



April 1, 2022

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The Honorable Susan Richard Nelson
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VIA ECF AND EMAIL

**Re: Supplemental Authority Related to Pending Motions in *GS Labs v. Medica*
Court File No.: 21-CV-2400 (SRN/TNL)**

Dear Judge Nelson,

On behalf of GS Labs, LLC (“GS Labs”), we write to provide the Court with additional supplemental authority related to the parties’ respective pending motions in the above-referenced case. In those motions, the parties reference the FFCRA’s prohibition on imposing conditions precedent to reimbursement for COVID-19 diagnostic testing in the form of “prior authorization or other medical management requirements,” such as utilization review or medical necessity. *See* FFCRA § 6001(a); *e.g.*, Dkt. No. 10 at 7, 16-17; Dkt. No. 39 at 7-8; Dkt. No. 40 at 13-14. Professors Amy B. Monahan and Daniel Schwarcz of University of Minnesota Law School have just published an article on this very subject entitled, *Rules of Medical Necessity*, in the most recent issue of the *Iowa Law Review*, discussing the history and effects of insurers’ use of medical necessity, which provides useful context for the FFCRA’s provisions. *See* Amy B. Monahan & Daniel Schwarcz, *Rules of Medical Necessity*, 107 *Iowa L. Rev.* 423 (2022). Because this scholarship is germane to the issues before the Court and may be referenced in the upcoming oral argument, we are attaching a copy of this article for the Court’s convenience.

We will continue to stay abreast of new developments and apprise the Court accordingly. Please do not hesitate to contact us if the Court has any questions or desires supplemental briefing.

Very truly yours,

WINTHROP & WEINSTINE, P.A.

s/Thomas H. Boyd

Thomas H. Boyd

Enclosure (1)
23718724v1

Rules of Medical Necessity

Amy B. Monahan and Daniel Schwarcz*

ABSTRACT: Health insurance contracts have long excluded coverage for care that is “experimental” or not “medically necessary.” Historically, insurance policies defined these key terms of coverage using broad standards. For example, “medically necessary” care might be defined as care that is “generally accepted in the medical community.” This contractual structure provided insurers with significant flexibility when making coverage determinations, even though denying coverage could pad their bottom line. For this reason, lawmakers developed various tools to prevent insurers from exploiting their discretion to determine when care was “medically necessary” or “experimental.” These safeguards allowed insureds to challenge coverage denials internally within the insurance company, externally to an independent medical expert, and before courts via a contract law or ERISA cause of action. Additionally, state and federal mandates required insurers to cover specific medically necessary treatments and services. This Article documents a dramatic shift in health insurers’ contracts and practices from a standard-based approach to determining the medical and scientific appropriateness of health care towards a rule-based approach for making these determinations. It shows how health insurers have increasingly made incredibly detailed and specific rules of medical necessity part of their formal contractual obligations to policyholders. The Article then argues that health insurers’ shift from standards to rules for defining medically and scientifically appropriate health care undermines the effectiveness of traditional legal tools designed to constrain the risk of health insurer over-reaching. The Article concludes by exploring reforms that might effectively address the increasing rulification of medical necessity.

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I. INTRODUCTION.....	425
II. FROM COVERAGE STANDARDS TO COVERAGE RULES.....	429
A. <i>STANDARDS VERSUS RULES</i>	429
B. <i>THE HISTORICAL STANDARD-BASED APPROACH TO HEALTH INSURANCE COVERAGE</i>	431
C. <i>EARLY RESPONSES TO MEDICAL NECESSITY DETERMINATIONS UNDER A STANDARD-BASED APPROACH</i>	434
D. <i>THE REVOLT AGAINST STANDARDS AND THE THEORETICAL CASE FOR RULES OF MEDICAL NECESSITY</i>	435
III. RULES OF MEDICAL NECESSITY IN MODERN HEALTH INSURANCE PLANS.....	438
A. <i>GOVERNING DOCUMENTS AND RULES OF MEDICAL NECESSITY</i>	439
1. Four Strategies for Deploying Rules of Medical Necessity in Governing Documents.....	440
i. <i>Governing Documents that Incorporate by Reference Rules of Medical Necessity Contained in Separate Medical Policies</i>	440
ii. <i>Governing Documents that Directly Include Rules of Medical Necessity</i>	443
iii. <i>Governing Plan Documents that Authorize the Development and Use of Rules of Medical Necessity</i>	445
iv. <i>Governing Plan Documents that Do Not Authorize or Incorporate by Reference Rules of Medical Necessity</i>	446
2. Empirically Examining the Frequency of Health Insurers' Use of Rules of Medical Necessity in Governing Documents.....	447
B. <i>THE EXTENT TO WHICH RULES OF MEDICAL NECESSITY BIND INTERNAL HEALTH PLAN DECISIONS</i>	451
C. <i>THE DEVELOPMENT, MAINTENANCE, AND PUBLIC AVAILABILITY OF RULES OF MEDICAL NECESSITY</i>	454
1. Internally Drafted Rules of Medical Necessity.....	454
2. Rules of Medical Necessity Produced by Third Parties.....	457
IV. THE LEGAL IMPLICATIONS OF RULIFICATION.....	458
A. <i>INTERNAL REVIEW</i>	459
B. <i>EXTERNAL REVIEW</i>	462
C. <i>COVERAGE LITIGATION</i>	468
1. Cases Involving Deferential Review.....	469

