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Step Therapy: Legal and Ethical Implications of a Cost-Cutting Measure

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The very high and ever-increasing costs of medical care in the United States are well-recognized and much discussed. Health insurers have employed a variety of strategies in an effort to control their expenditures, including one that is common but has received relatively little attention: step therapy. Step therapy programs require patients to try less expensive treatments and find them to be ineffective or otherwise problematic before the insurer will approve a more high-priced option. This Article is the first law journal piece dedicated to analyzing this important cost control measure.

The Article explores the strengths and weaknesses of step therapy and its legal and ethical implications. It argues that in some cases, step therapy reduces insurers' drug costs in the short term but causes significant harm to patients that ultimately results in both human suffering and increased long-term health care costs. Some insurers are also less than transparent with patients about their programs, adhere to one-size-fits all approaches that ignore nuanced clinical and economic evidence, and implement their policies in a discriminatory way. The Article examines how several states have responded to step therapy through legislation and discusses review mechanisms that federal law provides for adverse insurance decisions. The Article concludes with a detailed set of recommendations. These include legislative interventions to ensure that step therapy programs are sufficiently flexible and responsive to patients' individual needs and measures to enhance transparency and expeditiously address emerging scientific and economic evidence.

INTRODUCTION

My husband was diagnosed with Parkinson's disease at the age of fifty-five in October of 2013. Happily, he is managing his disease well and still works full-time as a professor of computer science. He exercises regularly and takes several medications. We are hopeful that the disease will progress slowly and that there are still many good years ahead.

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Imagine our dismay when, in late 2016, our pharmacy benefit manager (PBM)[1] informed us that it was denying coverage for the drug that Andy found most helpful and that it had previously covered. The PBM's explanation was as follows:

> Your plan approved criteria covers this drug when the patient has tried and had an inadequate treatment response, intolerance, or contraindication to all formulary alternatives for the given diagnosis (or to at least 1 agent within each of a given class of agents when more than 1 class is available for the diagnosis), or when the drug is the only product the patient can use for their condition. Your use of this drug does not meet the requirement.[2]

This was our introduction to step therapy, a policy that requires patients to take cheaper drugs first and find that they fail before being approved for more expensive treatments.[3] After calling several pharmacies, I determined that the drug, at Andy's dosage, would cost us over $8000 a year if we were to pay out-of-pocket. Because Andy had already tried several less effective therapies, we undertook an appeal process and were ultimately rewarded with a temporary reprieve. However, our PBM has reserved the right to revisit the matter in the future.

This Article is the first law journal piece dedicated to the step therapy phenomenon. Unbeknownst to most patients, step therapy is pervasive in health insurance plans.[4] Step therapy programs raise a variety of compelling legal and ethical challenges that are analyzed in this paper. Although it is often PBMs that institutes step therapy programs (insurers can contract with external PBMs or have their own, internal ones),[5] the remainder of the Article will refer to those who operate step therapy programs collectively as "insurers" for the sake of simplicity.

Insurers can hardly be blamed for undertaking initiatives to control their expenditures. Indisputably, the United States suffers from a dramatic and worrisome rise in health care costs.[6]

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[1] A pharmacy benefits manager administers the drug benefit program for a health plan. It processes and pays prescription drug claims, negotiates with manufacturers for lower drug prices, and can employ other cost-saving mechanisms. PBMs thus act as intermediaries between the insurer and pharmacies. *See* Joanna Shepherd, *The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary*, 9 NORTHWESTERN J. L & SOC. POL'Y, 1, 7-9 (2013); Jessica Wapner, *Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers*, NEWSWEEK, March 17, 2017, http://www.newsweek.com/big-pharma-villain-pbm-569980. For additional information about PBMs *see infra* note 86 and accompanying text.

[2] Notice of Adverse Determination, dated Nov. 15, 2016, in author's possession.

[3] Rahul K. Nayak & Steven D. Pearson, *The Ethics of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies*, 33 HEALTH AFFAIRS 1179, 1779 (2014).

[4] *See infra* note 23 and accompanying text.

[5] Wapner, *supra* note 1 (stating that insurance giant United Healthcare has its own PBM that is called OptumRx).

[6] *See infra* Part I.B; Doug Holtz-Eakin, *More Government Is Not the Remedy for High Drug Prices*, FORBES, March 2, 2017, *available at* https://www.forbes.com/sites/realspin/2017/03/02/more-government-is-not-the-remedy-for-high-drug-prices/#6d7691082bb5.

The question is whether step therapy programs are a sound solution. There is no categorical answer to this query. For some patients, step therapy requirements are reasonable and meet their treatment needs. However, it is not uncommon for step therapy to provide patients with inadequate care that can cause serious harm.

Eitan Kling-Levine, an ulcerative colitis patient, related in a *Boston Globe* opinion piece that his insurer required that he fail several drugs during a six-month period before approving the physician's chosen biologic therapy.[7] During that six month period, his health deteriorated to such an extent that he ultimately had his colon surgically removed. He speculates that he might have been able to avoid this radical surgery and considerable pain and suffering had he been allowed to take the biologic as soon as his doctor prescribed it.[8] Kathleen Arntsen, a glaucoma[9] patient, stated in an interview that she was required to try two inexpensive drugs over seven weeks before being allowed to use the Travatan Z eye drops that her physician had initially prescribed.[10] She experienced swelling, increased pressure, and loss of vision in her eye and, at the time of writing, was considering having the eye removed because it continued to hurt.[11] She too believes that the delay contributed to her poor outcome.[12]

For patients, receiving the medication that is most effective for them and causes the least severe side effects can make the difference between being homebound and being able to work, care for one's family, and enjoy life. Working can engender not only financial stability, but also strong self-esteem, social ties, and a sense of purpose, all of which contribute to good mental and even physical health.[13]

When an insurer denies coverage for a drug that a physician selects as the best fit for the patient, (in Andy's case, a drug that he has taken successfully for many

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[7] Eitan Kling-Levine, *A Medical Therapy That's No Therapy at All*, BOSTON GLOBE, July 23, 2016, https://www.bostonglobe.com/opinion/2016/07/23/medical-therapy-that-therapy-all/wttF75QVPmvEXWJknhW6MO/story.html. Biological therapy "involves the use of living organisms, substances derived from living organisms, or laboratory-produced versions of such substances to treat disease." National Cancer Institute, *Biological Therapies for Cancer*, https://www.cancer.gov/about-cancer/treatment/types/immunotherapy/bio-therapies-fact-sheet#q1 (last reviewed June 12, 2013). For example, a form of cancer treatment called immunotherapy uses "vaccines or bacteria to stimulate the body's immune system to act against cancer cells." *Id*.

[8] Kling-Levine, *supra* note 7.

[9] Glaucoma is a disease that damages the eye's optic nerve and is usually associated with fluid build- up in the front part of the eye that increases eye pressure. Kierstan Boyd, *What Is Glaucoma?* AM. ACAD. OPHTHALMOLOGY, March 1, 2017, https://www.aao.org/eye-health/diseases/what-is-glaucoma.

[10] Bob Tedeschi, *Are Insurance Policies Saving Patients Money, or Keeping Them from the Treatment They Need*?, STAT, August 22, 2016, https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments/.

[11] *Id*.

[12] *Id*.

[13] WORLD HEALTH ORGANIZATION & INTERNATIONAL LABOR ORGANISATION, MENTAL HEALTH AND WORK: IMPACT, ISSUES AND GOOD PRACTICES 5 (2000), *available at* http://www.who.int/mental_health/media/en/712.pdf (asserting that "[a]lthough it is difficult to quantify the impact of work alone on personal identity, self-esteem and social recognition, most mental health professionals agree that the workplace environment can have a significant impact on an individual's mental well-being.").

months), the patient can suffer severe consequences, such as adverse reactions to a different drug, complications, and deteriorating health.[14] Insurers, in turn, ultimately cover the cost of treatments for these adverse outcomes.[15] Patients who wish to dispute the denial must ask physicians to assist them with an appeal and hope that their doctors have the time and the gumption to do so. Handling such requests is a burdensome task for which physicians do not get paid.[16]

Step therapy thus impacts multiple parties with often conflicting agendas. Patients seek treatments that are as safe and effective as possible, want comprehensive insurance coverage, and often expect to be able to choose among different treatment options. Insurers have a duty to serve their enrollees' health needs but wish to save costs whenever practicable. Physicians devote themselves to patient care, worry about patient satisfaction and their professional reputations,[17] and wish to minimize cumbersome administrative work. Also in the mix are pharmaceutical companies that market their products aggressively to health care providers and to patients through direct-to-consumer advertising.[18]

Step therapy, therefore, has more complicated implications than initially meet the eye. Step therapy policies should be carefully designed to achieve cost savings while remaining flexible, responsive to patients' needs, and consistent with relevant clinical data. Insurers should be careful not to strive single-mindedly to reduce short-term costs at the expense of ignoring patients' overall well-being, physicians' treatment goals, and the prospect of increased long-term expenditures.

The Article proceeds as follows. Part I provides background information about step therapy. It also discusses the need for cost control measures in light of skyrocketing pharmaceutical prices. In addition, it analyzes whether step therapy is effective in meeting cost reduction goals. Part II argues that step therapy raises a number of legal and ethical concerns. These include lack of transparency, inflexibility that may disregard emerging evidence from precision medicine and other research initiatives, and discrimination. Part III assesses state and federal legislation that is relevant to step therapy. A number of states have passed step therapy statutes that outline the circumstances under which insurers must grant waivers and require that they do so expeditiously upon receiving appropriate requests. Federal law in the form of the Employee Retirement Income Security Act of 1974 (ERISA),[19] the

[14] *See infra* Part I.C.
[15] *Id*.
[16] Pfizer, *Step Therapy and Fail First Policies Backgrounder*, Oct. 2011, https://failfirsthurts.org/ffh/wp-content/uploads/2012/10/WWP-Purple-Paper-Step-Therapy-and-Fail-First-Policies.pdf.
[17] James F. Sweeney, *Physicians Dissatisfied with Patient Satisfaction Surveys*, MEDICAL ECONOMICS, November 10, 2016, http://medicaleconomics.modernmedicine.com/medical-economics/news/physicians-dissatisfied-patient-satisfaction-surveys.
[18] U.S. Food and Drug Administration, *The Impact of Direct-to-Consumer Advertising*, https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143562.htm (last updated Oct. 23, 2015).
[19] 29 U.S.C. §§ 1001-1461 (2010).

