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THE PAIN OF PRIOR AUTHORIZATIONS: CONSEQUENCES OF THE DE-PRIORITIZATION OF HUMAN LIFE IN FAVOR OF COST CONTAINMENT

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INTRODUCTION

Linda H. recounts how her son's oncologist recommended that he have a PET scan every three months.[1] But her son's health care insurer[2] denied the PET scan during its prior authorization review process, delaying the scans beyond his oncologist's recommended timeframe.[3] The delay resulting from the prior authorization process led to a delayed confirmation of melanoma on her son's skin.[4] This delayed confirmation of her son's melanoma delayed his PD-1 treatment for the melanoma, which his cancer was very responsive to.[5] Kathy's son died two weeks before receiving his PD-1 treatment.[6] Linda concludes her story, stating how her son's outcome could have been different had it not been for the multiple delays during the prior authorizations process.[7]

Kathleen Valentini was enrolled in a health insurance benefits plan with Group Health, Inc. (Group Health).[8] Through the benefits plan, Group Health was Kathleen's health care insurer.[9] Group Health contracted with eviCore to conduct its prior authorization review process. In 2018, Kathleen started physical therapy and pain medication when her hip began to hurt, which Group Health covered.[10] After six weeks, Kathleen was still experiencing excruciating pain, so she was referred to an orthopedic surgeon.[11] The orthopedic surgeon requested

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[1] *Patients and Physicians Speak Out*, AM. MED. ASS'N, https://fixpriorauth.org/stories (last visited Oct. 2, 2022).

[2] This paper uses the word "insurer" to refer generally to the entity that provides health insurance coverage to a patient. "Insurer" is inclusive of, but not limited to, insurance companies, health plans, employers, and other payers.

[3] *Patients and Physicians Speak Out*, *supra* note 1.

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] Valentini v. Grp. Health Inc., No. 20 CIV. 9526 (JPC), 2021 WL 2444649, at *4 (S.D.N.Y. June 15, 2021).

[9] *See id.*

[10] *See id.*

[11] *Id.*

Group Health to authorize an MRI for Kathleen's hip.[12] eviCore denied the request for the MRI.[13] eviCore did not reverse its decision on the MRI for forty days.[14] When the MRI was finally conducted, the imaging revealed that Kathleen had sarcoma, requiring her doctors to amputate Kathleen's hip, pelvis, and leg. Kathleen's doctors stated that had she gotten the MRI one month earlier, she could have been treated with chemotherapy only.[15] The delay during the prior authorization process cost Kathleen half of her lower body and contributed to her subsequent death.[16]

A physician describes how they prescribed a specific inhaler for their patient, only to have it denied through the prior authorization process of the patient's insurer.[17] Following its prior authorization processes, the insurer required the patient to try different inhalers first before using the one that the patient's physician initially prescribed.[18] The physician stated that it took about a month for the patient to find an inhaler that worked and that the insurer would approve—a process that involved the collective efforts of seven to ten people.[19] These stories, and many others like them, beg the question—how many patients must suffer adverse consequences due to prior authorization delays until state and federal law makers enact legislation that prioritizes patients' lives?

The current system of prior authorization review does not prioritize the lives and health of patients. As of 2021, 34% of physicians reported that issues resulting from prior authorizations led to a serious adverse event for a patient in their care.[20] Specifically, 24% of

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[12] *Id.*

[13] *Id.*

[14] *See Valentini*, 2021 WL 2444649, at *4.

[15] *Id.*

[16] *See id.*; *see also* Tanya Albert Henry, *Cancer killed Kathleen Valentini, but prior auth shares the blame*, AM. MED. ASS'N, (June 16, 2022), https://www.ama-assn.org/practice-management/prior-authorization/cancer-killed-kathleen-valentini-prior-auth-shares-blame.

[17] LACEY COLLIGAN ET AL., AM. MED. ASS'N., SOURCES OF PHYSICIAN SATISFACTION AND DISSATISFACTION AND REVIEW OF ADMINISTRATIVE TASKS IN AMBULATORY PRACTICE: A QUALITATIVE ANALYSIS OF PHYSICIAN AND STAFF INTERVIEWS 10 (2016).

[18] *Id.*

[19] *Id.*

[20] AM. MED. ASS'N, 2022 AMA PRIOR AUTHORIZATION (PA) PHYSICIAN SURVEY (2023).

physicians reported that prior authorization issues led to a patient's hospitalization, 18% of physicians reported that prior authorization issue led to a life-threatening event or required intervention to prevent permanent impairment or damage, and 8% of physicians reported that prior authorization issues led to a patient's disability, permanent damage, congenital anomaly, or even death.[21]

Physicians, nurses, and other medical staff also constantly suffer the pain of prior authorizations.[22] Because insurers require prior authorization for many types of medical care, including prescriptions, tests, therapies, surgeries, among others, clinicians spend significant amounts of time navigating the requirements of multiple insurers and communicating with insurers across various communication channels, such as phone calls, faxes, and electronic notifications.[23] Oftentimes, the prior authorization process requires multiple phone calls or lengthy conversations before an insurer approves or denies the prescribed treatment.[24] Some physicians experience such significant dissatisfaction with the prior authorization process that they will refuse to participate in the grievance process and will inform their patients that their insurer refuses to cover their treatment.[25] The administrative hurdles intrinsic to the prior authorization process are equally burdensome on physicians, nurses, and other medical staff and contribute to the delay of patient care.[26] Figure 1 showcases the burdens that prior authorization review poses to providers, clinical staff, and patients.

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[21] *Id.*

[22] COLLIGAN ET AL., *supra* note 17, at 9.

[23] *Id.*

[24] *Id.*

[25] *Id.* at 10.

[26] *Id.*

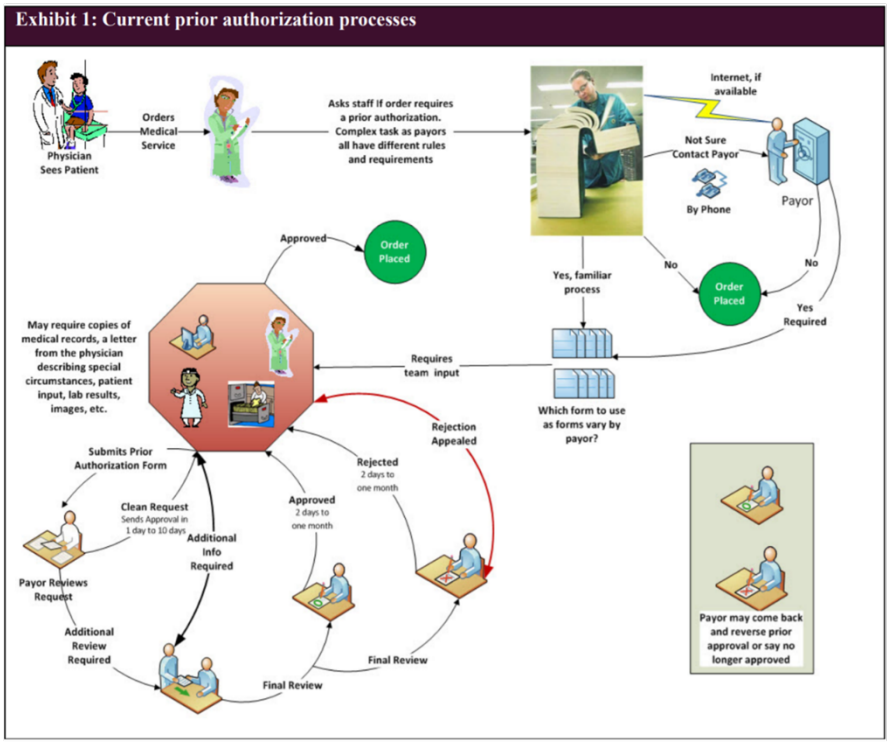

Figure 1: Exhibit 1 in the American Medical Association White Paper on the Standardization of Prior Authorization Process for Medical Services

This Comment argues that the prior authorization review process does not currently serve the health and livelihood of patients with chronic medical conditions or symptoms whose diagnoses are either known or unknown—those who depend on access to medications, treatments, and other health care services to manage their existing medical conditions and/or prevent other conditions from developing. Further, this Comment argues that there must be a better way to prioritize patient care and the necessary treatments that patient's doctors recommend, while also keeping the costs of health care as low as reasonably possible. Specifically, this Comment will recommend that patients should be able to receive their medication, treatment, or other health care service that they need without having to wait for approval through the prior authorization review in certain circumstances where

their medical conditions or symptoms are at risk of worsening without access to the requisite medication, treatment, or other health care service. The scope of this Comment will focus on the prior authorization requirements and federal and state regulations of commercial health insurers.

