

Loyola University Chicago Law Journal

Volume 48
Issue 4 Summer 2017

Article 8

2017

Now or Never: The Urgent Need for Action Against Unfair Coverage Denials for Quality Health Care

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Now or Never: The Urgent Need for Action Against Unfair Coverage Denials for Quality Health Care

*Stacey L. Worthy, Daniel C. McClughen, & Shruti Kulkarni**

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INTRODUCTION

In 2007, James Skelcy was diagnosed with dermatomyositis, a connective tissue disease, and interstitial lung disease.¹ After receiving several ineffective medications, Mr. Skelcy's rheumatologist prescribed him two doses of rituximab (i.e., a drug used to treat autoimmune diseases and certain types of cancer), allowing him to enter and maintain remission for almost a full year.² In 2010, when his symptoms returned, his insurer refused to cover the medication, ignoring his rheumatologist's urgent

1. Skelcy v. UnitedHealth Grp., Inc., 620 F. App'x 136, 138 (3d Cir. 2015).

2. *Id.*

request for the medication.³ After a thirty-two-day delay in treatment due to back-and forth-communications with the insurer, Mr. Skelcy died of chronic dermatomyositis, interstitial pulmonary fibrosis, endomyocardial fibrosis, and cardiac arrhythmia—conditions the prescribed medication likely could have prevented if authorized in time.⁴

In 2011, Shima Andre was diagnosed with hepatitis C, a chronic liver disease.⁵ Her physician prescribed her a medication that cost \$99,000 without insurance coverage but cured the deadly virus in most individuals with hepatitis C.⁶ Ms. Andre’s insurer refused to cover the medication, deeming it “not medically necessary.”⁷ The insurer explained that it would only cover the medication for individuals who had evidence of “advanced liver damage,” meaning Ms. Andre’s disease would have to progress to the point in which she needed a liver transplant before she could access the cure.⁸

Mr. Skelcy’s and Ms. Andre’s stories are not uncommon. In fact, a 2011 study revealed that the United States ranked last among sixteen developed nations for preventing deaths from treatable conditions—including certain forms of cancer, diabetes, and stroke—through timely access to effective health care.⁹

With the enactment of the Patient Protection and Affordable Care Act (“ACA”) in 2010, millions of Americans gained access to health care.¹⁰ Yet, many individuals with conditions that have been historically more expensive to treat, such as cancer, HIV, and hepatitis C, still find themselves subject to overly restrictive benefit utilization management practices that forbid access to medically necessary, life-sustaining treatments.¹¹ Moreover, with the new administration calling for the

3. *Id.* “Insurer,” as used in this Article, refers to private health insurers, health plans, fiduciaries, and administrators.

4. *Id.* at 139.

5. Stuart Pfeifer, *Woman Sues Anthem Blue Cross for Refusing to Cover Hepatitis C Drug*, L.A. TIMES (May 18, 2015, 10:14 PM), <http://www.latimes.com/business/la-fi-anthem-blue-cross-harvoni-lawsuit-20150518-story.html>.

6. *Id.*

7. *Id.*

8. *Id.*

9. COMMONWEALTH FUND COMM’N ON A HIGH PERFORMANCE HEALTH SYS., WHY NOT THE BEST?: RESULTS FROM THE NATIONAL SCORECARD ON U.S. HEALTH SYSTEM PERFORMANCE 9 (Oct. 2011), http://www.commonwealthfund.org/~media/files/publications/fund-report/2011/oct/1500_wntb_natl_scorecard_2011_web_v2.pdf.

10. 42 U.S.C. § 300gg-11 (2015).

11. The term “benefit utilization management” as used in this Article, refers to insurers’ cost-saving techniques that are intended to influence practitioners’ and patients’ health care decision making.

repeal of the ACA, insurers may find it easier to discriminate against individuals based on their health conditions.

Insurers' overly burdensome benefit utilization management practices are unethical, inefficient, and, in some instances, illegal. They result in poor quality of care and take health care decisions away from practitioners and patients. Therefore, consumers must be empowered to bring suits, and federal and state authorities must enforce laws currently in place to ensure that individuals with chronic, debilitating, and rare health conditions have timely access to coverage of quality care. Where such protections are lacking, states must enact stronger laws.¹² This Article examines several benefit utilization management practices, including step therapy, adverse tiering, nonmedical switching, prior authorization, narrow networks, and clinical pathways. It analyzes relevant statutory and case law, including consumer protection laws, tort law, and contract law and calls for greater enforcement. This Article also provides consumers with the information necessary to bring a lawsuit or file a complaint, recommends state legislation addressing burdensome insurance practices, and encourages states to provide regulators with the proper authority to take enforcement actions.

I. COMMON BENEFIT UTILIZATION MANAGEMENT PRACTICES

Providing quality care to individuals with chronic conditions can be expensive. To save on costs, insurers essentially ration out health care. They do this by using benefit utilization management policies to limit access to more expensive treatments. Yet, insurers sometimes employ benefit utilization management policies in a manner that excludes large patient populations from accessing life-saving treatments in favor of treatments that are typically older and may be inferior or are known to produce adverse effects. Such policies interfere with the physician-patient relationship in a detrimental manner and may violate both state and federal laws. This Part discusses some of those commonly employed benefit utilization management policies and the laws that the policies may violate.

A. *Step Therapy*

Step therapy policies, which are also referred to as "fail first" policies, require individuals to try and fail on less expensive treatments, sometimes with adverse effects, before the insurer will cover the original, likely

12. This Article does not address self-funded employer plans, which are governed by the Federal Employee Retirement Income Security Act ("ERISA"), rather than state law.

more expensive, treatment prescribed to them.¹³ Pursuant to medical practice, individuals are supposed to begin with the safest and most cost-effective treatment and then progress to riskier and costlier treatments.¹⁴ In reality, step therapy policies can be cruel and unethical. For instance, a recent study showed that 45 percent of individuals who were prescribed immunological agents and biologics were forced to first “step through” a treatment with a black-box warning (i.e., a medication with a known risk for a severe adverse reaction) before their insurers would cover the prescribed treatment.¹⁵ Step therapy policies can also significantly delay access to effective treatments, causing the individuals’ conditions to worsen while they wait.¹⁶

1. The ACA’s Nondiscrimination Provision

President Obama signed the ACA into law on March 23, 2010 to improve the accessibility of quality health care. As part of those efforts, section 1557 of the ACA (i.e., the nondiscrimination provision) expressly prohibits all entities principally engaged in providing or administering health insurance coverage, including public and private insurers and pharmacy benefit managers (“covered entities”), from excluding from participation, denying a benefit for, or discriminating against any individual on the basis of a health condition.¹⁷

On May 18, 2016, the United States Department of Health and Human Services (“HHS”) issued a final rule implementing the nondiscrimination provision, which clarified that covered entities are prohibited from employing “marketing practices or benefit designs”¹⁸ that discriminate

13. Paul Sisson, *Bill Would Quicken Access to Newer Meds*, SAN DIEGO UNION-TRIB. (Oct. 3, 2015, 9:42 AM), <http://www.sandiegouniontribune.com/news/2015/oct/03/ab374-chronic-disease/>.

14. Gary Branning et al., *Formulary Management of Branded Drugs with and Without Boxed Warnings Within Therapeutic Categories*, 18 J. INT’L SOC’Y FOR PHARMACOECONOMICS & OUTCOMES RES. A100, A100 (2015).

15. *Id.* at A100. Biologics are medical products made from natural sources (e.g., human, animal, and microorganism) to prevent, diagnosis, or treat medical conditions. *What Is a Biological Product?*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm> (last updated May 31, 2016).

16. *See* Fox Ins. Co. v. Ctrs. for Medicare & Medicaid Servs., 715 F.3d 1211, 1213–14 (2013) (noting that the Centers for Medicare and Medicaid Services (“CMS”) terminated a Medicare contract because the defendant imposed benefit utilization management strategies, including step therapy, to significantly delay patient access to needed medication, thereby placing patients in imminent and serious risk).

17. 42 U.S.C. § 18116 (2015); *Callum v. CVS Health Corp.*, 137 F. Supp. 3d 817, 853 (D.S.C. 2015). The nondiscrimination provision contains a private cause of action. *Callum*, 137 F. Supp. 3d at 848.

18. Benefit design refers to the treatments covered by a health care plan and the restrictions

on the basis of a health condition.¹⁹ For the purpose of this rule, covered entities are those that operate a health program or activity that receives federal funding and any entity established under the ACA to administer health care (e.g., health care exchanges), including health insurers, hospitals, health care clinics, and Medicaid agencies and contractors.²⁰

Given that step therapy is a part of a health plan's benefit design, if a step therapy policy is required for most or all drugs used to treat a particular condition in a manner that is inconsistent with medical evidence, that policy may violate the nondiscrimination provision and its implementing regulations. Such a policy discriminates against individuals with that condition and places an undue burden on them to receive necessary therapies.²¹ It requires the individual to take a less than optimally effective treatment for a period of time, resulting in a delay of proper treatment.²² In one case, for example, a physician prescribed a biologic infusion treatment to an individual with rheumatoid arthritis.²³ The physician submitted proof that the medications the individual's insurer required her to step through were ineffective and that her rheumatoid arthritis had progressed to the point where she lost her job; could not drive or care for her son; and needed help with simple tasks, such as bathing. Yet, her insurer required her to first attempt and "fail" on six other drugs over the course of one year before she could gain access to the originally prescribed biologic infusion treatment.²⁴ This step therapy policy may violate the nondiscrimination provision because it is designed to create a burden on individuals with rheumatoid arthritis and delay access to effective treatment.

placed on coverage of those treatments, including pharmacy tiers and any benefit utilization management policies.

19. Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,189 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 92).

20. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (to be codified at 45 C.F.R. Part 92).

21. See OHIO DEP'T OF INS., NON-DISCRIMINATION IN BENEFIT DESIGN 5 (2015), http://www.insurance.ohio.gov/Company/Documents/2015_Non-Discriminatory_Benefit_Design_QHP_Standards.pdf (clarifying nondiscrimination standards under the Affordable Care Act ("ACA") and giving examples).

22. Spenser G. Bengé, *Section 1557 of the Affordable Care Act: An Effective Means of Combatting Health Insurers' Discrimination Against Individuals with HIV/AIDS?*, 13 IND. HEALTH L. REV. 193, 225 (2016).

23. Arloishia Israel, *Insurers Win, Patients Lose with Step Therapy*, CHARLOTTE OBSERVER (Dec. 14, 2015, 6:10 PM), <http://www.charlotteobserver.com/opinion/op-ed/article49743935.html>.

24. *Id.*

2. The Medicaid Act: Reasonable Promptness Provision

Step therapy may also violate the “reasonable promptness” provision of the Medicaid Act, which requires Medicaid plans to provide medical assistance “with reasonable promptness to all eligible individuals.”²⁵

Prior to the enactment of the ACA, several of the federal circuits had interpreted the term “medical assistance” to mean only “financial assistance” for medical services and not the medical services themselves,²⁶ serving to effectively foreclose most reasonable promptness suits. But the ACA amended the Medicaid Act’s definition of “medical assistance” to clarify that the term includes “payment of part or all of the cost of . . . care and services *or the care and services themselves, or both.*”²⁷ Therefore, a Medicaid enrollee can potentially bring a successful action pursuant to the reasonable promptness provision of the Medicaid Act when medical assistance is not provided in a reasonably prompt fashion (i.e., an insurer requires individuals to attempt and fail on less expensive treatments before covering the more effective treatments).²⁸

The Medicaid Act does not define “reasonable promptness,” and the few regulations related to the provision are not particularly illuminating.²⁹ For example, the regulations provide that the responsible state agency must “furnish Medicaid promptly to recipients without any delay caused by the agency’s administrative procedures,”³⁰ and “continue to furnish Medicaid regularly to all eligible individuals until they are found ineligible.”³¹ The lack of regulatory clarity on the meaning of reasonable promptness may be due to the fact that what qualifies as a reasonably prompt provision of care depends entirely on the condition that the care is treating.³²

Given the provision’s vague language, courts have failed to formulate a consistent standard in making reasonable promptness determinations. Nonetheless, courts may find defendants liable for violating the

25. 42 U.S.C. § 1396a(a)(8) (2015); Jeffrey Chen, *In the Nick of Time: Using the Reasonable Promptness Provision to Challenge Medicaid Spending Cutbacks*, 15 YALE J. HEALTH POL’Y L. & ETHICS 349, 349 (2015).

26. Chen, *supra* note 25, at 370.

27. 42 U.S.C. § 1396d(a) (2015) (emphasis added).

28. As used in this Article, the term “enrollee” means an individual who has enrolled in a private or federally funded insurance plan, including Medicare, Medicaid, or marketplace exchange plans.

29. Chen, *supra* note 25, at 373.

30. 42 C.F.R. § 435.930(a) (2013).

31. *Id.* § 435.930(b).

32. *See id.* (“The agency must . . . [c]ontinue to furnish Medicaid regularly to all eligible individuals until they are found to be ineligible.”).

provision, which may lend support to a potential plaintiff's case. For example, *Sobky v. Smoley* supports the proposition that *any* delay in the delivery of services is a violation of the provision.³³ There, the court found the State of California liable for failing to comply with the reasonable promptness provision where insufficient funding from California's Medicaid program caused providers of methadone maintenance therapy to place eligible individuals with substance use disorders on waiting lists for treatment.³⁴

In *Oklahoma Chapter of American Academy of Pediatrics v. Fogarty*, the Northern District of Oklahoma found that the defendant violated the reasonable promptness provision when the plaintiffs offered substantial evidence that the delays in treatment for children with specific conditions [were] medically inappropriate.³⁵ Furthermore, the plaintiffs showed that system-wide delays for treatment existed and were unreasonable.³⁶ This case may suggest that a Medicaid program has violated the reasonable promptness provision if a plaintiff can show that enrollees are subject to "medically inappropriate" delays.³⁷

These cases demonstrate that unreasonable delays to prescribed treatment for Medicaid enrollees, such as the delays resulting from step therapy policies, may give rise to a cause of action for a violation of the reasonable promptness provision. For example, step therapy unreasonably delays access to treatment for Medicaid enrollees by requiring enrollees to start on treatments that are less effective or not effective at all, or ones that cause known adverse events before starting a prescribed treatment. Furthermore, delays caused by step therapy protocols unsupported by medical evidence that require enrollees to first fail on medications with known, severe adverse effects, are not only medically inappropriate, but also unethical. Therefore, Medicaid enrollees may have a claim under the reasonable promptness provision of the Medicaid statute if they cannot access the treatment prescribed to them due to a burdensome step therapy policy.

3. State Claim Based on the Interference with the Physician-Patient Relationship

Burdensome step therapy policies may meet the standards for intentional interference with a contractual relationship (i.e., a common

33. *Id.*; *Sobky v. Smoley*, 855 F. Supp. 1123, 1148 (E.D. Cal. 1994).

34. *Sobky*, 855 F. Supp. at 1140.

35. *Okla. Chapter of Am. Acad. Pediatrics v. Fogarty*, 366 F. Supp. 2d 1050, 1109 (N.D. Okla. 2005).

36. *Id.*

37. *Chen*, *supra* note 25, at 375.

law tort) because they significantly disrupt the physician-patient relationship, preventing physicians from fulfilling their duty and affecting the health and well-being of patients.

According to the Restatement (Second) of Torts, a claim for intentional interference with a contractual relationship exists if (1) there is a valid contract; (2) the defendant had knowledge of the contract; (3) the defendant acted intentionally and improperly; and (4) the plaintiff was injured by the defendant's actions beyond the fact of the interference itself ("Restatement elements").³⁸ A defendant's liability "may arise from improper motives or from the use of improper means."³⁹

The Restatement of Torts is relevant here because the physician-patient relationship creates a contract, whether it be express or implied, pursuant to which the physician must treat the patient with proper professional skill and the patient must pay for such treatment.⁴⁰ Once the contractual relationship forms, the physician has a duty to bring skill and care to treat the condition,⁴¹ and to make decisions in the best interest of the patient.⁴² In *Baptist Health v. Murphy*, the Arkansas Supreme Court considered the issue of intentional interference in the context of the physician-patient relationship.⁴³ In *Murphy*, the board of trustees of the defendant, Baptist Health, instituted a policy that prohibited physicians who owned an interest in a competing hospital from practicing at Baptist Health.⁴⁴ Pursuant to the policy, the plaintiffs-physicians sued for tortious interference with a contractual relationship or business expectancy when Baptist Health restricted the physicians from practicing at Baptist Health because they owned an interest in a competing specialty heart hospital.⁴⁵ The Arkansas Supreme Court held that the hospital

38. *United Truck Leasing Corp. v. Geltman*, 551 N.E.2d 20, 21 (Mass. 1990).

39. *Id.*

40. AMY G. GORE ET AL., 61 AM. JURIS. § 130 (2d ed. 2017); J. Gregory Lennon, *Easing the Medical Malpractice Crisis: Restricting the Creation of Duty Through an Implied Doctor-Patient Relationship*, 7 J. HEALTH CARE L. & POL'Y 363, 365 (2004).