Patient Protection and Affordable Care Act (ACA),[20] and the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA),[21] also feature mechanisms for challenging adverse insurance decisions and for the review process that insurers must implement. Part IV develops recommendations to address concerns about step therapy. It proposes first that all states enact step therapy laws; second, that federal law specifically address step therapy programs; third that insurers improve transparency by disseminating clear information about step therapy requirements in print and on their websites; fourth, that expert panels such as insurers' pharmacy and therapeutics committees monitor and incorporate up-to-date scientific and financial evidence into their policies; and fifth, that insurers implement step therapy programs in a non-discriminatory way. Part V concludes the Article.

I
STEP THERAPY: WHAT, WHY, AND WHEN

Step therapy is a common cost reduction tool of which many insurance enrollees are unaware. This Part explains step therapy, discusses the need for cost control measures, and analyzes whether step therapy is effective in reducing medical costs.

A. Step Therapy Basics

Step therapy, also called "fail first" policies, require patients to try less expensive treatments and find them to be ineffective or otherwise problematic before the insurer will approve a more costly option.[22] According to the American Academy of Dermatology, in 2010, almost sixty percent of commercial insurers had implemented step therapy, and as of 2014, seventy-five percent of large employers had insurance plans with step therapy.[23] Some Medicare Part D plans utilize step therapy as well.[24]

[20] 42 U.S.C. §§ 18001 et seq. (2010).
[21] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 26 and 42 U.S.C.).
[22] Nayak & Pearson, *supra* note 3, at 1779.
[23] American Academy of Dermatology, *Step Therapy Legislation*, https://www.aad.org/advocacy/state-policy/step-therapy-legislation (last visited May 1, 2017). *See also*, National Psoriasis Foundation, *Step Therapy*: *The Red Tape between You and Your Meds*, http://www.steptherapyinfo.com/ (last visited June 1, 2017).
[24] Q1Medicare.com, *What Is Step Therapy in Medicare Part D?*, https://q1medicare.com/q1group/MedicareAdvantagePartDQA/FAQ.php?faq=What-is-Step-Therapy-in-Medicare-Part-D-&faq_id=200&category_id=1 (last visited May 1, 2017).

In some cases step therapy programs require patients to try one or more generic drugs[25] before approving brand-name medications.[26] In other cases insurers mandate that patients try a class of drugs that is less costly before allowing a switch to a more expensive class.[27]

Some insurers publish lists of drugs that are subject to step therapy. Insurers often require step therapy for drugs to treat the following conditions: allergies, asthma, attention deficit hyperactivity disorder, depression, diabetes, gastrointenstinal problems, glaucoma, high cholesterol, high blood pressure, insomnia, menopause, multiple sclerosis, osteoporosis, pain, Parkinson's disease, psoriasis, rheumatoid arthritis, and more.[28] Other insurers provide patients with only a generic description of step therapy.[29] Even detailed websites, however, can be difficult to navigate, and patients and physicians are very unlikely to scour the insurer's website before deciding on a treatment plan.

B. The Need for Cost Control Measures

Insurers' desire to implement cost control measures is understandable. Prescription drug prices rose 10.9 percent in 2014 and another ten percent in 2015.[30] According to the AARP, "[t]he average cost for a year's supply of medication for someone with a chronic illness has more than doubled since 2006 to over $11,000."[31] The costs of some drugs such as EpiPens and Daraprim, have notoriously risen far more precipitously than that. The price of EpiPens, which treat severe allergic

[25] Generic drugs are less expensive "copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." U.S. Food & Drug Administration, *Generic Drugs*, https://www.fda.gov/Drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm (last updated April 26, 2017).

[26] Michael A. Fischer & Jerry Avorn, *Step Therapy – Clinical Algorithms, Legislation, and Optimal Prescribing*, 317 JAMA 801, 801 (2017).

[27] *Id.*

[28] BlueCross BlueShield of Oklahoma, Step Therapy: What You Need to Know, https://www.bcbsil.com/pdf/Group_Pharmacy_Step_Therapy_Member_Flier.pdf (last visited May 1, 2017); Medimpact Healthcare Systems, PEEHIP Step Therapy List, http://www.rsa-al.gov/uploads/files/Step_Therapy_List.pdf (last revised Oct. 1, 2015).

[29] *See e.g.* CVS Caremark, *Let's talk about Prior Authorizations and Formulary Exceptions* (2017) (in author's possession) (stating that "[e]ven though your doctor may prescribe one medicine, treatment guidelines may recommend trying alternative therapy first. If that alternative treatment isn't effective, you will be eligible for the medicine you were originally prescribed.").

[30] Brady Dennis, *Prescription Drug Prices Jumped More than 10 Percent in 2015, Analysis Finds*, WASH. POST, Jan. 11, 2016, https://www.washingtonpost.com/news/to-your-health/wp/2016/01/11/prescription-drug-prices-jumped-more-than-10-percent-in-2015/?utm_term=.9c950115de36.

[31] Jo Ann Jenkins, *Let's Cut Drug Costs*, 58 AARP BULLETIN 24 (May 2017).

reactions, rose from $100 for a two-pack in 2009 to $608 in 2016,[32] and Turing Pharmaceuticals' embattled chief executive, Martin Shkreli raised the price of Daraprim, a drug to treat infections caused by parasites, by more than 4,000 percent from $18 a pill to $750 a pill.[33]

Furthermore, insurers worry that some prescribing decisions are driven by pharmaceutical companies' intensive marketing efforts.[34] Whether because of advertising or for other reasons, some physicians do not follow experts' recommendations for first-choice drugs that are relatively inexpensive.[35] For example, one study showed that thirty five percent of newly diagnosed diabetes patients did not receive metformin, recommended as the initial treatment choice in clinical guidelines.[36] A 2013 expose in the *Washington Post* revealed that many doctors injected macular degeneration patients with Lucentis at a cost of approximately $2000 an injection rather than with Avastin, which would cost a mere $50,[37] though not all physicians agree about which drug is the better alternative.[38]

Step therapy is one of several cost-saving measures that insurers employ. Examples of other techniques are medical necessity determinations, requirements for prior authorization, quantity limits, and tiering.[39] Medical necessity determinations deny coverage based on an insurer's determination that the prescribed therapy is not needed to prevent, diagnose, or treat a medical condition.[40] Prior authorization mandates establish that physicians must receive the insurer's permission to prescribe

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[32] Daniel Kozarich, *Mylan's EpiPen Pricing Crossed Ethical Boundaries*, FORTUNE, Sep. 27, 2016, at http://fortune.com/2016/09/27/mylan-epipen-heather-bresch/.

[33] Ariana Eunjung Cha, *CEO Martin Shkreli: 4,000 Percent Drug Price Hike is 'Altruistic,' not Greedy*, WASH. POST, Sep. 22, 2015, *available at* https://www.washingtonpost.com/news/to-your-health/wp/2015/09/22/turing-ceo-martin-shkreli-explains-that-4000-percent-drug-price-hike-is-altruistic-not-greedy/?utm_term=.61a1ccfc50e3.

[34] Fischer & Avorn, *supra* note 26, at 802.

[35] *Id*.

[36] Nihar R. Desai, *Patterns of Medication Initiation in Newly Diagnosed Diabetes Mellitus: Quality and Cost Implications*, 125 AM. J. MED. 302.e1, 302.e1 (2012).

[37] Peter Whoriskey & Dan Keating, *An Effective Eye Drug is Available for $50. But Many Doctors Choose a $2,000 Alternative*, WASH. POST, Dec. 7, 2013, available at https://www.washingtonpost.com/business/economy/an-effective-eye-drug-is-available-for-50-but-many-doctors-choose-a-2000-alternative/2013/12/07/1a96628e-55e7-11e3-8304-caf30787c0a9_story.html?utm_term=.315eedac0a1d. Macular degeneration is an eye disease, and the drugs are used to prevent blindness. *Id*.

[38] AMD.org Macular Degeneration Partnership, *Lucentis vs. Avastin* (Nov. 2013), http://www.amd.org/lucentis-vs-avastin/ (noting that the FDA has not approved Avastin for use in the eye (it is approved to treat colon cancer) but that it is commonly used and has been shown by most studies to be as safe and effective as Lucentis).

[39] Laura E. Happe, *A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization*, 20 J. MAN. CARE & SPECIALTY PHARM. 677, 677 (2014); Joshua Cohen et al., *Clinical and Economic Challenges Facing Pharmacogenomics*, 13 PHARMACOGENOMICS J. 378, 380 (2013).

[40] Janet L. Dolgin, *Unhealthy Determinations: Controlling "Medical Necessity*," 22 VA. J. SOC. POL'Y & L. 435, 438-43 (2015) (discussing varying definitions of medical necessity).

a drug in order to have the drug covered by the insurance plan.[41] Quantity limits restrict the amount of a particular medication that an insurer will cover over a specific period of time (e.g. only thirty pills per month).[42] Tiering categorizes drugs into tiers and assigns different co-payment sums to different drug tiers.[43]

The insurer's bottom line is not the only thing that is hurt by exorbitant drug prices. Insurers are likely to shift at least some of the costs to patients, raising their premiums, charging higher co-payments, and increasing deductibles.[44] Therefore, patients themselves have much to lose from growing coverage costs.

In principle, therefore, insurers are justified in pursuing initiatives to control expenditures. But cost-reduction measures must be implemented thoughtfully and responsibly, and step-therapy may all too often do more harm than good.

C. Does Step Therapy Reduce Insurers' Expenses?

Step therapy aims to reduce insurers' costs without compromising patient care. Whether it consistently does so in practice is debatable.

Some studies have shown meaningful cost savings. For example, a study of blood pressure medications found that a step therapy program saved thirteen percent in drug costs.[45] Likewise, a study involving antidepressants concluded that step therapy generated savings of nine percent.[46] A literature review published in 2011 concluded that step therapy generally led to statistically significant savings in drug costs, though this was not clearly true in the case of antipsychotics.[47] Furthermore,

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[41] eHealth Medicare, *What Is Prior Authorization, Step Therapy, and Quantity Limit?* https://www.ehealthmedicare.com/faq-what-are-prior-authorizations-quantity-limits-and-step-therapy/ (last updated May 6, 2017).

[42] *Id*.