This Comment will proceed as follows: Part I will provide a brief history of managed care and utilization review and the purposes of each approach. Part II will analyze current challenges posed by prior authorization processes, including adverse determinations and grievance processes that patients must follow. Part II will also analyze current statutory and regulatory law from various jurisdictions on prior authorizations as well as prior authorization reforms. In addition, this section will also critique current prior authorization laws and in-flight reformatory measures through the lens of their impact to patients. Part III will recommend a solution that deviates from prior authorizations in certain circumstances where patients are at risk of adverse outcomes and conclude this Comment.

I. THE EVOLUTION OF MANAGED CARE INSURANCE PLANS AND UTILIZATION MANAGEMENT

Broadly speaking, "managed care" refers to a health care approach that aims to minimize health care costs while delivering appropriate care and related services to patients.[27] Health insurers offer managed care insurance plans[28] that provide certain medical benefits to members at a reduced cost by contracting with health care providers and medical facilities who make up the plan's network. [29] Four main types of managed care plans exist: (1) Health Maintenance Organizations (HMOs); (2) Preferred Provider Organizations (PPOs); (3) Point of Service (POS) Organizations; and (4) Exclusive Provider

[27] ANGELO P. GIARDINO & ORLANDO DE JESUS, NAT'L LIBR. OF MED., MANAGED CARE (2022), https://www.ncbi.nlm.nih.gov/books/NBK564410/.

[28] *Managed Care*, MEDLINEPLUS, https://medlineplus.gov/managedcare.html (Aug. 30, 2019).

[29] *Id.*

Organizations (EPOs).[30] Most Americans who receive health insurance through a commercial provider are enrolled in an HMO plan.[31]

Enrollment in managed care insurance plans gained popularity in the 1980s and 1990s, with over 70% of Americans enrolled in a managed care plan by 1993, but the principles underlying managed care have existed since the beginning of the 20th century.[32] Prior to the introduction of health insurance plans, patients paid directly out-of-pocket for the medical services they received.[33] However, "public awareness of the increasingly prohibitive costs of health care prompted the development of innovative approaches to financing and delivering health care services" in the early 1900s.[34] As a result, prepaid health care plans were created to meet the needs of particular populations, "often the employees of large industries, such as railroads, mining, and lumber."[35] Eventually, the broader business community developed an interest in prepaid plans throughout the 1930s and 1940s.[36] Some of the precursors to the modern-day HMO, such as Kaiser-Permanente, Health Insurance Plan of Greater New York, and Group Health Cooperative of Puget Sound in Seattle, Washington, developed during these years.[37]

By World War II, most Americans received health insurance through their employer, which continues to this day.[38] Employers

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[30] Mila Araujo, *HMO, PPO, POS, EPO: What's the Difference?*, THE BALANCE, https://www.thebalancemoney.com/health-and-medical-insurance-2645378 (Apr. 2, 2022).

[31] Sydney Garrow, *What's the Most Popular Health Insurance Plan?*, EHEALTHINSURANCE SERVS., INC., https://www.ehealthinsurance.com/resources/individual-and-family/whats-popular-health-insurance-plan (Oct. 21, 2022).

[32] Sherry Glied, *Chapter 13 – Managed Care*, 1 HANDBOOK OF HEALTH ECON. 707, 707 (2005) https://doi.org/10.1016/S1574-0064(00)80172-9; Niharika Namburi & Prasanna Tadi, *Managed Care Economics*, NAT'L LIBR. OF MED., https://www.ncbi.nlm.nih.gov/books/NBK556053/ (Jan. 30, 2023).

[33] George B. Moseley, *The U.S. Health Care Non-System, 1908-2008*, 10 AMA J. of Ethics 324, 324 (2008).

[34] Karen Davis et al., *I. Essay: Managed Care: Promise and Concerns*, 13 HEALTH AFFS. 178, 179 (1994).

[35] Ralph O. Bischof & David B. Nash, *Managed Care: Past, Present, and Future*, 80 MED. CLINICS OF N. AM. 225, 226 (1996).

[36] *Id.*

[37] *Id.*

[38] *Id.*

desired the ability to provide employees with a small additional benefit without outright increases to their employees' salaries and providing health care coverage was the ideal solution.[39] However, significant increases in the cost of health insurance throughout the 1950s became increasingly burdensome on employers paying for their employees' health coverage, and, as a result, prepaid health care became more attractive to the national policymakers.[40] Looking to curb the burgeoning costs of health care, Congress passed the Health Maintenance Organization (HMO) Act in 1973, in effect until 1982, which provided funding to broaden the development and expansion of HMOs and required employers to offer HMOs to employees in certain circumstances.[41] The HMO Act lead to the growth of HMOs throughout the country and the development of PPOs.[42]

From the mid-1980s to the mid-1990s, the managed care industry continued to mature and take new forms, which led to increased enrollment.[43] Entrepreneurs sensing potential financial gain "acquired or started HMOs with the goal of profiting by later selling the HMO to a larger company."[44] The market ultimately consolidated as acquisitions ensued starting in the early 1990s.[45] Both health care providers and hospitals consolidated, respectively, which led to "diminished competition to the point of bringing into question the viability of the competitive model in the delivery of [health care] services."[46] This consolidation period also led to the collaboration between hospitals and health care providers to form integrated delivery systems or networks as a method of contracting with payors, including managed care plan insurers.[47] By 1993, more than 122 million Americans were enrolled in

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[39] *Id.*

[40] *Id.* at 226-27.

[41] Bischof & Nash, *supra* note 35, at 227; PETER R. KONGSTVEDT, HEALTH INSURANCE AND MANAGED CARE 7 (5th ed. 2020).

[42] Bischof & Nash, *supra* note 35, at 227; KONGSTEVDT, *supra* note 41, at 9.

[43] KONGSTEVDT, *supra* note 41, at 10.

[44] *Id.* at 11.

[45] *Id.* at 12.

[46] *Id.*

[47] *Id.*

either an HMO or a PPO plan.[48] Currently, HMOs remain the most popular health insurance plan with 49% of consumers enrolling in an HMO plan in 2020, with PPOs and EPOs following not far behind.[49]

With the rise of managed care insurance plans came the rise of utilization management as an approach to contain the burgeoning costs of health care, which is now a prominent pillar of the managed care methodology.[50] The utilization management approach began growing in the 1950s to control fee-for-service payments[51] for "unnecessary and inappropriate hospital services."[52] Part of this initial growth included medical societies that established Foundations for Medical Care (FMCs), which "pioneered many utilization [management] tools, including model treatment profiles to assess physician performance, protocols for reviewing ambulatory care, and computerized screening of claims."[53]

The utilization management approach continued to spread throughout the 1960s and 1970s.[54] In the early 1960s, over sixty Blue Cross plans reviewed hospital claims for the appropriateness of admissions, and more than fifty looked at the length of a patient's stay.[55] Some plans also required physicians to certify at admission that hospital care was necessary for specific types of cases, such as diagnostic or dental admissions, and "more than two dozen [plans] required physicians to certify the need for continued hospital care after a specified length of stay."[56] Additionally, FMCs continued to grow over the next

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[48] Bischof & Nash, *supra* note 35, at 227.

[49] Garrow, *supra* note 31.

[50] Thomas M. Wickizer & Daniel Lessler, *Utilization Management: Issues, Effects, and Future Prospects*, 23 ANN. REV. OF PUB. HEALTH 233, 233 (2002); THE ROLE OF UTILIZATION MANAGEMENT 36 (Bradford H. Gray & Marilyn J. Field eds., 1989), https://www.ncbi.nlm.nih.gov/books/NBK235000/pdf/Bookshelf_NBK235000.pdf [hereinafter THE ROLE OF UTILIZATION MANAGEMENT].

[51] *fee-for-service?*, HEALTHINSURANCE.ORG, https://www.healthinsurance.org/glossary/fee-for-service/ (last visited Jan 30. 2023); INST. OF MED., CONTROLLING COSTS AND CHANGING PATIENT CARE? THE ROLE OF UTILIZATION MANAGEMENT, *supra*, note 50, at 44.