2. Coverage Disputes Involving De Novo Review.....	472
D. MANDATED BENEFITS.....	475
V. POTENTIAL RESPONSES.....	481
A. PROHIBITING RELIANCE ON RULES OF MEDICAL NECESSITY AFTER INTERNAL APPEALS.....	482
B. ADDING SUBSTANCE TO STATE UTILIZATION REVIEW LAWS.....	485
C. MANDATING USE OF SPECIFIC RULES OF MEDICAL NECESSITY.....	487
D. TRANSPARENCY REFORMS FOR RULES OF MEDICAL NECESSITY.....	491
VI. CONCLUSION.....	493

I. INTRODUCTION

The structure and substance of health insurance contracts have changed markedly over the last half-century as medical care has advanced and become dramatically more expensive. During that time, health insurers shifted from defining coverage based on the broad standards that care must be “medically necessary” and “non-experimental,” to relying on a more rule-based approach for determining when care is covered. To accomplish this, health insurers increasingly rely on numerous complex and lengthy “medical policies” or “coverage guidelines” that detail the precise circumstances in which particular medical treatments will and will not be covered. This Article documents the shift to a rule-based approach to health insurance coverage and argues that it can, and often does, substantially undermine many of the central strategies that law and regulation use to police health insurers’ coverage determinations.

Health insurers have long contractually required that care be both “medically necessary” and “non-experimental” in order to be covered. Historically, these coverage standards were contractually defined using broad and malleable language.¹ For instance, “medically necessary” care might be defined as care that is “consistent with generally accepted practice parameters as recognized by health care providers in the same or similar general specialty as typically treat or manage the diagnosis or condition.”² Similarly, care might be deemed “experimental” if “the peer-reviewed medical literature does not permit conclusions concerning its effect on health outcomes.”³

1. For an excellent overview of the use of the term “medically necessary,” see Linda A. Berghold, *Medical Necessity: Do We Need It?*, 14 HEALTH AFFS. 180, 180–89 (1995).

2. *Murray v. Int’l Bus. Machs. Corps.*, 557 F. Supp. 2d 444, 450–51 (D. Vt. 2008).

3. *Parsons v. Sisters of Charity of Leavenworth Health Sys., Inc.*, 832 F. Supp. 2d 1222, 1224 (D. Mont. 2011).

Health insurers initially used these requirements that covered care be medically necessary and non-experimental to police the outer bounds of physician behavior.⁴ But with the rise of managed care in the 1980s and 1990s, health insurers increasingly began to scrutinize a broad array of physician-ordered medical care to determine whether it met these two standards.⁵ These efforts were intended to limit payment for unnecessary and ineffective care, the prevalence of which had been documented in various studies.⁶ Towards that end, health insurers implemented various forms of “utilization review,” such as requirements that certain types of care receive prior authorization from the insurer or its delegate before being provided to the patient.⁷ As a result, conflicts between health insurers and patients involving medical care became more common.⁸ Perhaps not surprisingly, when these disputes were litigated, courts often sided with patients. Frequently, courts justified their holdings by finding insurers’ broad contractual definitions of “medical necessity” and “experimental” care ambiguous and therefore to be construed against the insurer.⁹

Patients’ court victories over health insurers prompted significant backlash, both among health insurers and many commentators. For instance, various leading health scholars voiced serious concern that courts were disregarding contractual language and refusing to allow insurers to place even reasonable limits on coverage, thereby driving up the cost of health insurance and health care.¹⁰ These concerns became particularly salient after a number of high-profile cases rejected insurers’ attempts to deny coverage for high-dose chemotherapy with autologous bone marrow transplant for breast

4. Mark A. Hall & Gerard F. Anderson, *Health Insurers’ Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1641 (1992). For instance, a health insurer might deny a claim to pay for two weeks of hospitalization for a patient to recuperate from minor injuries or deny claims for alternative treatments that were prohibited in the United States but available in other countries. *See id.*

5. *Id.* at 1652.

6. *See infra* Section II.B.

7. *See* Hall & Anderson, *supra* note 4, at 1652–53.

8. *See* Aaron Seth Kesselheim, *What’s the Appeal? Trying to Control Managed Care Medical Necessity Decisionmaking Through a System of External Appeals*, 149 U. PA. L. REV. 873, 884–85 (2001) (describing how the utilization review process created increased conflicts between health insurers and patients).

9. *See infra* text accompanying notes 48–52.

10. *See* Hall & Anderson, *supra* note 4, at 1657 (noting that “[c]ourts continually fail to see beyond the heart-rending facts of the immediate case” with the result that “parties to the health insurance contract are frequently precluded from enforcing the terms they have chosen to define the limits of coverage”); Clark C. Havighurst, *Prospective Self-Denial: Can Consumers Contract Today to Accept Health Care Rationing Tomorrow?*, 140 U. PA. L. REV. 1755, 1767–69 (1992). *See generally* William M. Sage, *Managed Care’s Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 593 (2003) (providing an early examination of administrative procedures to govern medical necessity disputes).

cancer, a treatment widely considered experimental at the time and subsequently found to provide no better outcomes than established, less-expensive treatments.¹¹

The solution to judicial over-reach, according to some prominent commentators, was for health insurers to move away from broad and potentially vague contractual standards of medically necessary and non-experimental treatment, and instead to specify coverage terms in more detail.¹² Doing so, it was argued, would limit courts' capacity to rule in favor of sympathetic patients seeking coverage of ineffective or unproven services, thus benefitting the entire health system. This call to action was not easy to heed. Health plans' use of flexible standards for defining "medically necessary" and "non-experimental" care was historically thought necessary to account for the immense complexity involved in medical determinations, especially in the modern era of rapidly evolving medical knowledge, which can turn yesterday's standard of care into today's malpractice.¹³ Relying on broad standards for defining when health care was "medically necessary" or "experimental" allowed health insurers to account for this inherent complexity and fluidity of modern health care.