41. GORE ET AL., *supra* note 40, § 130; Lennon, *supra* note 40, at 365.

42. *See, e.g.*, STATE MED. BD. OF OHIO, STATEMENT OF THE STATE MEDICAL BOARD OF OHIO ON THE CORPORATE PRACTICE OF MEDICINE 2 (2012), <http://www.med.ohio.gov/Portals/0/DNN/PDF-FOLDERS/Laws-Rules/Position-Statements/Corporate-Practice-of-Medicine.pdf> ("No matter the business entity, a physician must exercise professional judgment to render medical services based on the best interest of the patient."); Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 234 (1999) (describing the guiding principles behind medical licensing boards).

43. *Baptist Health v. Murphy*, 373 S.W.3d 269, 281–82 (Ark. 2010).

44. *Id.* at 275.

45. *Id.* at 281.

tortiously interfered with the plaintiffs-physicians' relationships with their patients.⁴⁶

Like the conflict of interest policy in *Murphy*, an insurer's step therapy policy could give rise to a patient's or practitioner's claim for tortious interference. First, it is clear that a physician has a contractual relationship with a patient where a physician agrees to provide care and a patient agrees to accept care for a fee.⁴⁷ It can be presumed that an insurer has knowledge of the physician-patient relationship and intends to interfere with that relationship when it requires compliance with a step therapy policy.⁴⁸ Step therapy policies inherently influence decision making between patients and their doctors. By enforcing such policies, insurers often require a physician to prescribe, and a patient to use and fail on, a medication different than the one deemed to be in the patient's best interest.

As to the damages element required for a claim for intentional interference with a contractual relationship, the defendant-hospital's conflict of interest policy injured the *Murphy* physicians by disrupting the physician-patient relationship and causing a loss of professional fees. Likewise, step therapy policies disrupt physicians' relationships with their patients because they take away a physician's ability to make individualized health care decisions in the best interest of the patient. Furthermore, such policies increase the administrative burden and expense because physicians who seek an exception or appeal a denial for patients must spend time contacting the insurer.⁴⁹ Physicians, nursing staff, and clinical staff spend approximately three weeks, twenty-three weeks, and forty-four weeks per year, respectively, interacting with insurers.⁵⁰ The time spent communicating with insurers results in less time available to spend with patients, lower net professional fees, and higher costs for patients.

From the patient's perspective, the patient may experience harm to his or her health. Step therapy policies negatively impact patient outcomes

46. *Id.* at 289.

47. *Id.* at 282.

48. *See id.* at 284 (holding that "a party is presumed to intend the natural and probable consequences of his or her actions").

49. Adrienne Chung et al., *Does a "One-Size-Fits-All" Formulary Policy Make Sense?*, HEALTH AFF. BLOG (June 2, 2016), <http://healthaffairs.org/blog/2016/06/02/does-a-one-size-fits-all-formulary-policy-make-sense/>.

50. Lawrence P. Casalino et al., *What Does It Cost Physician Practices to Interact with Health Insurance Plans?*, 28 HEALTH AFF. W533, W540 (2009), <http://content.healthaffairs.org/content/28/4/w533.full.pdf+html>.

through delays in treatment and higher health care costs.⁵¹ Some policies require patients to fail on more than five different medications with adverse events for nearly two years before insurers will provide coverage for the prescribed medication.⁵² Furthermore, these policies result in patients spending a significant amount of time on the phone, in doctors' offices, and in pharmacies.

Lastly, to satisfy a prima facie case against an insurer for intentional interference, the plaintiff must show that the insurer's conduct is improper. In *Murphy*, the court reviewed the circuit court's extensive findings of the hospital's impropriety against the Restatement elements for improper conduct. In short, the nature of Baptist Health's conduct was against public policy because its conflict of interest policy disrupted the physician-patient relationship.⁵³ In addition, the court held that the physicians' interest in physician-patient relationships and the continuity of care outweighed Baptist Health's interest in protecting its economic viability.⁵⁴ The court reasoned that while society has a strong interest in Baptist Health's continued viability, the evidence showed that its finances were never at risk.⁵⁵

When applying the Restatement elements to insurers' use of step therapy policies, the factors may weigh in favor of physicians and patients. Physicians' interests are in the physician-patient relationship and satisfying their duty of care pursuant to that relationship. Patients have an interest in their own health and well-being, as well as decreasing the costs of health care. But insurers' principal motive in utilizing step therapy policies is to decrease their short-term costs. Insurers implement these policies despite their negative effect on physicians and patients, and without regard to the long-term benefits and cost-savings associated with providing timely access to the prescribed treatment.

B. Adverse Tiering

Drug formularies (i.e., insurers' lists of medications approved for coverage) often classify medications into tiers based on price.⁵⁶ While insurers usually charge a flat-rate copayment for prescriptions on lower

51. *Limiting Step Therapy Policies to Protect Patients*, CAL. RHEUMATOLOGY ALLIANCE, <http://cqrcengage.com/cra/steptherapy> (last visited May 7, 2017).

52. *Id.*

53. *Baptist Health*, 373 S.W.3d at 286.

54. *Id.* at 286–87.

55. *Id.* at 287.

56. Joseph J. Hylak-Reinholtz & Jay R. Naftzger, *Is It Time to Shed a "Tier" for Four-Tier Prescription Drug Formularies? Specialty Drug Tiers May Violate HIPAA's Anti-Discrimination Provisions and Statutory Goals*, 32 N. ILL. U. L. REV. 22, 34 (2011).

tiers,⁵⁷ they may charge a percentage of the drug cost (i.e., coinsurance) for prescriptions on upper tiers, sometimes referred to as “specialty tiers.”⁵⁸ Specialty tiers typically contain many innovative and life-saving drugs that tend to be costlier.

While specialty tiers were once reserved for treatments of rare diseases, they are now often used for drugs that treat chronic conditions, including cancer, HIV, and rheumatoid arthritis.⁵⁹ Given that coinsurance in specialty tiers typically ranges from 20 to 50 percent of a drug’s cost,⁶⁰ consumers may be required to pay thousands of dollars a month for vital medications.⁶¹ The ACA currently limits out-of-pocket maximums for health care costs to \$7,150 for individuals and \$14,300 for families for 2017 individual, small-group, large-group, and self-insured plans.⁶² Nevertheless, a single treatment may cost over \$12,750, meaning that the family has the financial burden of paying that cost upfront. Moreover, it is quite common for Medicare beneficiaries to spend more than \$600 per month on specialty medications.⁶³

In a growing trend, insurers have placed most or all drugs that treat a specific condition, including generics, on the highest cost specialty tiers, making treatment for individuals with that illness unaffordable and inaccessible.⁶⁴ This practice is often referred to as “adverse tiering.” For example, in 2015, 51 percent of silver plans placed all multiple sclerosis drugs on a specialty tier (up from 42 percent in 2014).⁶⁵ Likewise, a recent study showed that most insurance plans in California, Florida, Illinois, North Carolina, Texas, and Washington placed all, or nearly all,

57. *Id.* at 36–38.

58. Chad Brooker, *Waging War on Specialty Pharmaceutical Tiering in Pharmacy Benefit Design*, 7 HEALTH L. & POL’Y BRIEF 25, 29 (2013).

59. DEL. HEALTH CARE COMM’N, SPECIALTY-TIER PRESCRIPTION DRUGS: REPORT TO THE GENERAL ASSEMBLY 2 (2012), <http://dhss.delaware.gov/dhss/dhcc/files/tierdrugreport.pdf>.

60. Brooker, *supra* note 58, at 29.

61. *Id.*

62. HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,750, 10,826 (Feb. 27, 2015) (to be codified at 45 C.F.R. pts. 144, 147, 153, 154, 155, 156, and 158); *Out-of-Pocket Maximum Limits*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/> (last visited May 22, 2017).

63. Jack Hoadley et al., *It Pays to Shop: Variation in Out-of-Pocket Costs for Medicare Part D Enrollees in 2016*, KAISER FAM. FOUND. (Dec. 2, 2015), <http://kff.org/report-section/it-pays-to-shop-variation-in-out-of-pocket-costs-for-medicare-part-d-enrollees-in-2016-findings/>.

64. HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10,750, 10,821, 10,823 (Feb. 27, 2015) (to be codified at 45 C.F.R. pts. 144, 147, 153, 154, 155, 156, and 158).

65. AVALERE, AVALERE PLANSCAPE ANALYSIS OF PRESCRIPTION DRUG TIER PLACEMENT AND COST SHARING IN HEALTH INSURANCE EXCHANGE PLANS 4 (2015), http://go.avalere.com/acton/attachment/12909/F-017c/1/-/-/-/20150211_Avalere%20Planscape%202015_Class%20Tiering%20Analysis.pdf.

of twenty-two well-known cancer medications into the highest-cost tier.⁶⁶ Higher cost sharing can often have a negative impact on plan enrollees seeking coverage of treatments in specialty tiers, including skipping doses or missing treatments, thereby resulting in adverse events and development of drug resistance.⁶⁷

1. The ACA's Nondiscrimination and Preexisting Condition Provisions

Adverse tiering could violate the ACA's nondiscrimination provision and its implementing regulations. The ACA also prohibits insurers from imposing a "preexisting condition exclusion," which is "a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date."⁶⁸ Yet, insurers often use adverse tiering to discourage individuals with preexisting conditions from enrolling in health plans because the applicable treatments are inadequately covered. Therefore, adverse tiering schemes could effectively serve as preexisting-condition exclusions.

The ACA also prohibits insurers from employing "marketing practices or benefit designs that have the effect of discouraging the enrollment in such plans by individuals with significant health needs."⁶⁹ A 2015 HHS regulation further clarified that insurers may violate the nondiscrimination provision if they place most or all drugs for a certain condition on a formulary's highest cost tier if there is no appropriate, nondiscriminatory reason for the practice or without regard to the actual cost the insurer pays for the drug.⁷⁰ The Centers for Medicare and Medicaid Services ("CMS"), which reportedly covers 100 million people through Medicare, Medicaid, and other federal health care programs, has emphasized this point.⁷¹ A representative of CMS stated that while

66. Julie Appleby, *Cancer Meds Often Bring Big Out-of-Pocket Costs for Patients*, *Report Finds*, KAISER HEALTH NEWS (Nov. 19, 2015), <http://khn.org/news/cancer-meds-often-bring-big-out-of-pocket-costs-for-patients-report-finds/>.

67. Administrative Complaint at 3, *The AIDS Inst. v. Coventry Health Care, Inc.*, (May 29, 2014), <http://www.natap.org/2014/newsUpdates/NHeLPTheAIDSInstituteHIVcomplaintHHSOCR5.29.14copy.pdf> [hereinafter *AIDS Institute Administrative Complaint*].

68. 42 U.S.C. § 300gg-3(a) (2015).

69. *Id.* § 18031(c)(1)(a); 45 C.F.R. § 156.225(b) (2017).

70. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 54,189 (May 18, 2016) (to be codified at 45 C.F.R. pt. 92).

71. See Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. at 31,434 (stating that "placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers" is an example of a discriminatory benefit design); *CMS Covers 100*

having a specialty tier is not discriminatory on its face, adverse tiering may be discriminatory in application “when looking at the totality of the circumstances.”⁷²

In September 2016, the Center for Health Law and Policy Innovation of Harvard Law School (“CHLPI”) and the AIDS Foundation of Chicago filed an administrative complaint with the HHS Office of Civil Rights (“OCR”) alleging that the cost-sharing design that Humana employed in its marketplace exchange plans discriminated against individuals with HIV in violation of the nondiscrimination provision, the preexisting condition provision, and the ACA regulations.⁷³ The complaint argued that a benefit design may be discriminatory if it does not provide meaningful access to a certain patient population. Access is not meaningful if the patient population is not afforded the same opportunities to benefit from the services that are available to others.⁷⁴

The complaint stated that the insurer’s formulary placed sixteen of the twenty-four most common HIV medications in its highest cost-sharing tier, with coinsurance rates between 40 and 50 percent.⁷⁵ Therefore, an individual enrolled in Humana’s Illinois qualified health plan (“QHP”) was allegedly required to spend between 8 and 14 percent of his or her average monthly income for an HIV treatment regimen.⁷⁶ By comparison, Humana only required a fifty dollar copay for two similarly priced chemotherapy medications, or around 1 percent of the Illinois median household income.⁷⁷ The groups argued that such cost-prohibitive adverse tiering subjected those with HIV to discrimination by preventing meaningful access available to other patient populations. Such policies also allegedly led individuals with HIV to avoid enrolling in, or withdrawing from, Humana’s plans altogether, thereby serving as a preexisting condition exclusion.⁷⁸ While HHS has yet to respond to the

Million People, CTR. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/> (last visited Apr. 17, 2017). CMS has sole enforcement authority in four states and concurrent enforcement authority in the remainder of states. *Compliance and Enforcement*, CTR. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/ccio/programs-and-initiatives/health-insurance-market-reforms/compliance.html> (last visited Apr. 26, 2017).

72. Bob Herman, *Aetna Revises HIV Drug Policy for All Exchange Plans*, MOD. HEALTHCARE (Mar. 27, 2015), <http://www.modernhealthcare.com/article/20150327/NEWS/150329914>.

73. Administrative Complaint at 2, Ctr. for Health Law & Policy Innovation v. Humana (Sept. 6, 2016), <http://www.aidschicago.org/resources/content/9/2/5/documents/ocr-complaint-humana-1.pdf>.

74. *Id.* at 7.

75. *Id.* at 8.

76. *Id.* at 9.

77. *Id.* at 12.

78. *Id.* at 3.

complaint, Humana's actions, if true, would be in direct conflict with the nondiscrimination provision, the preexisting condition provision, and the ACA's implementing regulations.

2. The Federal Rehabilitation Act

Adverse tiering may also violate the Rehabilitation Act of 1973 ("Rehab Act"). The Rehab Act prohibits programs and services that receive federal funds from providing "benefits or services in a manner that limits or has the effect of limiting the participation of qualified persons with disabilities."⁷⁹ It states that no otherwise qualified individual with a disability "shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under a program or activity receiving Federal financial assistance."⁸⁰ The Rehab Act's implementing regulations define "disability" as (1) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (2) a record of such impairment; or (3) being regarded as having such impairment.⁸¹ The Rehab Act applies to federally funded health plans and if any such health plan imposes a discriminatory adverse tiering policy, plan enrollees may be able to bring a claim under the Rehab Act.⁸²

In *Alexander v. Choate*, Medicaid recipients challenged Tennessee's decision to reduce the annual cap on reimbursed hospital days from twenty to fourteen days.⁸³ The plaintiffs argued that the reduction had a disproportionate effect on individuals with disabilities in violation of the Rehab Act. The court balanced the individuals' medical needs against the State's burden to determine whether the plaintiffs had "meaningful access" to health care.⁸⁴ The court cited three relevant factors in its analysis of meaningful access: (1) the reductions must not "have a particular exclusionary effect" on an individual with a disability; (2) the limitation must be neutral on its face; and (3) the individual must be able to benefit meaningfully from the coverage, although it ultimately ruled in favor of the defendants finding that the reduction in annual inpatient

79. 45 C.F.R. § 84.52(a)(iv) (2004).

80. 29 U.S.C. § 794(a) (2015).

81. 29 C.F.R. § 1630.2(g) (2011); 45 C.F.R. § 84.52(d) (2004).

82. 42 U.S.C. § 18116 (2015). The ACA explicitly states that the Rehab Act applies to federally funded health plans, clearing up previous ambiguity. *Id.*

83. Alexander Abbe, "Meaningful Access" to Health Care and the Remedies Available to Medicaid Managed Care Recipients Under the ADA and the Rehabilitation Act, 147 U. PENN. L. R. 1161, 1166 (1999).

84. *Alexander v. Choate*, 469 U.S. 287, 301 (1985).

hospital days did not result in discrimination.⁸⁵

In *Katie A.*, ex rel. *Ludin v. Los Angeles City*, the Ninth Circuit further elaborated on the *Choate* test that the required services must be provided in “an effective manner.”⁸⁶ A plan benefit design may be considered ineffective for the purposes of the Rehab Act if it does not provide the individual with a disability with the same opportunities to benefit from the services that are available to others.⁸⁷

Pursuant to the opinions of the courts, it can be argued that Medicare, Medicaid, and exchange plans deny meaningful access to health care for individuals with disabilities if they employ adverse tiering, thereby violating the Rehab Act. For example, CHLPI and the AIDS Research Consortium of Atlanta filed an administrative complaint with OCR in September 2016 alleging that Humana, through its exchange plans, unlawfully discriminated against individuals with HIV in violation of the Rehab Act.⁸⁸ The complainants alleged that Humana placed sixteen out of the twenty-two HIV medications on the highest cost-sharing tier within each of its five QHPs, thereby intentionally making such medications unaffordable for the majority of individuals with HIV on that plan.⁸⁹ The groups provided statistics showing that Humana enrollees with HIV had to spend between 17 and 30 percent of the median monthly income in Georgia to receive their medications.⁹⁰ This problem is exacerbated by the fact that over 18 percent of Georgia residents live in poverty, and 23 percent of those impoverished residents have HIV.⁹¹

The complainants also argued that Humana’s benefit design is outside of market norms in Georgia, with the majority of other insurers in the state offering HIV drug benefits at a significantly lower cost than Humana. The complainants stated that these prohibitively high cost-sharing levels discourage any reasonable individual with HIV from enrolling or staying in Humana’s QHPs, amounting to a de facto denial of meaningful access in violation of the Rehab Act.⁹² This case is currently pending.