[52] THE ROLE OF UTILIZATION MANAGEMENT, *supra* note 50, at 36.

[53] *Id.* at 37.

[54] *See id.*

[55] *Id.*

[56] *Id.*

two decades, and, by 1973, there were sixty-one FMCs in twenty-seven states.[57]

However, the costs of health care continued to rise, and the "share of national spending for health services and supplies accounted for by business[es] grew from 17% in 1965 to around 30% in 1987."[58] Employers realized that they needed to be both more aggressive and prudent in providing health benefits to their employees.[59] Many larger employers, specifically, became actively involved in managing their health benefit plans and took steps to secure better terms and rates for their purchase of medical care for their employees.[60] As such, private and public employers and purchasers of health insurance acted as both a "stimulus and a lever for the development and application of new approaches to modifying medical practice matters and limiting the unnecessary use of services."[61]

In addition to the actions of purchasers, insurers themselves were motivated to contain costs throughout the 1960s and 1970s.[62] This motivation stemmed in part from expanding bodies of research suggesting that some medical services were unnecessary or inappropriate and the growth of "information resources, assessment tools, and organizations that made case-by-case review of proposed services feasible on a large scale."[63] Moreover, in response to the motivation to control health care costs, "the federal government, many medical societies, and other organizations" encouraged the "development of practice guidelines or protocols for the appropriate and cost-effective use of special medical services."[64]

Eventually, the demand by both large public and private purchasers for ways to both manage and review health care utilization was matched by the emergence of organizations that supplied these

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[57] *Id.*

[58] THE ROLE OF UTILIZATION MANAGEMENT, *supra* note 50, at 40.

[59] *Id.*

[60] *See id.* at 41.

[61] *Id.* at 43.

[62] *Id.*

[63] *Id.*

[64] THE ROLE OF UTILIZATION MANAGEMENT, *supra* note 50, at 46.

utilization management services.[65] These organizations fell into two categories: (1) organizations that would "integrate utilization and cost control with service delivery" and (2) organizations that would "offer specialized utilization management services to both health care providers and purchasers."[66] By the late 1980s, "hundreds of organizations offer[ed] utilization management services to thousands of clients" who employed approximately "half to two-thirds of all American workers."[67] The inception of these organizations led to the development of the utilization management industry, which still exists today.[68] Presently, utilization management and review may now be conducted by health insurance companies, hospitals, home health companies, utilization management companies, and a myriad of other types of health care providers.[69]

Today, utilization management remains a "well-recognized component of a cost management approach in the health care service delivery and payment arenas."[70] Utilization management processes currently include "interventions that take place before, during, and after the clinical encounter."[71] Each of these types of review seek to determine: (1) whether the patient's health plan covers the requested intervention and, if so, (2) whether the requested intervention is medically necessary.[72]

Utilization management that occurs before a clinical event is called prior authorization.[73] During the prior authorization process, the requested clinical service or procedure ordered by the physician will be assessed through utilization review to determine if the service or

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[65] *Id.* at 49.

[66] *Id.*

[67] *Id.* at 59.

[68] *See id.* at 14.

[69] *See* Elizabeth Davis, *How Utilization Review Works*, VERYWELL HEALTH, https://www.verywellhealth.com/utilization-review-what-it-is-how-it-works-1738788 (Nov. 26, 2023).

[70] Angelo P. Giardino & Roopma Wadhwa, *Utilization Management*, NAT'L LIBR. OF MED., https://www.ncbi.nlm.nih.gov/books/NBK560806/ (July 10, 2023).

[71] *Id.*

[72] *Id.*

[73] *Id.*

procedure is appropriate.[74] Whether the service or procedure is determined to be appropriate is generally based on a set of criteria and, when available, national standards of care associated with the ordered service or procedure are used.[75] If a patient's condition or symptoms do not fall within the set of criteria or if the requested procedure falls outside the national standard of care, the clinical service or procedure will most likely be denied.[76]

Utilization management that occurs while a patient admitted to a facility is receiving clinical care is called concurrent review.[77] The purpose of concurrent review is to have an oversight process that scrutinizes the type of care being delivered to a patient, the necessity for the type of care, and the level and the setting of that care that the patient has already started to receive.[78] Like prior authorization review, concurrent review uses a set of criteria when determining the necessity of continuing a patient's care.[79]

Utilization management that is conducted after the clinical event is called retrospective review.[80] Specifically, retrospective review occurs after the patient's care has already been delivered and the bill for that care has been submitted.[81] Retrospective review seeks to confirm if the care provided to the patient was both appropriate and provided at the most efficient level.[82] However, if the retrospective review concludes that the care provided to the patient was not appropriate, the insurer may choose to deny coverage of the care to the patient.[83] Given long-standing history of high costs of health care, patients denied payment for their care are subsequently left with a large bill that they are solely responsible for.[84]

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[74] *Id.*

[75] *Id.*

[76] *See* Giardino & Wadhwa, *supra* note 70.

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *Id.*

[81] *Id.*

[82] Giardino & Wadhwa, *supra* note 70.

[83] *See id.*

[84] *See id.*

II. PRIOR AUTHORIZATION: OVERVIEW, CHALLENGES, AND REFORMS

The stated goals of prior authorization review, concurrent review, and retrospective review are to ensure the delivery of cost-effective patient care.[85] However, utilization management often poses its own challenges to patients, providers, and other clinical staff.[86] This section will analyze the current challenges posed specifically by prior authorization processes, including adverse determinations and grievance processes that patients must follow. Additionally, this section will analyze and critique current statutes and regulations from various jurisdictions that regulate the prior authorization process. Moreover, this section will analyze and critique in-flight prior authorization reforms and their impact to patient care.

Prior authorization—also known as precertification, preauthorization, prior approval, prior notification, prospective review, and prior review—is the most common utilization management tool used by health care insurers in the U.S.[87] Prior authorization requires health care providers to establish that a patient is eligible for a requested clinical service, event, or procedure and obtain approval from the patient's health plan before care is delivered to determine if the patient is qualified for payment.[88] Generally, health care insurers or payers will employ health care professionals, including physicians, nurses, or other health care professions to support the development and execution of prior authorization policies.[89] However, the types of medications, treatments, or other health care services that require prior authorization will vary by insurer or payer, utilization patterns, clinical evidence, financial considerations, and government regulations and

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[85] *Id.*

[86] *See* COLLIGAN ET AL., *supra* note 17, at 9; *see also* AM. MED. ASS'N, PRIOR AUTHORIZATION AND UTILIZATION MANAGEMENT REFORM PRINCIPLES 1, *https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.*

[87] ANI TURNER ET AL., NAT'L INST. FOR HEALTH CARE REFORM, IMPACTS OF PRIOR AUTHORIZATION ON HEALTH CARE COSTS AND QUALITY 4 (2019), https://www.nihcr.org/wp-content/uploads/Altarum-Prior-Authorization-Review-November-2019.pdf.

[88] *Id.*

[89] *Id.*

statutes, creating different types of varied processes that clinicians must follow when requesting approval from insurers.[90]

Prior authorization review is often used for multiple types of medications, treatments, or other health care services, including prescription drugs, medical equipment, diagnostic radiology, surgical procedures, inpatient stays, and behavior health treatments, among others.[91] Consequently, clinicians and support staff must spend hours every week to meet the varied needs and requirements of the insurers just to receive authorization at the outset.[92] Further, a lack of standardization and streamlining in submitting requests for prior authorization, often using antiquated communication methods, creates an administrative burden for clinicians, resulting in significant delays for patients anxiously awaiting reception of their prescribed medication, treatment, or other health care service.[93]

A. Prior Authorization Request Process

Processes to apply and obtain prior authorization vary across insurers.[94] But generally, the process involves "obtaining the [insurer's prior authorization] form, completing all required clinical and administrative information, submitting the form to [the insurer], and, if needed, contacting service representatives [] for a follow up."[95] Depending on the type of technology that an insurer may use, the prior authorization process may or may not be automated, possibly requiring prior authorization requests to be submitted via fax, secure email, or phone.[96] Once a prior authorization request is submitted, it is reviewed by clinical staff, such as pharmacists or registered nurses, who will either approve or deny the requests.[97]

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[90] *Id.*

[91] *Id.*

[92] *See* COLLIGAN ET AL., *supra* note 17, at 9.