This Article explores how, over the last 20 years, health plans have overcome these barriers and increased their reliance on rules rather than standards to define when recommended care is medically necessary and non-experimental, and thus covered.¹⁴ These *rules of medical necessity* narrow the circumstances in which otherwise-covered treatments will be covered for particular patients based on judgments about the treatment's appropriateness for that patient. They are thus distinguishable from contractual provisions that exclude entire categories of care, irrespective of whether they are medically necessary, non-experimental, or the most appropriate treatment for the patient. Such *categorical coverage exclusions* have a variety of rationales, but they do not attempt to personalize coverage decisions based on an individual patient's clinical presentation.

To evaluate health insurers' current reliance on rules of medical necessity, this Article systematically reviews published caselaw, health insurer

11. Sage, *supra* note 10, at 612; Michelle M. Mello & Troyen A. Brennan, *The Controversy Over High-Dose Chemotherapy with Autologous Bone Marrow Transplantation for Breast Cancer*, 20 HEALTH AFFS. 101, 107–09 (2001).

12. See *infra* Section II.D.

13. See, e.g., Russell Korobkin, *The Efficiency of Managed Care "Patient Protection" Laws: Incomplete Contracts, Bounded Rationality, and Market Failure*, 85 CORNELL L. REV. 1, 29 (1999); John V. Jacobi, Tara Adams Ragon & Kate Greenwood, *Health Insurer Market Behavior After the Affordable Care Act: Assessing the Need for Monitoring, Targeted Enforcement, and Regulatory Reform*, 120 PENN. ST. L. REV. 109, 130–31 (2015).

14. We occasionally describe this process as "rulification," borrowing from Michael Coenen, *Rules Against Rulification*, 124 YALE L.J. 644, 646–48 (2014). For a discussion of the impact of the proliferation of these rules on doctors, see Sandeep Jauhar, *The Crushing Burden of Healthcare Microregulation*, WALL ST. J. (Apr. 28, 2021, 11:01 AM), <https://www.wsj.com/articles/the-crushing-burden-of-healthcare-microregulation-11619622081> [<https://perma.cc/J6A7-979L>].

filings with state regulators, and prior academic studies. It finds that rules of medical necessity can take various forms. In some cases, they are directly incorporated into health insurance contracts, which provide that specific treatments and services will only be covered under pre-determined circumstances. More commonly, health insurers adopt detailed rules of medical necessity in lengthy documents or sets of documents that are separate from their insurance policies, but which are—to varying degrees—described or incorporated by reference therein. These documents have labels like “medical policies,” “clinical bulletins,” “utilization review procedures” or “medical criteria.” They might provide, for instance, that a health plan will only cover a liver transplant “for biliary atresia and certain congenital metabolic disorders”¹⁵ or that proton beam radiation therapy may be medically necessary only “in patients who have undergone biopsy or partial resection of chordoma or low-grade (I or II) chondrosarcoma of the basisphenoid region.”¹⁶ These rules are sometimes drafted internally by the health insurer, are sometimes purchased off-the-shelf from third parties, and sometimes piggyback on Medicare coverage rules or other publicly available guidelines.¹⁷

After documenting health plans’ increasing reliance on rules of medical necessity, this Article examines the impact that this rulification has had on the traditional tools that law and regulation use to police health plan coverage decisions. As described above, litigation historically played a major role in constraining health insurer coverage decisions. And as anticipated by the earlier generation of legal scholarship, health insurers’ embrace of rules of medical necessity has indeed made it very difficult for courts to overturn insurers’ coverage decisions. But this Article argues that health insurers’ embrace of rules of medical necessity has also undermined or altered various other legal mechanisms for regulating health insurers’ coverage decisions, including internal appeals, independent external review, and coverage mandates. Each of these tools, the Article argues, is premised, to varying degrees, on the assumption that health plans use broad standards to define when care is medically necessary and non-experimental, and hence covered. As health plans have moved towards rules to specify their coverage obligations, they have also undermined the capacity of each of these legal tools to regulate these determinations.

This Article proceeds as follows. Part II describes the historical dominance of coverage standards for defining medical necessity and non-experimental care in health insurance policies, and the subsequent backlash against such malleable and potentially vague terms. Part III then documents health insurers’ shift from standards to rules of medical necessity by

15. *Hyde v. Humana Ins. Co.*, 598 So. 2d 876, 878 (Ala. 1992).

16. *Linn v. BCBSM, Inc.*, 905 N.W.2d 497, 504 (Minn. 2018).

17. *See infra* Section III.C.

examining caselaw, insurance policy filings, and prior academic research. Part IV considers the legal implications of these changes on four key legal tools that are intended to limit health insurer discretion over coverage determinations: internal appeals, external review, litigation, and mandated benefit laws. It argues that health plans' embrace of rules of medical necessity has significantly limited the effectiveness of these tools, thereby affording health plans much broader discretion to make coverage decisions than lawmakers intended. Finally, Part V considers a menu of potential responses to these developments, the desirability of which vary depending on one's priors regarding the need for government constraints on health plans' coverage decisions.