In sum, adverse tiering may violate the Rehab Act because such a

85. *Id.* at 302.

86. *Katie A. v. L.A. Cty.*, 481 F.3d 1150, 1159 (9th Cir. 2007); Administrative Complaint, Ctr. for Health L. & Pol’y Innovation v. Humana (Sept. 6, 2016), <http://media.bizj.us/view/img/10145208/ga-humana.pdf>.

87. *Katie A.*, 481 F.3d at 1159.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

policy often limits qualified persons with disabilities from participating properly in their health plans.

3. State Claim Based on Unfair and Deceptive Trade Practices

Adverse tiering may also violate state unfair and deceptive trade practice (“UDTP”) laws, which are generally intended to protect consumers from predatory business practices.⁹³ Though UDTP laws vary from state to state, every state has at least one consumer protection law that prohibits deceptive trade practices, such as bait-and-switch tactics, false or misleading advertising, and other fraudulent marketing practices.⁹⁴ A majority of states prohibit unfair acts and practices, and a minority of states have laws prohibiting unconscionable business practices.⁹⁵

States also have UDTP laws that target specific industries and practices.⁹⁶ For example, a Florida law prohibits unfair practices in the underwriting of insurance with respect to HIV by preventing health insurance policies from limiting coverage for medications or treatments for HIV.⁹⁷ Therefore, this Florida law reduces the possibility that an insurer could unfairly discriminate against an individual purchasing insurance.

In 2014, the AIDS Institute and the National Health Law Program filed a complaint with the Florida Office of Insurance Regulations (“OIR”) against four Florida insurers—Coventry Health Care, Cigna, Humana, and Preferred Medical.⁹⁸ The complainants alleged that the insurers placed all drugs used to treat HIV, including generics, in the highest cost-sharing tier for which a 40–50 percent coinsurance applied.⁹⁹ In comparison, other insurers varied tiering, or placed HIV drugs on more affordable tiers.¹⁰⁰ The complainants argued that the defendants-insurers’ policies violated Florida law by discriminating against

93. CAROLYN L. CARTER, NAT’L CONSUMER L. CTR. INC, CONSUMER PROTECTION IN THE STATES: A 50-STATE REPORT ON UNFAIR AND DECEPTIVE ACTS AND PRACTICES STATUTES 13 (2009), https://www.nclc.org/images/pdf/car_sales/UDAP_Report_Feb09.pdf.

94. JULIE RALSTON AOKI, PUB. HEALTH LAW CTR. AT WILLIAM MITCHELL COLL. OF LAW, CONSUMER PROTECTION: AN OVERVIEW OF STATE LAWS AND ENFORCEMENT 1 (2010), <http://publichealthlawcenter.org/sites/default/files/resources/phlc-fs-agconsumer-2010.pdf>.

95. *Id.*

96. *Id.*

97. FLA. STAT. ANN. § 627.429 (2013); Consent Order, *In Re Cigna Health & Life Ins. Co.*, No. 162232-14-CO (Off. of Ins. Reg. 2014), <http://www.floir.com/siteDocuments/Cigna162232-14-CO.pdf>.

98. AIDS Institute Administrative Complaint, *supra* note 67, at 2.

99. *Id.* at 9.

100. *Id.*

individuals with HIV and deterring such individuals from enrolling in the insurers' QHPs. Several months after the public interest groups filed the complaint, the OIR ultimately settled with all four insurers without making any finding on whether the insurers violated Florida law. But subsequent to the settlement, each insurer agreed to make changes to its drug benefit designs.

Cigna agreed to relocate generic HIV medications to a lower cost tier and cap customers' costs on certain drugs to \$200 per month.¹⁰¹ It also agreed to remove the thirty-day supply limit per prescription for HIV medications. Similarly, Humana agreed to limit its subscribers' cost-sharing responsibilities for all HIV medications and move all such medications below a certain cost to a lower tier.¹⁰² The Cigna and Humana agreements applied only to their exchange plans in Florida, however.¹⁰³ Aetna (which wholly owns Coventry Health) agreed to move nearly all HIV medications across all of its exchange plans nationwide to lower-cost generic or nonpreferred tiers, effective June 1, 2015.¹⁰⁴ Preferred Medical, the last to respond, issued a letter in early 2015 stating that it would cap out-of-pocket costs at \$200 per month for certain HIV medications.¹⁰⁵

Subsequent to the settlement agreements, OIR issued a notice in spring 2015 to all Florida insurers warning them that OIR would begin "reviewing 2016 [QHPs] for possible discriminatory practices in how they cover all prescription medications," and that the office "would deem plans as discriminatory if the tiered formulary of HIV medications was not at least as favorable as the state's benchmark plan."¹⁰⁶ The action taken by OIR is a strong indication that adverse tiering practices may violate UDTP laws, such as Florida law.

101. Associated Press, *Cigna Changes Plan Amid HIV Drug Complaint*, MOD. HEALTHCARE (Nov. 8, 2014), <http://www.modernhealthcare.com/article/20141108/INFO/311089945>.

102. Letter from Steve DeRaleau, President, HumanaOne, & Kevin M. McCarty, Comm'r, Fla. Office of Ins. Regulation, to Kevin M. McCarty, Comm'r, Fla. Office of Ins. Regulation (Dec. 15, 2014), <http://www.theaidsinstitute.org/sites/default/files/attachments/Humana%20Medical%20Plan%20and%20OIR%20agreement%20dec%202014.pdf>.

103. Herman, *supra* note 72.

104. *Id.*

105. Letter from Tamara Meyerson, President & CEO, Preferred Med. Plan, to Kevin M. McCarty, Comm'r, Fla. Office of Ins. Regulation (Jan. 14, 2015), <http://www.miamiherald.com/news/health-care/article7893081.ece/binary/Preferred%20OIR%20Letter.pdf>.

106. Daylina Miller, *Insurance Regulators to Cap HIV Drug Costs*, HEALTH NEWS FLA. (June 29, 2015), <http://health.wusf.usf.edu/post/insurance-regulators-cap-hiv-drug-costs#stream/0>.

C. *Nonmedical Switching*

Nonmedical switching occurs when an insurer requires a stable patient to switch from his or her current, effective medication to a cheaper, alternative drug.¹⁰⁷ An insurer effectuates nonmedical switching by moving a drug to a higher cost tier, increasing the out-of-pocket costs owed after the plan year has begun, or dropping a medication from the formulary altogether. Nonmedical switching does not involve switching a patient from a brand-name drug to a generic drug, but instead, from one drug to an entirely different, therapeutic equivalent.¹⁰⁸ Nonmedical switching is done without consideration of the medical repercussions or reasoning behind the prescriber's selection of the original medication, and often without the prescriber's knowledge.¹⁰⁹

Recent studies have determined that nonmedical switching does not save money or maintain quality of care.¹¹⁰ Instead, nonmedical switching disrupts the individual's medication stability, which can cause adverse reactions and loss of effectiveness, resulting in high-cost medical outcomes.¹¹¹ Yet, many plans continue to employ this bait-and-switch tactic. For example, half of the plans in a 2015 study revised their formularies after the plan year began.¹¹² Of the forty-one plans with revised formularies, thirty-three reduced drug coverage, twenty-seven eliminated coverage for up to seven medications across classes, and six plans removed between fifteen and fifty-seven products, reducing formulary coverage by 6 percent to 63 percent.¹¹³

107. *Non-Medical Switching*, COALITION ST. RHEUMATOLOGY ORG., <http://www.csro.info/Switching> (last visited May 7, 2017).

108. *Id.*

109. *Id.*

110. See, e.g., Bryan R. Cote & Elizabeth A. Petersen, *Impact of Therapeutic Switching in Long-Term Care*, 14 AM. J. MANAGED CARE SP23, SP23 (2008) (concluding that nonmedical switching in long-term care settings increased administrative time, side effects, and downstream costs to plans); D.T. Rubin et al., *P354 Analysis of Outcomes After Non-Medical Switching of Anti-Tumor Necrosis Factor Agents*, EUR. CROHN'S & COLITIS ORG. (2015), <https://www.ecco-ibd.eu/index.php/publications/congress-abstract-s/abstracts-2015/item/p354-analysis-of-outcomes-after-non-medical-switching-of-anti-tumor-necrosis-factor-agents.html> (finding that "non-medical switching of anti-TNF agents was associated with an increase in side effects and lack of efficacy that led to subsequent treatment change as well as increases in health care utilization").

111. *Non-Medical Switching*, *supra* note 107.

112. AVALERE, *supra* note 65.

113. Karyn Schwartz, *New Analysis: Midyear Formulary Changes in Marketplace Plans Can Significantly Reduce Access to Needed Medications for Patients*, PHRMA (Feb. 5, 2015), <http://catalyst.phrma.org/new-analysis-midyear-formulary-changes-in-marketplace-plans-can-significantly-reduce-access-to-needed-medications-for-patients>.

1. State Breach of Contract Claim

An insurance policy is a contract between the insurer and the enrollee; therefore, the insurer has a duty to honor the plan terms as they are written at the start of the plan year, including terms pertaining to the drug formulary, drug tiers, and cost-sharing structure.¹¹⁴ Absent a contract provision granting the insurer a right to unilaterally modify these terms, the insurer breaches its duty to honor the plan language when it engages in nonmedical switching practices. In some states, even if the contract contains a provision permitting a unilateral modification to the plan, such provision may not be valid.¹¹⁵ For example, Utah law states that a modification of an insurance contract during the term of the policy must be in writing and agreed to by the parties against whose interest the modification operates.¹¹⁶

Nonmedical switching may constitute a breach of contract because it is a unilateral change to an insurance policy after the enrollee has enrolled in a plan. To prevail on a claim for breach of contract, the plan enrollee must establish the existence of a contract, an obligation or duty arising out of the contract, a breach of that obligation, and damages caused by the breach.¹¹⁷

Unilateral modifications often cause individuals to incur damages due to the forced change in medication. These damages come in many forms, including health complications due to the regimen change, increased emergency room visits, lab tests, and other costly interventions. For example, in *Taub v. Blue Cross of California*, an insurer sent a letter two months into the plan year to its enrollees stating that it planned to unilaterally reduce the plan's coverage scope by increasing the deductible from \$1,500 to \$1,750. As a result, the plaintiffs filed a suit and argued that the insurer breached its contract with its enrollees by unilaterally changing annual deductibles, copay obligations, and other plan terms and benefits after the plan year had begun, thereby severely degrading the level and quality of health services that enrollees were able to access.¹¹⁸ The insurer argued that its contracts permitted the plan increases with proper notice. The plaintiffs alleged that the insurer breached the terms

114. *Anderson v. Nw. Bell Tel. Co.*, 443 N.W.2d 546, 549 (Minn. Ct. App. 1989).

115. *Seymour v. Blue Cross/Blue Shield*, 988 F.2d 1020, 1024 (10th Cir. 1993).

116. *See id.* (discussing UTAH CODE ANN. § 31-19-26 (repealed 1985)). It should be noted that this statute created an exemption for ERISA plans.

117. *Tsintolas Realty Co. v. Mendez*, 984 A.2d 181, 187 (D.C. 2009).

118. *Taub v. Blue Cross of Cal.*, No. BC457809 (May 31, 2015), http://www.consumerwatchdog.org/resources/kassouf_taub_-_settlement_agreement.5.29.15_noe.pdf (class settlement agreement and release) [hereinafter *Taub*, settlement agreement].

and provisions of the health insurance contract by refusing to pay for benefits promised under the contract.¹¹⁹ The case settled, and in October 2015, Anthem agreed to reimburse 50,000 consumers, totaling around \$8.3 million.¹²⁰ In addition, Anthem agreed to refrain from making subsequent mid-year changes to deductibles, copays, or other plan terms in the future, thereby holding the insurer accountable for the promises it made in the insurance contract.¹²¹

In sum, if an insurer implements nonmedical switching by dropping a medication from the policy's formulary, increasing out-of-pocket spending, or placing the medication on a higher cost tier, it is unilaterally modifying its policy after the plan year has begun. The enrollee incurs damages if an insurer requires an enrollee to pay additional out-of-pocket costs, endure adverse events, or take a different medication. Therefore, given that the policy is a contract between the enrollee and the insurer, the enrollee may have a claim for breach of contract, depending on the contract terms and the jurisdiction.

2. State Breach of Duty of Good Faith and Fair Dealing Claim

Nonmedical switching policies may also result in a breach of duty of good faith and fair dealing.¹²² Every contract imposes a duty of good faith and fair dealing,¹²³ which requires both honesty and reasonableness in the enforcement of the contract.¹²⁴ This duty prevents one contracting party from unfairly frustrating the other party's right to receive the benefits of the agreement actually made.¹²⁵ Courts have found that an insurer has an implied-in-law duty to act in good faith and deal fairly with the plan enrollee to ensure that the enrollee receives the policy benefits.¹²⁶ This protection is in place largely because the enrollee lacks

119. *Id.*

120. Samantha Masunaga, *Anthem Blue Cross to Repay \$8.3 Million to California Customers*, L.A. TIMES (Oct. 27, 2015, 11:55 AM), <http://www.latimes.com/business/la-fi-blue-cross-settlement-20151027-story.html> (discussing the settlement agreed to by Anthem Blue Cross after accusations of breach of contract and engaging in unfair business practices).

121. *Id.*

122. It is important to note that the implied covenant of good faith and fair dealing exists for all contracts. But there is a related tort, referred to as "insurance bad faith." Some courts have conflated the two concepts. This Part refers only to the implied covenant of good faith and fair dealing, whereas the tort of insurance bad faith is discussed in detail, *infra*, Part I.D.5.

123. It should be noted that ERISA preempts any state law claims for breach of duty of good faith and fair dealing. *Dockter v. Aetna Life Co.*, 510 U.S. 917, 919 (1993). Therefore, individuals with employer-sponsored plans should not bring this claim. *Id.*

124. *Florence Urgent Care v. Healthspan, Inc.*, 445 F.Supp.2d 871, 879 (S.D. Ohio 2006).

125. *Guz v. Bechtel Nat'l, Inc.*, 8 P.3d 1089, 1111–12 (Cal. 2000).

126. *E.g.*, *Badillo v. Mid Century Ins. Co.*, 121 P.3d 1080, 1093 (Okla. 2005); *Christian v. Am. Home Assurance Co.*, 577 P.2d 899, 901 (Okla. 1977). In the Fifth Circuit, an insurer breaches the

bargaining power and cannot protect himself or herself from the kinds of hardships that an insurer may impose (e.g., nonmedical switching policies).¹²⁷

When nonmedical switching occurs, either when an insurer drops a medication from a formulary or increases out-of-pocket costs, the insurer breaches its duty to act in good faith and deal fairly because the insurer is frustrating the ability of the enrollee to receive the benefits originally anticipated when the individual signed up for that insurance policy. For example, in *Taub*,¹²⁸ the plaintiffs alleged that the defendant-insurer breached its duty of good faith and fair dealing because it unreasonably changed the scope of coverage under the health insurance contracts after the plan year had begun, and denied enrollees the coverage that they purchased for the entire year, which led to denials of enrollees' insurance coverage claims.¹²⁹ As the proximate result of such unreasonable and bad faith conduct, plaintiffs suffered damages.¹³⁰

In sum, given that insurers contract with plan enrollees, they owe the enrollees a duty of good faith and fair dealing. This duty requires insurers to reasonably guarantee that the enrollees will receive the benefits promised to them. When insurers implement nonmedical switching policies, individuals cannot access medications that the insurer originally promised to cover with the agreed-upon out-of-pocket costs, thereby breaching the duty to act in good faith and deal fairly. Therefore, nonmedical switching could result in a claim for bad faith.

3. State Claim Based on Unfair and Deceptive Trade Practices

Additionally, nonmedical switching may violate states' UDTP laws.¹³¹ For example, in 2011, plan enrollees filed a class action in California against Anthem Blue Cross alleging that Anthem used unlawful bait-and-switch tactics to dramatically increase annual deductibles and other yearly out-of-pocket costs after the plan year had begun, in violation of California's Consumers Legal Remedies Act ("CLRA") and Unfair

duty of good faith and fair dealing if it "has no reasonable basis for denying or delaying payment of a claim." *Henry v. Mut. of Omaha Ins. Co.*, 503 F.3d 425, 429 (5th Cir. 2007) (citations omitted). Therefore, in the Fifth Circuit, a claim alleging a breach of the duty of good faith and fair dealing against an insurer will likely fail if the insurer had any reasonable basis for denying coverage. *Id.*

127. *Christian*, 577 P.2d at 902; *Fletcher v. W. Nat'l Life Ins. Co.*, 10 Cal.App.3d 376, 403-04 (1970).