[93] *Id.* at 14.; J. Collins Corder, *Streamlining the Insurance Prior Authorization Debacle*, MO. MED. JUL.-AUG. 2018, at 312.

[94] *See* TURNER ET AL., *supra* note 87, at 4.

[95] *Id.*

[96] *See id.* at 12.

[97] *Id.* at 5.

An insurer's approval of a prior authorization review may often be conditional on the patient trying lower-cost drugs before a costlier or brand name drug will be covered, a process known as step therapy[98] Also known also as the "fail-first" approach, step therapy protocols require that patients must try and find ineffective (failed) one or more therapeutic agents that the insurer considers the "first-step" before they will reimburse a patient for considered to be a second or higher step.[99] Step therapy is largely used by insurers to manage prescription drug use.[100]

Step therapy protocols have been shown to harm patients.[101] By only allowing a patient to receive care following their insurer's step therapy protocols, step therapy protocols create additional barriers that lead patients to forgo their necessary and prescribed medications all together.[102] Moreover, step therapy protocols could cause patients' medical conditions to deteriorate, increasing the need for additional medical interventions and, consequently, raising the cost of health care while the patient continues to suffer both mental and physical anguish.[103] Consequently, step therapy protocols increase the risk of non-adherence to the first-step therapeutic agent and self-medication.[104]

B. Federal and State Regulations on Prior Authorization Decisions and Grievance Timeframes

In contrast, an insurer may deny a prior authorization request.[105] Prior authorizations are generally denied for one of the following reasons: (1) the patient's health plan lacks coverage of the requested medication, treatment, or other health care service, or (2) the patient lacks the requisite "medical necessity" for a specific medication, treatment,

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[98] *Id.* at 4.

[99] Louis Tharp & Zoe Rothblatt, *Do patients benefit from legislation regulating step therapy?*, 17 HEALTH ECON., POL'Y AND L. 282, 284 (2021).

[100] TURNER ET AL., *supra* note 87, at 8.

[101] Tharp & Rothblatt, *supra* note 99, at 284.

[102] *Id.*

[103] *Id.*

[104] *Id.*

[105] *See* Giardino & Wadhwa, *supra* note 70.

or other health care service.[106] "Medical necessity refers to a decision by [a patient's] health plan that [the patient's service or procedure] is necessary to maintain or restore [the patient's] health or to treat [the patient's] diagnosed medical problem."[107] As such, even if a patient's provider reasonably believes that the prescribed medication, treatment, or other health care service that the physician has ordered is medically necessary, if the patient's insurer does not deem the physician's prescribed order medically necessary based on a set of criteria[108] applied to each prior authorization request form, the insurer can effectively usurp the physicians medical judgment and discretion.[109] Broadening this inequity is that the medical necessity decisionmakers, at least initially, may not even be physicians but instead clerks, nurses, and pharmacists.[110]

If a prior authorization request is denied on the grounds of medical necessity, patients and providers are given the option to appeal the denial under the Affordable Care Act, which requires that all health plans have an appeals process.[111] The Affordable Care Act requires that a "group health plan and a health insurance issuer offering group or individual health insurance coverage" implement an "effective appeals process for appeals of coverage determinations and claims."[112] At a minimum, an insurer must "have in effect an internal claims appeal process; provide notice to enrollees . . . of available internal and external appeals processes, and the availability of any applicable office of health insurance consumer assistance or ombudsman established under section 300gg-93 to assist such enrollees with the appeals

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[106] *See generally* Michael Bihari, M.D., *The Definition of Medical Necessity in Health Insurance*, VERYWELL HEALTH, https://www.verywellhealth.com/medical-necessity-1738748 (Sep. 24, 2023).

[107] *Id.*

[108] Giardino & Wadhwa, *supra* note 70.

[109] *See id.*

[110] Sara J. Singer & Linda A. Bergthold, *Prospects for Improved Decision Making About Medical Necessity*, 20 HEALTH AFFS. 200, 201 (2001); TURNER ET AL., *supra* note 87, at 5.

[111] TURNER ET AL., *supra* note 87, at 5.

[112] 42 U.S.C.A. § 300gg-19 (Westlaw through Pub. L. No. 118-13); *see also* Karen Pollitz, *Consumer Appeal Rights in Private Health Coverage*, KAISER FAM. FOUND. (Dec. 10, 2021), https://www.kff.org/private-insurance/issue-brief/consumer-appeal-rights-in-private-health-coverage/. Note that the requirement that health plans offer appeals processes does not include grandfathered health plans. *See* Pollitz, *supra* note 112.

processes."[113] Additionally, the Act provides that enrollees must be able to "review their file, present evidence and testimony as part of the appeals process, and to receive continued coverage pending the outcome of the appeals process."[114]

Promulgated by the Department of Health and Human Services ("HHS"), Title 45, Section 147.136 of the Code of Federal Regulations implements the Affordable Care Act and more specifically lays out types of appeal processes that group health plans and health insurance issuers of group or individual health insurance coverage must make available to patients.[115] Section 147.136 largely incorporates the appeals process requirements under Section 29 C.F.R. 2520.102-3 of the Employment Retirement Income Security Act of 1974 ("ERISA") except under limited circumstances.[116] However, Section 2520.102-3 sets forth the "*minimum* requirements for employee benefit plan procedures pertaining to claims" for claimants.[117]

Specifically, "pre-service claims," which includes prior authorizations, must be decided within "a reasonable time" but no later than fifteen days after receiving the claim. But a plan may extend the period up to an additional fifteen days, if the plan cannot make a decision within the first fifteen days,[118] possibly making the claimant wait an entire month before receiving a decision on whether they can obtain the care that their doctor has prescribed for them. If a pre-service claim is denied, a claimant may have to wait up to thirty days for their appeal to be reviewed.[119] The outer limits of 29 C.F.R. § 2560.503-1 permit a claimant to wait a total of sixty days to have a claim and their appeal reviewed.[120] Only in the event of urgent care claims must an internal review take place within seventy-two hours after the receipt of the

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[113] § 300gg-19 (Westlaw).

[114] *Id.*

[115] 45 C.F.R. § 147.136 (2021).

[116] *Id.*

[117] 29 C.F.R. § 2560.503-1 (2020) (emphasis added).

[118] *Id.*

[119] *Id.*

[120] *Id.*

claim, both under Section 2520.102-3 ERISA and Section 147.136 of HHS's regulations.[121]

The Affordable Care Act also gives patients the right to an external review, meaning that a patient can take their appeal to an independent third party for review of the insurer's decision.[122] This right applies both to group health plans and plans by health insurance issuers offering group or individual health insurance coverage, including plans governed by ERISA which were not required to provide an external review process prior to the passage of the Affordable Care Act.[123] A group health plan or plans by health insurance issuers offering group or individual health insurance coverage will either be governed by a state or federal external review process.[124] Plans governed by either the state or federal process must, at a minimum, provide written notice of their decision to uphold or reverse the prior authorization within no more than 45 days after the receipt of the request for external review.[125] However, states can reduce that timeframe if they so choose.[126] Patients are only eligible to receive an external review decision either upholding or reversing their prior authorization decision within 72 hours in cases of urgent care claims.[127]

While the Affordable Care Act did provide patients with the right to an internal appeal and external review, patients may still endure long waiting periods not only to have their claim initially reviewed but also to have their appeal reviewed if they do not meet criteria for

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[121] *Id.*

[122] 42 U.S.C.A. § 300gg-19 (Westlaw through Pub. L. No. 118-13).

[123] Juliette Forstenzer Espinoza, *Strengthening Appeals Right*s *for Privately Insured Patients: The Impact of the Patient Protection and Affordable Care Act*, 127 Pub. Health Reps. 460, 461-62 (2012); *see* 80 Fed. Reg. 72,192, 72,225 (Nov. 18, 2015) (to be codified at 26 C.F.R. pts. 54, 29 C.F.R 2590, 45 C.F.R. pts. 145, 146, 149).

[124] § 300gg-19 (Westlaw); 45 C.F.R. § 147.136 (2021).

[125] § 300gg-19 (Westlaw); DEP'T OF HEALTH & HUM. SERVS., GUIDANCE ON EXTERNAL REVIEW FOR GROUP HEALTH PLANS AND HEALTH INSURANCE ISSUERS OFFERING GROUP AND INDIVIDUAL HEALTH COVERAGE, AND GUIDANCE FOR STATES ON STATE EXTERNAL REVIEW PROCESSES 3 (2011), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/appeals_srg_update.pdf. [hereinafter GUIDANCE ON EXTERNAL REVIEW]; 45 C.F.R. § 147.136.

