individuals and that are effective no earlier than the first day of the next plan year after the amendment is adopted are not considered to be directed at individual participants and beneficiaries*.)[129]

So it would seem that as long as plans are not taking *mid-year* steps to alter the benefits of a specific individual or small groups of individuals, a tier for specialty drugs would be acceptable. Indeed, proponents of specialty drug tiers might suggest that the Department of Labor is saying Part 2590.702(b)(2)(C) of the Final Rule creates a conclusive presumption that a plan amendment is not directed at individual participants or beneficiaries if it is adopted at the start of the next plan year.[130] Moreover, HIPAA's provisions *do not*

> require a group health plan . . . to provide particular benefits other than those provided under the terms of such plan or coverage, or . . . to prevent such a plan . . . from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.[131]

According to congressional intent, this language means that a health plan "cannot knowingly be designed to exclude individuals and their dependents [from obtaining or continuing in health care coverage] on the basis of health status."[132] The language also should be interpreted to allow a health insurance plan to include "generally applicable terms" that "have a disparate

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129. *Id.* (emphasis added).

130. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039.

131. 29 U.S.C. § 1182(a)(2)(A)-(B) (2006).

132. H.R. REP. NO. 104-736, at 186 (1996) (Conf. Rep.), *reprinted in* 1996 U.S.C.C.A.N. 1990, 1999.

impact on individual enrollees . . . a plan may exclude *all* coverage of a specific condition, or may include a lifetime cap on benefits, or a lifetime cap on specific benefits."[133]

Consequently, a specialty tier formulary designed to be effective at the beginning of the next plan year, that applies the benefit structure uniformly to all similarly situated individuals in the pertinent groupings will not be found to be discriminatory even if it has a disparate impact on individual enrollees.

3. The Opposing Argument: Specialty Drug Tiers Violate HIPAA's Anti-Discrimination Provisions

Alternatively, specialty drug tiers could be found to violate HIPAA's anti-discrimination provisions if similarly situated individuals are not treated uniformly or the benefit structure is viewed as being directed at individuals based on health factors, a practice prohibited by HIPAA's anti-discrimination provisions.

(i) Similarly Situated Groups

The argument that specialty drug tiers violate HIPAA begins by attacking the characterization of specialty tier users as an acceptable grouping of similarly situated individuals. In order to determine whether this grouping is acceptable under HIPAA, you have to go beyond the stated, facially neutral identifier of cost and look at the participants singled out by the identifier. Persons who need specialty medications are small in number. One estimate shows that individuals in need of specialty medications comprise only one percent of the market share.[134] These individuals are very sick and could have been identified just as easily by their illnesses, such as a specific cancer or AIDS. These smaller groups theoretically exist within every group Congress identified in its conference agreement—full-time employees, part-time employees, and all collective bargaining units. Each of these groupings includes myriad subsets of people—for example, some people need specialty medications, others have heart disease, while others are in the process of child bearing. Thus, classifying individuals by a specific health status factor was not what Congress intended when it enacted HIPAA.

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133. *Id.*

134. Young, *supra* note 121 (reporting that specialty medications are new to the market, and because utilization is low—about 1 percent of prescribed drugs—most biotech drugs appear on the formulary's fourth tier).

The congressional conference agreement provides that coverage "cannot require a premium *or contribution* which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor . . . ."[135] The legislative history also shows that Congress intended that

> these provisions preclude insurance companies from . . . charging [beneficiaries] higher premiums based on their health status and other related factors that could lead to higher health costs. This does not mean that an *entire group* cannot be charged more. But it does preclude health plans from singling out individuals in the group for higher premiums or dropping them from coverage altogether.[136]

When the purpose and effect of the cost identifier for specialty drug tiers is fully understood, it becomes clear that its purpose is to accomplish indirectly that which could not be accomplished directly, i.e. the creation of a group based on health status. HIPAA's Final Rule, when examined closely, supports this contention. The rulemaking's commentary in relation to similarly situated individuals, found at Part 2590.702(d), indicates that "a plan or issuer may treat participants as two or more distinct groups of similarly situated individuals if the distinction between or among the groups . . . is based on a bona fide employment-based classification."[137] The commentary further provides that "a classification based on any health factor is not a bona fide employment-based classification . . . ."[138] The commentary next asserts that

> if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor . . . the classification is not permitted . . . . Thus, if an employer modified an *employment-based* classification to single out, based on a health factor, individual participants and beneficiaries and *deny* them health coverage, the new classification would not be permitted.[139]

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135. H.R. REP. NO. 104-736, at 187 (1996) (Conf. Rep.), *reprinted in* 1996 U.S.C.C.A.N. 1990, 2000 (emphasis added).