II. FROM COVERAGE STANDARDS TO COVERAGE RULES

Legal scholarship has long explored the distinctions between rules and standards, and the ideal conditions under which each approach should be used in public laws and private contracts. After briefly highlighting this literature, this Part turns to the historical standard-based approach to health insurance contracting and the evolution of this approach in response to perceived shortcomings. It concludes by describing the theoretical justifications for health insurers increasing their use of rule-based coverage terms.

A. STANDARDS VERSUS RULES

Perhaps the simplest distinction between standards and rules focuses on whether the content of a law, contract term, or other test is determined *ex ante* or *ex post*.¹⁸ Rules tend to define permissible conduct in advance, thereby leaving adjudicators limited discretion when applying those rules in particular cases. By contrast, standards typically entrust adjudicators with discretion to determine how a broad principle should be applied in individual circumstances. To illustrate, a speed limit of 70 miles per hour is a rule, while a speed limit that requires drivers not to exceed a reasonable speed given the circumstances is a standard.¹⁹

There are several widely acknowledged tradeoffs between rules and standards. Standards are particularly useful when it is difficult to define the proscribed conduct and when any effort to do so risks becoming quickly

18. Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 559–60 (1992).

19. While this review will treat standards and rules as distinct approaches, note that it is perhaps more accurate in the real world to think of standards and rules as existing along a continuum, with highly general standards on one end and highly detailed rules on the other. Standards can become more rule-like as they start to constrain the factors that are taken into account under the standard. And rules can become more standard-like as they include factors that allow some decision making discretion. *See, e.g., id.* at 566; Frank Cross, Tonja Jacobi & Emerson Tiller, *A Positive Political Theory of Rules and Standards*, 2012 U. ILL. L. REV. 1, 17 (2012).

outdated, as in areas where technology is rapidly evolving.²⁰ Standards may also be preferable to rules when it is essential to get the right outcome in individual cases, as they allow adjudicators to consider all potentially relevant facts and circumstances.²¹ Of course, these advantages of standards come along with costs. The inherent flexibility of standards may make it harder and more costly to predict how they will be applied in individual cases. That uncertainty means that adjudications are more frequent when standards are employed, and competent, impartial adjudicators are vital to ensure that standards produce their intended outcomes.²² For these reasons, standards may tend to be preferable to rules when the regulated conduct is relatively infrequent.²³

Rules, on the other hand, tend to provide relatively clear guidance to stakeholders about the permissible boundaries of conduct and require less ex-post adjudication. Rules also tend to promote greater uniformity in the application of the relevant law or contract term. Each of these factors makes rules particularly well suited to situations in which the regulated conduct occurs frequently.²⁴ As with standards, however, the benefits of rules come along with costs. Rules require a greater up-front investment than standards because the rule-maker must determine the precise contours of the prohibited or regulated behavior at the drafting stage, rather than leaving adjudicators to interpret a general standard.²⁵ In addition, the specificity of rules often leaves them inflexible, both to unique circumstances and to technological²⁶ or other societal changes.²⁷ This rigidity can result in rules being “both over- and under-inclusive with respect” to the targeted conduct.²⁸ For example, a speed limit of 70 miles per hour may punish some individuals who are driving at a reasonable rate of speed given the circumstances, while failing to punish those who are going too fast for current road conditions.

20. See, e.g., Clayton P. Gillette, *Rules, Standards, and Precautions in Payment Systems*, 82 VA. L. REV. 181, 222 (1996); Derek E. Bambauer, *Rules, Standards, and Geeks*, 5 BROOK. J. CORP. FIN. & COM. L. 49, 52 (2010).

21. Cross et al., *supra* note 19, at 18.

22. Larry Alexander, *Incomplete Theorizing: A Review Essay of Cass R. Sunstein's Legal Reasoning and Political Conflict*, 72 NOTRE DAME L. REV. 531, 542 (1997) (reviewing CASS R. SUNSTEIN, *LEGAL REASONING AND POLITICAL CONFLICT* (1996)).

23. Kaplow, *supra* note 18, at 563.

24. *Id.*

25. *Id.* at 577.

26. Bambauer, *supra* note 20, at 52 (2010) (“Rule-based specifications may decay quickly when technology changes rapidly.”).

27. This rigidity of rules has led to some higher courts prohibiting lower courts from turning pronounced judicial standards into rules. Coenen, *supra* note 14, at 647.

28. Alexander, *supra* note 22, at 542.

B. THE HISTORICAL STANDARD-BASED APPROACH TO HEALTH
INSURANCE COVERAGE

Historically, health insurance contracts have mostly taken a standard-based approach to defining their scope of coverage. Rather than attempting to spell out in detail every possible covered service, health insurance policies defined coverage principally by requiring that covered care be “medically necessary” and not “experimental” or “investigational.” These key terms would then be defined using broad standards.²⁹ For instance, one common definition of medically necessary care was that it be “safe, effective, and appropriate.”³⁰ The exclusion for “experimental” treatments and services was often similarly broad and standard-like. For example, a policy might define a treatment as experimental when it “[i]s under clinical investigation by health professionals and is not generally recognized by the medical profession as tested and accepted medical practice[.]”³¹