128. For the facts in this case, see *supra* Part I.C.1.

129. *Taub*, settlement agreement, *supra* note 118.

130. *Id.*

131. See *infra* Part III.B.4 (discussing state legislation aimed at limiting specialty tiers).

Competition Law (“UCL”).¹³² The complaint stated that Anthem violated the CLRA. The plaintiffs further alleged that Anthem marketed its health plans in a misleading manner by stating the plan had “annual” deductibles and other “yearly” benefits and out-of-pocket costs when it did not. The complaint also stated that the defendant unilaterally increased its annual deductibles and out-of-pocket costs after the plan year had begun, thereby forcing plan enrollees to pay more than the plan initially stated; adopted a new contract term that allowed the insurer to change its plan as long as it provided sixty days’ notice to enrollees; and advertised particular services without the intent to sell them.¹³³

Additionally, the plaintiffs argued that Anthem violated the UCL by engaging in unlawful, unfair, and fraudulent business practices, including advertising and soliciting business in an untrue, misleading, and deceptive manner. For example, the plaintiffs argued that the defendant used deceptive coverage descriptions regarding annual deductibles and out-of-pocket costs and benefits; made inaccurate representations about coverage offered; and misleadingly implied that contract terms and benefits remained unchanged throughout a calendar year.¹³⁴

The plaintiffs alleged that they suffered harm as a result of these practices because they had to pay significantly more out-of-pocket costs than they initially agreed.¹³⁵ In April 2015, Anthem settled the class action by agreeing to pay the plaintiffs up to \$8.2 million.¹³⁶ Anthem also agreed that, in the future, it would not make any material modifications after the plan year began to any California-issued individual health plans, unless a change in regulation or law supported such mid-calendar-year modifications.¹³⁷

Nonmedical switching is a unilateral modification to a health plan, often executed in the middle of a plan year, and is analogous to the unilateral modifications at issue in the Anthem Blue Cross class action lawsuit. Enrollees rely on representations and marketing materials regarding the cost and availability of medications when deciding whether to purchase a health insurance plan. By unilaterally changing a drug formulary, removing a drug from the formulary altogether, or increasing cost sharing for the drug, an insurer arguably changes the terms of the plan and forces the plan enrollee either to pay more than promised or to

132. Complaint, *Kassouf v. Blue Cross of Cal.*, No. BC473408, 2011 WL 5561811 (Cal. App. Dep’t Super. Ct. Nov. 4, 2011).

133. *Id.*

134. *Id.*

135. *Id.*

136. Masunaga, *supra* note 120.

137. *Id.*

change the course of treatment and put his or her health at risk. These actions are unfair and deceptive and, therefore, may be actionable under UDTP laws.

D. Prior Authorization

Prior authorization policies require a physician or a plan enrollee to obtain the insurer's advance approval before the insurer will cover the cost of certain treatments and medications.¹³⁸ After the request, the insurer then conducts a review to determine if the treatment is medically necessary. While the definition of "medical necessity" varies from plan to plan, the following definition from New Mexico Administrative Code is an example:

[H]ealth care services determined by a provider, in consultation with the health care insurer, to be appropriate or necessary, according to any applicable generally accepted principles and practices of good medical care or practice guidelines developed by the federal government, national or professional medical societies, boards and associations, or any applicable clinical protocols or practice guidelines developed by the health care insurer consistent with such federal, national, and professional practice guidelines, for the diagnosis or direct care and treatment of a physical, behavioral, or mental health condition, illness, injury, or disease.¹³⁹

The process is often burdensome and can delay or interrupt care, waste time, and complicate medical decisions.¹⁴⁰ It often involves completing various forms using outdated modes of communication (e.g., paper copies submitted via mail or fax) and lengthy follow-up calls.¹⁴¹ A recent study showed that the cost of conducting a standard medical-necessity review often exceeds the savings generated in most areas of medicine.¹⁴² According to a national survey, the prior authorization process costs the

138. Philippe Saxe, *Commentary: Time to Reform Costly, Burdensome Prior Authorization and 'First Fail' Protocols*, PALM BEACH POST (Mar. 2, 2014, 12:00 AM), <http://www.palmbeachpost.com/news/news/opinion/commentary-time-to-reform-costly-burdensome-prior-nd3Zz/>.

139. N.M. CODE R. § 13.10.17.7(AA) (LexisNexis 2017); *Ironworkers Local Union 68 v. Astrazeneca Pharm.*, 634 F.3d 1352, 1367–68 (11th Cir. 2011).

140. John Commins, *Prior Authorization Hurts Patient Care, AMA Survey Finds*, HEALTH LEADERS MEDIA (Nov. 23, 2010), <http://healthleadersmedia.com/content/PHY-259364/Prior-Authorization-Hurts-Patient-Care-AMA-Survey-Finds>.

141. AM. MED. ASS'N, STANDARDIZATION OF PRIOR AUTHORIZATION PROCESS FOR MEDICAL SERVICES WHITE PAPER 10–11 (June 2011), <http://massneuro.org/Resources/Transfer%20from%20old%20sit/AMA%20White%20Paper%20on%20Standardizing%20Prior%20Authorization.pdf> [hereinafter AMA WHITE PAPER].

142. Mark A. Hall, *State Regulation of Medical Necessity: The Case of Weight-Reduction Surgery*, 53 DUKE L.J. 653, 664 (2003).

United States health care system an estimated \$23–31 billion each year.¹⁴³

Moreover, insurers sometimes make prior authorization determinations that are inconsistent with medical standards of care and clinical recommendations. A medical-necessity determination may place too much weight on cost savings rather than on the individual needs of plan enrollees, and initial determinations are often made by insurance representatives without medical training.¹⁴⁴

The prior authorization process is time consuming and can impose a significant impediment to health care. Physicians spend an average of twenty hours per week completing paperwork to satisfy prior authorization requirements for treatments and tests, and it may be weeks before a physician receives a response, thereby causing an unnecessary delay in care.¹⁴⁵ Even a short-term delay in access to medications for conditions such as HIV, cancer, and seizures poses a serious risk to the health and safety of plan enrollees, including permanent damage or death.¹⁴⁶

Additionally, more than half the physicians experience a 20 percent rejection rate from insurers on first-time prior authorization requests for medications.¹⁴⁷ Oftentimes, each insurer may require a different form for each drug prescribed. On top of that, these forms differ from insurer to insurer. The sheer number of forms creates wide room for error, thereby resulting in denials. If the insurer rejects the request for prior authorization, the enrollee can appeal, the provider can recommend an alternative treatment for which he or she might have to restart the prior authorization process from the beginning, the enrollee can pay for the service out of pocket, or, in the worse scenarios, the enrollee might give up and never receive the necessary treatment. For these reasons, approximately 76 percent of physicians have switched treatments at least once to avoid the prior authorization process.¹⁴⁸ As a result, enrollees

143. Christopher P. Morley et al., *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, 26 J. AM. BOARD FAM. MED. 93, 93 (2013).

144. AMA WHITE PAPER, *supra* note 141, at 21.

145. *Id.*

146. Letter from Brenda Tranchida, Dir., Program Compliance & Oversight Grp., Ctr. for Medicare & Medicaid Servs., to Kary Shankar, CEO, Senior Official for Contracting, Fox Ins. Co. (Mar. 9, 2010), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Downloads/Fox_Termination_Letter.pdf [hereinafter Letter from Tranchida to Shankar].

147. AMA WHITE PAPER, *supra* note 141, at 21.

148. FROST & SULLIVAN, THE IMPACT OF THE PRIOR AUTHORIZATION PROCESS ON BRANDED MEDICATIONS: PHYSICIAN REFERENCE, PHARMACIST EFFICIENCY AND BRAND MARKET SHARE

receive the treatment dictated by insurers instead of receiving the best treatment for their condition as determined by their physicians.

1. The Medicaid Act's Payment for Covered Outpatient Drugs Provision

Certain prior authorization policies may violate the Federal Medicaid Act's section on the payment for covered outpatient drugs. The statute states that if the United States Food and Drug Administration ("FDA") approves a drug and the drug's manufacturer has a rebate agreement with HHS, then the drug must be covered by state Medicaid programs, consistent with FDA labeling, and without discrimination in drug coverage.¹⁴⁹ A state "may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition."¹⁵⁰ A Medicaid program must make a drug available whenever medically necessary. But though available, prior authorization may limit payment to the drug's FDA-approved uses.¹⁵¹ If the insurer denies treatment by rejecting the prior authorization request, the Medicaid program must give written notice explaining the reason for denial, provide an appeal, and allow a hearing to the Medicaid enrollee.¹⁵² Despite these requirements, many states have adopted cumbersome, and potentially illegal, prior authorization procedures.

In *B.E. & A.R. v. Teeter*, Medicaid enrollees brought suit against the Washington State Health Care Authority ("WHCA") (i.e., the state Medicaid program) for arbitrarily restricting access to hepatitis C medications.¹⁵³ In their motion for a preliminary injunction, the plaintiffs alleged that the WHCA had instituted overly burdensome prior authorization requirements in violation of the Medicaid Act.¹⁵⁴ The WHCA limited access to a medication that could not only prevent progression of hepatitis C, but could cure the disease altogether in more than 90 percent of individuals, by providing coverage of that medication

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<https://epascorecard.covermymeds.com/images/FrostSullivanPrior%20AuthorizationWhitepaper%20FINAL.pdf> (last visited May 7, 2017).

149. 42 U.S.C. § 1396r-8 (2016).

150. 42 C.F.R. § 440.230 (2012).

151. 42 U.S.C. § 1396r-8.42(d)(4) (2016); 42 C.F.R. § 440.230(d) (2012).

152. U.S. CONST. amend. XIV, § 1; 42 U.S.C. § 1396a(a)(3) (2016); 42 C.F.R. § 431.200 (2017); 42 C.F.R. § 431.221 (2017).

153. *B.E. & A.R. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at *1 (W.D. Wash. May 27, 2016).

154. *Id.*

to only enrollees who had a high fibrosis score (i.e., those whose disease had progressed to the point of liver damage severe enough to require a liver transplant).¹⁵⁵ Pursuant to the WHCA's restriction on this hepatitis C medication, the plaintiffs alleged that the WHCA's prior authorization policies (1) excluded qualified Medicaid recipients from medically necessary treatment; (2) discriminated among similarly situated Medicaid recipients; and (3) failed to provide medically necessary treatment with reasonable promptness.¹⁵⁶

The plaintiffs argued that the medication was medically necessary regardless of a plan enrollee's fibrosis score and unlimited access to it was consistent with the standard of care. Pursuant to the Washington Administrative Code, the WHCA determines whether a service is medically necessary by rating the evidence of a service's effectiveness and safety with a score from "A" to "D."¹⁵⁷ If the service receives a grade of "A" or "B," then it must be approved so long as it does not subject the enrollee "to a greater risk of mortality or morbidity" and "is not more costly" when compared to an equally effective treatment.¹⁵⁸ Though the WHCA gave the medication at issue an "A," and conceded that there was no "equally effective treatment" available, the WHCA offered "monitoring" to enrollees without a high fibrosis score as the "equally effective treatment."¹⁵⁹ But the plaintiffs argued that monitoring alone was not equally effective because waiting until an enrollee's liver is damaged before covering the medication is harmful to the enrollee's health and significantly increases the risk of both morbidity and mortality.¹⁶⁰

The court found that the plaintiffs' evidence would likely establish that the WHCA failed to follow its own definition of medical necessity by merely providing monitoring to certain individuals based on levels of liver damage in lieu of the highly effective medication.¹⁶¹ The court cited CMS' 2015 Notice—"Assuring Medicaid Beneficiaries Access to Hepatitis C Drugs"—in which CMS expressed concern that some states, contrary to statutory requirements, restricted access to hepatitis C medications by imposing prior authorization coverage conditions that unreasonably restricted access to those drugs, such as limiting treatment

155. *Id.*

156. *Id.*

157. WASH. ADMIN. CODE § 182-501-0165 (2017).

158. *Id.* § 182-501-0165(6) (2017); *Teeter*, 2016 WL 3033500, at *2-3.

159. *Teeter*, 2016 WL 3033500, at *3.

160. *Id.* at *4-5.

161. *Id.* at *3-5.

based on the extent of an enrollee's liver damage.¹⁶² Ultimately, the court granted the plaintiffs' motion for preliminary injunction, finding that the plaintiffs were likely to suffer irreparable harm in the absence of an injunction; they were likely to succeed on the merits of their case; a balancing of equities favored the plaintiffs over the state agency; and an injunction would be in the public interest. The court noted that when faced with "a conflict between financial concerns and human suffering, [it had] little difficulty concluding that the balance of hardships tips decidedly in the plaintiffs' favor."¹⁶³ As such, the court enjoined the WHRC from continuing to apply its overly burdensome prior authorization policy and required the agency to provide coverage for prescription medications for hepatitis C without regard to the extent of liver damage.¹⁶⁴

2. The Medicaid Act's Reasonable Promptness Provision

Prior authorization requirements that delay access to medically necessary prescription drugs may also violate the reasonable promptness provision of the Medicaid Act.¹⁶⁵ In some instances, the delay results from a lack of established timelines to respond to prior authorization requests, giving the program leeway to take as long as it wants to provide an answer. In the absence of a specific regulation requiring an established timeline, courts have approved decrees or imposed time limits for the processing of prior authorization requests for Medicaid-covered services.¹⁶⁶

For example, in *Ladd v. Thomas*, Medicaid recipients sued the Commissioner of the Connecticut State Department of Social Services ("DSS") for violating the Federal Medicaid Act, including the reasonable

162. *Id.*; DEP'T OF HEALTH & HUM. SERVS., CTRS. FOR MEDICAID & CHIP SERVS., MEDICAID DRUG REBATE PROGRAM NOTICE: ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C DRUGS (2015), <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf>.

163. *Teeter*, 2016 WL 3033500, at *6 (quoting *Lopez v. Heckler*, 713 F.2d 1432, 1437 (9th Cir. 1983)).

164. Other states, including Delaware, Florida, Massachusetts, New York, and Pennsylvania, have taken measures to remove burdensome prior authorization processes for individuals with hepatitis C. Judith Graham, *Medicaid, Private Insurers Begin to Lift Curbs on Pricey Hepatitis C Drugs*, KAISER HEALTH NEWS (July 5, 2016), <http://khn.org/news/medicaid-private-insurers-begin-to-lift-curbs-on-pricey-hepatitis-c-drugs/>; Jen Rini, *State Changes Hep C Medication Guidelines, Avoids Lawsuit*, NEWS J. (June 10, 2016, 10:53 AM), <http://www.delawareonline.com/story/news/health/2016/06/07/state-changes-hep-c-medication-guidelines-avoids-lawsuit/85554396/>.

165. 42 U.S.C. § 1396a(a)(8) (2016); *see supra* Part I.A.2 (discussing the reasonable promptness provision).

166. *Kirk T. v. Houston*, No. 99-3253, 2000 WL 830731, at *3 (E.D. Pa. June 27, 2000).

promptness provision.¹⁶⁷ The state Medicaid regulations required prior authorization for all rentals of durable medical equipment (“DME”), regardless of cost; all replacement equipment and repairs; and any DME item over \$100.¹⁶⁸ The plaintiffs sought a permanent injunction to impose specific deadlines for the defendant to respond to prior authorization requests for DMEs.¹⁶⁹ The court stated that Medicaid programs must use reasonable promptness in acting on prior authorization requests. It noted that when a state agency fails to promulgate regulations that establish an express time to respond to prior authorization requests, courts are “uniquely suited to determining what is reasonable” under the Medicaid Act.¹⁷⁰ The court then set a twenty-day-turnaround time for such determinations, noting that the DSS’ suggestion of thirty days was unreasonable.¹⁷¹

Similarly, in *Smith v. Miller*, Medicaid providers filed a class action suit against the director of the Illinois Department of Public Aid (“DPA”) alleging that the DPA had not processed prior authorization requests for specialized medical care promptly enough to satisfy the reasonable promptness provision.¹⁷² The plaintiffs sought injunctive relief to establish fixed time limits.¹⁷³ In finding that the failure to promulgate time limits and the resulting delays violated the reasonable promptness provision, the court enjoined the DPA to process such requests within ten to thirty days. If the DPA failed to meet the thirty-day deadline to respond to a request, the court would deem the request automatically approved.¹⁷⁴ The court noted that the “prompt action by the [S]tate is crucial in the medical assistance program . . . because even retroactive payment may not be fully remedial for the delays and ‘delay beyond the time limits may . . . impose lingering, if not irreversible, hardships upon recipients.’”¹⁷⁵ Therefore, if an insurer fails to set a time limit in which it must respond or takes too long to respond to a prior authorization request, a Medicaid enrollee may be able to bring a case for violation of the reasonable promptness provision.