[126] *See* 45 C.F.R. § 147.136(c)(2)(xii) (Section 147.136(c)(2) provides the *minimum* standards for external review processes that states comply with).

[127] DEP'T OF HEALTH & HUM. SERVS., *supra* note 125; 45 C.F.R. § 147.136.

"urgent care."[128] Further, the patient must then continue to wait if their claim is denied again on appeal and must seek out external review.[129]

Most jurisdictions have attempted to reduce the timeframes for prior-authorization decisions to some extent through their own legislation. In Texas, "a utilization review agent shall provide notice of an adverse determination" within "three working days in writing to the provider of record and the patient," if the patient is not hospitalized at the time of the adverse determination, but the timeframe only starts once the agent receives all information necessary to complete the review.[130] If a patient internally appeals an adverse determination, then the appeal must be completed, and the patient notified no later than the 30th calendar day after the agent receives the appeal.[131] Additional time may be added to the process if the patient's physician seeks to discuss their treatment plan for the patient with the utilization review agent before the adverse determination is issued.[132]

Like Texas, California requires that prior authorization requests be completed within seventy-two hours for non-urgent requests and within twenty-four hours for urgent requests specifically for prescription drugs.[133] Moreover, an internal appeal must be reviewed, and the claimant must be notified within thirty days of receipt of the appeal request.[134] If a claimant is denied coverage following the internal appeal, the claimant may seek an independent review, which could take upwards of thirty days.[135]

Similar to Texas and California, other jurisdictions have limited their prior-authorization timeframes to three days.[136] Others have

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[128] *See* 45 C.F.R. § 147.136.

[129] GUIDANCE ON EXTERNAL REVIEW, *supra* note 125, at 3; 45 C.F.R. § 147.136.

[130] TEX. INS. CODE ANN. §§ 4201.302, 4201.304 (West 2007).

[131] TEX. INS. CODE ANN. § 4201.359 (West 2007).

[132] TEX. INS. CODE. ANN. § 4201.206 (West 2021).

[133] CAL. CODE REGS. tit. 28, § 1300.67.241 (West 2017).

[134] CAL. CODE REGS. tit. 28, § 1300.68(d)(3) (West 2023).

[135] *Independent Medical Review Program*, CALIFORNIA DEP'T INS., https://www.insurance.ca.gov/01-consumers/110-health/60-resources/01-imr/ (last visited Jan. 5, 2024).

[136] *See* AM. MED. ASS'N, 2022 PRIOR AUTHORIZATION (PA) STATE LAW CHART 1, 4, 8-9, 12, 16, 18-19, 21-22 (2022), https://fixpriorauth.org/sites/default/files/2022-12/2022%20Prior%20Authorization%20State%20Law%20Chart.pdf.

limited the timeframe but have only downsized it to five or seven days.[137] However, some jurisdictions have kept their prior authorizations in line with the federal requirements at fifteen days.[138]

On its face, these shorter turn-around times for processing prior authorization requests seem like they would not lead to the delays that so frequently accompany the delivery of care to patients.[139] However, all of the different timeframes add up when a patient is continuously denied benefit coverage and must continue to fight the denials through an internal review process, an external review process, and other ancillary processes such as a peer-to-peer process.[140] Further, if a prior authorization request form is not properly filled out, then a claim may be denied solely on this basis, causing the patient to restart the process of obtaining the requisite prior authorization.[141] As another example, if a physician prescribes a certain type of drug brand for a patient but is unaware that the drug is not covered by the patient's health plan, then the patient must initiate the prior authorization process again through coordination with both their physician and their insurer.[142] Moreover, these shorter timeframes under state law may not even apply to employee benefit plans governed by ERISA if the state law is preempted by ERISA[143], which provide health insurance coverage to approximately 159 million people.[144] As such, millions of people do not benefit from state efforts targeted to reduce delays in the prior authorization and appeals process.[145]

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[137] *Id.* at 5-10, 12-13, 16, 28-30.

[138] *Id.* at 4 (Colorado).

[139] *See* AM. MED. ASS'N, 2021 AMA PRIOR AUTHORIZATION (PA) PHYSICIAN SURVEY 1 (2022), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf [hereinafter PA PHYSICIAN SURVEY].

[140] *See* COLLIGAN ET AL., *supra* note 17, at 6-7.

[141] *See* TURNER ET AL., *supra* note 87, at 5.

[142] *See id.* at 4-5, 8-9.

[143] CATHERINE STAMM ET AL., MERCER, A PRIMER ON ERISA'S PREEMPTION OF STATE LAWS 1 (2022), https://www.mercer.com/assets/migrated-assets/blogs/law-and-policy/2022/03/gl-2022-a-primer-on-erisas-preemption-of-state-laws.pdf.

[144] GARY CLAXTON, ET AL., KAISER FAM. FOUND., 2022 EMPLOYER HEALTH BENEFITS SURVEY 6 (2022), https://files.kff.org/attachment/Report-Employer-Health-Benefits-2022-Annual-Survey.pdf.

[145] STAMM ET AL., *supra* note 143, at 1, 4; CLAXTON ET AL., *supra* note 144, at 6.

In the aggregate, all these delays force patients to jump through the administrative hoops intrinsic to the prior authorization process.[146] Further, prior authorization delays can harm patients and lead to serious adverse life events, including a patient's hospitalization, a life-threatening event or required intervention to prevent permanent impairment or damage, or even a patient's disability or permanent bodily damage, congenital anomaly or birth defect or death, despite circumstances in which the patient has not been considered to be in an urgent care situation at the time of the initial prior authorization request.[147] Some patients actually never even attain relief because they abandon their prescribed treatment all together due to the delays and administrative burdens they face through the prior authorization process.[148] Despite a physician deeming a specific type of prescribed care for their patient to be medically necessary, an insurer may still claim that the prescribed care is not medically necessary even if the care is evidence-based and in accordance with the standard of care.[149]

C. Prior Authorization Legal Disputes and Implications

Left without recourse, patients or their families may look to the courts for recovery but may often come up short because coverage denials are largely governed by contract law principles.[150] Consequently, an insurer may continuously delay prior authorization of a patient's prescribed care but still be found to have fulfilled their coverage obligation if they eventually approve the requested care or treatment.[151] In

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[146] TURNER ET AL., *supra* note 87, at 4-5.

[147] PA PHYSICIAN SURVEY, *supra* note 139, at 1.

[148] *Id.* at 1.

[149] *See id.* at 2.

[150] *See, e.g.*, 29 U.S.C. § 1132(a)(1)(b); Linn v. BCBSM, Inc., 905 N.W.2d 497, 504 (Minn. 2018) ("Insurance policies are contracts and, absent statutory provisions to the contrary, general principles of contract law apply."). Plans governed by ERISA, such as self-insured benefit plans are not governed by state law, so patients can only bring claims against their insurer under the remedies that ERISA puts forth under 29 U.S.C. § 1132(a)(1)(b). *See generally* Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355 (2002); *see generally* Aetna Health Inc. v. Davila, 542 U.S. 200, 312 (2004); *See generally* Patricia McDonnell et al., *Self-Insured Health Plans*, Volume 8 No. 2 HEALTH CARE FIN. REV. 1 (1986), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4191537/; Fred J. Hellinger & Gary J. Young, *Health Plan Liability and ERISA: The Expanding Scope of State Legislation*, Volume 95 No. 2 AM. J. OF PUB. HEALTH 217, (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449155/.

[151] *See* Valentini v. Grp. Health Inc., No. 20 CIV. 9526 (JPC), 2021 WL 2444649, at *13-14 (S.D.N.Y.