To be sure, insurance policies have long used rules to exclude certain treatments, services, or categories of care from coverage irrespective of their medical necessity or non-experimental status. For instance, health insurance policies might explicitly exclude coverage for vision, dental, cosmetic surgery, fertility services, or educational benefits.³² These *categorical coverage exclusions* had various rationales. Such exclusions were often motivated by judgments about what types of care were fundamentally medical at all, and hence even potentially within the scope of what a health insurance policy might cover.³³ But unlike exclusions for “experimental” or “medically unnecessary” care, categorical coverage exclusions did not attempt to make specific types of care

29. Because the term is typically defined in the contract, there is significant variation among insurers. In some contracts medical necessity is defined by reference to commonly accepted medical practice, while in others it is based on clinical evidence or cost effectiveness. See E. Haavi Morreim, *ERISA Takes A Drubbing: Rush Prudential and Its Implications for Health Care*, 38 TORT TRIAL & INS. PRAC. L.J. 933, 949–53 (2003); see also Jacobi et al., *supra* note 13, at 130 (suggesting that medically necessity definitions typically require adherence to “customary medical practice . . . ‘effective[ness]’ in treating [the] illness or injury,” and a purpose beyond being “provided merely ‘as a convenience’” (citations omitted)). Over time, some states have regulated the permissible definition of medical necessity, either through a mandatory standard or regulatory review of contractual language. Wendy Netter Epstein, *The Health Insurer Nudge*, 91 S. CAL. L. REV. 593, 623 (2018).

30. E. Haavi Morreim, *Playing Doctor: Corporate Medical Practice and Medical Malpractice*, 32 U. MICH. J.L. REFORM 939, 1021 (1999).

31. Angela R. Holder, *Funding Innovative Medical Treatment*, 57 ALB. L. REV. 795, 799 (1994).

32. See Havighurst, *supra* note 10, at 1774.

33. See, e.g., Mark A. Hall, *State Regulation of Medical Necessity: The Case of Weight-Reduction Surgery*, 53 DUKE L.J. 653, 669 (2003) (noting that insurers report excluding categories of coverage that “bridge the boundary between medically necessary and cosmetic or ‘lifestyle’ enhancements” such as weight loss surgery).

available to some insureds but not others based on the insured's specific medical circumstances.³⁴

Structuring health insurance coverage predominantly around the broad standards of medical necessity and experimental care has long been explained as a practical necessity. The range of possible medical treatments and clinical presentations was thought to be too vast and likely to evolve to specify in the terms of a contract.³⁵ Standards of treatment for medical care are constantly advancing, technology is changing, clinical evidence is expanding, and individual patients often have unique presentations. Insurance policies that relied on a standard-based approach allowed insurers and other adjudicators of coverage to adjust to that evolution organically and to personalize determinations when warranted.³⁶ These benefits of using broad standards to define when care was medically necessary and non-experimental were generally thought to outweigh the downsides of standards, such as their tendency to make it difficult for treating physicians and patients to know what will and will not be paid for in advance.

This standard-based approach to health insurance contracts was not always the norm. When health insurance contracts first were offered in the United States, they typically covered any services ordered by a treating physician.³⁷ This approach embraced a very simple rule, whose shortcomings quickly became obvious to the insurance companies that were forced to reimburse highly questionable care, such as lengthy hospital stays for recuperation following a minor fall, or care that was on the outer fringes of medical practice and in some cases illegal to offer in the United States.³⁸ Health insurers began imposing the additional requirements that services be "medically necessary" and not "experimental" or "investigative" in the 1970s to protect against these abuses.³⁹

As they were first implemented, these coverage standards were not used to closely scrutinize treating physicians' judgments.⁴⁰ When insurers

34. Havighurst, *supra* note 10, at 1774 (noting that these exclusions are "clumsy" given that they exclude "whole categories of disease or treatment from coverage").

35. See, e.g., David C. Hsia, *Benefits Determination Under Health Care Reform: Who Should Decide Coverage Policy?*, 15 J. LEGAL MED. 533, 539 (1994)

36. Structuring coverage terms as standards is also consistent with the theory of incomplete contracts. Gillian K. Hadfield, *Weighing the Value of Vagueness: An Economic Perspective on Precision in the Law*, 82 CALIF. L. REV. 541, 547 (1994). Contract theory posits that incomplete contracts are rational where "the transaction costs of explicitly contracting for a given contingency are greater than the benefits." Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 92 (1989). If we think of all possible medical treatments and services, and all possible clinical presentations suggesting medical treatment is necessary, it becomes clear that in many situations the costs of including specific coverage rules would outweigh the expected benefit of such specificity.

37. Hall & Anderson, *supra* note 4, at 1644-45.

38. *Id.*

39. *Id.* at 1645-47.