167. *Ladd v. Thomas*, 141 F.Supp.2d 222, 223 (D. Conn. 1998).

168. *Id.*

169. *Id.*

170. *Id.*

171. *Id.*

172. *Smith v. Miller*, 665 F.2d 172, 177 (7th Cir. 1981).

173. *Id.*

174. *Id.*

175. *Kessler v. Blum*, 591 F. Supp. 1013, 1032 (S.D.N.Y. 1984) (citing *Smith*, 665 F.2d at 177).

3. The Medicare Act's Part D Formulary Requirements

Under the Medicare Act, CMS has the authority to issue enforcement actions against Medicare plan sponsors that impose overly restrictive prior authorization policies on enrollees.¹⁷⁶ Each year, CMS reviews Medicare prescription drug plans and their proposed use of prior authorization processes to adjudicate Medicare prescription drug claims ("Part D claims").¹⁷⁷ While Medicare prescription drug plan sponsors are permitted to use prior authorization, pharmacy and therapeutic committees must develop and review such policies, and the sponsor must establish an exception process.¹⁷⁸

Failing to follow these requirements can result in civil money penalties and termination of contracts.¹⁷⁹ For example, in November 2015, SilverScript Insurance Company failed to properly effectuate prior authorization and exception requests and applied unapproved prior authorization policies.¹⁸⁰ As a result, enrollees experienced inappropriate denials of coverage at the point of sale and were delayed access to drugs, never received the drugs, or incurred increased out-of-pocket costs.¹⁸¹ In response, CMS imposed a \$594,100 penalty on the insurance company.¹⁸²

Additionally, Medicare enrollees must have uninterrupted access to all or substantially all of the drugs in six drug classes that CMS has specifically designated. Prescription drug plans are not permitted to require prior authorization policies for enrollees stabilized on drugs from these six protected classes, which include antidepressants, antipsychotics, anticonvulsants for seizures, antiretroviral for treatment of HIV,

176. 42 U.S.C. § 1395w-27(c)(2) (2012) (incorporated into Medicare Part D by 42 U.S.C. § 1395w-112(b)(3)(B)); 42 C.F.R. § 423.509(a) (2008); *Part C and Part D Enforcement Actions*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.html> (last visited May 8, 2017) [hereinafter *Part C and Part D Enforcement*].

177. See 42 C.F.R. § 423.272(b)(2) (2015) (stating plan designs); CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, CMS Pub.100-18, ch. 6, § 30.2 (rev. 18 Jan. 15, 2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> (outlining the review and negotiation process of bids, and approval of plans submitted by potential Part D sponsors).

178. 42 C.F.R. § 423.10(b)(x) (2015).

179. 42 U.S.C. § 1395w-271(2) (2010); *Part C and Part D Enforcement*, *supra* note 176.

180. Letter from Gerard J. Mulcahy, Dir., Medicare Parts C & D Oversight & Enf't Grp., to Todd Meek, President, SilverScript Ins. Co. (Nov. 20, 2015), https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/SilverScript_CMP_11_20_2015.pdf.

181. *Id.*

182. *Id.*

antineoplastic for treatment of cancer, and immunosuppresses to prevent the rejection of transplants.¹⁸³

Enforcement actions can stem from an insurer's failure to comply with CMS' guidelines regarding drug formularies. For example, in 2010, CMS terminated its contract with Fox Insurance Company ("Fox") for imposing improper prior authorization protocols that resulted in imminent and serious risk to the health of enrollees.¹⁸⁴ CMS found that Fox delayed and denied access to medically necessary drugs and therapies in protected classes, including HIV, cancer, and anti-seizure medications, and never obtained approval from CMS for the application of prior authorization criteria for these drugs.¹⁸⁵

Specifically, Fox inappropriately utilized "high-cost edits" (i.e., it flagged drugs in its systems simply because the drugs were expensive or exceeded a certain cost threshold). Health plans can appropriately use high-cost edits to prevent inadvertent overbilling claims. Pharmacists routinely resolve these edits at the pharmacy counter with no significant delays. But Fox inappropriately utilized the edit when it notified the pharmacist that prior authorization requirements—requirements not approved by CMS—had not been met for formulary drugs. Fox's actions resulted in thousands of rejected claims. Inappropriate denials for high-cost drugs forced enrollees to make a decision whether to pay for their drugs out of pocket or forego the life-sustaining medication. Given the low-income status of 90 percent of Fox's enrollees, the option of paying out of pocket proved too cost prohibitive and thus, many enrollees had to leave pharmacies without their prescriptions.

As a result, CMS terminated Fox's Medicare Part D services contract and ordered Fox to immediately repay funds that the government paid to Fox during the month in which the contract was terminated.¹⁸⁶ Therefore, if a prescription drug plan uses prior authorization in an unapproved manner, resulting in inappropriate denials, CMS can take an enforcement action.

4. State Claim Based on Unfair and Deceptive Trade Practices

Prior authorization policies may violate UDTP laws if determinations

183. 42 U.S.C. § 1395w-104(b)(3)(G)(i) (2012); 42 C.F.R. § 423.120(b)(2)(v) (2015); CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, CMS Pub.100-18, ch. 6, § 30.2.5 (rev. 18 Jan. 15, 2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

184. Letter from Tranchida to Shankar, *supra* note 146.

185. *Id.*

186. Fox Ins. Co., Inc. v. Ctrs. for Medicare & Medicaid Servs., 715 F.3d 1211, 1214 (9th Cir. 2013).

are made in a deceptive or misleading manner. An insurer may engage in deceptive trade practices if its actual practices are contrary to those represented to consumers in plan documents.¹⁸⁷ For example, if the insurer makes a medical necessity determination that is inconsistent with the definition of medical necessity in its own policy, such a determination may violate UTDP laws.¹⁸⁸ Additionally, an insurer may also violate UTDP laws if it refuses to pay a claim without conducting a reasonable investigation of medical necessity or makes its decision based on cost alone.¹⁸⁹ As the American Civil Liberties Union has stated in relation to a class action lawsuit against Indiana's Medicaid program, "a medically necessary treatment is a medically necessary treatment, no matter what the cost."¹⁹⁰

In April 2016, New York's attorney general sued Capital District Physician's Health Plan ("CDPHP") for violating the State's UDTP laws for unlawfully restricting coverage of treatment for individuals with hepatitis C.¹⁹¹ Similar to the WHCA in *Teeter*,¹⁹² CDPHP allegedly denied coverage for the treatment unless an enrollee could prove advanced liver damage, as diagnosed by a specialist rather than a primary care provider. CDPHP also restricted coverage to individuals who could prove that they had not used drugs or alcohol within the past six months. Also, if the enrollee did not have liver scarring, the enrollee would have to wait until he or she developed liver scarring before the treatment would be covered.

The attorney general stated that "forcing patients to wait for care, risking internal organ damage . . . violate[d] the law and the company's own policies."¹⁹³ The attorney general further argued that such practice

187. N.M. CODE R. § 13.10.17.7(L) (LexisNexis 2017); *Rodarte v. Presbyterian Ins. Co.*, 371 P.3d 1067 (N.M. Ct. App. 2016).

188. Complaint at 17–19, *New York v. Capital Dist. Physicians' Health Plan, Inc.*, No. 450471 (N.Y. Sup. Ct. Apr. 14, 2016).

189. *Hunter v. Regence Blue Shield*, No. 56638-5-I, 2006 WL 2396643, at *8 (Wash. Ct. App. Aug. 21, 2016) (referring to WASH. ADMIN. CODE § 284-30-330 (2017)).

190. Michael Ollove, *Are States Obligated to Provide Expensive Hepatitis C Drugs?*, PEW CHARITABLE TR., (Feb. 9, 2016), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/02/09/are-states-obligated-to-provide-expensive-hepatitis-c-drugs>.

191. Complaint at 2–3, *Capital Dist. Physicians' Health Plan, Inc.*, No. 450471 (N.Y. Sup. Ct. Apr. 14, 2016); Claire Hughes, *AG Reaches Hepatitis C Agreement with 7 Insurers, but not CDPHP*, TIMESUNION (Apr. 26, 2016, 11:08 PM), <http://www.timesunion.com/local/article/AG-reaches-hepatitis-C-agreement-with-7-insurers-7377599.php>.

192. *B.E. & A.R. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at *1 (W.D. Wash. May 27, 2016).

193. Press Release, Eric T. Schneiderman, Att'y Gen., A.G. Schneiderman Lawsuit Accuses Health Insurer CDPHP of Unlawfully Denying Coverage of Hepatitis C. Treatment (Apr. 14, 2016), <http://www.ag.ny.gov/press-release/ag-schneiderman-lawsuit-accuses-health-insurer-cdphp>

violated New York's UDTP law because CDPHP failed to disclose the role that cost plays in making medical necessity determinations. He argued that the plan documents misled enrollees into believing that medically necessary care would be covered when, in fact, CDPHP refused to cover treatment for hepatitis C consistent with generally accepted standards of care, prevailing medical guidelines, and the FDA-approved indications for the medications on the insurer's formulary.¹⁹⁴ The complaint alleged that, rather than covering care for all enrollees for whom treatment was medically necessary, it only covered treatment for enrollees whose care was deemed *most* medically necessary.¹⁹⁵ The attorney general and CDPHP settled weeks later. CDPHP agreed to change its policy and no longer restricted coverage of certain hepatitis C treatments to individuals with the most severe symptoms.¹⁹⁶ The insurer also stopped denying coverage based on individuals' drug or alcohol use, and began to allow treatment authorization from any trained provider (not just a liver specialist).¹⁹⁷

5. State Common Law Claim for Insurance Bad Faith

An individual may be able to bring a common law claim for insurance bad faith if an insurer implements an overly burdensome prior authorization policy. The tort of insurance bad faith arises out of the implied covenant of good faith and fair dealing and applies when an insurer denies or refuses to settle a claim within policy limits.¹⁹⁸ To recover under a common law claim of bad faith, the plaintiff must show that the defendant did not have a reasonable basis for denying benefits under the policy and that the defendant knew or recklessly disregarded its lack of reasonable basis in denying the claim.¹⁹⁹ For example, an individual may be able to bring a claim for bad faith if the insurer denied his or her claim by interpreting "medical necessity" in a manner that is

unlawfully-denying-coverage.

194. Complaint at 18, *Capital Dist. Physicians' Health Plan, Inc.*, No. 450471 (N.Y. Sup. Ct. Apr. 14, 2016).

195. *Id.*

196. Hughes, *supra* note 191.

197. *Id.*

198. See, e.g., *Anderson v. Cont'l Ins. Co.*, 271 N.W.2d 368, 378 (Wis. 1978) (discussing that there only needs to be a showing of "knowledge or reckless disregard of the lack of a reasonable basis for denying or refusing to honor or negotiate on an insured's claim"); *Crisci v. Sec. Ins. Co.*, 426 P.2d 173, 176-77 (Cal. 1967) (demonstrating instances where courts held against the insurer for breach of implied covenant of good faith).

199. E.g., *Prod. Source Int'l, LLC v. Foremost Signature Ins. Co.*, 195 F.Supp.3d 660 (D.N.J. 2016); *Terletsky v. Prudential Prop. & Cas. Ins. Co.*, 649 A.2d (Pa. Super. Ct. 1994) (explaining the common law burden that the plaintiff must reach to be successful on a claim of bad faith).

inconsistent with the standard of care, by denying coverage for a treatment based on the insurer's desire to decrease costs and increase profits, or unduly delaying payment for treatment.²⁰⁰

The plaintiff may also have to prove that the insurer was motivated by self-interest or ill will.²⁰¹ An insurer cannot shield itself from bad-faith liability by merely investigating a claim in a manner calculated to construct a pretextual basis for denying a claim.²⁰² As part of its common law duty, an insurer has an obligation to conduct an *adequate* investigation before denying a claim.²⁰³ Moreover, if the insurer's conduct is part of a pattern or practice of bad-faith behavior toward its enrollees, a court may award punitive damages.²⁰⁴

Other states have codified bad faith causes of action, and therefore, may not recognize common law actions for bad faith.²⁰⁵ For example, under Colorado law, "a person engaged in the business of insurance shall not unreasonably delay or deny payment of a claim for benefits owed to or on behalf of any first-party claimant."²⁰⁶ Likewise, Montana's unfair claim settlement practices statute provides that an insurer may not conduct the following activities as part of its general business practice: (1) misrepresent pertinent facts or insurance policy provisions relating to coverages; (2) fail to acknowledge and act reasonably promptly in response to claim communications; (3) refuse to pay claims without conducting a reasonable investigation; (4) fail to make good faith attempts for prompt, fair, and equitable settlements of claims if liability

200. Complaint, *Pieper v. UnitedHealth Grp. Inc.*, No. 0:16-cv-00687 (D. Minn. Mar. 16, 2016); see, e.g., *McEvoy by Finn v. Grp. Health Co-op. of Eau Claire*, 570 N.W.2d 397 (Wis. 1997) (explaining that, given health maintenance organization ("HMO") subscribers' inferior position for enforcing their contractual health care rights, the application of the tort of bad faith is an additional means of ensuring that HMOs do not give cost containment and utilization review such significant weight so as to disregard the legitimate medical needs of subscribers).

201. *Andrews v. Merchs. Mut. Ins. Co.*, No. 14-5147, 2016 WL 3690091, at *4 (D.N.J. July 12, 2016).

202. *Tex. Mut. Ins. Co. v. Ruttiger*, 265 S.W.3d 651, 661 (Tex. Ct. App. 2008), *rev'd*, 381 S.W.3d 430 (Tex. 2012); *United Servs. Auto Ass'n v. Croft*, 175 S.W.3d 457, 469–70 (Tex. Ct. App. 2005).

203. *Ruttiger*, 265 S.W.3d at 661.

204. E.g., *Mock v. Mich. Millers Mut. Ins. Co.*, 554 Cal.App.4th 306 (2d Dist. 1992) (showing that a court can award punitive damages if a pattern of bad faith toward an insurer's enrollees is proven).

205. See, e.g., *Spencer v. Aetna Life & Cas.*, 611 P.2d 149, 151–52 (Kan. 1980); see generally *Rossman v. GFG Corp. of Mo.*, 596 S.W.2d 469 (Mo. Ct. App. 1980) (discussing different states' approaches to bad faith causes of actions).

206. COLO. REV. STAT. § 10-3-1115 (2008); *Wilson v. Humana Health Plan, Inc.*, No. 14-cv-03259, 2015 WL 849210, at *5 (D. Colo. 2015). These laws are sometimes referred to as "prompt payment" laws.

is reasonably clear; or (5) force enrollees to institute litigation to obtain reimbursement by offering substantially less than the amounts ultimately recovered in actions brought by the enrollees.²⁰⁷

An insurer's delay or denial is unreasonable "if the insurer delayed or denied authorizing payment of a covered benefit without a reasonable basis for that action."²⁰⁸ In *McEvoy v. Group Health Cooperative of Eau Claire*, a Health Maintenance Organization ("HMO") refused to authorize more than six weeks of inpatient treatment for a thirteen-year-old girl with anorexia despite recommendations from the girl's physicians that she needed to remain in treatment longer.²⁰⁹ Even though the girl had not met her treatment goals, the HMO would only authorize a weekly outpatient group therapy session, not an inpatient treatment. Though plaintiffs typically bring a claim for bad faith against traditional insurers, the court permitted the plaintiff in *McEvoy* to bring the claim against her HMO.²¹⁰ The court noted that the "application of the tort of bad faith is an additional means of ensuring that HMOs do not give cost containment and utilization review such significant weight so as to disregard the legitimate medical needs of subscribers."²¹¹ The court noted that the HMO denied reimbursement without establishing a reasonable basis. While the court stated that reasonably debatable claims were not subject to bad faith claims, it refused to find that the HMO was not required to pay for the plaintiff's extended care simply because the contract required the HMO's prior authorization for the expenditure.²¹² It noted that "[s]uch unilateral authority would give [the HMO] the sole power to determine when and to what extent it would be bound to its subscriber contracts."²¹³ The court, therefore, held that

[w]here an HMO authorizes a referral to an out-of-network provider, the HMO may not end that referral against the recommendation of the treating physicians solely on the basis of cost-containment concerns when the subscriber has not reached the contractual coverage limits.

Thus, such an improper denial can constitute a bad faith denial.²¹⁴

Therefore, enrollees may be able to bring a claim for bad faith for burdensome or abusive prior authorization policies if such policies are

207. MONT. CODE ANN. § 33-18-201 (2015).

208. COLO. REV. STAT. § 10-3-1115 (2008); *Wilson*, 2015 WL 849210, at *5.

209. *McEvoy by Finn v. Grp. Health Co-op of Eau Claire*, 570 N.W.2d 397, 400-01 (Wis. 1997).

210. *Id.* at 405.

211. *Id.* at 403.

212. *Id.* at 404-05.