Valentini v. Group Health Incorporated, the court dismissed claims brought by Valentini's family following her death after being denied an MRI by her insurer's utilization review company that her doctor ordered forty days prior.[152] Among other things, Valentini's family sued Group Health Incorporated (GHI) and eviCore, the utilization review company who conducted the prior authorization, for negligence and breach of contract.[153] Despite GHI and eviCore denying Valentini medical care for forty days that ultimately contributed to her death, the district court dismissed the family's breach of contract claim because the family did not "alleg[e] an injury that would support a claim for damages" as GHI and eviCore eventually did pay for the MRI, "even if they did so belatedly."[154] Because Valentini was not seeking emergency treatment at the time her provider requested the MRI notwithstanding the "excruciating pain" that she was experiencing, she had to wait not only to receive the initial prior authorization denial but also an additional forty days for the appeal to be reviewed.[155]

Ultimately, the length of time between when the prior authorization request for the MRI was submitted, when the initial request was denied, and when the appeal was reviewed, Valentini's cancer worsened until her death.[156] But because GHI and eviCore fulfilled their contractual obligation on paper, the breach of contract claim could not survive, and the defendants were not liable.[157] Further, Valentini's negligence claim also held no water as the district court held that GHI and eviCore did not owe Valentini a duty of care, so her family's negligence claim was dismissed.[158] The court found that a duty of care did not exist because GHI and eviCore did not medically examine Valentini directly nor did they affirmatively provide her with medical advice.[159]

Jun. 15, 2021).

[152] *Id. at *16*.

[153] *Id.* at *5.

[154] *Id.* at *12.

[155] *Id.* at *4.

[156] *See id.*

[157] *Valentini*, 2021 WL 2444649, at *12.

[158] *Id.* at *10.

[159] *Id.*

The district court's holding in Valentini's cases showcases how the governance of prior authorizations and coverage denials through contract law trumps the prioritization of human life.[160] Due to the supposed arms-length transaction between Valentini and eviCore, eviCore had no duty to ensure that Valentini's case was handled in a prompt manner, despite her excruciating hip pain and lack of improvement through physical therapy.[161] Moreover, eviCore faced no repercussions for waiting forty days to approve Valentini's MRI, despite the delay contributing to her death, merely because eviCore contractually fulfilled its obligations by "belatedly" paying for Valentini's MRI.[162]

Without owing Valentini a duty of care and merely abiding by its contractual obligation in a halfhearted manner[163], the district court's holding indicates that insurers—and, by extension, utilization review companies—can do whatever they so choose as long as they technically operate within the wide bounds of the law to avoid liability.[164] As such, the structure of insurance law as it pertains to prior authorizations and coverage denials does not prioritize human life because the question of what will happen if a patient does not receive their requested medical care is not answered, at least by any legal authority. Rather, the question that insurers are answering when reviewing a claim is whether a given claim is "medically necessary" under the insurer's definition, provided that the claim is covered in the patient's plan. This question is purely a financial one because the insurer is deciding on whether or not they will pay for the prescribed medical care, regardless of how necessary a patient's provider deems the care.[165] Consequently, a financial decision governs the quality of care that a patient receives by being the last word on what type of health care and treatment that a patient can receive, purely based on their insurance coverage.

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[160] *See id.* at *16.

[161] *See id.* at *10.

[162] *See id.* at *12.

[163] *See Valentini*, 2021 WL 2444649, at *12.

[164] *See id.*

[165] *See* WILLIAM A. HELVESTINE, NAT'L. LIB. OF MED., LEGAL IMPLICATIONS OF UTILIZATION REVIEW 169-171 (1989), https://www.ncbi.nlm.nih.gov/books/NBK234991/.

The governance of prior authorizations and coverage denials begs an understanding of why it is structured this way when other areas of the law prioritize human life. In tort law and property law, defendants can claim the affirmative defense of necessity[166] if they were in a position where they engaged in imminent bodily harm to avoid imminent bodily harm. Additionally, in criminal law and tort law, defendants could use the affirmative defense of self-defense[167] if they harmed another to protect themselves or others against immediate or imminent bodily harm, depending on the jurisdiction's definition. However, when it comes to receiving medical care, especially to prevent the worsening of a condition, a life-threatening event, a hospitalization, or otherwise adverse effect of not receiving timely care, the law looks the other way if the insurer deems the medical care not medically necessary and bolsters the preservation of contracts over the human life. Fundamentally, the governance of prior authorizations and coverage denials through the interpretation and enforcement of health insurance policies unnecessarily operates differently than other areas of the law and should prioritize on ensuring the livelihood and safety of patients rather than focusing on making a financial decision.

Currently, the U.S. health care system only prioritizes human life for patients with emergency medical conditions or issues under the Emergency Medical Treatment & Labor Act (EMTALA).[168] EMTALA requires the treatment of patients with emergency medical conditions with emergency services regardless of the ability to pay.[169] But if a patient is not experiencing an emergency medical condition, a patient is

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[166] *Necessity*, BLACK'S LAW DICTIONARY (11th ed., 2019) ("*Torts.* A privilege that may relieve a person from liability for trespass or conversion if that person, having no alternative, harms another's property in an effort to protect life or health").

[167] *Self-Defense*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("The use of force to protect oneself, one's family, or one's property from a real or threatened attack. Generally, a person is justified in using a reasonable amount of force in self-defense if he or she reasonably believes that the danger of bodily harm is imminent and that force is necessary to avoid this danger. — Also termed defense of self").

[168] *Emergency Medical Treatment & Labor Act (EMTALA)*, CTR. FOR MEDICARE AND MEDICAID SERVS., https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA (Sept. 6, 2023, 4:51 PM). Notably, the Affordable Care Act prohibits the use of prior authorizations for emergency care. Kaye Pestania, *Examining Prior Authorization in Health Insurance*, KAISER FAM. FOUND. (May 20, 2022), https://www.kff.org/policy-watch/examining-prior-authorization-in-health-insurance/.

[169] *Id.*

subjected to being treated as a financial decision first before they can receive care. In effect, the current structure of the U.S. health system coupled with the governance of coverage denials largely through contract law can force patients to wait for prolonged periods of time until they receive approval from their insurer for care or maneuver through different levels of appeals and other grievance dispute processes if their request for care is denied. Consequently, a patient's condition can worsen, and the patient may only receive care to treat if their condition deteriorates or otherwise leads to an emergency condition that the patient can then receive treatment for under EMTALA.[170]

But EMTALA only requires emergency providers to stabilize a patient with a medical condition rather than provide the treatment that their treating provider initially requested for them.[171] As a result, while a patient may be temporarily stabilized, if they do not receive approval for their prescribed care, they may find themselves seeking emergency treatment again. Thus, current governance of prior authorizations and coverage denials through contract law may propagate this cycle of patients seeking emergency care to stabilize their symptoms until they are ultimately able to receive the care they need to treat their medical conditions.

D. Current Regulatory Reforms

The medical community has long been vocal about the pain that prior authorizations cause providers and patients.[172] In response, legislatures across multiple jurisdictions have passed regulations with the hope of improving upon the prior authorization process.[173] However,

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[170] *Understanding EMTALA,* AM. COLL. OF EMERGENCY PHYSICIANS, https://www.acep.org/life-as-a-physician/ethics—legal/emtala/emtala-fact-sheet (last visited Oct. 30, 2023).

[171] 42 U.S.C. § 1395dd(b)(1)(A) ("If any individual . . . comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to *stabilize* the medical condition . . . .") (emphasis added); Guide *for Interfacility Patient Transfer - Appendix D: EMTALA,* NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., https://one.nhtsa.gov/people/injury/ems/interfacility/pages/AppD.htm (last visited Oct. 30, 2023).

[172] *Id.*

[173] *See e.g.*, Kevin B. O'Reilly, *Bills in 30 States Show Momentum to Fix Prior Authorization*, AM. MED. ASS'N. (May, 10, 2023), https://www.ama-assn.org/practice-management/prior-authorization/bills-30-states-show-momentum-fix-prior-authorization.

these reforms are generally meant to improve the prior authorization experience from the provider perspective while still maintaining the current structure of prior authorizations. As such, these reforms miss the mark by not reforming the prior authorization process so that patients are the ones who benefit directly. Consequently, the prior authorization regulatory reforms will likely not lead to any significant changes in providing timely care to patients in the short term.

1. Standardization of Prior Authorization Process

One of the most requested reforms is the standardization of the prior authorization process.[174] As discussed, *supra,* Part I, the current prior authorization process requires providers to respond to different insurers' prior authorization processes through different mediums, based on each insurers' specific guidelines for submitting a request for prior authorization.[175] In June 2011, the American Medical Association (AMA) published a white paper on the need for standardization of prior authorization processes.[176] In the white paper, the AMA described the prior authorization process as "extremely burdensome to physician practice," using Figure 1[177] discussed *supra* Part I as an example of how tedious and time-consuming the process can be due to the multiple points of connection between provider, insurer, and patient just for the provider's prescribed medical care to be approved.[178]

Notably, the AMA's white paper calls for the rebuilding of trust between insurers and the providers and poses considering the elimination of prior authorization requirements completely because providers know their patients the best and are in the "best position to provide alternatives to patients when costs benefit limitations are real

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[174] *See e.g., Prior authorization practice resources*, AM. MED. ASS'N, https://www.ama-assn.org/practice-management/sustainability/prior-authorization-practice-resources (May 18, 2023).