136. *Id.* (emphasis added).

137. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75,014, 75,041 (Dec. 13, 2006) (to be codified at 45 C.F.R. pt. 146).

138. *Id.*

139. *Id.* (emphasis added).

Therefore, in connection with scrutinizing a four-tier drug benefit structure, those persons needing specialty tier drugs is not an acceptable grouping. To conclude otherwise would be to eliminate the anti-discrimination provisions entirely. All it would take to avoid the anti-discrimination provisions would be to define the group of similarly situated individuals so narrowly that it would be impossible to show that the members of the group were not treated identically. Consequently, all the proponents' arguments based on specialty tier individuals being an acceptable grouping under HIPAA must fail.

The same definitional issue dooms the grouping of all enrollees as being an acceptable grouping under HIPAA when analyzing the propriety of specialty tier drug plans. Just as defining the group of similarly situated individuals narrowly obscures improper discrimination, so too does defining the group too broadly. It is simply not appropriate to allow improper discrimination for the reason that the plan discriminates improperly against everyone. The only grouping of similarly situated individuals that satisfies HIPAA and shines any light on the issue whether four-tier drug plans improperly discriminate based on health status or medical condition is the group of all enrollees accessing the drug benefit on any tier. And so the next question to be answered is whether specialty drug tiers treat persons needing those drugs the same as persons who need drugs listed on the formulary's other tiers.

(ii) Specialty Tier Drug Plans Do Not Apply Uniformly to Similarly Situated Individuals

The examples in the Final Rule provide help answering the question whether specialty tier plans apply uniformly to all similarly situated individuals. Part 2590.702(b)(2)(D) of the Final Rule includes several examples that can guide the analysis to this question. Example 5 provides:

> (i) *Facts.* A group health plan applies a $2 million lifetime limit on all benefits. However, the $2 million lifetime limit is reduced to $10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.
>
> (ii) *Conclusion.* In this *Example 5*, the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits

> does not apply uniformly to all similarly situated individuals.[140]

The hypothetical facts show an employer who sponsored a group health plan for seven employees, and all of the employees had an identical benefit package.[141] Six of the seven employees had the same job title; however, employee G had a different job title.[142] Employee G then files an expensive health care claim and subsequently the employer modifies the health care coverage for employees with G's job title only.[143] According to the commentary, "changing the coverage classification for G based on the existing employment classification . . . is not permitted . . . because the creation of the new coverage classification for G is directed at G based on one or more health factors."[144] The plan violates HIPAA because benefits are not uniformly *available to* all similarly situated individuals.[145] Unless every person in the pertinent grouping has the same lifetime limits, the plan's services are not similarly available to all plan enrollees. The plan also violates the law because the plan's limitation does not apply *uniformly to* all similarly situated individuals.[146] Basically, a plan can provide a benefit limitation if the distinction is drawn by bona fide employment-based classifications, but the plan violates the law when the benefit limitation breaks out groups by health factors.

In the context of specialty tier plans, the question is whether a formulary's design that classifies drugs by *disease* is improper because it creates a scheme that does not apply uniformly to all similarly situated individuals. The critical conclusion that must be drawn here is that a specialty tier plan does not apply uniformly to all enrollees. Instead, persons with certain medical conditions are treated differently than other similarly situated individuals *because of their disease* state.

But, are specialty tier plans dramatically different from traditional three-tier plans? Is it important to draw a distinction? Example 6 shows that the government finds drug formularies do not violate HIPAA because formularies "are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual

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140. *Id.* at 75,040.
141. *Id.* at 75,042.
142. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,042.
143. *Id.*
144. *Id.*
145. *Id.*
146. *Id.*

participants or beneficiaries."[147] However, the example does not indicate if it was analyzed in light of a traditional three-tier plan or if, in fact, the government considered four-tier plans as well when it created Example 6. Nevertheless, specialty tier plans can be distinguished from a traditional three-tier formulary because specialty drug tiers carve out a group of drugs by disease state, whereas traditional three-tier plans apply uniformly regardless of disease state. For example, in a three-tier plan, generally, every disease state has a treatment drug appear on each tier; however, the same is not true with drugs on a fourth tier as most do not have acceptable, alternative products. Thus, specialty tier plans are quite different than their predecessors and drawing a distinction between each plan design can be important, especially because it may make Example 6 inapplicable to the present analysis.