213. *Id.* at 404.

214. *Id.* at 404.

misleading, result in undue delay in payment, are inconsistent with standards of care, or are based on cost containment alone.

E. Network Adequacy

Network adequacy “refers to a health plan’s ability to deliver the benefits promised by providing reasonable access to a sufficient number of in-network primary care and specialty physicians, as well as all health care services included under the terms of the contract.”²¹⁵ For a network to be considered adequate, it must offer access to adequate care, at the appropriate time, and without requiring an unreasonable amount of travel.²¹⁶ By contrast, inadequate networks often result in individuals forgoing treatment or paying large sums out of pocket to see more conveniently located out-of-network providers.²¹⁷ Overly “narrow network” schemes designed to limit access to quality health care providers are increasingly restricting access to quality health care.²¹⁸ For example, if a network has an insufficient number of in-network providers, the plan enrollee may be forced to see an out-of-network provider.

Moreover, while the ACA limits out-of-pocket costs for the 2017 plan year to \$7,150 for individuals and \$14,300 for families, these limits do not apply to any services provided by an out-of-network provider.²¹⁹ Therefore, if an individual were to obtain treatment from an out-of-network provider at an in-network hospital, he or she may receive a surprise medical bill—an occurrence that one in five individuals who visit the emergency department have faced.²²⁰

1. Federal Claim Based on the ACA’s Network Adequacy Standards

The ACA established network adequacy standards for QHPs, which gave lawmakers and policymakers a vehicle for ensuring standards are met and consumer needs are addressed.²²¹ ACA regulations require plans to ensure that their networks include essential community providers and

215. *Network Adequacy*, NAT’L ASS’N INS. COMMISSIONERS (July 14, 2016), http://www.naic.org/cipr_topics/topic_network_adequacy.htm.

216. 45 C.F.R. § 156.230 (2012).

217. *Network Adequacy*, *supra* note 215.

218. *Id.*

219. Matthew Rae et al., *Patient Cost-Sharing in Marketplace Plans, 2016*, KAISER FAM. FOUND. (Nov. 13, 2015), <http://kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016/>.

220. Dan Mangan, *Many Get Hit with Surprise ‘Out-of-Network’ Bill After Emergency Rooms: Study*, CNBC (Nov. 16, 2016, 5:00 PM), <http://www.cnbc.com/2016/11/16/many-get-hit-with-surprise-out-of-network-bill-after-emergency-rooms-study.html>.

221. *Network Adequacy*, *supra* note 215.

maintain sufficient numbers and types of providers.²²² Insurers offering QHPs must publish up-to-date, accurate, and complete provider directories online.²²³ The general public must be able to view all current providers for a plan in the provider directory on the plan issuer's public website through a clearly identifiable link or tab.²²⁴ If an insurer or self-funded nonfederal governmental group plan fails to meet the ACA's network adequacy requirements, an individual can file a complaint with the State under the Public Health Services Act.²²⁵ Given the recent enactment of the ACA and this requirement, no complaints appear to be filed alleging ACA violations for narrow networks as of yet, but if an insurer were to fail to meet the network adequacy requirements under the ACA, filing a complaint is an option.

2. CMS' Transparency Rule

Failure to provide accurate network directories may violate CMS rules. As of 2016, CMS requires Medicare Advantage Organizations ("MAOs"), public or private organizations that states license to provide services to Medicare beneficiaries, to communicate at least every three months with providers to ascertain their availability and whether they are accepting new patients.²²⁶ CMS also expects MAOs to update their online provider directories in real time and provide complete information on all active contracted providers, including notations highlighting providers who are closed or not accepting new patients.²²⁷ In a separate rule, CMS requires insurers to provide online and to update monthly

222. *Id.* An "essential community provider" is a provider that serves predominantly low-income, medically underserved individuals, including a health care provider; a state-owned family planning service site; governmental family planning service site; or not-for-profit family planning service site that does not receive federal funding under special programs.

223. *Id.*

224. *Id.*

225. The Public Health Services Act contemplates the states as being the primary enforcers of the ACA's private health insurance market reforms. But if the Secretary of the United States Department of Health and Human Services ("HHS") determines that a state has failed to substantially enforce a provision, including the ACA's network adequacy requirements, HHS may take enforcement action and impose civil penalties. 42 U.S.C. § 300gg-22(a)(2), (b)(2) (2012); Jennifer Staman, *Enforcement of Private Health Insurance Market Reforms Under the Patient Protection and Affordable Care Act (PPACA)*, CONG. RES. SERVS. 1, 5 (Feb. 7, 2011).

226. Brian Eastwood, *CMS Tighten Provider Directory Rules for 2016*, FIERCE HEALTHCARE (Mar. 9, 2015, 12:01 PM), <http://www.fiercehealthcare.com/payer/cms-tightens-provider-directory-rules-for-2016>.

227. CTRS. FOR MEDICARE & MEDICAID SERVS., ADVANCE NOTICE OF METHODOLOGICAL CHANGES FOR CALENDAR YEAR (CY) 2016 FOR MEDICARE ADVANTAGE (MA) CAPITATION RATES, PART C AND PART D PAYMENT POLICIES AND 2016 CALL LETTER (Feb. 20, 2015), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2016.pdf>.

directories for QHPs sold in federally facilitated marketplaces.²²⁸ MAOs providing inaccurate directories face a penalty fine of up to \$25,000 per day per enrollee or restrictions on new enrollment and marketing.²²⁹ Plans sold on the federal exchange face penalties of up to \$100 a day per affected enrollee for deficient directories.²³⁰ It appears that no enforcement actions have been taken yet pursuant to violations of these transparency rules.

3. State Claim Based on Network Adequacy Laws

Narrow networks may also violate state network adequacy laws. State approaches to regulating network adequacy vary widely, due in part to a state's need to "maintain robust health insurance markets by balancing access needs with the goals of controlling costs and attracting a healthy number of insurers."²³¹ For example, in some states, network adequacy rules may only apply to certain subsets of plans.²³² Furthermore, while some states do not use quantitative standards to measure adequacy, a majority of states have at least one quantitative standard (e.g., standards related to maximum travel time or distance, provider-to-enrollee ratios, maximum appointment waiting times, and hours of operation).²³³ State regulations also differ on whether regulators have the authority to conduct ongoing oversight investigations.²³⁴

In California, network adequacy regulations require insurers offering individual health or group disability insurance to ensure that "network providers . . . are sufficient in number, capacity, and specialty to be capable of furnishing the health care services covered by the insurance contract, taking into account the number of covered persons, their

228. CTRS. FOR MEDICARE & MEDICAID SERVS., FINAL 2016 LETTER TO ISSUERS IN THE FEDERALLY-FACILITATED MARKETPLACES (Feb. 20, 2015), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016_Letter_to_Issuers_2_20_2015.pdf.

229. Susan Jaffe, *Obamacare, Private Medicare Plans Must Keep Updated Doctor Directories in 2016*, KAISER HEALTH NEWS (Mar. 9, 2015), <http://khn.org/news/health-exchange-medicare-advantage-plans-must-keep-updated-doctor-directories-in-2016/>.

230. *Id.*

231. Sally McCarty & Max Farris, *ACA Implications for State Network Adequacy Standards*, STATE HEALTH REFORM ASSISTANCE NETWORK, ROBERT WOOD JOHNSON FOUND. 1, 1 (Aug. 2013), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2013/rwjf407486.

232. Justin Giovannelli, *Implementing the Affordable Care Act: State Regulation of Marketplace Plan Provider Networks*, COMMONWEALTH FUND (May 5, 2015), <http://www.commonwealthfund.org/publications/issue-briefs/2015/may/state-regulation-of-marketplace-plan-provider-networks>.

233. *Id.*

234. *Id.*

characteristics and medical needs.”²³⁵

The regulations also incorporate quantitative adequacy measures. These measures may include having a particular number of full-time physicians, including primary care physicians, per enrollees; a sufficient number of primary care providers, mental health professionals, and network hospitals within thirty minutes of an enrollee’s residence or workplace; and a sufficient number of specialists accepting new patients within sixty minutes of an enrollee’s residence or workplace.²³⁶ Other regulations include standards on hours of operation²³⁷ and several quantitative and nonquantitative standards related to appointment waiting times.²³⁸

The California Department of Insurance is responsible for oversight and enforcement of the regulations cited above.²³⁹ Consumers may reference their state’s network adequacy laws and regulations or consult their state’s insurance department for more information. If a consumer believes that an insurer is in violation of a network adequacy standard, the consumer may file a complaint with his or her state’s insurance department. But while network adequacy laws and regulations exist, courts tend to favor the defendant.²⁴⁰

4. State Breach of Contract Claim

If a Medicare Advantage (“MA”) insurance provider terminates its contract with health care providers midyear, such a bait-and-switch tactic to narrow the network can result in a breach of contract claim. For example, in *Fairfield County Medical Association v. United Healthcare of New England*, two professional organizations sued United Healthcare (“United”) on behalf of approximately 2,200 physicians that United terminated “without cause” from its MA program.²⁴¹ United sent the physicians a letter notifying them that they would be removed from United’s MA network in approximately three months.²⁴² The insurer characterized the change as an “amendment” to its contract with the

235. CAL CODE REGS. tit. 10, § 2240.1(b)(1) (2017).

236. *Id.* § 2240.1(c).

237. *Id.* § 2240.15.

238. *Id.* § 2240.1(b)(4).

239. The 12921 California Department of Managed Health Care enforces separate network adequacy laws related to HMOs and preferred provider organizations (“PPOs”).

240. *E.g.*, *Appalachian Reg’l Healthcare, Inc. v. Coventry Health & Life Ins. Co.*, 714 F.3d 424 (6th Cir. 2013); *Capital Health Sys., Inc. v. N.J. Dep’t of Banking & Ins.*, 139 A.3d 134 (N.J. Super. Ct. App. Div. 2016).

241. 985 F.Supp.2d 262, 266 (D. Conn. 2013).

242. *Id.*

physicians.²⁴³ The physicians argued that United's actions constituted a breach of contract and sought an injunction to prevent the unilateral termination.²⁴⁴

The court held that United's argument that it had a unilateral right to terminate participating providers from the MA plan by an "amendment" of that plan is not supported by the language of the contract or the parties' experience under it.²⁴⁵ Furthermore, it held that the providers who were subject to the termination notices would suffer irreparable harm due to "(1) disruption of their relationships with their Medicare Advantage patients, (2) loss of goodwill and reputational harm, and (3) a resulting loss of ability to compete in the market for provision of Medicare services."²⁴⁶ The court found that even if the providers were to prevail on their claim against the insurer, it was unlikely that the former patients would return to the providers once they rejoined the network because most patients would have found other providers in the meantime.²⁴⁷ Therefore, the court granted the providers a preliminary injunction preventing United from removing the affected physicians from its MA network based on their breach of contract claim.²⁴⁸

5. State Claim Pursuant to Unfair and Deceptive Trade Practice Laws

Narrow network schemes may violate state UDTP laws. For example, California's CLRA prohibits any person from committing certain "unfair methods of competition and unfair or deceptive acts or practices in a transaction intended to result or which results in the sale or lease of goods or services to any consumer."²⁴⁹ The California statute instructs courts to liberally construe and apply its underlying purpose (i.e., "to protect consumers against unfair and deceptive business practices and to provide efficient and economical procedures to secure such protection").²⁵⁰ Prohibited practices include (1) representing that services have approval, characteristics, uses, or benefits that they do not have;²⁵¹ (2) advertising services with the intent not to sell them as advertised;²⁵² (3) representing that a transaction confers or involves certain rights, remedies, or

243. *Id.*

244. *Id.*

245. *Id.*

246. *Id.*

247. *Id.*

248. *Id.*

249. CAL. CIV. CODE § 1770(a) (West 2017).

250. *Id.* § 1760.

251. *Id.* § 1770(a)(5).

252. *Id.* § 1770(a)(9).

obligations which it does not have;²⁵³ and (4) inserting an unconscionable term in a contract.²⁵⁴

Similarly, the UCL is designed to protect consumers and business competitors from unfair business practices. The UCL contains a general, broad prohibition against unfair competition, which is defined as including “any unlawful, unfair or fraudulent business act or practice.”²⁵⁵

In July 2014, a California class of plaintiffs filed a lawsuit against Blue Cross of California alleging that the insurer canceled all of its existing non-ACA-compliant health plans and only made available new ACA-compliant plans.²⁵⁶ According to the complaint, Blue Cross marketed and represented its new plans as having specific in-network physicians and hospitals, and then reduced these networks during the open enrollment period. Consumers did not discover that the networks did not include the providers that Blue Cross represented as “in-network” until after they were already enrolled in the new plans.

The plaintiffs and class members alleged that “Blue Cross’s bait-and-switch tactics of representing and advertising that its [health plans had] certain providers in the plans’ networks when those providers [were] not actually in the plans’ networks” violated the CLRA.²⁵⁷ Specifically, they alleged that Blue Cross (1) represented that the health plans had provider network characteristics that they did not have; (2) advertised health plans as having provider network characteristics with the intent not to sell them as advertised; (3) represented that a transaction conferred certain provider network rights, remedies, or obligations which they did not have; and (4) adopted “unconscionable contract provisions requiring undisclosed higher deductible limits for out-of-network providers, adopting inadequate provider networks, and concealing material terms of the coverage.”²⁵⁸

The complaint also contained allegations that Blue Cross violated the UCL because Blue Cross’s actions were unlawful, unfair, and fraudulent business practices.²⁵⁹ Although Blue Cross did not admit to any wrongdoing, it settled the case, along with three other class action suits against it, in March 2016.²⁶⁰ Blue Cross agreed to reimburse class

253. *Id.* § 1770(a)(14).

254. *Id.* § 1770(a)(19).

255. CAL. BUS. & PROF. CODE § 17200 (West 2017).

256. Complaint at 2, *Felser v. Blue Cross of Cal.*, No. BC550739 (Cal. App. Dep’t Super. Ct. July 8, 2014).

257. *Id.* at 5.

258. *Id.* at 3–4.

259. *Id.* at 5.

260. Amended Class Settlement Agreement and Release at 3, *Felser*, No. BC550739 (Cal. App.

members for all of their out-of-pocket expenses for the period at issue, with an estimated aggregate total of approximately \$15 million.

F. Clinical Pathways Programs

Clinical pathways are “multidisciplinary care plans that provide specific guidance on the sequencing of care steps and the timeline of interventions” to influence practitioners’ treatment decisions.²⁶¹ When an independent panel with proper medical or scientific training creates clinical pathways, they may be an appropriate tool to guide a physician’s treatment decisions. But insurers use their own, internally developed clinical pathways to steer providers toward their preferred sequence of treatment by offering them a financial incentive or disincentive.²⁶² For example, WellPoint offers oncologists monthly payments of \$350 for each patient treated in compliance with the insurer’s recommended treatment pathways.²⁶³ A recent survey of managed care insurers showed that 46 percent of network physicians are provided with financial incentives to follow the pathways, 38 percent are encouraged but not incentivized, and 23 percent are required to follow the pathways to remain in the plan’s network.²⁶⁴

The growing use of financial incentives to encourage the promotion of certain treatments over others is unethical and creates a conflict of interest. Practicing physicians have a moral obligation to use sound, professional judgment when making treatment decisions. Physicians must recommend treatments that are best suited for their patients, and not those that would provide them with greatest financial gain.

Clinical pathways also limit patient access to new and effective treatments and technologies, discourage personalized care, are not suitable for unusual or unpredicted conditions, and do not respond to unexpected changes to an individual’s condition.²⁶⁵ Instead, clinical pathways are designed to align treatment protocols with insurers’

Dep’t Super. Ct. Mar. 18, 2016).

261. AVALERE HEALTH LLC, CLINICAL PATHWAYS: OVERVIEW OF CURRENT PRACTICES AND POTENTIAL IMPLICATIONS FOR PATIENTS, PAYERS, AND PROVIDERS 4 (2015).

262. *Id.* at 10. Hereinafter, please note that “clinical pathways” refers to insurer-driven clinical pathways, and not those that are developed by medical and scientific experts, hereinafter. *Id.* at 6.

263. Anna Wilde Mathews, *Insurers Push to Rein in Spending on Cancer Care*, WALL STREET J. (May 27, 2014, 3:51 PM), <http://www.wsj.com/articles/insurer-to-reward-cancer-doctors-for-adhering-to-regimens-1401220033>.

264. *Clinical Pathways: An Evolutionary Approach to Cancer Care*, ONELIVE (June 14, 2013), <http://www.onclive.com/publications/oncology-business-news/2013/april-2013/clinical-pathways-an-evolutionary-approach-to-cancer-care/1>.