[43] Thomas Reinke, *Benefit and Formulary Options Appear in Specialty Pharmacy*, MANAGED CARE (Jan. 2014) https://www.managedcaremag.com/archives/2014/1/benefit-and-formulary-options-appear-specialty-pharmacy. A co-payment is "an amount of money that a person with health insurance is required to pay at the time of each visit to a doctor or when purchasing medicine." Merriam-Webster, *Learner's Definition of Co-Payment*, http://www.learnersdictionary.com/definition/co-payment (last visited July 4, 2017).

[44] James D. Chambers, *Do Changes in Drug Coverage Policy Point to an Increased Role for Cost-Effectiveness Analysis in the USA?*, 32 PHARMACOECON. 729, 732 (2014). The premium is the price that individuals pay for insurance. Merriam-Webster, *Definition of Premium*, https://www.merriam-webster.com/dictionary/premium (last visited July 4, 2017). For a definition of co-payment, *see supra* note 43. A deductible is the amount of money the insured individual has to pay before the insurer pays the remaining costs of care. Merriam-Webster, *Definition of Deductible*, https://www.merriam-webster.com/dictionary/deductible (last visited July 4, 2017).

[45] Krista Yokoyama et al., *Effects of a Step-Therapy Program for Angiotensin Receptor Blockers on Antihypertensive Medication Utilization Patterns and Cost of Drug Therapy*, 13 J. MANAG. CARE PHARM. 235, 242 (2007).

[46] Jeffrey D. Dunn, *Utilization and Drug Cost Outcomes of a Step-Therapy Edit for Generic Antidepressants in an HMO in an Integrated Health System*, 12 J. MANAG. CARE PHARM. 294, 298 (2006).

[47] Brenda R. Motheral, *Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature*, 17 J. MANAG. CARE PHARM. 143, 143 (2011).

step therapy policies for nonsteroidal anti-inflammatory drugs and proton pump inhibitors[48] reduced drug costs without causing an increase in consumption of other medical services.[49]

Other studies, however, cast doubt on whether step therapy achieves significant overall expense reductions. A 2010 article that analyzed fifteen prior studies confirmed that step therapy lowered drug costs for insurers.[50] However, it concluded that it generally does not reduce, and may even increase, overall health care expenditures.[51] The researchers explained that patients subject to step therapy restrictions often stop taking medication or underutilize it, a phenomenon that can explain why drug costs drop while other health care costs rise as a patient's condition goes untreated.[52]

Several additional studies support the conclusion that step therapy is often unsuccessful in reducing long-term medical costs. A study focusing on treatment for attention deficit hyperactivity disorder concluded that step therapy resulted in no overall cost difference but did cause patients to experience treatment delays and to underutilize needed drugs.[53] A study of a step therapy policy involving Pregabalin, a nerve pain medication, found that the policy decreased use of Pregabalin but did not reduce total health care costs for patients.[54] An economic model designed to determine the cost implications of a generic step therapy program for selective serotonin reuptake inhibitors (SSRIs) to treat anxiety disorders predicted an adverse cost outcome.[55] Drug costs would decrease by $0.26 per patient per month but medical costs would increase by $0.32 per patient per month.[56]

It is worth emphasizing that step therapy has the potential to severely exacerbate health problems.[57] As noted above, patients who do not receive their drug of choice may stop taking medication or take it only intermittently, and thus their

[48] These drugs reduce gastric acid production. See Rena Yadlapati & Peter J. Kahrilas, *When Is Proton Pump Inhibitor Use Appropriate?* 15 BMC MED. 36, 36 (2017), *available at* https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-017-0804-x.
[49] *Id.*
[50] Rashad I. Carlton, *Review of Outcomes Associated With Formulary Restrictions: Focus on Step Therapy*, 2 AM. J. PHARM. BENEFITS 50, 56-7 (2010).
[51] *Id.*
[52] *Id.*
[53] Brandon T. Suehs et al., *Impact of a Step Therapy for Guanfacine Extended-Release on Medication Utilization and Health Care Expenditures Among Individuals Receiving Treatment for ADHD*, 21 J MANAG. CARE SPEC. PHARM. 793, 801 (2015).
[54] Margarita Udall, *Impact of a Step-Therapy Protocol for Pregabalin on Healthcare Utilization and Expenditures in a Commercial Population*, 16 J. MED. ECON., 784, 784 (2013).
[55] Patt Ellen Panzer et al., *Implications of an SSRI Generic Step Therapy Pharmacy Benefit Design: An Economic Model in Anxiety Disorders*, 11 AM J MANAG CARE S370, S370 (2005).
[56] *Id.* at S375.
[57] Joseph Burns, *Is Step Therapy a Move In the Wrong Direction?*, MANAGED CARE (January 2017), https://www.managedcaremag.com/archives/2017/1/step-therapy-move-wrong-direction.

health may decline.[58] Moreover, physicians may have good reasons to select a particular drug for a patient. A different (cheaper) medication may be less effective for a patient or cause debilitating side effects.[59]

For example, Dr. Benjamin Kopp, a pediatric pulmonologist, relates: "I have prescribed certain pulmonary medications for a toddler, only to have the health insurer insist on a lower cost medication that is designed for a teenager. This shows me the decisions about step therapy requirements do not involved pediatricians, asthma specialists, and pharmacists who know the most about the medications."[60] Dr. Kopp further asserts that switching a child who was stable on one drug to a different asthma drug can cause complications and hospitalizations.[61]

The same is true for many other illnesses. In the case of Parkinson's disease, patients and their physicians must carefully weigh the benefits and risks of various drug options because medications can cause hallucinations, extreme fatigue, compulsive and impulsive behavior, gastrointestinal problems, and more.[62] Patients have different levels of tolerance for these side effects, and some patients wish to avoid the risk of certain side effects at all costs and choose their medication accordingly.

At times, even switching from a brand name to a generic of the same drug can have adverse consequences because of lower efficacy of the generic drug, allergic reactions, or patients' unwillingness to take a new pill that looks different from the one to which they are accustomed.[63] In reality, generics are not an exact duplicate of the original, brand name drug.[64] The FDA acknowledges that it is "aware that there are reports noting that some people may experience an undesired effect when switching from [a] brand name drug to a generic formulation or from one generic drug to another generic drug."[65] Problems may arise because of quality discrepancies

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[58] Panzer et al., *supra* note 55, at S372; Arthur Lazarus, *Formulary Restrictions Sometimes Harm Patients*, MANAGED CARE (Oct. 2004), *available at* https://www.managedcaremag.com/archives/2004/10/formulary-restrictions-sometimes-harm-patients (stating that "[i]n the mentally ill, lack of appropriate care can also trigger a downward spiral that ends in homelessness or incarceration.").

[59] Nayak & Pearson, *supra* note 3, at 1780.

[60] Benjamin Kopp, *Step Therapy Can Disrupt Best Care for Children's Health: Dr. Benjamin Kopp (Opinion)*, CLEVELAND.COM, June 4, 2017, http://www.cleveland.com/metro/index.ssf/2017/06/step_therapy_can_disrupt_best.html.

[61] *Id.*

[62] Parkinson's Disease Foundation, *Coping with Symptoms and Side Effects*, http://www.pdf.org/coping_symptoms (last visited June 1, 2017).

[63] Evan H. Langdon, *Switching to Generic: The Need for Physician and Patient Consent when Substituting Antiepileptic Medication*, 25 J. CONTEMP. HEALTH L. & POL'Y 166, 180-85 (2008); Fischer & Avorn, *supra* note 26, at 802.

[64] Katherine Eban, *Are Generics Really the Same as Branded Drugs?* FORTUNE, Jan. 10, 2013, http://fortune.com/2013/01/10/are-generics-really-the-same-as-branded-drugs/.

[65] U.S. Food & Drug Administration, *Facts about Generic Drugs*, https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm (last updated June 28, 2016).

among different manufacturers. For example, in 2007 the FDA noted variations among levothyroxine pills[66] produced by different pharmaceutical companies.[67] Because of concerns about the stability of the drug, the FDA required that the potency of levothyroxine products degrade by no more than five percent over their shelf lives.[68] Likewise, a study of the antipsychotic drug olanzapine found significantly lower concentrations of the medicine in patients who had switched from the brand-name to the generic form of the drug.[69] It is also noteworthy that generic drugs need not contain the same inactive ingredients[70] as brand name products,[71] so patients who tolerated the original drug well may have an adverse reaction to an inactive component of the generic substitution.[72]

In addition, patients who have to try multiple drugs sequentially before being approved for the doctor's drug of choice may suffer symptoms of drug withdrawal and find it difficult to adjust to new medications.[73] This is true both for patients initially took the doctor's recommended drug but were later subjected to step therapy requirements and for those who immediately were denied coverage and may try several less costly drugs with which they are dissatisfied before requesting a step therapy waiver. The Mayo Clinic lists the possible symptoms of antidepressant withdrawal (especially if the drug is stopped too quickly) as follows: anxiety, insomnia or vivid dreams, headaches, dizziness, tiredness, irritability, flu-like symptoms, including achy muscles and chills, nausea, electric shock sensations,

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[66] Levothyroxin is used to treat hypothyroidism (diminished or absent thyroid function). U.S. Food & Drug Administration, *Questions and Answers on Levothyroxine Sodium Products*, October 3, 2007, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm161266.htm.

[67] *Id*.

[68] *Id*. *See also*, Michael Bihari, *Brand Name and Generic Levothyroxine: Is There a Difference between Brand Name and Generic Thyroid Drugs?* VERYWELL, May 28, 2017, https://www.verywell.com/levothyroxine-brand-name-vs-generic-versions-1124055.

[69] Domenico Italiano et al., *Generic Olanzapine Substitution in Patients with Schizophrenia: Assessment of Serum Concentrations and Therapeutic Response After Switching*, 37 THERAPEUTIC DRUG MONITORING 827, 827 (2015).

[70] Inactive ingredients are components of a drug that do not increase or affect its therapeutic action. Examples are binding materials, dyes, preservatives, and flavoring. Drugs.com, *Inactive Ingredients*, https://www.drugs.com/inactive/ (last visited July 4, 2017).

[71] U.S. Food & Drug Administration, *Facts about Generic Drugs*, https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm (last updated June 28, 2016); Eban, *supra* note 64.