Furthermore, as we stated earlier, with the first three tiers in a multi-tier structure, consumers have a choice between medications for the same disease or health condition; that is, a chemically equivalent, lower-cost choice (most likely a generic drug) is available in place of a higher-cost, brand-name medication.[148] There is no such choice available to those who need specialty drugs. The first three tiers remain consistent with the insurance industry's long-standing mission to minimize moral hazard in insurance[149] by giving consumers an incentive to make more informed, cost-conscious choices when filling a prescription and purposefully selecting a brand-name medication over its generic equivalent. The ability to have a choice is critical to understanding the true nature of specialty drug tiers. The first three tiers provide the users of the drug benefit a *choice* between more and less expensive equivalent medications for the same disease or health condition. That is, someone prescribed a Tier 3 drug who did not want to pay the higher copayment could find an equivalent drug on Tiers 1 or 2 at a lower cost. There are no such choices available to those who need

147. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,040.

148. A generic drug is "[a] medication whose active ingredient, safety, and quality will produce the same effects as the brand name drug." *See Four-Tier Prescription Drug Benefit*, PARAMOUNT HEALTH CARE (July 2011), http://www.paramounthealthcare.com/documents/prescription-drugs/four-tier-benefit.pdf (the generic drugs produce the same effects as the comparable brand name drug).

149. *See* BAKER, *supra* note 12, at 4 (describing that "[i]n the insurance context . . . []moral hazard[] typically is used to refer to the theoretical tendency for insurance to reduce incentives (1) to protect against loss or (2) to minimize the cost of a loss."). As an example, the author explains that moral hazard is "leaving a car door unlocked, comfortable in the knowledge that if the car is stolen the insurance company will pay." *Id.* Likewise, in a health insurance context, the same would be true when an insured does not care about the type or amount of drugs prescribed or the cost difference between a generic and brand-name equivalent medication because the insurance company covers the bulk of the cost. *See id.* Formulary tiers were designed to combat moral hazard in the insured's decision when choosing medications. *See id.*

drugs placed on a specialty tier. While three-tier plans provide a tool to address insured moral hazard that was exacerbated by drug company advertising and by undifferentiated drug reimbursement by insurers, a specialty tier does nothing to address insured moral hazard.

The final part of the analysis should be considered at this point. Under HIPAA, a benefit limitation is permitted if, and only if, "it is not directed as individual participants or beneficiaries."[150] Therefore, does a specialty tier formulary violate the law because it is a benefit limitation that is directed at a person's health status or medical condition?

(iii) Specialty Drug Tiers are Impermissibly Directed at Individual Participants or Beneficiaries

HIPAA's legislative history and the Final Rule declare that "discrimination directed at individuals" will *not* be found *only* if a benefit limitation applies uniformly to all beneficiaries *and* "if the creation or modification of an employment or coverage classification is [not] directed at individual participants or beneficiaries based on any health factor."[151] According to the legislative history, a plan cannot knowingly be designed to exclude individuals on the basis of health status.[152] While a benefit limitation may have a disparate impact on certain members of the group, that limitation is not permissible if it is "directed at individual sick employees or dependents."[153]

Part 2590.702(d), Example 2 in the Final Rule prohibits a health plan from modifying benefits directly related to claims made by plan enrollees during the course of an ongoing benefit year.[154] In this example, a plan provided a $2 million lifetime limit for all plan enrollees but reduced the lifetime cap mid-year to $10,000 for persons diagnosed with AIDS, where the evidence strongly suggested that the plan was modified due to the high cost claims of a known beneficiary diagnosed with AIDS.[155] The commentary in the Final Rule concludes that this violates the anti-discrimination provisions because the circumstances "strongly" suggested that the plan modification was directed at the insured person, based on the insured's claim history.[156] A tier for specialty drugs is conceptually identical to Example 2. One pre-

150. *Id.*

151. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,041.

152. H.R. REP. NO. 104-736, at 186 (1996) (Conf. Rep.), *reprinted in* 1996 U.S.C.C.A.N. 1990, 1999.

153. *Id.* at 187.

154. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039.

155. *Id.*

156. *Id.*; *see also* 29 U.S.C. § 1182(a)(1)(C) (2006) (prohibiting discrimination against a person based on claims experience).

scription drug plan indicated that the creation of specialty drug tiers was important because only "one to three percent of the population utilizes specialty medications, but . . . account for roughly twenty percent of all pharmaceutical costs."[157] Plans that adopt specialty drug tiers do so to impact a very small and easily identifiable portion of the enrollee population based on the high claim costs associated with their medical conditions. A tier targeting specialty drugs is as impermissibly directed at individual enrollees as the lifetime cap is directed at AIDS patients in Example 2.

Example 2 addressed plan changes made mid-year, but, what if a plan waits and makes the plan modification effective in the next plan year? Does implementation of a specialty drug tier at the beginning of a plan year insulate a plan from HIPAA liability? As we said earlier, proponents of specialty drug tiers would say the Department of Labor views Part 2590.702(b)(2)(C) of the Final Rule as conclusively establishing that an amendment adopted on a plan anniversary was not directed at individual participants or beneficiaries. The response must be that the Department of Labor did not mean to raise form over substance. An improperly directed plan amendment is just as offensive when implemented at the beginning of a plan year as it is when implemented mid-year. The key is the purpose of the amendment. While a mid-year implementation may have a stronger implication of an improper purpose than a plan anniversary implementation, a plan anniversary implementation alone should not and cannot shield an amendment improperly directed at individual participants or beneficiaries. A plan anniversary may be some evidence of a proper purpose, or perhaps even create a rebuttable presumption of a proper purpose, but actual purpose must be objectively discerned. And with any specialty tier drug plans, it is clear that the purpose is to identify the sickest members of the similarly situated grouping and, at their moment of greatest need and vulnerability, direct onto them a severe financial burden that they cannot avoid by selecting other drugs on less expensive tiers like other similarly situated individuals can do. It becomes clear that specialty drug tiers are directed at those persons individually.

Example 3 provides instructive commentary.[158] In Example 3, a plan discovers that a participant's coverage includes benefits for an adverse health condition, and the next year, the plan offers the participant coverage but includes a rider stating that the adverse health condition will no longer

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157. *See, e.g.*, PRECISIONRX SPECIALTY SOLUTIONS SPECIALTY DRUG LIST, http://www.anthem.com/wps/portal/ahpmember?content_path=shared/ky/f0/s0/t0/pw_ad092969.htm&state=ky&rootLevel=2&label=PrecisionRx%20Specialty%20Solutions (last visited Nov. 15, 2011).

158. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039.

be covered under the plan.[159] The commentary notes that "[e]ven though the rider is made effective the first day of the next plan year, because the rider does not apply uniformly to similarly situated individuals, the issuer violates [HIPAA]."[160] The proposition that plans that adopt a specialty have acted improperly, just like in Examples 2 and 3 above, by knowingly modifying their plans under the potentially neutral guise of cost when in fact they were targeting a small subset of employees identifiable by health status has some support. The United States Department of Labor, Employee Benefits Security Administration, provides on its website answers to frequently asked questions about the HIPAA nondiscrimination requirements.[161] The site poses the question of whether a plan can charge an individual with a history of high claims more than similarly situated individuals based on their claims experience.[162] The answer provided was "[n]o . . . plans cannot charge an individual more for coverage[163] than other similarly situated individuals based on any health factor."[164]

4. Which Argument Prevails?

It is our belief that the argument that specialty drug tiers violate HIPAA's anti-discrimination provisions carries the day. The dispositive difference between four-tier drug plans with a specialty drug tier and traditional three-tier drug plans is the lack of pharmaceutically equivalent alternative drugs for the specialty drugs that can be placed on one of the first three tiers. This difference exposes specialty drug tiers for what they are—blatant discrimination against individuals based on health status.