265. *Clinical Pathways: Multidisciplinary Plans of Best Clinical Practice*, OPEN CLINICAL, <http://www.openclinical.org/clinicalpathways.html> (last visited Apr. 17, 2017).

interests (i.e., cost reduction).²⁶⁶

1. State Medical Practice Acts

Clinical pathways may cause health care practitioners to violate state medical practice acts. All fifty states have enacted medical practice acts, which set out the structure and responsibilities of a state's medical board.²⁶⁷ State statutes and regulations define unethical conduct and authorize a state's medical board to receive complaints, perform investigations, and discipline medical professionals for committing acts prohibited by the statute.²⁶⁸ If deemed to be in violation of the law, some states permit the state medical board to revoke a physician's license to practice medicine, place a physician on probation, or impose any other sanctions authorized by the law.²⁶⁹

Nevada's medical practice act ("Nevada Act"), for example, provides at least four grounds by which a physician could be disciplined for following an insurer's incentive-based pathway. First, the Nevada Act states that the medical board may initiate disciplinary action or deny a license if a physician engages in conduct "that violates the trust of a patient and exploits the relationship between the physician and the patient for financial or other personal gain."²⁷⁰ By accepting an incentive from an insurer for administering care according to the insurer's pathway, the physician exploits the physician-patient relationship for financial gain where the patient would be better served under an alternative treatment regimen.

Second, physicians are subject to discipline when they receive from "any person, corporation or other business organization any fee, commission, rebate or other form of compensation which is intended or tends to influence the physician's objective evaluation or treatment of a patient."²⁷¹ Under an incentive-based clinical pathway program, the physician receives, and the insurer pays, a cash incentive for which the insurer intends to influence the physician to care for a patient according to the insurer's cost-based pathway. Therefore, this program provides a prohibited reward to influence a physician's views and treatment

266. Roxanne Nelson, *WellPoint Offers Oncologists Incentives to Follow Pathways*, MEDSCAPE MED (June 12, 2014), <http://www.medscape.com/viewarticle/826681>.

267. FED'N OF STATE MED. BDS, U.S. MEDICAL REGULATORY TRENDS AND ACTIONS 6 (2016).

268. *Id.*

269. *Investigations Division—Frequently Asked Questions*, NEV. STATE BOARD MED. EXAMINERS, http://medboard.nv.gov/Resources/FAQs/Investigations_Division/ (last visited Apr. 26, 2017).

270. NEV. REV. STAT. ANN. § 630.301(7) (2016).

271. *Id.* § 630.305(1)(a).

decisions.

Third, the Nevada Act allows the medical board to discipline physicians who fail to disclose to a patient any conflicts of interest. Clinical pathway programs could create a conflict of interest when an insurer provides an incentive to a physician as a way to influence the physician's patient-care decisions. Therefore, if physicians fail to notify their patients of such conflict, they could be subjected to discipline.

Finally, the Nevada Act authorizes the state medical board to initiate disciplinary proceedings where a physician "engages in conduct that brings the medical profession into disrepute."²⁷² Given that clinical pathway practices create conflicts of interest, they have the potential to affect a physician's objective medical judgment and violate patients' trust. Therefore, a state medical board could potentially bring a disciplinary action here if it could prove that these programs negatively tainted the reputation of the medical profession.

2. State Commercial Bribery Statutes

Commercial bribery is generally understood as giving, or offering to give, something of value with the intent to influence a relation between commercial parties.²⁷³ Generally, laws prohibiting commercial bribery are based upon agency principles regarding the impropriety of influencing an agent to breach a duty it owes to a principal.²⁷⁴ But the formulation of commercial bribery statutes varies from state to state, differing in degrees of culpability, levels of intent or knowledge required, and the relationship among the parties involved.²⁷⁵ Despite these variations, many commercial bribery statutes are arguably broad enough to encompass an insurer's offer of incentives as a means of influencing a physician to follow the insurer's clinical pathway.

Connecticut's law is representative of states with broad commercial bribery statutes.²⁷⁶ In Connecticut, an offeror violates the statute where he or she "confers, or agrees to confer, any benefit upon any employee, agent or fiduciary without the consent of the latter's employer or principal, with intent to influence his conduct in relation to his employer's

272. *Id.* § 630.301(9).

273. James G. Park, *Extraterritorial Impact of United States Antitrust Laws and Commercial Bribery Consideration*, 1 DICKINSON INT'L L. ANN. 105, 119 (1982); Ryan J. Rohlfen, *Recent Developments in Foreign and Domestic Criminal Commercial Bribery Laws*, 2012 U. CHI. LEGAL F. 151, 163.

274. Rohlfen, *supra* note 273, at 151.

275. *Id.* at 163.

276. Illinois, New York, Kentucky, North Dakota, South Dakota, and Alabama also have laws with similar language. *Id.* at 165, 172, 174, 185.

or principal's affairs."²⁷⁷ An employee, agent, or fiduciary who receives such a benefit violates the statute when, "without the consent of his employer or principal, he solicits, accepts or agrees to accept any benefit from another person upon an agreement or understanding that such benefit will influence his conduct in relation to his employer's or principal's affairs."²⁷⁸

It is not uncommon for states to pursue claims against health care professionals under commercial bribery laws. In June 2015, five doctors were indicted in New Jersey for commercial bribery for referring patients to a medical imaging center in exchange for cash and other kickbacks.²⁷⁹ Discussing the indictment, acting Attorney General Hoffman said, "[a] doctor's duty is to his patients' care and well-being, not to his personal wealth. By allegedly selling their medical opinion for kickbacks, the five medical practitioners indicted today have abandoned that duty, thus breaking the law and the trust of those who sought their advice."²⁸⁰

An insurer offering incentives to a physician under a clinical pathway arrangement is no different than the owner of a medical imaging center who offers incentives for referrals. In both instances, an offer of cash is made, without the patient's consent, and with intent to influence the physician's conduct in relation to the patient's affairs. Under the plain language of a Connecticut's commercial bribery statute, the insurer (i.e., the offeror of the benefit), would fall within the reach of the statute.

Pursuant to the New Jersey indictment, physicians participating in a kickback scheme fall within the reach of state commercial bribery statutes. But it is unclear whether a physician participating in a clinical pathways arrangement violates a state commercial bribery statute. Under such arrangement, the physician, as the patient's fiduciary,²⁸¹ accepts a cash incentive from the insurer without the patient's consent. Therefore, the clinical pathways arrangement violates the statute if a plaintiff can show that the physician accepted the incentive knowing the benefit would influence him or her to follow the insurer's lower-cost treatment pathway.

277. CONN. GEN. STAT. § 53a-160 (2015).

278. *Id.* § 53a-161.

279. *Five Medical Practitioners Indicted for Taking Bribes in Exchange for Referring Patients to Medical Imaging Centers Run by Criminal Enterprise*, STATE N.J. DEP'T L. & PUB. SAFETY, OFF. ATT'Y GEN. (June 3, 2015), <http://nj.gov/oag/newsreleases15/pr20150603a.html>.

280. *Id.*

281. Courts have long recognized that a physician is a fiduciary to his or her patients. *See, e.g., Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972) (noting that a doctor-patient relationship has "fiducial qualities"); *United States v. Neufeld*, 908 F. Supp. 491, 500 (S.D. Ohio 1995) (noting that the "elements of a fiduciary relationship" exist in doctor-patient relationship); *Stafford v. Shultz*, 270 P.2d 1, 7 (Cal. 1954) (finding a doctor-patient fiduciary relationship).

A physician may argue in defense that he or she did not know the benefit would influence his or her decision. But one study analyzing the dynamics between physicians and prescription drug representatives concluded that, even though physicians recognized the conflict of interest and understood the concept in general, the relationship with the drug representative created psychological dynamics that influenced physicians' reasoning.²⁸² Another recent study revealed that payments received from the medical industry affect doctors' prescribing practices.²⁸³ According to the study, on average, doctors who receive payments from an interested party prescribe drugs differently than doctors who do not accept payments.²⁸⁴ For example, the more money a doctor receives, the more brand-name medications he or she tends to prescribe.²⁸⁵ The same principles apply when the insurer offers incentives to the provider. Therefore, a physician may be indicted under a state commercial bribery statute for accepting incentives to follow an insurer's clinical pathway.

3. State Ethics

Clinical pathways may also violate ethical standards for which many prescribers take an oath to uphold. For example, the American Medical Association ("AMA") first adopted its code of medical ethics ("Code") in 1847 in an effort to establish uniform standards for professional education, training, and conduct.²⁸⁶ Nearly 170 years later, the ever-evolving Code is still the authoritative ethics guide for practicing physicians, reflecting the profession's core values and how they apply in day-to-day practice.²⁸⁷ The Code covers a wide range of topics, including the physician-patient relationship, conflicts of interest, and gifts from members of the health care industry.

While the AMA is a voluntary organization, and therefore, prescribers are not legally required to comply with the Code,²⁸⁸ a violation of the

282. Susan Chimonas et al., *Physicians and Drug Representatives: Exploring the Dynamics of the Relationship*, 22 J. GEN. INTERNAL MED. 184, 189 (2007).

283. Charles Ornstein et al., *Drug-Company Payments Mirror Doctors' Brand-Name Prescribing*, NPR (Mar. 17, 2016, 5:00 AM), <http://www.npr.org/sections/health-shots/2016/03/17/470679452/drug-company-payments-mirror-doctors-brand-name-prescribing>.

284. *Id.*

285. *Id.*

286. *AMA History*, AM. MED. ASS'N, <https://www.ama-assn.org/ama-history> (last visited Apr. 17, 2016).

287. *Id.*

288. AM. MED. ASS'N, *Preamble, Principles of Medical Ethics*, in ASS'N, *AMA CODE OF MEDICAL ETHICS* 1, <https://www.ama-assn.org/sites/default/files/media-browser/principles-of-medical-ethics.pdf> (last updated June 2001).

Code can have significant consequences at the state level. For example, Kentucky’s medical practice act incorporates the Code by reference and provides that the State’s board of medical licensure may deny an application or reregistration for a medical license; place a licensee on probation; suspend a license; limit or restrict a license for an indefinite period; or revoke any license issued by the board, upon proof that the licensee has “[e]ngaged in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public or any member thereof.”²⁸⁹ “Unethical conduct” includes a failure to conform to the principles of medical ethics of the AMA.²⁹⁰ Therefore, a violation of the Code may have serious disciplinary repercussions at the state level, including losing the license to practice medicine.

The Code describes the physician-patient relationship as one based on trust, “giving rise to the physicians’ ethical obligations to place patients’ welfare above their own self-interest and above obligations to other groups, and to advocate for their patients’ welfare.”²⁹¹ This basic tenet is the foundation for several sections of the Code dedicated to conflicts of interest, which require physicians to avoid such conflicts and to resolve any conflicts that may arise to the patient’s benefit.²⁹² Furthermore, a physician must avoid conflicts of interest to satisfy the guidelines related to a patient’s right to informed consent, whereby the physician “has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice.”²⁹³

The Code’s guidelines on gifts from pharmaceutical, biotechnology, and medical device companies adequately illustrate these principles. Due to concerns that these gifts can create conditions that may bias, or be perceived to bias, a physician’s professional judgement in caring for patients, the Code states that, to “preserve the trust that is fundamental to the physician-patient relationship and public confidence in the profession, physicians should . . . decline cash gifts in any amount from

289. KY. REV. STAT. ANN. § 311.595(9) (2017).

290. *Id.* § 311.597.

291. AM. MED. ASS’N, *The Physician-Patient Relationship*, in AMA CODE OF MEDICAL ETHICS 1.1.1 (2016), <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-1.pdf>.

292. AM. MED. ASS’N, *Opinions on Financing & Delivery of Health Care*, in AMA CODE OF MEDICAL ETHICS: OPINIONS ON FINANCING & DELIVERY OF HEALTH CARE 5 (2016), <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-2.pdf>.

293. AM. MED. ASS’N, *Informed Consent*, in AMA CODE OF MEDICAL ETHICS: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING 2 (2016), <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-2.pdf>.

an entity that has a direct interest in physicians' treatment recommendations."²⁹⁴

While the Code does not have specific guidelines on incentives from insurance companies, incentive-based clinical pathways similarly create a conflict of interest that may directly violate the Code's guidelines on the physician-patient relationship and avoiding conflicts of interest. By giving physicians incentives to follow the insurer's pathway, the physician is forced to decide between the insurer's cost-saving pathway and a treatment plan that may be better suited for a specific patient's health care needs. If the physician follows the insurer's pathway instead of choosing a treatment most suitable for the patient's individual needs, then the physician may violate the Code by failing to resolve the conflict in favor of the patient. Therefore, to avoid conflicts of interest and preserve the trust that is fundamental to the physician-patient relationship, physicians should decline cash incentives from insurers just as they should decline cash gifts from other participants in the health care industry.

III. RECOMMENDATIONS

Health care must be patient centered. Physicians need the autonomy to independently consider a patient's unique circumstances, recommend a course of treatment that is most appropriate for the patient, and have confidence that the patient will receive that prescribed medication. Consumers must be empowered to bring lawsuits or file complaints so that they not only obtain remedies for any sustained wrongdoing derived from the lack of treatment access, but also to serve as a powerful deterrent for bad actors in the insurance industry.

Additionally, where piecemeal lawsuits and investigations prove to be an insufficient deterrent to systematically prevent insurers from blocking access to care, lawmakers must take action to limit each of the specific insurance practices that interfere with the physician-patient relationship. While some states have already passed consumer-protection legislation addressing some of the unfair business practices discussed above, many states have yet to do so. These laws must contain key provisions with strong language to ensure their effectiveness. Furthermore, current and future laws need to be enforced and, in some cases, state lawmakers need to increase the enforcement authority of their state's insurance commissioners and attorneys general.

294. AM. MED. ASS'N, *Gifts to Physicians from Industry*, in *AMA CODE OF MEDICAL ETHICS: OPINIONS ON FINANCING & DELIVERY OF HEALTH CARE* 9 (2016), <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-9.pdf>.

A. Empowering Consumers to Take Action

In addition to strong enforcement by state and federal regulators, educating, empowering, and encouraging consumers to take action would help create disincentives for insurers to continue to implement unfair and discriminatory policies. If an insurer uses a benefit utilization management policy in a discriminatory manner, enrollees have several options at their disposal that they can use to protect and enforce their rights.

The first step is to appeal an adverse benefit determination. The ACA requires insurers to strictly follow specific rules prior to rendering adverse benefit determinations.²⁹⁵ For instance, the insurer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision.²⁹⁶ The insurer may not reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review.²⁹⁷ As such, if coverage has been denied, the enrollee should request a copy of the denial letter explaining the reason for any denial of reimbursement or payment and disclosure of the criteria for medical necessity determinations. He or she should then file an internal appeal in which his insurance company conducts its own full and fair review of its decision.²⁹⁸ It is important to note that the ACA and its interim final regulations require an insurer to provide continued coverage pending the outcome of an internal appeal.²⁹⁹

If the internal appeal is unsuccessful, the enrollee may then request an external review in which an independent third party reviews the decision.³⁰⁰ It may be necessary to seek the assistance of a patient advocacy group or a state's consumer assistance program with the appeal process, some of which provide services free of charge. If the external

295. Complaint at 38–39, *N.Y. State Psychiatric Ass'n, Inc. v. UnitedHealth Grp.*, 980 F. Supp. 2d 527 (S.D.N.Y. 2013) (No. 13 CV 1599).

296. *Id.* at 72 (citing Interim Final Rules for Group Health Plans and Health Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 43,330, 43,333 (July 23, 2010)).

297. Complaint at 283, *UnitedHealth Grp.*, 980 F. Supp. 2d 527.

298. All plans must implement an effective internal appeals process of coverage determinations and claims and comply with any applicable state external review process. 26 C.F.R. § 2590.715-2719 (2016); see also *How Do I Appeal a Health Plan Decision?*, HEALTHCARE.GOV, <https://www.healthcare.gov/how-do-i-appeal-a-health-insurance-companys-decision/> (last visited Apr. 17, 2016) (guidance on appealing health care determinations).

299. 26 C.F.R. § 2590.715-2719 (2015); Complaint at 83, *UnitedHealth Grp.*, 980 F. Supp. 2d 527.

300. *How Do I Appeal a Health Plan Decision?*, *supra* note 298.

reviewer overturns the insurer's denial, the insurer must give the enrollee payments or services requested in the enrollee's claim.³⁰¹

If an appeal is unsuccessful, the enrollee can then either file a lawsuit or a complaint. Individuals with employee benefit plans³⁰² should bring suits under the Employee Retirement Income Security Act ("ERISA") to challenge a denial of benefits that violates the ACA.³⁰³ ERISA governs almost all health benefits plans offered through private employers, and ERISA preempts state law.³⁰⁴ Under ERISA, plan participants and beneficiaries can bring a case "to recover benefits due to [them] under the terms of [their plans], to enforce [their] rights under the terms of the plan[s], or to clarify [their] rights to future benefits under the terms of the plan[s]."³⁰⁵ By bringing a claim to enforce employee benefit rights, the enrollee can challenge a wide range of noncompliant plan design features that can be addressed prospectively, without awaiting denial of a health service.³⁰⁶

For private plans that ERISA may not govern, the enrollee may be able to bring a lawsuit for state causes of action (e.g., violations of unfair trade practice laws) after exhausting the plan's appeals process. For systematic denials, plaintiffs can band together and file a class action.³⁰⁷ Alternatively, parties can file complaints with their state insurance commissioner or attorney general, depending on the authority granted to each party under state laws and regulations.