[175] COLLIGAN ET AL., *supra* note 17, at 10.

[176] AM. MED. ASS'N., STANDARDIZATION OF PRIOR AUTHORIZATION PROCESS FOR MEDICAL SERVICES WHITE PAPER 1 (2011), https://www.massneuro.org/Resources/Transfer%20from%20old%20sit/AMA%20White%20Paper%20on%20Standardizing%20Prior%20Authorization.pdf [hereinafter PA WHITE PAPER].

[177] *Id.*

[178] *See id.*

considerations."[179] Nevertheless, the AMA's first recommendation in its white paper is "[t]he development of a standard uniform prior authorization form that can be submitted to and accepted by all payers in a paper or online format or in the preferred electronic standard transaction . . ."[180]

Many jurisdictions have implemented legislation that aims to standardize all or part of the prior authorization process for health insurers that insure patients within their state. For example, Michigan passed Senate Bill No. 247 which required, among other things, that "an insurer that delivers, issues for delivery, renews, or administers a health benefit plan in [Michigan], if the health benefit plan requires prior authorization with respect to any benefit, the insurer or its designee utilization review organization shall, by June 1, 2023 make available a standardized electronic prior authorization request transaction process utilizing an internet webpage portal, or similar electronic, internet, and web-based system."[181]

Additionally, in Florida, an insurer "which does not provide an electronic prior authorization process for use by its contracted providers, shall only use the prior authorization form that has been approved by the Financial Services Commission for granting prior authorization for a medical procedure, course of treatment, or prescription drug benefit."[182] The statute goes on to describe how many pages may not be exceeded and what health insurers prior authorization form must include, including "(1) sufficient patient information to identify the member, date of birth, full name, and Health Plan ID number; (2) provider name, address and phone number; (3) the medical procedure, course of treatment, or prescription drug benefit being requested, including the medical reason therefor, and all services tried and failed; (4) any laboratory documentation required; and (5) an attestation that all information provided is true and accurate."[183]

While standardization efforts may slightly move the needle towards authorizing care for patients much quicker, they will likely fall

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[179] *Id.*

[180] *Id.*

[181] S.B. 247, 101st Leg. Assemb., Reg. Sess. (Mich. 2022).

[182] Fla. Stat. § 627.42392 (2022).

[183] *Id.*

short of resulting in quicker delivery of patient care for services requiring prior authorization because the focus of these efforts are to standardize the submission of prior authorization documentation rather than to decrease the turnaround time for when a patient will receive a decision about whether their prescribed care has been approved. Moreover, the benefits of a standardized prior authorization process halt if a patient needs to file an appeal and work through an insurer's grievance processes.

2. Transparency of Prior Authorization Requirements

In conjunction with standardization, another requested reform of the prior authorization process is transparency within the prior authorization process.[184] Specifically, increasing transparency between providers, insurers, and patients on what medical services and prescription drugs are subject to prior authorization. Additionally, increasing transparent communication between providers, insurers, and patients to more effectively resolve prior authorization requests in a timely manner.[185] Several states have passed legislation to strengthen transparency of information and communication within the prior authorization process.[186] For example, Title 18, Chapter 33, Subchapter II of Delaware's Insurance Code requires that a "utilization review entity shall make any current pre-authorization requirements and restrictions readily available on its website and in written or electronic form upon request for covered persons, health-care providers, and others with access to the website."[187] Moreover, Section 3372 of Delaware's Insurance Code also mandates that the "pre-authorization" requirements and restriction be made available on an online portal that is accessible in real-time.[188] Additionally, Section 3372 requires that the "pre-authorization" "[r]equirements shall be described in detail but also in clear, easily understandable language."[189]

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[184] *See* PA WHITE PAPER, *supra* note 176, at 11.

[185] AM. MED. ASS'N., CONSENSUS STATEMENT ON IMPROVING THE PRIOR AUTHORIZATION PROCESS 2, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

[186] O'Reilly, *supra* note 173.

[187] DEL. CODE ANN. tit. 18, § 3372 (2023).

[188] *Id.*

[189] *Id.*

Similarly, Section 23-99-1104 of the Arkansas Insurance Code requires utilization review entities to "disclose all of its prior authorization requirements and restrictions, including any written clinical criteria, in a publicly accessible manner."[190] Further, Section 23-99-1104 requires that utilization review entities "make statistics available regarding prior authorization approvals and denials on its website in a readily accessible format."[191] These statistics must include a categorization of denials and approvals by: "(A) Physician specialty; (B) Medication or diagnostic test or procedure; (C) Medical indication offered as justification for the prior authorization denial request; and (D) Reason for denial."[192]

Transparency within the prior authorization process will certainly arm providers and patients with more information on how to prepare a prior authorization request per the requirements of a patient's health insurer or the utilization review entity that the insurer utilizes. Moreover, if an insurer is required to post statistics of authorizations and denials, a patient can gain an understanding of why similarly situated patients were either approved or denied their health service. Thus, patients now armed with this information can work with their provider to determine what needs to be included in the prior authorization request to avoid a denial.

Some providers may be willing to work closely with their patients on filling out prior-authorization paperwork or take the time to look at the requirements, which could reduce any delays or denials due to mistakes on the prior-authorization request form.[193] However, transparency within the prior authorization process alone would likely not affect how burdensome and tedious the prior authorization process is for clinicians.[194] Additionally, transparency within the prior authorization process would not affect the timelines that health insurers and utilization review entities must abide by. Therefore, a patient could still experience prolonged periods of time before receiving approval for a

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[190] ARK. CODE ANN. § 23-99-1104 (2020).

[191] *Id.*

[192] *Id.*

[193] COLLIGAN ET AL., *supra* note 17, at 9.

[194] *Id.*

health service, especially if they must navigate through the grievance process.

More than half of Americans are confused by their health insurance, so patients still may not necessarily understand how best to prepare for the prior authorization process, what they can do to help their provider throughout the process, or even what the prior authorization process entails despite transparency efforts.[195] However, transparency within the prior authorization process coupled with standardization and a reduction in the turnaround times by state legislators as discussed *supra* Part II.B will likely lessen the burden on providers and the pain on patients due to delays and administrative hurdles. Notwithstanding the potential combined effect of transparency, standardization, and a reduction in turnaround times for insurers or utilization review entities, it is still possible for a patient's condition to worsen if a patient is denied coverage and must seek recourse using the insurer's grievance process or through legal representation, if continuously denied.

3. Gold Card Legislation

Some states have passed "Gold Card" laws, which allow physicians with high prior authorization approvals to bypass prior authorization requirements.[196] "Gold Card" legislation was first introduced in West Virginia, which passed the "Gold Card" legislation in 2019.[197] West Virginia's legislation allow physicians with 100% of prior authorizations for a certain service to bypass prior authorization for six months for that specific service.[198] Texas passed similar legislation in 2021, which permits physicians who "earn approvals on at least 90% of prior authorization requests [of at least twenty prior authorization requests] for a given service or medication" to earn exemptions from the prior authorization requirements for that service or medication for

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[195] *See More than Half of Americans Confused by Health Insurance, Including HSAs*, BEND FIN. (Feb. 3, 2021, 8:00 AM), https://www.bendhsa.com/newsroom/more-than-half-of-americans-confused-by-health-insurance-including-hsas.

[196] Douglas W. Lundy, *Gold Card Legislation Can Aid in Prior Authorization Reform*, AM. ACAD. OF ORTHOPEDIC SURGEONS (Nov. 2022), https://www.aaos.org/aaosnow/2022/nov/advocacy/advocacy01/.