[72] Rong-Kun Chang et al., *Generic Development of Topical Dermatologic Products: Formulation Development, Process Development, and Testing of Topical Dermatologic Products*, 15 AAPS J. 41, 45 (2013) (noting that "[s]pecial attention should be paid to the use of fragrance in the formulation, because 1% of the general population suffers from fragrance allergies").

[73] Mayo Clinic, *Depression* (Major Depressive Disorder) (Jan. 16, 2016), http://www.mayoclinic.org/diseases-conditions/depression/expert-answers/antidepressant-withdrawal/faq-20058133; Panzer, *supra* note 55, at S372 (discussing the risks of therapy change and discontinuation of treatments for anxiety and depression).

return of depression symptoms.[74] All of these can be debilitating for patients who are trying to work and lead normal lives.

Thus, step therapy may often save costs in the very short term but increase costs in the long term because of complications, health deterioration, and the patient's need to seek more and more medical care in order to find relief.[75] Some insurers may ignore the risk of long-term consequences in hope that when these materialize, the patient will be working for a different employer with a different policy[76] or will have turned sixty-five and enrolled in Medicare. But ignoring the risks of step therapy is bad policy for patients, health care providers, and the American public at large.

II
LEGAL, ETHICAL, AND POLICY IMPLICATIONS OF STEP THERAPY

Beyond the possibility of poor health outcomes, step therapy raises several legal and ethical concerns. First, insurers may not be transparent about step therapy requirements. Second, the one-size-fits-all approach is in tension with the emerging trend of precision medicine. Third, insurers may apply the policy in a discriminatory fashion that violates federal anti-discrimination mandates.

A. Lack of Transparency

Transparency is a core value in health care.[77] As the American Health Policy Institute explains, "[i]n a fully transparent market, measures that disclose the relative cost, quality and customer experience for all elements of the health care supply chain would be publicly available."[78] Full transparency would allow consumers to become more informed purchasers of health plans and health care services and to demand market accountability.[79] Without transparency it is nearly impossible "to create a rational marketplace in which those who provide superior value are rewarded with more business, and those who don't suffer the consequences."[80]

Assuming that Andy's experience is representative, patients often have no idea that their insurer has implemented a step therapy program and remain ignorant of which drugs are subject to it.[81] The news that an insurer has refused to pay for a

[74] *Id.*
[75] Burns, *supra* note 57.
[76] Younger workers are especially likely to change jobs frequently. *See The New Normal: 4 Job Changes by the Time You're 32*, CNN, April 12, 2016, http://money.cnn.com/2016/04/12/news/economy/millennials-change-jobs-frequently/index.html.
[77] STEVE WETZELL, TRANSPARENCY: A NEEDED STEP TOWARDS HEALTH CARE AFFORDABILITY 1(American Health Policy Institute 2014), *available at* http://www.americanhealthpolicy.org/Content/documents/resources/Transparency%20Study%201%20-%20The%20Need%20for%20Health%20Care%20Transparency.pdf.
[78] *Id.* at 2.
[79] *Id.* at 4.
[80] *Id.*
[81] See *supra* notes 28-29 and accompanying text.

prescribed drug comes as an unwelcome surprise for the patient and prescribing provider, who must decide whether to fight the decision or opt for another treatment.[82]

Moreover, patients may find that busy medical practices are less than enthusiastic about engaging in combat with insurers over denials, an activity for which they do not get paid.[83] A 2011 Government Accountability Office report indicated that between eleven and twenty-four percent of claims and preauthorization requests were denied in the six states that were studied.[84] Health care providers, therefore, may feel overwhelmed by requests for assistance with patient appeals.

Full transparency about step therapy requirements may enable individuals to choose more wisely among different health plans. Admittedly, however, many will not have a choice because the majority of employers offer only one insurance plan.[85] Even those whose employers offer several options may find that all plans are served by the same PBM. In fact, three large PBMs, ExpressScripts, CVSHealth (also known as CVS Caremark), and OptumRx control approximately eighty percent of the market.[86]

At the very least, however, transparency will enable patients and their doctors to make more informed decisions about medical care. When physicians and patients initially decide on a course of treatment, they must be aware of any limitations that the insurer is likely to impose in order to avoid any harmful treatment delays or disruptions.

B. At Odds with Precision Medicine Approach

Precision medicine can be defined as an "approach for disease prevention and treatment that takes into account individual differences in lifestyle, environment, and

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[82] Linda Berthold, *Health Insurance Claim Denied? Don't Despair. Fight Back.*, HUFFINGTON POST, August 21, 2011, http://www.huffingtonpost.com/linda-bergthold/health-insurance-claim-de_b_881538.html; David Lazarus, *How to Fight Back when an Insurer Denies Your Healthcare Claim*, L. A. TIMES, Jan. 17, 2017, http://www.latimes.com/business/lazarus/la-fi-lazarus-winning-insurance-appeals-20170117-story.html

[83] Pfizer, *supra* note 16.

[84] UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, PRIVATE HEALTH INSURANCE: DATA ON APPLICATION AND COVERAGE DENIALS 2 (March 2011), *available at* http://www.gao.gov/new.items/d11268.pdf. The six states studied were California, Connecticut, Florida, Maryland, New York, and Ohio. *Id*. at 3.

[85] The Henry J. Kaiser Family Foundation, *2016 Employer Health Benefits Survey*, Sept. 14, 2016, http://www.kff.org/report-section/ehbs-2016-section-four-types-of-plans-offered/ (stating that "[m]ost firms that offer health benefits offer only one type of health plan (83%)" and that "[l]arge firms are more likely to offer more than one plan type than small firms.").

[86] *The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces: Hearing Before the House Judiciary Subcommittee on Regulatory Reform, Commercial, and Antitrust Law* 2, Nov. 17, 2015 (statement of David A. Balto); Wapner, *supra* note 1 (stating that the three PBMs "control an estimated 80 to 85 percent of the market").

biology."[87] President Obama's Precision Medicine Initiative, launched in January of 2015 has fueled precision medicine,[88] and emerging resources such as genetic technologies, large-scale biologic and electronic health record databases, and advanced computational tools make precision medicine a promising approach.[89] The Trump administration continues to support the initiative and calls it the *All of Us* Research Program.[90]

Precision medicine aims to enable physicians to tailor treatment to patients' attributes and characteristics.[91] Thus, physicians may be able to match treatments to patients based on factors such as genetic variations, microbiome composition,[92] medical histories, lifestyles, and diet.[93] Precision medicine is already improving cancer treatments as physicians have begun to test patients and their tumors for particular genetic markers to determine what treatment, if any, is appropriate.[94] For example, the breast cancer drug trastuzumab (Herceptin) has been found to work only for women whose tumors have a particular genetic profile called HER-2 positive, and lung cancer patients whose tumors are positive for EGFR mutations receive the drugs

[87] National Institutes of Health, *About the All of Us Research Program*, https://allofus.nih.gov/about/about-all-us-research-program (last visited June 16, 2017).

[88] The White House, *FACT SHEET: President Obama's Precision Medicine Initiative*, Jan. 30, 2015, https://obamawhitehouse.archives.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.

[89] Francis S. Collins & Harold Varmus, *A New Initiative on Precision Medicine*, 372 N. ENGL. J. MED. 793, 793 (2015); Larry J. Jameson & Dan L. Longo, *Precision Medicine—Personalized, Problematic, and Promising*, 70 OBST. & GYN. SURVEY 612, 612 (2015). Nevertheless, commentators also note various barriers to implementing precision medicine in the clinical setting and caution that expectations must be realistic. *Id*.; Michael J. Joyner & Nigel Paneth, *Seven Questions for Personalized Medicine*, 314 JAMA 999, 999-1000 (2015) (stating that "[e]ven though personalized medicine will be useful to better understand rare diseases and identify novel therapeutic targets for some conditions, the promise of improved risk prediction, behavior change, lower costs, and gains in public health for common diseases seem unrealistic").

[90] National Institutes of Health, *All of Us Research Program*, https://allofus.nih.gov/ (last visited July 15, 2017) (explaining that "[t]he mission of the *All of Us* Research Program is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us).

[91] The White House, *The Precision Medicine Initiative*, https://obamawhitehouse.archives.gov/node/333101 (last visited June 15, 2017). *See e.g.*, Xiwen Ma et al., *Personalized Effective Dose Selection in Dose Ranging Studies* in STATISTICAL APPLICATIONS FROM CLINICAL TRIALS AND PERSONALIZED MEDICINE TO FINANCE AND BUSINESS ANALYTICS 91, 91 (Jianchang Lin et al., eds. Springer (2016)) (aiming to "identify subgroups with enhanced benefit/risk profiles with appropriate doses"); Ilya Lipkovich et al., *Tutorial in Biostatistics: Data-Driven Subgroup Identification and Analysis in Clinical Trials*, 36 STATIST. MED. 136, 136 (2017) (introducing a "general framework for evaluating predictive biomarkers and identification of associated subgroups").

[92] *Data & Samples*, PERSONAL GENOME PROJECT, HARV. MED. SCH., http://www.personalgenomes.org/harvard/data. Microbiome data focuses on "the types of bacteria in and on a participant's body."

[93] *Id*.

[94] Collins & Varmus, *supra* note 89, at 793; Jameson & Longo, *supra* note 89, at 612.

gefitinib (Iressa) and erlotinib (Tarceva) that target this mutation.[95] Precision medicine has yielded benefits in other areas as well, such as treatments for cystic fibrosis and reproductive health.[96]

By contrast, step therapy constitutes a one-size-fits-all approach. Insurers require that, as a rule, doctors prescribe a particular medication before turning to more expensive alternatives.[97] In some cases, such mandates may prevent physicians from harnessing new knowledge derived from precision medicine research and customizing treatment protocols to fit their patients' particulars. Such inflexibility could ultimately raise health care costs.[98] Some patients may receive therapies that are doomed to be sub-optimal for them and that doctors versed in up-to-date research outcomes would not have prescribed absent step therapy restrictions.