Medicaid recipients may also need to first exhaust the Medicaid plan's appeals process.³⁰⁸ A recipient may request to continue to receive

301. *Appealing Health Plan Decisions*, U.S. DEP'T HEALTH & HUM. SERVS., <http://www.hhs.gov/healthcare/rights/appeal/appealing-health-plan-decisions.html> (last visited Apr. 7, 2017).

302. ERISA employee benefit plans include all private sector employee benefit plans except for church plans; plans in which the sole purpose is to comply with workers' compensation, unemployment, or disability insurance laws; plans maintained outside of the United States primarily for the benefit of non-United States residents; or excess benefit plans. Additionally, ERISA does not cover governmental plans. 29 U.S.C. § 1003(a)-(b) (2015).

303. *Id.* § 1132(a); see Daniel F. v. Blue Shield of Cal., 305 F.R.D. 115, 130-31 (N.D. Cal. 2011) (providing an example of a plaintiff bringing a claim pursuant to section 502 of the ERISA for federal parity violations).

304. THE CAL. PATIENT'S GUIDE, YOUR RIGHTS TO APPEAL AND LITIGATE BENEFIT DENIALS UNDER ERISA 50 (2002).

305. 29 U.S.C. § 1132(a)(1)(B) (2015); Ellen Weber, *Equity Standards for Health Insurance Coverage: Will the Mental Health Parity and Addiction Equity Act End the Discrimination?*, 43 GOLDEN GATE U. L. REV. 179, 225 (2013).

306. Weber, *supra* note 305, at 225.

307. See NB *ex rel.* Peacock v. D.C., 682 F.3d 77, 80 (D.C. Cir. 2012) (discussing a class action medical denial suit).

308. Many states have an exhaustion requirement before a Medicaid recipient may request a

coverage during the appeals process, but may be required to repay the cost of such services if an adverse determination is given.³⁰⁹ If the appeal has been unsuccessful, the participant has a right to a fair hearing through the state regardless of whether the recipient obtains benefits through a fee-for-service system or a managed care organization.³¹⁰ The state Medicaid agency must provide the recipient with written notice of appeal rights when it denies coverage. The State will try the case de novo.³¹¹ If the State overturns the Medicaid administrator's decision, the agency must promptly make corrective payments, retroactive to the date that the incorrect action was taken, and, if appropriate, provide for admission or readmission of an individual to a facility.³¹²

B. Passing State Consumer Protection Legislation

Legislation, when thoughtfully drafted, is an effective way to mitigate unfair, burdensome, and discriminatory insurance practices. This Part discusses examples of recent consumer protection legislation aimed at these practices, while highlighting key provisions of effective bills.

1. Step Therapy

As of July 2016, at least fifteen states enacted legislation to address step therapy policies.³¹³ An effective step therapy bill should include provisions such as a clinical review criteria requirement;³¹⁴ a step therapy override determination process, which would allow an enrollee or provider to request that a step therapy protocol not apply in certain situations; time limits for insurers to respond to override requests; and a requirement that enrollees do not have complete any particular step more than once.

Lawmakers in Ohio introduced an effective step therapy bill in

state fair hearing. *Navigating Medicare and Medicaid: Medicaid—Online Version*, KAISER FAM. FOUND. (Feb. 11, 2005), <http://kff.org/other/navigating-medicare-and-medicaid-medicaid-online-version/>.

309. KY. PROT. & ADVOCACY, *MEDICAID DENIED MY REQUEST FOR SERVICES, NOW WHAT?* 15 (2010).

310. 42 C.F.R. § 431.205 (2016); 42 C.F.R. § 431.220 (2016).

311. 42 C.F.R. § 431.244 (2016).

312. *Id.* § 431.246.

313. *Step Therapy*, COALITION ST. RHEUMATOLOGY ORGS., <http://www.csro.info/failfirst> (last visited May 8, 2017).

314. “Clinical review criteria” means “written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by a health plan issuer or utilization review organization to determine the medical necessity and appropriateness of health care services.” S.B. 243, 131st Gen. Assemb. Reg. Sess. (Ohio 2015–2016).

2015.³¹⁵ The bill requires every insurer or utilization review organization implementing a step therapy protocol to use clinical review criteria. An independent panel of experts must develop the clinical review criteria based on high-quality research and create a transparent process to ensure that all steps are evidence based and consistent with medical standards of care.³¹⁶ Furthermore, the bill provides for a step therapy exemption determination, which allows a provider to override an insurer's step therapy protocols if the provider finds that:

- The medication is contraindicated, would likely cause an adverse reaction, or would likely result in harm to the enrollee;
- the medication is likely to be ineffective for the enrollee;
- the enrollee has already tried the requested medication under the current or previous insurance plan and it was ineffective;
- the medication required by the insurer is not in the best interest of the enrollee or medically appropriate; or
- the enrollee is stable on a particular medication currently selected by the health care provider.³¹⁷

Strong step therapy legislation, such as the Ohio bill, can help protect consumers, prevent loopholes, and ensure that all step therapy decisions are rooted in science and medicine.

2. Adverse Tiering

Several states have also introduced legislation aimed at limiting specialty tiers. Both Oregon and Illinois have introduced bills with effective provisions. For example, Oregon introduced a bill in 2015 that prohibits insurers from placing all drugs within a therapeutic or pharmacological class in the cost tier with the highest out-of-pocket costs.³¹⁸ Similarly, in 2015, Illinois introduced legislation that allows enrollees to request an exception to the tiered cost-sharing structure so that an insurer would have to cover nonpreferred medications under the same cost-sharing structure as preferred drugs.³¹⁹ An enrollee could request the exception if the enrollee's prescriber determines that the preferred drug for treatment of the same condition would either be ineffective for the individual, result in an adverse effect, or both.³²⁰

Strong legislation in this area should also include the following provisions:

315. S.B. 243, 131st Gen. Assemb. Reg. Sess. (Ohio 2015–2016).

316. *Id.*

317. *Id.*

318. H.B. 2951, 78th Gen. Assemb., Reg. Sess. (Or. 2015).

319. H.B. 3605, 99th Gen. Assemb., Reg. Sess. (Ill. 2015–2016).

320. *Id.*

- A requirement that copayments and coinsurance apply to a single deductible that includes both prescription medications and health care services;
- a requirement that placement of prescription medications on a specific tier is based on clinical review criteria developed through a transparent process by an independent commission of experts to provide access; and
- a streamlined review and appeals process for adverse prior authorization determinations, providing an expedited process for urgent care services.

Some state legislation also includes caps on prescription copayments or coinsurance.³²¹ These caps range from \$100 per month to \$3,500 per year.³²² This type of protection need not be reserved to lawmakers; other state agencies could ensure caps as well. For example, in 2015, the board of California's health insurance exchange agreed to impose a cap on cost sharing for high-priced specialty drugs on state-run exchange plans.³²³ The cap for most enrollees on California's exchange is now set at \$250 per prescription per month.³²⁴ Under the prior system, enrollees had to pay costs up to their plan deductible, which could amount to thousands of dollars per month. Strong legislation and rules for state exchanges that address specialty tiers provide enrollees with better access to care. These rules also prevent and restrict insurers from limiting access on the basis of a medical condition or disability.

3. Nonmedical Switching

Effective state legislation can curb nonmedical switching and allow stable enrollees with chronic or rare conditions to maintain their current, effective medication regimens. For example, in 2016, Florida lawmakers introduced a bill that prohibits pharmacy benefit managers, individual

321. Sabrina Corlette et al., *State Efforts to Reduce Consumers' Cost-Sharing for Prescription Drugs*, COMMONWEALTH FUND (Nov. 16, 2015), <http://www.commonwealthfund.org/publications/blog/2015/nov/state-efforts-to-reduce-consumers-cost-sharing-for-prescription-drugs>.

322. Michael Ollove, *States Limiting Patient Costs for High-Priced Drugs*, PEW CHARITABLE TR. (July 2, 2015), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/07/02/states-limiting-patient-costs-for-high-priced-drugs>.

323. Peter Sullivan, *Calif. ObamaCare Exchange Caps Patient Drug Costs*, HILL (May 22, 2015, 1:13 PM), <http://thehill.com/policy/healthcare/242951-calif-obamacare-exchange-caps-patient-drug-costs>.

324. Chad Terhune, *Obamacare: California Exchange Caps Specialty Drug Costs for Patients*, L.A. TIMES (May 22, 2015, 8:00 AM), <http://www.latimes.com/business/healthcare/la-fi-obamacare-specialty-drug-costs-20150522-story.html>. Bronze-level plans have a monthly cap of \$500, after a \$500 pharmacy deductible is met. *Id.*

and group insurers, and HMOs from limiting or excluding coverage for a drug for individuals with complex, chronic, or rare conditions if (1) the drug was previously approved for coverage by the insurer; (2) the prescriber continued to prescribe the drug; and (3) the drug is appropriately prescribed and is considered safe and effective for treating a medical condition.³²⁵ The bill also prohibits insurers from placing limitations on the maximum coverage of prescription drug benefits, increasing out-of-pocket costs for the drug, and moving the drug to a higher tier after the plan year has begun.³²⁶

Strong legislation should also require insurers to provide adequate and advance notice to an enrollee if the insurer decides, during the annual renewal period, to no longer cover a prescription medication or move it to a different formulary tier. To protect enrollees from year to year, effective legislation should also include a provision that requires the insurer to continue such coverage for grandfathered plans. A comprehensive nonmedical switching bill that incorporates these provisions, as well as the provisions discussed above, can ensure uninterrupted, continuous care for enrollees who are stable on their medications.

4. Prior Authorizations

To ensure that prior authorization policies are consistent with evidence-based standards of care and do not result in undue delays or denials of care, several states have introduced bills that govern the prior authorization process.³²⁷ For example, West Virginia introduced a bill in 2016 that requires insurers to accept universal prior authorization forms, permit electronic submission of prior authorization forms, respond to authorization requests within certain deadlines, and recognize approved requests as valid for no less than one year.³²⁸

Strong legislation should also standardize prior authorization requirements and criteria across all plans by seeking to create a uniform prior authorization form, urging the creation of an electronic submission process, and requiring insurers to meet deadlines when responding to a request to cut down on wait times. It should also include a requirement that prior authorization be valid for the entirety of the enrollee's

325. S.B. 1142, 2016–2017 Leg., Reg. Sess. 89 (Fla. 2016).

326. *Id.*

327. *See, e.g.*, S.B. 273, 2016 Leg., Reg. Sess. (W. Va. 2016) (imposing deadlines and requiring universal authorization forms); H.B. 1608, 2016 Leg., Reg. Sess. (N.H. 2016) (amending prescription drug authorization procedures); H.B. 3605, 99th Gen. Assemb., Reg. Sess. (Ill. 2015–2016) (requiring insurers to state reasons for denying coverage).

328. S.B. 273, 2016 Leg., Reg. Sess. (W. Va. 2016).

eligibility period, inclusive of any renewal period (i.e., grandfathered plans); a presumption of approval for coverage of a limited supply of medication in certain defined cases where a delay in approval would jeopardize an enrollee's health; defined response deadlines, including expedited response times for urgent care services; and a streamlined appeals process for adverse prior authorization determinations. By preventing insurers from implementing overly burdensome prior authorization policies, these laws can help reduce undue delays of quality care.

5. Network Adequacy

States have also enacted network adequacy laws or introduced legislation to protect from surprise medical bills and ensure that individuals have access to providers.³²⁹ For example, Kentucky law requires managed care plans to “arrange for a sufficient number and type of primary care providers and specialists throughout the plan’s service area to meet the needs of enrollees.”³³⁰ The law includes many of the key components of a strong network adequacy bill including requirements that: a network contain a sufficient number of providers, providers be accessible in each geographic location, information be accurate and easily accessible, and a system be in place to report inaccurate information and ensure such inaccuracies are corrected within a reasonable timeframe. These provisions are intended to provide all enrollees, regardless of geographic location, with accessible care without unreasonable burden or delay.

6. Clinical Pathways

Some states have introduced legislation designed to prevent insurers from providing improper incentives to health care providers. For example, Nevada introduced legislation in 2015 that would require insurers to disclose to all enrollees any incentive offered to a health care provider to encourage the prescribing of certain medications, as well as any compensation program designed to encourage a provider to withhold treatment.³³¹

In May 2016, California introduced a bill aimed specifically at clinical pathways to “ensure transparency and accountability when health plans

329. *See, e.g.*, KY. REV. STAT. ANN. § 304.17A-515 (2016) (imposing requirements for managed care in Kentucky); 20 ILL. COMP. STAT. 20/13.20(b) (2016) (imposing requirements for managed care in Illinois).

330. KY. REV. STAT. ANN. § 304.17A-515 (2016).

331. S.B. 219, 2015 Leg., Reg. Sess. (Nev. 2015).

develop and implement clinical care pathways.”³³² The bill required plans to ensure that clinical pathways are developed in accordance with specified procedures, and it prohibited plans from developing and implementing pathways that discouraged patient access to clinical trials.³³³ While the bill is a step in the right direction, strong legislation should also improve transparency and prohibit improper incentive systems, such as the bill introduced in Nevada.

Many states—including California, Minnesota, Massachusetts, and Vermont—prohibit or limit gifts from pharmaceutical or medical device manufacturing companies to health care providers.³³⁴ For example, Minnesota prohibits “any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner.”³³⁵ States should consider amending these laws by extending their reach to apply to insurers as well.

C. *Strong Enforcement of Consumer Protection Laws*

Insurers must be held accountable for unfair, deceptive, and discriminatory practices. Proper enforcement of current laws and new regulations can serve as a meaningful incentive for insurers to create policies that are fair and transparent, thereby improving access to quality health care for enrollees. Strong oversight and enforcement measures by regulators of current consumer-protection laws can effectively achieve this goal. Additionally, states with diluted consumer protection laws or UDPT laws must enact stronger laws that protect its consumers against predatory and unscrupulous business practices.

The effectiveness of consumer protection laws and regulations, including the new legislation dealing with specific benefit utilization management policies discussed in the previous Part, vary widely from state to state.³³⁶ Many states have placed legal obstacles in the path of officials charged with the enforcement of these consumer protection laws, or imposed ceilings as low as \$1,000 on civil penalties, effectively making consumer protection laws meaningless because they cannot be properly enforced.³³⁷ For example, states such as Alabama, Delaware, Florida, and New Hampshire exempt insurers completely from the state

332. A.B. 2209, 2015–2016 Leg., Reg. Sess. (Cal. 2016).

333. *Id.*

334. CAL. HEALTH & SAFETY CODE §§ 119400, 119402 (West 2017); MINN. STAT. § 151.461 (2016); 105 MASS. CODE REGS. §§ 970.000–970.011 (2013); 18 VT. STAT. ANN., § 4631a (2015).

335. MINN. STAT. § 151.461 (2016).

336. *Id.*

337. *Id.*

consumer protection laws; and other states such as Colorado, Indiana, Nevada, North Dakota, and Wyoming impede the attorney general's ability to stop ongoing unfair or deceptive practices by conditioning relief upon proof that unfair or deceptive practices were done knowingly or intentionally.³³⁸

While states face the challenge of managing tight budgets and allocating limited resources, they should recognize the importance of consumer protection in this area and empower insurance commissioners and attorneys general to aggressively monitor claims of unfair, deceptive, and discriminatory practices. Aggressive monitoring alone is not enough, however. Regulators must take a strong response to well-founded claims against insurers, beginning with the completion of a thorough investigation, and following up by pursuing equitable, monetary, and, if appropriate, criminal penalties against insurers who violate state or federal laws and regulations substantial enough to serve as a deterrent for wrongdoing.

Additionally, states with weak consumer protection laws must amend their statutes so that insurance companies must abide by the same consumer protection laws as other businesses and are not given special immunity, and attorneys' general are not impeded from enforcing consumer protection laws currently in place.

CONCLUSION

The use of unfair, burdensome, and discriminatory utilization management practices continues to grow in the United States. These practices put Americans at risk of receiving inferior treatments and paying prohibitively higher costs. For those who cannot afford the added expense, they have no choice but to forgo treatment or ration their care. These practices are in direct violation of many federal and state laws that were passed to protect access to treatment. Consumers, regardless of their health condition, deserve access to timely and quality treatment, as determined by their providers. Therefore, consumers must be empowered to sue under current laws, policymakers must pass stronger consumer protection laws, and regulators must enforce existing protections once they are provided with adequate authority to do so.

338. ALA. CODE § 8-19-7(3) (2017); DEL. CODE ANN. tit. 6, § 2513(b) (2017); FLA. STAT. § 501.212(4) (2016); N.H. REV. STAT. ANN. § 358-A:3(I) (2017); CARTER, *supra* note 93, at 3.