[197] *Id.*

[198] *Id.*

six months.[199] Under the Texas law, "gold cards" are granted per plan, per procedure.[200] "Providers and physicians do not apply for the cards."[201] "Rather, insurers run an evaluation to see if the providers meet the 90% threshold, and the plans are responsible for notifying the provider of whether they qualify."[202] However, the Texas law still requires peer-to-peer calls "to be conducted by a Texas-licensed physician in the same or similar specialty as the physician who requested the service."[203]

Many states have also introduced "Gold Card" legislation, including "New York, Colorado, Indiana, Kentucky, Mississippi, and Oklahoma."[204] Some of these states have also allowed "Gold Card" legislation for both commercial insurers and public insurers.[205] Moreover, medical societies in different states that have not yet passed "Gold Card" legislation—like Ohio—are currently working on comparable legislation.[206] "Gold Card" legislation has even been introduced at the federal level by Rep. Michael Burgess and Rep. Vicente Gonzalez and aptly named The Getting Over Lengthy Delays in Care as Required by Doctors (i.e. GOLD CARD) Act of 2022.[207] The GOLD CARD Act would "exempt physicians from Medicare Advantage prior authorization so long as 90% of their requests were approved in the preceding twelve months."[208]

"Gold Card" legislation is achieving what the AMA posed in its 2011 White Paper: Dissolution of the prior authorization process, albeit for a specified period of time.[209] Nonetheless, this legislation is a huge

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[199] Emma Freer, *What's Next for Prior Authorization: Texas' 'Gold Card' Law Winds Through Rulemaking*, TEX. MED. ASS'N (June 29, 2022), https://www.texmed.org/Template.aspx?id=59701.

[200] Andrew Cass, *Texas Physician 'Gold Card' Rule Takes Effect Oct. 1,* BECKER'S HOSP. REV. (Sept. 20, 2022), https://www.beckershospitalreview.com/finance/texas-physician-gold-card-rules-take-effect-oct-1.html.

[201] *Id.*

[202] *Id.*

[203] Freer, *supra* note 199.

[204] Lundy, *supra* note 196.

[205] *Id.*

[206] *Id.*

[207] *Id.*

[208] *Id.*

[209] *Id.*; *see generally* PA WHITE PAPER, *supra* note 176, at 1.

win for providers as they will have to spend less time dealing with the administrative burdens for a given service or medication.[210] Moreover, patients who are prescribed a service or medication that their provider is gold-carded for, will likely experience little to no delays in receiving care due to prior authorization administration hurdles.[211] As a result, patients will be more likely to experience less adverse health events, such as hospitalization, a worsening of a condition, permanent bodily damage, or a life-threatening event.[212]

However, while "Gold Card" legislation will reduce some of the burdens of prior authorizations, the issue with "Gold Card" legislation is that they are not patient-focused. Rather, "Gold Card" legislation primarily aims at reducing the administrative burdens of providers.[213] As such, any benefits that patients experience as a result of the "Gold Card" laws are fortuitous, second-degree benefits, depending on whether their provider has received an exemption for the exact service or treatment that the patient needs and whether the exemption is still active.

Moreover, in jurisdictions like Texas that require a minimum of twenty prior authorization requests, there may be some circumstances where it is uncommon for a provider to prescribe a certain type of medical care; for instance, if the patient has a rare condition that requires uncommon but specific types of treatment or if a provider is trying to diagnose a patient's rare condition which requires specialized treatment and/or testing to reach a diagnosis. In these instances, it may be that a provider might not be able to reach the minimum threshold of prior authorization requests to even receive an exemption for the aforementioned treatment, depending on the types of patients that the provider sees.[214] As such, while "Gold Card" laws are a strong step in the direction of limiting when prior authorization requests are required by insurers, whether patients benefit from these laws depends

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[210] *See generally* COLLIGAN ET AL., *supra* note 17.

[211] *See* Freer, *supra* note 199.

[212] PA PHYSICIAN SURVEY, *supra* note 139, at 1.

[213] *See e.g.*, Freer, *supra* note 199; Kevin B. O'Reilly, *"Gold Card" Approach to Prior Authorization Introduced in Congress*, AM. MED. ASS'N (July 26, 2022), https://www.ama-assn.org/practice-management/prior-authorization/gold-card-approach-prior-authorization-introduced-congress.

[214] *See* Freer, *supra* note 199.

on what diseases or conditions they are being treated for and whether their provider has met the requirements under the legislation that governs their practice to receive an exemption.

There are other additional prior authorization regulatory reforms affecting Medicare, Medicare Advantage organizations, state Medicaid fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care plans, or Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs) that have recently been passed or are currently being proposed but are not within the scope of this Comment and will not be analyzed.

CONCLUSION

This Comment will conclude with a brief review of what has been presented and end with recommendations on how to mitigate the pain that prior authorizations cause patients. As discussed in Part I, efforts throughout the 1900s sought to control the continuing rise of health care costs, including the introduction of managed care insurance plans.[215] With the rise of managed care insurance plans came utilization review methods to control high costs of health care.[216] Prior authorization review is a utilization management tool used by health care insurers in the U.S, which require health care providers to establish that a requested clinical service, event, or procedure is medically necessary to obtain approval from the patient's health plan to determine if the patient is qualified for payment before care is delivered.[217] However, prior authorization reviews are overly burdensome for providers and clinical staff and often lead to undue delays in a patient receiving care if an insurer continues to deny the prescribed health service or medication after multiple levels of appeal. [218] Consequently, patients may experience adverse outcomes or even abandon their prescribed care completely as a result of their insurer's denials.[219]

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[215] *See* Davis et al., *supra,* note 34 at 179.

[216] Wickizer & Lessler, *supra,* note 50, at 233.

[217] Giardino & Wadhwa, *supra* note 70.

[218] PA PHYSICIAN SURVEY, *supra* note 139, at 1.

[219] *Id.*

As discussed in Part II, in-flight prior authorization reforms may improve the patient experience with prior authorization and appealing coverage denials in some capacity. But because they are not patient-focused, a patient's experience obtaining prior authorization under current legislation may still be prolonged. Moreover, if the insurer has in some way breached its obligation to cover a specific health service or medication and fails to do so, the patient may have to seek legal recourse to eventually get the care that they need.

Prior authorization determinations are essentially considered financial determinations. But patients deserve to have their livelihood not treated as a business expense. Due to the harm that prior authorizations can cause,[220] patients with non-emergency chronic conditions, diseases, illnesses, or symptoms should be able to receive a health service or medication that their provider deems to be medically necessary to adequately treat and/or diagnose the patient without having to navigate the prior authorization process in select circumstances.

This Comment recommends that these circumstances are: (1) if the patient has cancer; (2) if the patient is at risk of recurrent infections or symptoms that could proximately lead to the worsening of an existing medical condition or the development of a new medical condition or disease; (3) if the patient is at risk of death without treatment; (4) if the patient is at risk of permanent impairment, damage, or disability without treatment; (5) if the patient is at risk of hospitalization; or (6) patients at risk of congenital abnormalities/birth defects. Additionally, this Comment recommends that a patient should be able to have any tests or examinations conducted that their provider has prescribed for said patient exempted from prior authorization if: (1) the provider deems the test medically necessary to diagnose the patient if the patient is exhibiting chronic symptoms with an unknown diagnosis but the present symptoms could meet scenarios (2)-(6) above; or (2) the provider has a reasonable suspicion that the patient may have cancer.

In addition to the requirements listed above that would permit the exemption of prior authorization, this Comment recommends that the prescribed treatment or medical testing be within the standard of care[221] for the treatment for a given disease, illness, or condition or the

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[220] *See id.*

[221] *See generally* Trisha Torrey, *Understanding Standard of Care for Patients*, VERYWELL HEALTH, https://www.verywellhealth.com/standard-of-care-2615208 (Mar. 4, 2020).

standard course of action when a diagnosis is unknown but impacting the quality of a patient's life. As an added level of protection and to ensure the quality of the service or prescription being ordered, the physician can have another physician in the same department, ideally a supervisor of the department, review the order and attest to its necessity.

The cost of health care in the United States is incredibly high—approximately $3.5 trillion per year—so the need to contain costs is necessary.[222] However, cost containment should not be prioritized above patients' lives, primarily those with chronic medical conditions or cancer who need care to treat or test their medical issues in order to prevent against an adverse outcome. The restrictions recommended in this Comment will still help to keep health care costs as low as reasonably possible while also allowing patients who meet these criteria to receive the medical care that they need in a timely manner.

[222] David Cutler, *The World's Costliest Health Care*, HARVARD MAG., https://www.harvardmagazine.com/2020/05/feature-forum-costliest-health-care (May-June 2020).