C. Potential Discrimination

Step therapy can constitute unlawful discrimination if insurers do not thoughtfully select the medications that are subject to this policy. Insurance policies are governed by a variety of state and federal laws that protect people with disabilities, including the Americans with Disabilities Act of 1990 (ADA)[99] and the ACA.[100]

Almost half of all Americans are covered by employer-provided health insurance.[101] Title I of the ADA prohibits employers from discriminating against qualified individuals because of their disabilities, and this mandate extends to benefits such as health insurance.[102] Likewise, Title II of the ADA prohibits disability discrimination with respect to public services provided by state or local entities,[103]

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[95] National Cancer Institute & National Human Genome Research Institute, *Impact of Cancer Genomics on Precision Medicine for the Treatment of Cancer*, https://cancergenome.nih.gov/cancergenomics/impact (last visited June 16, 2017).
[96] W. Gregory Feero, *Introducing "Genomics and Precision Health,"* 317 JAMA 1842, 1842 (2017).
[97] *See supra* Part I.A.
[98] *See supra* Part I.C.
[99] 42 U.S.C. §§ 12101-12213 (2010).
[100] 42 U.S.C. §§ 18001 et seq. (2010).
[101] The Henry J. Kaiser Family Foundation, *Health Insurance Coverage of the Total Population* (2015), http://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (indicating that 49% are covered by policies that are provided by employers).
[102] 42 U.S.C. § 12112(a) (2010). The provision reads:

> No covered entity shall discriminate against a qualified individual with a disability because of the disability of such individual in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of employment.

[103] 42 U.S.C. § 12132 (2010) providing that

> No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations

and Title III governs "public accommodations and services provided by private entities."[104] These titles thus apply to insurance policies that individuals obtain through the private market or state programs (rather than employers). Note that Medicare and Medicaid are federal programs and are covered by Section 504 of the Rehabilitation Act, but this law's anti-discrimination mandate is identical to the ADA's.[105]

The ADA includes a provision that specifically addresses insurers.[106] Section 501(c) permits insurers to underwrite, classify, or administer risks and to establish the terms of bona fide benefit plans in a manner that is not inconsistent with state law.[107] Nevertheless, it prohibits insurers from adopting practices that are "a subterfuge to evade the purposes" of the law.[108] As I have argued in prior scholarship, Section 501(c) obligates insurers "to provide a cost-based justification for discriminatory benefit limitations or exclusions and provides a defense only for those who can do so."[109]

Consequently, insurers who select particular conditions for step therapy but exclude others to which step therapy could apply could be violating the ADA's anti-discrimination mandate. For example, insurers might implement a step therapy requirement for anti-depressants but not for diabetes or asthma, and this choice could constitute discrimination against mental health patients. Indeed, a 2015 Connecticut

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> of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.

See also 42 U.S.C. § 12131 (defining a "public entity" as including any instrumentality of a state or local government).

[104] 42 U.S.C. § 12182 (2010). Title III provides that

> No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.

Title III "public accommodations" include banks, insurance offices, private educational institutions, sales establishments, service establishments, and many other private entities. 42 U.S.C. § 12181(7) (2010). *See also*, Sharona Hoffman, *AIDS Caps, Contraceptive Coverage, and the Law: An Analysis of the Federal Anti-Discrimination Statutes' Applicability to Health Insurance*, 23 CARDOZO L. REV. 1315, 1330-33 (2002) (discussing the applicability of the ADA's Title I and Title III to insurance policies).

[105] 29 U.S.C. § 701 (2010). The provision reads:

> No otherwise qualified individual with a disability in the United States … 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 any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency.

[106] 42 U.S.C. § 12201(c) (2010).

[107] *Id*.

[108] *Id*.

[109] Hoffman, *supra* note 104, at 1334.

report (that did not focus specifically on step therapy) found that the state's largest managed care insurers denied approximately one in twelve initial requests for mental health services, a rate that represented approximately a seventy percent increase between 2013 and 2014.[110] By contrast, during the same two years, the denial rate for overall health services claims declined slightly.[111] To avoid liability, insurers should be able to articulate actuarial and medical reasons for the structure of their step therapy programs. To that end, they might require that patients first try (or switch to) an inexpensive drug only in cases in which there is strong evidence that the inexpensive medication, for most patients, is more effective than or equally as effective as more costly alternatives, unless the physician can identify specific reasons for an exemption (e.g. an allergy or prior history of failure with the drug).[112]

The ACA likewise has an anti-discrimination provision. Section 1557 of the law prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities that receive federal financial assistance or are run by a federal executive agency.[113] Thus, the ACA's anti-discrimination mandate extends to all insurers that receive federal support such as payments through Medicare Part D or the ACA Health Insurance Marketplaces.[114] To the extent that this provision survives current legislative reform efforts, it too should limit insurers' ability to pick and choose arbitrarily among health conditions that are subject to step therapy protocols.

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[110] Lisa Chedekel, *Report: Private Insurers Deny More Claims for Mental Health Care*, HARTFORD COURANT, May 13, 2016, http://www.courant.com/health/hc-insurance-mental-health-20160513-story.html.

[111] *Id*.

[112] See Nayak & Pearson, *supra* note 3, at 1782-84 (discussing the ethical implications of various scenarios in which a trial of inexpensive drug A might be required before approval of expensive drug B).

[113] 42 U.S.C. § 18116 (a) (2010). The provision reads:

> … an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title 1 (or amendments).

See also, U.S. Department of Health and Human Services, *Section 1557 of the Patient Protection and Affordable Care Act*, https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html (last reviewed Jan. 13, 2017).

[114] *Id*. U.S. Department of Health and Human Services, *Section 1557: Coverage of Health Insurance in Marketplaces and Other Health Plans*, https://www.hhs.gov/civil-rights/for-individuals/section-1557/fs-health-insurance/index.html (last reviewed August 25, 2016). For information about health insurance marketplaces *see* HealthCare.gov, *Health Insurance Marketplace*, https://www.healthcare.gov/glossary/health-insurance-marketplace-glossary/ (last visited June 15, 2017).

The ADA, Rehabilitation Act, and the ACA provide aggrieved individuals with a private cause of action.[115] Consequently, patients who believe they suffered harm because of discriminatory step therapy policies could potentially sue their insurers or employers who provided the allegedly discriminatory insurance benefit.

III
STATE AND FEDERAL LEGISLATION AFFECTING STEP THERAPY

The state and federal legislatures have not ignored the difficulties that some patients face in obtaining insurance coverage for their treatments. Some states have passed laws that specifically address step therapy. Both states statutes and federal law establish review mechanisms for insurance coverage denials. This Part analyzes these protections and the extent to which they apply to different types of insurance plans. It examines state step therapy laws, ERISA, the ACA, and the MMA.

A. State Step Therapy Legislation

The states have begun to respond to the step therapy phenomenon with legislation that governs how insurers apply these policies. As of mid-2017, thirteen states had passed legislation addressing step therapy,[116] and at least fourteen others had bills under consideration.[117]

No state law prohibits step therapy requirements altogether.[118] Instead, the statutes establish step therapy exemptions, require expedited review of physicians' requests for waivers, and/or limit the duration of step therapy protocols.[119]

Some provisions are brief and offer little guidance. For example, Arkansas requires only a "clear and convenient process to expeditiously request an override"

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[115] For ADA enforcement provisions *see* 42 U.S.C § 12117 (a) (2010) (referring to 42 U.S.C. § 2000e-5, which furnishes aggrieved individuals with a private cause of action for violations of Title VII of the Civil Rights Act of 1964); 42 U.S.C. § 12133 (referring to the Rehabilitation Act's 29 U.S.C. § 794a, which in turn refers to 42 U.S.C. 2000e-5(f), described above); 42 U.S.C. § 12188(a)(2) (1994) (providing for injunctive relief in private suits by affected parties). For the Rehabilitation Act *see* 29 U.S.C. § 794a (referring to 42 U.S.C. 2000e-5(f), described above). For the ACA's enforcement provision *see* 42 U.S.C. § 18116(a) (stating that the Rehabilitation Act's enforcement provisions applies to violations of the ACA's Section 1557).

[116] American Academy of Dermatology, *Step Therapy Legislation*, https://www.aad.org/advocacy/state-policy/step-therapy-legislation (last visited June 20, 2017). The states are Arkansas, California, Connecticut, Illinois, Indiana, Kentucky, Louisiana, Maryland, Missouri, Mississippi, New York, Washington, and West Virginia.

[117] *Id*. The states are Florida, Georgia, Iowa, Kansas, Massachusetts, Maine, Minnesota, New Mexico, Ohio, Oregon, Rhode Island, Texas, Utah, and Virginia.

[118] *Id*.

[119] Nayak & Pearson, *supra* note 3, at 1779.

of step therapy requirements,[120] and California mandates that such requests be handled in the same manner as requests for prior authorization.[121]

Other states have more detailed provisions that place restrictions upon insurers. Illinois has enacted a typical step therapy statute. It requires insurers to approve or deny requests for exemptions within 72 hours of receiving the request and to provide an explanation and information regarding alternative drugs and appeals in case of denial.[122] It further provides that:

(c) A step therapy requirement exception request shall be approved if:

(1) the required prescription drug is contraindicated;

(2) the patient has tried the required prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or

(3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan.[123]

Furthermore, approvals must be honored for at least twelve months or until renewal of the plan.[124]

Mississippi establishes an additional limitation, which is that "[t]he duration of any step therapy or fail-first protocol shall not be longer than a period of thirty (30) days when the treatment is deemed clinically ineffective by the prescribing practitioner."[125] If the physician believes, based on sound clinical evidence, that the originally prescribed medication takes longer than thirty days to become effective,

[120] ARK. CODE ANN. § 23-99-1112 (c)(1) (2015). *See also* W. VA. CODE, § 33-16-3aa (2016) (requiring a "clear and convenient process to request a step therapy exception determination" that is easily accessible on the insurer's website); WASH. REV. CODE § 69.41.190(2)(c)(iii) (2011) ("the endorsing practitioner shall have an opportunity to request as medically necessary, that the brand name drug be prescribed as the first course of treatment").

[121] CAL. INS. CODE § 10123.197(a) (West 2016). *See supra* note 41 for explanation of prior authorization.

[122] 215 ILL. COMP. STAT. ANN. 134/45.1(b)(2) (2018). *See also* N.Y. PUB. HEALTH LAWS § 4903.3-b (2017) (providing that if "the health of the insured [is]in serious jeopardy without the prescription drug or drugs prescribed by the insured's health care professional, the step therapy protocol override determination shall be granted within twenty-four hours of the receipt of information.").