Yet, we recognize arguments of specialty tier proponents. The law allows a plan to completely exclude coverage, but also prohibits discrimination based on an individual's health status. This is an odd juxtaposition. The law, on one hand, sends the message that a plan cannot discriminate against a person based on medical condition such as AIDS; but, on the other hand, it is acceptable to completely exclude coverage for all AIDS drugs. Part 2590.702(b)(2)(C) of the Final Rule states that "a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at

159. *Id.*
160. *Id.*
161. EMP. BENEFITS SEC. ADMIN., *supra* note 128.
162. *Id.*
163. *Id.* The use of the term "coverage" may infer that Congress meant premiums, not copayments; although, this is not clear. *See id.*
164. *Id.*

any individual[s]."[165] This statement, although it appears to assert that general plan amendments never create discrimination problems, cannot be entirely dispositive because of the conclusion reached in Example 3.[166]

Example 3 shows that a health plan, with knowledge of a person's adverse and costly health condition, cannot modify only one individual's plan the following year using a rider to exclude coverage because the limitation would not apply uniformly to all similarly situated individuals.[167] Does this example have equal applicability if the plan modification was the result of two people's claims? How far does this example go before a plan will be viewed as making a generalized determination versus individualized determinations? For example, the Final Rule asserts that a health plan with 100 members cannot identify one member who has expensive health care needs and modify only that member's coverage by a rider that excludes coverage for the member's high-cost services. But, the health plan can modify the benefits offered during the next plan year and exclude this particular benefit for the entire population, even if the benefit is utilized by this member alone. This appears like a loophole that Congress may not have intended; that is, Congress surely approved of health plan modifications that would have changes applicable to a large number of people but may not have intended to give health plans carte blanche authority to present plan modifications that the plan knows will affect a limited number of people. The ultimate question for specialty tier plans then is whether a formulary change adding a tier targeting specialty medications that affects a limited number of people is more analogous to a general plan amendment that is per se nondiscriminatory, or whether it is more analogous to a rider that affects a limited number of people that is prohibited by the conclusion provided in Example 3.

HIPAA's overall purpose, and more broadly, long-standing insurance law doctrines, should be utilized to reach a final answer on the legitimacy of specialty drug tiers. It is hard to imagine a law like HIPAA, with its stated statutory purpose of increasing access to, and the availability of health insurance coverage, endorsing a pharmacy benefit design that increases a plan participant's copayments exponentially by placing specialty drugs on a separate tier simply because of the high cost of drugs prescribed for treatment of medical conditions suffered by a small and easily identified

165. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039.

166. *Compare* 29 C.F.R. § 2590.702(b)(2)(C) (2006) (concluding that general plan amendments are not considered to be directed at individuals) *with* § 2590.702(D), Ex. 3.(ii) (concluding that, even after a new plan year, a rider that targeted an individual is prohibited under HIPAA).

167. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039.

subset of beneficiaries. The ultimate effect of specialty tier plans is contrary to HIPAA's broader intent. HIPAA was crafted to guarantee that Americans had access to affordable health insurance whether or not the person required high-cost medical care.[168] Yet, HIPAA does not mandate insurance coverage for specific diseases or conditions, not even high-cost medical services.[169] Benefits offered by a plan can be limited as long as the limitation applies uniformly to all persons similarly situated in an insurance pool.[170] From this, the law shows that once a health insurance plan decides to offer benefits for a specific disease or condition, the plan must be circumscribed within the scope of the law.

If specialty drug tiers do not violate HIPAA's anti-discrimination provisions specifically, are these benefit structures still wholly inconsistent with the overall legislative intent of HIPAA to improve the portability and continuity of health coverage for all insured Americans? If the answer is yes, can the broader intent of HIPAA be used to defeat four-tier plans? We believe the answer is yes. Longstanding rules of statutory construction show that sections of a statute which are inconsistent with the law's overall purpose can be defeated.

In the context of discrimination under the Individuals with Disabilities Education Act (IDEA), the United States Supreme Court applied rules of statutory construction and found facially neutral provisions in a law void because the provisions were inconsistent with the overall purpose of IDEA.[171] In *Winkelman ex rel. Winkelman v. Parma City School District*, the Supreme Court held that "a proper interpretation of the act requires a consideration of the entire statutory scheme."[172] In *Winkelman*, the court cautioned that courts asked to find that IDEA's provisions implicitly limit parents' rights must carefully consider whether such an interpretation is contrary to the statute's main purpose.[173] In this case, the court rejected a plain meaning argument and held that IDEA's statutory scheme and overriding goals (of ensuring that all children received a free and appropriate

168. 142 CONG. REC. S9521 (daily ed. Aug. 2, 1996) (statement of Sen. Dianne Feinstein) (stating that HIPAA was crafted for many reasons, including the need to reject preexisting condition exclusions in health insurance and the necessity of guaranteed access to health care regardless of health status).

169. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039; *see also* EMP. BENEFITS SEC. ADMIN., *supra* note 128.

170. Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. at 75,039.

171. Winkelman *ex rel.* Winkelman v. Parma City Sch. Dist., 550 U.S. 516, 523 (2007) (stating, under rules of statutory construction, that a proper interpretation of a law must consider the entire statutory scheme).

172. *Id.*

173. *Id.*

public education, and protecting the rights of parents and children) could justify looking beyond the language of a single statutory section.[174]

Applying the analysis used in *Winkelman* to the present question of specialty drug tiers, it is possible that HIPAA's statutory scheme could defeat an argument that the narrower anti-discrimination provisions do not preclude the creation of specialty drug tiers. However, HIPAA's statutory scheme may be difficult to determine because it addressed a number of issues including access to affordable health care, portability of insurance benefits, privacy of health information, security of health data, health savings accounts, and matters related to taxes.[175] However, it is worth noting that the first comments made by Senator Nancy Kassebaum (D-Kansas), the lead sponsor of the HIPAA legislation in 1996, focused on discrimination in health insurance.[176] Senator Kassebaum's initial remarks illustrate that the primary legislative intent of the statute was to "help . . . 25 million Americans each year who . . . face discrimination and live in fear that their health insurance . . . will be canceled if they change jobs, lose their job, *or become sick*."[177] If HIPAA was truly meant to stop our fear that becoming sick could lead to the end of health care coverage, then it should be equally improper under HIPAA to create a drug benefit structure that leads to a *de facto* end to a person's prescription drug coverage when the person cannot afford to make the required copayment. Senator Kassebaum called HIPAA "a dramatic victory for the American people . . . because [it] will help millions of Americans with preexisting illnesses . . . ."[178] However, HIPAA can become an empty victory if persons with high-cost health care are not protected.[179]

5. HIPAA Changes Under the Affordable Care Act

The Affordable Care Act was enacted in March 2010.[180] The Affordable Care Act, among many other insurance reforms, made several revisions to HIPAA. In many cases, including certain revisions affecting HIPAA, the full effect of the Affordable Care Act will not be known for several years. The salient question here is whether any provision in this new law alters the HIPAA provisions that form the basis of this Article.

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174. *Id.*

175. Crossley, *supra* note 7, at 113-14.

176. 142 CONG. REC. S9501 (daily ed. Aug. 2, 1996) (statement of Sen. Nancy Kassebaum).

177. *Id.* (emphasis added).

178. *Id.*

179. *See* Kolata, *supra* note 1.

180. Affordable Care Act, Pub. L. No. 111-148, § 1302(b), 124 Stat. 119 (2010).

Section 1302 is the only provision in the Affordable Care Act that may ultimately impact the conclusions and arguments raised herein. This section requires the Secretary of the U.S. Department of Health and Human Services (HHS) to define the "essential health benefits" that must be included in individual and small group health insurance markets.[181] The definition of "essential health benefits" will be used to create subsidized health insurance packages, which will be sold through a new system of health insurance exchanges beginning in calendar year 2014, and the definition will also be used outside of the exchange system.

Section 1302 also lists ten general categories of items and services that must be included in any major medical benefits package.[182] The ten general categories include:

> (A) Ambulatory patient services. (B) Emergency services. (C) Hospitalization. (D) Maternity and newborn care. (E) Mental health and substance use disorder services, including behavioral health treatment. (F) *Prescription drugs*. (G) Rehabilitative and habilitative services and devices. (H) Laboratory services. (I) Preventive and wellness services and chronic disease management. (J) Pediatric services, including oral and vision care.[183]

Insurance policies must cover these benefits in order to be certified and offered in health insurance exchanges; Medicaid State plans must cover these services by 2014.

Congress also requires the HHS Secretary to consider affordability and choice, as well the scope and value of benefits, when making up the list of essential benefits.[184] Most notably, the central focus of the Affordable Care Act is on "affordability" of health insurance, and Section 1302 directs HHS to examine the availability of prescription drugs as a core health service that must be provided to health insurance beneficiaries.[185] However, the Affordable Care Act fails to directly address specialty drug tiers; therefore, the lawfulness of specialty drug tiers remains uncertain at least for now.