40. See *id.* at 1645-46.

challenged physician-ordered care on the basis that it was not medically necessary or was experimental, they typically targeted the fringes of medical care and avoided critical care issues, such as potentially lifesaving treatments.⁴¹

That began to change in the 1980s as evidence grew that providers were ordering substantial amounts of unnecessary medical care.⁴² Studies found significant geographic differences in medical practice within the United States that did not impact overall health outcomes.⁴³ Insurers inferred that they were paying for a significant volume of unnecessary care in many regions of the country.⁴⁴ They also became more willing to challenge treating physicians' judgements about critical care, as studies suggested that high-cost procedures and inpatient services were at the root of questionable spending, not unconventional care.⁴⁵

This evidence, along with the quickly escalating cost of health care in the United States and the broader rise of managed care models of health insurance, led insurers to take a more active role in policing the medical necessity of potentially covered services. In addition to questioning the appropriateness of care after treatment had been provided, insurers also began to require patients to seek approval of certain types of treatment in advance, in a process known as prior authorization or "prospective utilization review."⁴⁶ This procedure provided doctors and insureds with more predictability about whether recommended care would be covered. But it also meant that coverage denials restricted access to care that patients could not pay for out of pocket. As insurers began restricting access to high-cost, potentially life-saving treatments, bitter disputes developed between insurers and insureds.⁴⁷

When these disputes were litigated, patients often won, even when experts believed the merits clearly favored the insurer.⁴⁸ While many factors likely contributed to these outcomes, courts often focused on insurers' standard-based contractual language to justify their holdings.⁴⁹ Insurers' broad standards for defining medical necessity and experimental treatment, courts reasoned, resulted in ambiguity about how individual disputes should be resolved.⁵⁰ Invoking the long-standing principle that ambiguities in

41. *See id.* at 1646.

42. *Id.* at 1652.

43. Edward B. Hirshfeld & Gail H. Thomason, *Medical Necessity Determinations: The Need for A New Legal Structure*, 6 HEALTH MATRIX 3, 18 (1996).

44. *Id.*

45. Sage, *supra* note 10, at 605–06.

46. Hall & Anderson, *supra* note 4, at 1652.

47. Havighurst, *supra* note 10, at 1768–69.

48. Morreim, *supra* note 30, at 1015–16.

49. Hall & Anderson, *supra* note 4, at 1648–49.

50. *See id.*

insurance policies should be construed against the insurer,⁵¹ courts routinely found in favor of insureds. Scholars observed “that the inclination of judges to adopt every conceivable argument in favor of coverage has essentially precluded insurers from exercising any meaningful oversight of medical appropriateness.”⁵²

C. *EARLY RESPONSES TO MEDICAL NECESSITY DETERMINATIONS*
UNDER A STANDARD-BASED APPROACH

By the 1990s, it seemed that no one was happy with health insurers’ use of broad contractual standards to resolve coverage disputes. Insurers were vilified for denying care based on economic motivations,⁵³ and federal and state lawmakers responded by enacting various patient protections.⁵⁴ Insurers, on the other hand, were frustrated by their inability to set limits on coverage and took some early steps to try to increase their ability to police determinations of medical necessity.⁵⁵

Managed care plans responded to their losses in court by increasing their use of prior authorization for expensive non-emergency care, thus allowing the insurer to deny coverage for a proposed treatment before it was provided.⁵⁶ This procedure provided two advantages to insurers. First, courts had shown an unwillingness to financially devastate patients who received expensive care that an insurer subsequently refused to cover.⁵⁷ Denying coverage pre-treatment was thought to limit courts’ potential sympathy for aggrieved patients. Second, and perhaps more importantly, very few patients appealed negative coverage determinations made prior to treatment, modifying their course of treatment instead.⁵⁸

States also responded to the problem of contested insurance coverage by adopting a range of laws targeting insurers’ medical necessity and experimental care determinations. For instance, various states enacted laws regulating insurers’ utilization review processes to require qualified physician

51. See Kenneth S. Abraham, *A Theory of Insurance Policy Interpretation*, 95 MICH. L. REV. 531, 531 (1996); Michelle Boardman, *Penalty Default Rules in Insurance Law*, 40 FLA. ST. U. L. REV. 305, 306–07 (2013).

52. Hall & Anderson, *supra* note 4, at 1644.

53. See, e.g., Sage, *supra* note 10, at 637–38; Kesselheim, *supra* note 8, at 884–85; Hirshfeld & Thomason, *supra* note 43, at 33.

54. Jacobi et al., *supra* note 13, at 132.

55. See Hall & Anderson, *supra* note 4, at 1651–54.

56. *Id.*

57. See *id.* at 1649–51.

58. See, e.g., Kanika Kapur, Carole Roan Gresenz & David M. Studdert, *Managing Care: Utilization Review in Action at Two Capitated Medical Groups*, 22 HEALTH AFFS. W3-275, W3-277–79 (2003); David M. Studdert & Carole Roan Gresenz, *Enrollee Appeals of Preservice Coverage Denials at 2 Health Maintenance Organizations*, 289 J. AM. MED. ASS’N 864, 868–69 (2003); Sharona Hoffman, *A Proposal for Federal Legislation to Address Health Insurance Coverage for Experimental and Investigational Treatments*, 78 OR. L. REV. 203, 239 (1999).

involvement, limit the time insurers had to render a decision, and even regulate the basis on which an insurer could deny coverage.⁵⁹ In addition, states began to adopt external review laws, which generally provided a right for patients denied coverage on the basis of medical necessity or experimental treatment limitations to appeal to an independent, qualified medical professional.⁶⁰ Both states and the federal government also enacted mandated benefit laws, requiring coverage of certain treatments and services irrespective of medical necessity or experimental treatment limitations.⁶¹

State laws regulating health insurers' medical necessity and experimental care determinations had an uneven impact on one of the most important types of health insurance plans: employer-sponsored health plans. The Employee Retirement Income Security Act of 1974 ("ERISA"), which governs nearly all employer-sponsored health plans, broadly preempts state law.⁶² However, state laws regulating insurance are not subject to that preemption, so long as they do not provide any remedies "that duplicate [], supplement [], or supplant [] . . . ERISA[']s" exclusive remedial scheme for wrongfully denied claims.⁶³ The functional result of these notoriously complicated preemption rules is that state laws regulating utilization review, providing external review rights, or mandating coverage of certain benefits could be applied to employer plans that financed coverage through a group insurance contract, but not to employers that self-insured their employee benefit plans.⁶⁴