[123] 215 ILL. COMP. STAT. ANN. 134/45.1(c) (2018). For similar statutes *see* CONN. GEN. STAT. ANN. § 38a-544(b)(1) (2015); IND. CODE § 27-8-5-30(h)(3) (2016); KY REV. STAT. ANN. § 304.17A-163(2) (Baldwin's 2012); LA. REV. STAT. ANN. § 46:460.34 (2014); MD. CODE ANN. INS. § 15-142 (2014); MO REV. STAT. §376.2034 (2016); MISS. CODE ANN. § 83-9-36(1) (2012); N.Y. PUB. HEALTH LAWS § 4903.3-a–3-c (2017)

[124] *Id*. at 134/45.1(e).

[125] MISS. CODE ANN. § 83-9-36(2) (2012). *See also* CONN. GEN. STAT. ANN. § 38a-544(a)(2) (2015) (establishing a 60 day limitation); KY REV. STAT. ANN. § 304.17A-163(3) (Baldwin's 2012).

the patient may be required to take the originally prescribed medication for an additional seven days.[126]

For its part, the federal Medicare program also provides guidance regarding step therapy. Medicare allows prescribing clinicians to submit a request for an exception along with a supporting statement if "the alternative(s) … required to be used in accordance with step therapy has (have) been or is (are) likely to be less effective or have adverse effects."[127] The plan sponsor must then provide notice of its benefits decision within seventy-two hours or twenty-four hours in the case of expedited requests.[128]

B. The ERISA Problem

ERISA is a federal law that governs benefit plans that are established and maintained by employers.[129] Employer-provided health plans cover forty-nine percent of Americans and thus are an extremely important component of the insurance landscape.[130]

ERISA's preemption clause prohibits insurance enrollees from pursuing state law claims and remedies.[131] Specifically, it states that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee [health] benefit plan."[132] Consequently, individuals may not bring actions against insurers based on tort, contract, and other state common law theories, including lawsuits for harm caused by treatment delays associated with step therapy protocols.[133]

However, the statute includes a significant preemption exception. ERISA's savings clause provides that ERISA does not preempt state statutes that regulate insurance.[134] Thus, for example, in 1985 the Supreme Court held that a Massachusetts statute mandating that group insurance policies provide particular minimum benefits was not preempted by ERISA.[135] Because of the savings clause, state statutes governing step therapy in principle would survive ERISA preemption.

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[126] *Id*.

[127] Centers for Medicare & Medicaid Services, *Exceptions*, (last modified Nov. 29, 2016), https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions.html; 42 C.F.R. §423.578(b) (2016).

[128] 42 C.F.R. §§ 423.568(b) & 423.572(a) (2016).

[129] United States Department of Labor, *Health Plans & Benefits: ERISA*, https://www.dol.gov/general/topic/health-plans/erisa (last visited June 22, 2017).

[130] The Henry J. Kaiser Family Foundation, *supra* note 101.

[131] 29 U.S.C. § 1144(a) (2010).

[132] *Id*.

[133] Cromwell v. Equicor-Equitable HCA Corp., 944 F. 2d 1272, 1275-76 (6th Cir. 1991); Sharona Hoffman, *A Proposal for Federal Legislation to Address Health Insurance Coverage for Experimental and Investigational Treatments*, 78 OR. L. REV. 203, 241-42 (1999).

[134] 29 U.S.C. § 1144(b)(2)(A) (2010) ("Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance…").

[135] Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724 (1985).

The savings clause, however, is limited in its reach because of another ERISA provision called the "deemer clause."[136] This clause establishes that state laws regulating insurance *are* preempted with respect to self-funded health insurance plans.[137] Employers with self-funded plans collect premiums and pay all medical claims themselves, though they may use a third party to do administrative work for the plan.[138] Step therapy statutes and other state health insurance laws, therefore, cannot be enforced with respect to self-funded plans. According to the Henry J. Kaiser Family Foundation, in 2016, sixty-one percent of workers were enrolled in self-funded health plans, which are particularly popular among large companies.[139] Consequently, the majority of individuals with employer-provided health plans cannot benefit from the protection of state step therapy laws.

C. Other Legislative Protections

Fortunately, all insured individuals are entitled to a review process for decisions with which they disagree. This right is furnished by ERISA and by the ACA.

ERISA requires that covered insurers afford participants whose medical claims are denied a "full and fair review" of adverse decisions.[140] Federal regulations provide detailed guidance concerning such appeals, which may consist of two different levels of review.[141] Because this right is created by federal law (not state law), anyone enrolled in an employer-provided plan is entitled to a review of claim denials, including individuals in self-insured health plans and those in states without step therapy statutes.[142]

The ACA also addresses health insurance appeals, and unlike ERISA, this federal law applies to all health insurance consumers, whether or not their policies are provided by employers.[143] The provision requires that at a minimum, insurers do the following: 1) have an internal claims appeals process; 2) provide an easily understood notice to enrollees regarding internal and external review opportunities and any available assistance for these processes; and 3) permit enrollees to review

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[136] *See id*. at 735 n. 14.
[137] 29 U.S.C. § 1144(b)(B) (2010).
[138] Healthcare.gov, *Self-Insured Plan*, https://www.healthcare.gov/glossary/self-insured-plan/ (last visited June 23, 2017).
[139] Henry J. Kaiser Family Foundation, *2016 Employer Health Benefits Survey - Section Ten: Plan Funding*, Sept. 14, 2016, http://www.kff.org/report-section/ehbs-2016-section-ten-plan-funding/.
[140] 29 U.S.C. § 1133 (2010).
[141] 29 C.F.R. § 2560.503-1(h) (2016); United States Department of Labor, *Benefit Claims Procedure Regulation FAQs*, https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/benefit-claims-procedure-regulation (last visited June 23, 2017).
[142] *See supra* Part III.B (explaining ERISA preemption).
[143] 42 U.S.C. § 300gg-19 (2010); National Conference of State Legislatures, *Right to Health Insurance Appeals Process*, Feb. 2011, http://www.ncsl.org/documents/health/hrhealthinsurapp.pdf.

their files, present evidence and testimony, and enjoy continued coverage until their appeals are decided.[144]

It is important to note that the ACA mandates that insurers offer not only internal reviews but also external ones.[145] External reviews are performed by independent third parties that are not associated with the health insurance plan.[146]

External reviews must comply with state external review laws that at the very least include "the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners.[147]" If the state has not established an appropriate external review process[148] or the plan is self-insured and thus not subject to state laws regulating insurance, the insurer must offer an external review process consistent with guidance from the Secretary of Health and Human Services.[149]

Medicare also enables participants to appeal unfavorable decisions.[150] Pursuant to the MMA, it establishes a five-level appeal process for those who disagree with coverage decisions. The steps include: 1) redetermination from the plan; 2) review by an independent review entity; 3) a hearing before an administrative law judge; 4) review by the Medicare Appeals Council; and 5) judicial review by a federal district court.[151]

Patients' success rates on appeal are encouraging. According to a 2011 federal government report, insurance denial reversals ranged between thirty-nine and fifty-nine percent on internal appeal, with an additional twenty-three to fifty-four percent reversed or revised as a result of external appeals.[152] The numbers vary significantly by state.[153] The report's authors noted that they could not determine an overall appeal rate for claim denials, but data from Ohio indicated that in the first

[144] 42 U.S.C. § 300gg-19(a) (2010).
[145] *Id*. at § 300gg-19(b).
[146] HealthCare.gov, *External Review*, https://www.healthcare.gov/glossary/external-review/ (last visited June 26, 2017).
[147] 42 U.S.C. § 300gg-19(b)(1) (2010); NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS, UNIFORM HEALTH CARRIER EXTERNAL REVIEW MODEL ACT (2010), http://www.naic.org/documents/committees_b_uniform_health_carrier_ext_rev_model_act.pdf.
[148] *See* Centers for Medicare & Medicaid Services, *Affordable Care Act: Working with States to Protect Consumers*, https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html (last updated Nov. 14, 2016) (listing the states and categorizing the types of external reviews they offer).
[149] *Id*. at § 300gg-19(b).
[150] 42 U.S.C.A. § 1395w-104(f)-(h); 42 C.F.R. § 423.562 (2016).
[151] Medicare.gov, *Appeals if You Have Medicare Prescription Drug Coverage*, https://www.medicare.gov/claims-and-appeals/file-an-appeal/prescription-plan/prescription-drug-coverage-appeals.html (last visited July 13, 2017).
[152] UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 84, at 23-24.
[153] *Id*.

quarter of 2010, patients internally appealed only 0.5 percent of coverage denials.[154] It is unclear why patients appealed so infrequently. While some may not have been upset by adverse decisions, it is likely that many others did not know that appealing was an option or did not have the mental ability or energy to initiate appeals. It is possible that news stories about insurance appeals in more recent years have raised the appeal figure.[155]

Nevertheless, as helpful as review processes may be for some patients, they can extend over several months. For services not yet received, such as a more expensive drug in a step therapy program, insurers must complete internal appeals within thirty days.[156] Insurers can then take up to sixty days after receiving a request to complete an external review.[157] During these months, the health of a patient who is receiving an inexpensive treatment that is a poor fit for her may deteriorate significantly. Thus, even if the coverage denial is ultimately reversed, the patient may suffer grave consequences from treatment delays.[158]

The ACA does not create a private cause of action for wrongful claim denials,[159] but ERISA does do so.[160] Therefore, as a last resort, after exhausting the administrative remedies described above, enrollees covered by ERISA plans can sue

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[154] *Id*. at 22, n. 45. The report also noted that "aggregate claim denial rates for the three states that we identified as collecting such data ranged from 11 percent in Ohio in 2009 to 24 percent in California in the same year." *Id*. at 22.

[155] *See e.g*. Pauline Bartolone, *Patients Often Win If They Appeal A Denied Health Claim*, NPR, April 14, 2014, http://www.npr.org/sections/health-shots/2014/04/14/302547851/patients-often-win-if-they-appeal-a-denied-health-claim; David Lazarus, *How to Fight Back when an Insurer Denies Your Healthcare Claim*, L.A. TIMES, Jan. 17, 2017, http://www.latimes.com/business/lazarus/la-fi-lazarus-winning-insurance-appeals-20170117-story.html.

[156] HealthCare.gov, *Appealing a Health Plan Decision: Internal Appeals*, https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals/ (last visited June 26, 2017).

[157] HealthCare.gov, *Appealing a Health Plan Decision: External Review*, https://www.healthcare.gov/appeal-insurance-company-decision/external-review/ (last visited June 26, 2016).