The Institute of Medicine (IOM), in coordination with HHS, established an ad hoc committee in the fall of 2010.[186] The committee will even-

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181. *Id.* at § 1302.
182. *Id.* at § 1302(b)(1).
183. *Id*. (emphasis added).
184. *See, e.g.*, Affordable Care Act, Pub. L. No. 111-148, § 1302(a)(2), 124 Stat. 119 (2010).
185. *See id.* § 1302(b)(1).
186. *See Defining and Revising an Essential Health Benefits Package for Qualified Health Plans*, THE NAT'L ACADS.,

tually make recommendations on the methods for determining and updating essential health benefits for qualified health plans that participate in health insurance exchanges.[187] The IOM notes that

> the committee will identify the criteria and policy foundations for determination of the essential health benefits offered by [qualified health plans] taking into account benefits as described in sections 1302(b)(1) and 1302(b)(2)(A), and the committee will assess the methods used by insurers currently to determine medical necessity and will provide guidance on the "required elements for consideration" taking into account those outlined in section 1302(b)(4)(A)-(G), including ensuring appropriate balance among the categories of care covered by the essential health benefits, *accounting for the health care needs of diverse segments of the population*, and *preventing discrimination against age, disability, or expected length of life*. The committee will also take into account language in 1302 on periodic review of essential health benefits, other sections of the Affordable Care Act, for example, coverage of preventive health services (section 2713), utilization of uniform explanation of coverage documents and standardized definitions (section 2715), and other relevant tasks found in the Affordable Care Act for the Secretary of HHS.[188]

The committee is directed to make an "accounting for the health care needs of diverse segments of the population" and to define essential health benefits in light of "preventing discrimination against age, disability or expected length of life."[189] Based on this language, specialty drug tiers appears to be within the committee's scope of work, at least in the context of health insurance exchanges and qualifying health plans. The likelihood of this committee considering specialty drug tiers and copayment amounts could hinge on the level of exposure New York's ban on specialty drug tiers and its progeny get in the national media and whether any opponents submit comments on specialty drug tiers to the IOM.[190] The committee must publish its recommendations by September 2011.[191]

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http://www8.nationalacademies.org/cp/projectview.aspx?key=IOM-HCS-10-04 (last visited May 29, 2011) (announcement by the Institute of Medicine).

187. *Id.*

188. *Id.* (emphasis added).

189. *Id.*

190. *See id.* (Institute of Medicine notes that the committee will accept public comments).

191. THE NAT'L ACADS., *supra* note 186.

The Affordable Care Act is silent on specialty drug tiers. In addition, the IOM committee may not address specialty drug tiers during its deliberations on essential health benefits. Thus, national health reform does not presently alter existing law, regulations, and guidance related to HIPAA's anti-discrimination provisions or its overall intent to ensure access to necessary health care services.

IV. CONCLUSION

Reasonable arguments can be made on both sides of the issue addressing whether specialty tier formularies direct the benefit limitation at individual participants, violating HIPAA's anti-discrimination provisions. We conclude that specialty drug tiers improperly discriminate in violation of HIPAA is a more convincing argument. Using cost as the justification for placing drugs on a specialty tier is a red herring designed to divert our attention away from improper discrimination based on health status. The persons grouped together by the purportedly neutral cost identifier are a very small subset of an insurance pool's membership and are readily identifiable by their individual medical conditions. These persons are not treated the same as similarly situated individuals; they are singled out for placement on a specialty tier, which makes the cost of their necessary prescription drugs so high that it is effectively a substantial limitation on the amount they can obtain or a de facto denial of the drug altogether. Moreover, the nature of specialty drug tiers is shown by the fact that such tiers are conceptually and substantively different than the first three tiers in that the cost differential leaves the participant with no pharmaceutical option in the other three tiers. Unlike the first three tiers, specialty drug tiers have no legitimate purpose based in insurance theory, such as dealing with moral hazard. It is nothing more than a de facto exclusion of certain drugs based on the health status of the user and a violation of HIPAA's anti-discrimination provisions.

Consequently, we believe it would be appropriate for state legislatures to follow New York's lead and resolve any doubt about the legality of specialty drug tiers by enacting legislation prohibiting their use; for HHS to issue regulations under the Affordable Care Act prohibiting specialty drug tiers in qualified health plans participating in the health insurance exchanges set for 2014; and for any other administrative or legislative action at the federal level to provide a clear, nationally uniform prohibition against the discriminatory practice of specialty drug tiers.