D. THE REVOLT AGAINST STANDARDS AND THE THEORETICAL CASE
FOR RULES OF MEDICAL NECESSITY

While politicians seemed primarily concerned with expanding the scope of health insurance coverage and limiting insurer discretion, health policy

59. See *infra* Section III.A.

60. See *infra* Section III.B.

61. At the federal level, in response to the well-publicized practice of certain managed care plans paying for only 24 hours of hospitalization following childbirth, minimum coverage requirements for postpartum hospital were enacted. See 29 U.S.C. § 1185 (2018); David A. Hyman, *Drive-Through Deliveries: Is "Consumer Protection" Just What the Doctor Ordered?*, 78 N.C. L. REV. 5, 29 (1999). At the state level, perhaps the most prominent example were laws requiring coverage for high-dose chemotherapy with autologous bone marrow transplant for treatment of advanced breast cancer—a treatment routinely denied as experimental by insurance companies and one that was later established to be of no greater benefit than existing treatments that were much less expensive. See RICHARD A. RETTIG, PETER D. JACOBSON, CYNTHIA M. FARQUHAR & WADE M. AUBRY, FALSE HOPE: BONE MARROW TRANSPLANTATION FOR BREAST CANCER 169–74 (2007).

62. 29 U.S.C. § 1144 (2018).

63. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 209 (2004). The Supreme Court has also held that state external review laws do not provide an additional remedy, and therefore survive ERISA preemption as applied to insured employer plans. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 375–87 (2002).

64. See Brendan S. Maher, *The Affordable Care Act, Remedy, and Litigation Reform*, 63 AM. U. L. REV. 649, 698–700 (2014).

experts decried the inability of insurers to set reasonable limits on coverage.⁶⁵ After all, if insurers were unable to limit the scope of covered services in any meaningful way, premiums would need to rise and fewer people would be able to afford coverage.

Some scholars argued that the solution was for health insurance contracts to move from standards to rules for defining when physician-ordered care was medically necessary and scientifically appropriate.⁶⁶ The premise was that courts would have much more difficulty requiring coverage where contractual language explicitly excluded it.⁶⁷ Consumers would gain greater clarity regarding the scope of the coverage they purchased, and insurers would be able to offer a greater range of coverage choices at different price points.⁶⁸ Although costly to develop and maintain, rules of medical necessity would also help insurers achieve consistent and relatively efficient internal decision-making at the initial claims-handling stage.⁶⁹

One factor driving this interest in health insurance rulification was the growing body of evidence-based medicine.⁷⁰ While medicine had traditionally been thought of as both art and science with significant variation in practice, robust studies began to illuminate statistical best practices in certain areas of

65. See Hall & Anderson, *supra* note 4, at 1655 (noting that insurers often have coverage denials overturned by courts “despite extremely attenuated grounds for coverage”); Havighurst, *supra* note 10, at 1764 (noting “substantial resistance in the legal and political culture to the idea of letting contracts be contracts whenever they operate to restrict the availability of health care financing”); Paul E. Kalb, *Controlling Health Care Costs by Controlling Technology: A Private Contractual Approach*, 99 YALE L.J. 1109, 1110 (1990) (“[D]escrib[ing] how most health insurance contracts not only fail to exclude wasteful technologies from coverage but actually promote their overuse”). See generally Einer Elhauge, *The Limited Regulatory Potential of Medical Technology Assessment*, 82 VA. L. REV. 1525 (1996) (noting that our legal system favors coverage of care that has any positive benefit); Clark C. Havighurst, *Contract Failure in the Market for Health Services*, 29 WAKE FOREST L. REV. 47 (1994) (arguing that the market fails to provide low-cost health insurance contracts in part because insurers are unwilling or unable to fight the legal battles necessary to deny coverage of medically beneficial care); Mark A. Hall, *A Theory of Economic Informed Consent*, 31 GA. L. REV. 511 (1997) (exploring the possibility of applying the theory of informed consent to the purchase of more economical forms of health insurance, and describing the uncertainty regarding courts’ likelihood of accepting such theory).

66. Hall & Anderson, *supra* note 4, at 1686–87; Havighurst, *supra* note 10, at 1795–98.

67. But see Elhauge, *supra* note 65, at 1549–56 (discussing cases where a denial of coverage for the treatment of temporomandibular joint syndrome (“TMJ”) was overturned on the basis that “a specific exclusion of TMJ was too complex to be understandable”).

68. See generally Havighurst, *supra* note 10 (stating that health care contracts would give consumers a greater degree of control over their spending).

69. Given both the frequency and the homogeneity of many types of health insurance claims, there is a classic case for the use of rules over standards at this stage of initial claims processing. See Kaplow, *supra* note 18, at 559–60.

70. See, e.g., Hall & Anderson, *supra* note 4, at 1687; Sage, *supra* note 10, at 635–36; Hirshfeld & Thomason, *supra* note 43, at 18; Ryan Abbott & Carl Stevens, *Redefining Medical Necessity: A Consumer-Driven Solution to the U.S. Health Care Crisis*, 47 LOY. L.A. L. REV. 943, 943–44 (2014).

medicine.⁷¹ To the extent that such evidence could be seen as establishing a right way and a wrong way of treating certain presentations of disease or illness, it was an easy leap to argue that insurers should only pay for the right method of treatment.