[158] *See* Kling-Levine, *supra* note 7 (relating the author's experience with step therapy for ulcerative colitis); Kopp, *supra* note 60 (discussing a pediatric pulmonologist's frustration with step therapy for children's asthma treatments). *See also infra* notes 7-12 and accompanying text.

[159] Letter from United States Government Accountability Office to Congressional Recipients regarding Causes of Action under the Patient Protection and Affordable Care Act (March 23, 2012) (stating "we do not believe that the implementation of the provisions identified in section 3512 of PPACA, including the development, recognition, or implementation of related guidelines and standards, is likely to give rise to new causes of action or claims"); Christine H. Monahan, *Private Enforcement of the Affordable Care Act: Toward an "Implied Warranty of Legality" in Health Insurance*, 126 YALE L. J. 1118, 1123 (2017). The one exception is the ability to sue for discrimination in violation of Section 1557 of the ACA. *See supra* notes 113-115 and accompanying text.

[160] 29 U.S.C. § 1132(a) (2010).

insurers to recover benefits to which they are entitled under their policies.[161] Other monetary damages, such as compensatory and punitive damages, are not available.[162]

A Westlaw search revealed no cases in which plaintiffs sued because of adverse decisions associated with step therapy.[163] However, numerous cases involve another cost-control strategy: medical necessity determinations.[164] A 2003 U.S. Department of Health and Human Services report focused on fifty-four medical necessity cases and found that most often, plaintiffs alleged that insurers arbitrarily and unfairly denied them coverage while approving claims in equivalent cases.[165] According to the report, insurers prevailed in twenty-nine lawsuits and had their decisions reversed in twenty-five instances.[166]

Litigation is expensive and can occupy many months if not years. It is an ineffectual tool for obtaining swift overrides of step therapy policies. However, it can be helpful for patients who opted to pay for an expensive drug out of pocket after receiving a coverage denial and wish to be reimbursed for their costs.

IV.
RECOMMENDATIONS

Patients and physicians have been vocal in expressing their frustration with step therapy.[167] At the same time, it is undeniable that health care expenses are spiraling upwards, and insurers have good reason to be concerned about treatment costs.[168] This Part develops a balanced set of recommendations that consider the interests of all stake holders. It proposes that 1) all states enact step therapy laws that, at minimum, include the elements outlined below; 2) ERISA and the ACA address step therapy programs; 3) insurers improve transparency by disseminating clear information about step therapy requirements in print and on their websites; 4) insurers monitor and incorporate up-to-date scientific and financial evidence into their policies; and 5) insurers implement step therapy programs in a non-discriminatory way.

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[161] *Id*.; *Miller v. Metropolitan Life Ins. Co*., 925 F. 2d 979, 986 (6th Cir. 1991).
[162] *Massachusetts Mutual Life Ins. Co. v. Russell*, 473 U.S. 134, 144-48 (1985) (stating that "we do not find in § 409 express authority for an award of extracontractual damages to a beneficiary.").
[163] This does not preclude the possibility that there are unreported step therapy cases.
[164] SARAH ROSENBAUM ET AL., MEDICAL NECESSITY IN PRIVATE HEALTH PLANS: IMPLICATIONS FOR BEHAVIORAL HEALTH CARE 19-21 (2003). For an explanation of medical necessity determinations, *see supra* note 40 and accompanying text.
[165] *Id*. at 21.
[166] *Id*. at 20. See e.g. Delmarva Health Plan v. Aceto, 750 A.2d 1213, 1218 (1999) (holding that an insurer must cover a lung transplant).
[167] See Kling-Levine, *supra* note 7; Kopp, *supra* note 60 (discussing a pediatric pulmonologist's frustration with step therapy for children's asthma treatments).
[168] *See supra* Part I.B.

A. All States Should Enact Step Therapy Statutes

Opponents decry step therapy legislation as an overly-rigid intervention and would prefer to be free of legislative constraints.[169] In truth, however, it is step therapy itself that is inflexible and a "one-size-fits-all" approach. It categorically requires patients to take particular drugs before being approved for others, no matter what their personal circumstances are.[170]

State step therapy statutes constitute a measured response to concerns about step therapy.[171] They do not prohibit it entirely or subject it to cumbersome requirements. Rather, they generally provide patients with an avenue to obtain relief quickly when needed without significantly undermining insurers' decision-making powers.

All states should enact step therapy statutes. The laws need not be identical but should include the following requirements:

- Approval or denial of requests for exemption within seventy-two hours of receiving the request or twenty-four hours if the request is urgent and there is serious risk to the insured's health.[172]
- Exemptions to be granted in the following circumstances:
  - The drug is contraindicated, that is, inappropriate because of the patient's medical history, attributes, or other circumstances;
  - The patient has previously tried the first-step drug, and the prescribing physician submits evidence that the drug was poorly tolerated or ineffective (evidence can come in the form of a physician statement or notations from the patient's record).
  - The patient is already stable on the drug selected by the physician.[173]
- Inclusion of a clear explanation and information about appeal mechanisms and covered alternative medications when the insurer denies a request for exemption.[174]
- Approval of drugs for at least twelve months when the insurer grants requests for exemption.[175]
- A clear definition of what step therapy "failure" means. For example, the law may require that patients be approved for the physician's drug of choice if they did not experience adequate improvement or symptom relief, as judged by the

[169] Fischer, *supra* note 26, at 802.
[170] *See supra* Part I.A.
[171] *See supra* Part III.A.
[172] *See* N.Y. PUB. HEALTH LAWS § 4903 (3) (2017).
[173] 215 ILL. COMP. STAT. ANN. § 134/45.1(c) (2018).
[174] Id. at § 134/45.1 (b)(2).
[175] *Id*. at 134/45.1(e).

physician, after thirty days.[176] It may also mandate that they try only one alternative drug before approval of the physician-recommended medication.[177]

Step therapy laws with lucid guidance will assure physicians that time requesting exemptions will be well-spent and assure patients that they can obtain treatments that will fit their needs. By requiring timely responses, the proposed legislation will prevent harmful treatment delays. Approving exemptions for at least twelve months will save patients and physicians from having to submit waiver requests every few months, a task that can be stressful and onerous. This may be especially helpful for patients with mental health or cognitive difficulties who must ask friends or relatives to assist them in interacting with doctors and insurers and may feel uncomfortable burdening these advocates repeatedly.

Clearly defining step therapy failure is also important.[178] Insurers should not have unlimited discretion to demand that patients try cheaper drugs indefinitely or try multiple drugs that do not work well for them. Such trials can severely impact patients' health, comfort, and ability to function.[179] State statutes should limit the duration of first-step drug trials and the number of drugs that must be taken before approval of the physician's drug of choice.

A complicating factor is that it is not always clear whether a drug has "failed." In the case of drugs that treat pain, discomfort, or certain mental health problems, success is judged by patients' own assessment of whether they feel better. Does the drug relieve the pain? Does the drug adequately reduce the symptoms of Parkinson's disease, such as tremor and rigidity? Is the patient less anxious or depressed? If the answers are negative, patients will return to their doctors and seek further care. It is therefore important that insurers rely on physicians' attestations regarding the failure of drugs instead of attempting to formulate objective criteria of their own.

B. Federal Law Should Address Step Therapy

As noted above, state step therapy statutes do not govern employer-provided self-funded health insurance plans because of ERISA's deemer clause.[180] The majority of American workers and their families are enrolled in self-funded plans,[181] and thus state law does not protect them. Consequently, step therapy provisions should be incorporated into federal law as well.

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[176] MISS. CODE ANN. § 83-9-36(2) (2012).

[177] See ASSEMBLY, NO. 1832, STATE OF NEW JERSEY, 215TH LEG. § 1.a(2), ftp://www.njleg.state.nj.us/20122013/A2000/1832_I1.HTM.

[178] *See supra* note 3 at 1781 (stating that "what constitutes the *failure* of the first-step drug can be one of the most contentious aspects of a step therapy policy.").

[179] *See supra* notes 7-12 and accompanying text.

[180] *See supra* notes 136-139 and accompanying text.

[181] *See supra* note 139 and accompanying text.

ERISA itself could address step therapy in its "Claims Procedure" section that mandates a "full and fair review" of adverse insurance decisions.[182] The provision should be detailed and include the requirements described above.[183]

While Medicare regulations already provide step therapy guidelines for Medicare plans,[184] the ACA should do so for all other insurance policies. The law could furnish step therapy guidelines in a new subpart of its "Appeals Process" provision.[185] However, given the current Congress' efforts to repeal the ACA, the law's future is uncertain, and it is unlikely that any of its provisions will be expanded in the near term.

C. Improving Transparency

Insurers should be fully transparent about their step therapy requirements and should disseminate clear and readable information about them through their websites and printed materials. They should keep in mind that fifty percent of adults cannot understand a book written at an eighth grade level, and thus informational materials should be written at a sixth grade reading level.[186] Insurers should be careful to educate both patients and physicians about step therapy policies. They should also ensure that their websites include tools that enable users to search for restrictions that apply to particular drugs. Medical appointments will be more productive if physicians and patients know to take step therapy requirements into account as they consider treatment alternatives. Physicians who feel strongly that specific drugs are best for patients despite contrary step therapy constraints could immediately initiate waiver requests in order to minimize delays and frustrations (and one hopes they will be willing to invest the time in doing so). Physicians who have no objections to insurers' preferences could explain them to patients and tailor their recommendations accordingly.

Existing legislative guidelines already embrace the value of transparency. ERISA requires insurers to furnish participants with "summary plan descriptions."[187] The provision details the "easily understood"[188] information that enrollees must receive and could be slightly revised to require specific disclosure of step therapy

[182] 29 U.S.C. §1133 (2010).
[183] *See supra* Part IV.A.
[184] See 42 C.F.R. §§ 423.568(b), 423.572(a), and 423.578(b) (2016).
[185] 42 U.S.C. §300gg-19 (2010). Note that federal regulations already require that insurers who receive a request to review an adverse coverage decision do so within 72 hours or 24 hours in exigent circumstances. 42 C.F.R. §156.122(c)(1)(ii) & (2)(iii) (2016).
[186] Literacy Project Foundation, *Staggering Illiteracy Statistics*, http://literacyprojectfoundation.org/community/statistics/ (last visited July 15, 2017); Tiffany M. Walsh & Teresa A. Volsko, *Readability Assessment of Internet-Based Consumer Health Information*, 53 RESP. CARE 1310 (2008) ("The literature indicates and the USDHHS [Department of Health and Human Services] recommends that consumer medical information be written at the 6th-grade reading level.").
[187] 29 U.S.C. §§ 1022 & 1024(b) (2010).
[188] *Id* at § 1022(a).

programs.[189] If the summary plan description is lengthy and participants are unlikely to read it, insurers would be wise to highlight the existence of step therapy policies in a separate newsletter or brochure. In addition, the information should be posted on user-friendly websites.

Several state laws also address transparency and disclosure by health insurers.[190] For example, a California law requires insurers that use a formulary[191] to post the formulary on their websites.[192] A Colorado statute requires the insurance commissioner to develop a website that discloses health insurance price information.[193] State legislatures could similarly establish disclosure requirements regarding step therapy.

Medicare empowers patients to determine whether specific drugs are subject to insurance restrictions, including step therapy, through a simple search on its website. It offers a page entitled "2017 Drug Finder: Search for Your Prescription Drug across All Medicare Part D or Medicare Advantage Plans."[194] Users can enter the name of any drug and obtain a wealth of information about whether and in what manner it is covered by various Medicare plans.[195] All insurers should enable participants to conduct such searches.

Full disclosure serves not only patients' interests but also those of insurers. Absent sound reasons for disagreement, patients and physicians who are aware of step therapy guidelines will comply and save insurers the trouble of processing requests for exemption and later appeals. By contrast, physicians who cannot easily learn of step therapy restrictions are more likely to prescribe medications for which insurers will deny coverage. Patients who are disappointed and distressed by insurers' decisions that are contrary to their physicians' recommendations may then attempt to obtain reversals, creating administrative work and costs for insurers.

D. Monitor and Incorporate Up-to-Date Scientific and Financial Evidence

Insurers should frequently review emerging medical evidence to ensure that their step therapy protocols are consistent with patients' best interests. Step therapy requirements should not become ossified and outdated. For example, if precision

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[189] *Id*. at § 1022(b).
[190] National Conference of State Legislatures, *Transparency and Disclosure of Health Costs and Provider Payments: State Actions*, http://www.ncsl.org/research/health/transparency-and-disclosure-health-costs.aspx (last updated March 2017).
[191] A formulary is "a list of prescription drugs covered by [an] … insurance plan offering prescription drug benefits." HealthCare.gov, *Formulary*, https://www.healthcare.gov/glossary/formulary/ (last visited July 3, 2017).
[192] CAL. HEALTH AND SAFETY CODE §1367.205(a)(1) (West 2016).
[193] COLO. REV. STAT. ANN. §§ 10-16-133, 10-16-134.
[194] Q1Medicare.com, *2017 Drug Finder: Search for Your Prescription Drug across All Medicare Part D or Medicare Advantage Plans*, https://q1medicare.com/PartD-SearchPDPMedicarePartDDrugFinder.php (last visited July 2, 2017).
[195] *Id*.

medicine studies reveal that individuals with particular genetic mutations or other characteristics (e.g. age, co-existing diseases, etc.) should take drug B rather than drug A, insurers with step therapy programs mandating initial trials of drug A should respond quickly and alter their coverage guidelines.[196]

Another source of relevant data is comparative effectiveness research.[197] This research, based on studies that compare drugs, devices, or other medical interventions, aims "to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options."[198] As just one example, a recent study published in *JAMA Internal Medicine* focused on treatments for clostridium difficile infection (a bacterium that causes diarrhea).[199] When researchers compared the antibiotics vancomycin and metronidazole, they concluded that patients who took vancomycin had a significantly reduced risk of death within thirty days, which suggested that vancomycin should be used as the initial therapy for patients with severe forms of the disease.[200] It is obvious that such a finding may require insurers to adjust their step therapy requirements.

Likewise, insurers should review their own financial data to determine whether step therapy requirements are cost-effective. If a first-step drug has a high failure rate or raises overall costs because patients often seek treatment for side-effects and complications, insurers should adjust the requirement in question.[201]

To these ends, insurers can use their existing pharmacy and therapeutics (P & T) committees.[202] Federal regulations detail standards for these committees, relating to their membership, conflicts of interest, quarterly meetings, documentation, and other obligations.[203] P & T committees are tasked with reviewing and approving step

[196] *See* Part II.B (discussing precision medicine).
[197] Agency for Healthcare Research and Quality, *What Is Comparative Effectiveness Research*, https://effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/ (last visited July 5, 2017).
[198] *Id*.
[199] Vanessa W. Stevens et al., *Comparative Effectiveness of Vancomycin and Metronidazole for the Prevention of Recurrence and Death in Patients with Clostridium Difficile Infection*, 177 JAMA INTERN. MED. 546, 546 (2017). For information about clostridium difficile infections, *see* U.S. National Library of Medicine, *Clostridium Difficile Infections*, https://medlineplus.gov/clostridiumdifficileinfections.html (last visited July 5, 2017).
[200] Stevens et al., *supra* note 199, at 546.
[201] *See* Nayak & Pearson, *supra* note 3, at 1781.
[202] *See* F. Randy Vogenberg, *The Changing Roles of P&T Committees: A Look Back at the Last Decade and a Look Forward to 2020*, 39 PHARM. & THERAP. 760, 760 (2014).
[203] 45 C.F.R. §156.122 (2016) (a)(3). Members must "represent a sufficient number of clinical specialties," be composed of a majority of individuals who are pharmacists or "health care professionals who are licensed to prescribe drugs," and be prohibited from voting on a matter concerning which they have a conflict of interest. In addition, at least 20 percent must "have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer." *Id*. at § 156.122(a)(3)(i).

therapy protocols[204] and should be sure to monitor new medical and economic data and modify the protocols as appropriate.[205]

E. Avoid Discrimination

Step therapy policies should be equitable and non-discriminatory.[206] This is not to say that insurers should subject every possible drug to step therapy requirements to avoid allegations of discrimination. Rather, step therapy policies must be thoughtful and well-supported by scientific and financial evidence. Thus, if patients question why a particular drug is subject to restrictions while others are not, insurers must be able to articulate sound justifications for their implementation decisions.

V
CONCLUSION

Insurers' concern about the rapidly rising cost of medical care is warranted, and they cannot be condemned for establishing cost-control measures.[207] In her best-selling book, *An American Sickness: How Healthcare Became Big Business and How You Can Take It Back*,[208] Elisabeth Rosenthal details a myriad of reasons for the United States' exorbitant health care prices. She also offers a variety of solutions,[209] as have many other commentators.[210]

Step therapy is an intervention that is favored by the majority of United States insurers.[211] Often, patients suffer no ill consequences from step therapy policies. For example, many patients tolerate generic drugs just as well as they tolerate brand-name drugs.[212]

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[204] *Id*. at §156.122(a)(3)(iii)(F).
[205] *Id*.
[206] *See supra* Part II.C (discussing potential discrimination).
[207] See *supra* Part I.B (discussing the need for cost control measures).
[208] ELISABETH ROSENTHAL, AN AMERICAN SICKNESS: HOW HEALTHCARE BECAME BIG BUSINESS AND HOW YOU CAN TAKE IT BACK (Penguin Press 2017)
[209] *Id*. at 241-327.
[210] See e.g. STEVEN BRILL, AMERICA'S BITTER PILL: MONEY, POLITICS, BACKROOM DEALS, AND THE FIGHT TO FIX OUR BROKEN HEALTHCARE SYSTEM (Random House 2015); ELIZABETH H. BRADLEY & LAUREN A. TAYLOR, THE AMERICAN HEALTH CARE PARADOX: WHY SPENDING MORE IS GETTING US LESS (PublicAffairs 2015).
[211] *See supra* Part I.A (providing background information regarding step therapy).
[212] *See supra* note 25 and accompanying text; U.S. Food & Drug Administration, *FDA Ensures Equivalence of Generic Drugs*, August 2002, https://www.fda.gov/drugs/emergencypreparedness/bioterrorismanddrugpreparedness/ucm134444.htm ; James McCormack & John T. Chmelicek, *Generic Versus Brand Name: the Other Drug War*, 60 CAN.

In other instances, however, step therapy promotes neither patient interests nor the insurer's economic goals. Patients may suffer grave harms when they do not receive their physician's drug of choice because of step therapy constraints.[213] These can include medical complication as well as severely diminished functionality, which in turn can result in an inability to work, financial difficulties, depression, and health problems stemming from a sedentary and inactive lifestyle.[214] Thus, step therapy at times is penny wise but pound foolish.

This Article has argued for a nuanced approach to improving step therapy programs and reducing their risks.[215] Insurers should establish expeditious and uncomplicated waiver mechanisms, guided by state and federal legislation, so that patients who truly need a more expensive drug can quickly obtain it and doctors are minimally burdened by administrative demands. Insurers must also enhance transparency, respond to emerging medical and financial evidence that necessitates policy modifications, and be wary of discrimination.[216]

Finally, the health insurance industry should conduct further research to determine if step therapy is in fact an effective cost reduction tool.[217] If the programs' economic benefits do not outweigh the burdens they impose on patients, physicians, and insurers, they should be altered or abandoned. Step therapy should not constitute a bludgeon that is used against patients and their doctors. Instead, it should be a vehicle for all stakeholders to work cooperatively to reduce treatment costs without compromising health outcomes.

FAM. PHYSICIAN 911, 911 (2014) (concluding that "[a]ccording to the best available evidence, generic medications are bioequivalent and produce similar clinical outcomes to brand-name medications.").

[213] *See supra* notes 57-74, 167-12 and accompanying text.

[214] *Id*; Arthur Lazarus, *Formulary Restrictions Sometimes Harm Patients*, MAN. CARE, Oct. 2004, https://www.managedcaremag.com/archives/2004/10/formulary-restrictions-sometimes-harm-patients.

[215] *See supra* Part IV.

[216] *Id*.

[217] Rashad I. Carlton et al., *Review of Outcomes Associated with Formulary Restrictions: Focus on Step Therapy*, AM. J. PHARM. BENEFITS, Apr. 6, 2010, http://www.ajpb.com/journals/ajpb/2010/vol2_no1/review-of-outcomes-associated-with-formulary-restrictions-focus-on-step-therapy; Motheral, *supra* note 47, at 143.