This push towards health insurance rulification was not without merit. Insurers may be in a better position than individual physicians to keep up to date on the scientific literature and best practices, and often have access to broad data that can be used to help draft effective coverage rules.⁷² Rules can also provide clarity for internal claims administrators and produce consistent results. Additionally, they can help both doctors and patients understand in advance what is or is not covered, thereby reducing the number of coverage disputes. If there is clear disclosure and understanding of these rules at the time of purchase, rules can also improve consumers' purchasing decisions. Furthermore, rules of medical necessity have the potential to improve medical care by encouraging providers and patients to make treatment decisions based on sound evidence, at least to the extent that those rules fully and fairly reflect that evidence.⁷³ For example, an insurer's rule that a treatment is not covered for a specific subset of patients because there is insufficient evidence about the treatment's impact on those patients could help to educate physicians and steer them to allocate limited medical resources more efficiently.

Of course, there are also downsides associated with rule-based coverage terms. Rules typically prevent individualized determinations,⁷⁴ and they may become outdated if the insurer is not constantly monitoring and responding to available clinical evidence. Even when rules are based on high-quality evidence, that evidence will generally reflect statistical differences in a broad population of subjects. Providing coverage based on these differences may be a sensible way of allocating scarce resources, but it also means that some medically beneficial care will be denied to individuals who do not conform to broader trends.

More cynically, rules may allow insurers to avoid covering relatively high-risk individuals or high-cost treatments. Rules could conceivably be deployed for both purposes. A health insurer that has clear rules limiting coverage in obvious ways might successfully avoid enrolling high-cost individuals who review the relevant rules prior to purchase. More likely, insurers could see insureds who were denied coverage under such rules switch to alternative

71. See David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFFS. 9, 9–11 (2005).

72. See Brendan S. Maher, *The Private Option*, 2020 MICH. ST. L. REV. 1043, 1043.

73. See James C. Robinson, *Applying Value-Based Insurance Design to High-Cost Health Services*, 29 HEALTH AFFS. 2009, 2009 (2010) (discussing how insurers can use cost-sharing techniques to steer patients and doctors to better health care decisions).

74. See Cross et al., *supra* note 19, at 15–16. “A rule singles out one or a few facts and makes it or them conclusive of legal liability; a standard permits consideration of all or at least most facts that are relevant to the standard’s rationale.” *Id.* (citing *Mindgames, Inc. v. W. Publ’g Co.*, 218 F.3d 652, 657 (7th Cir. 2000)).

carriers that they believe are more likely to cover relatively expensive claims. Independently of such selection effects, insurers may draft or adopt rules of medical necessity simply to limit their obligations to cover high-cost treatments, particularly when those treatments are relatively new. Although cost is certainly relevant when allocating scarce health care resources, insurers' rules of medical necessity may place undue emphasis on costs over clinical appropriateness given that doing so can directly increase their bottom line.⁷⁵

On a theoretical basis, then, both insurers and patients might benefit in some ways from rule-based coverage terms. At the same time, insurers' embrace of rules of medical necessity poses a variety of significant risks to insureds. The next Part explores the extent to which health insurers today have in fact embraced rules of medical necessity.

III. RULES OF MEDICAL NECESSITY IN MODERN HEALTH INSURANCE PLANS

As Part II makes clear, health insurers historically relied on broad standards rather than concrete rules to define when health care was "medically necessary" or "experimental." Increasingly, however, health insurers develop and make use of highly specific rules to determine coverage. These *rules of medical necessity* narrow the circumstances in which otherwise covered treatments will be covered for particular patients based on judgments about the treatment's medical and scientific appropriateness in specific circumstances.

Health insurers implement their rules of medical necessity through various different utilization review procedures—such as prior authorization⁷⁶ and step therapy requirements⁷⁷—as well as ultimate coverage determinations. A significant amount of empirical research in medical journals has described the content of insurers' medical necessity rules for specific types of care, such

75. While the ACA's medical loss ratio requirements put some limitations on an insurer's ability to retain profits, an insurer continues to have significant incentives to keep medical costs low in order to keep overall premiums low and therefore attract enrollees.

76. Prior authorization requirements make benefit coverage for certain treatments and services contingent upon obtaining permission from the plan in advance. If prior authorization is not obtained, the service will not be covered irrespective of the appropriateness or necessity of the service. *See* Part II.C.

77. Step therapy requirements typically require patients to first try relatively inexpensive forms of care before they are provided coverage for more costly forms of care. Jonathan J. Darrow & Donald W. Light, *Beyond the High Prices of Prescription Drugs: A Framework to Assess Costs, Resource Allocation, and Public Funding*, 40 HEALTH AFFS. 281, 285 (2021) (noting that step therapy is the most common cost control measure for prescription drugs).

as personalized medicine,⁷⁸ genetic testing,⁷⁹ and breast and ovarian prophylactic surgery.⁸⁰ But prior literature has not documented the extent to which health insurance contracts have shifted from reliance on broad standards to these more specific rules of medical necessity.

To begin to fill that gap, this Part documents key features of health plans' development and use of rules of medical necessity, relying on an exhaustive review of caselaw and publicly filed health insurance policies. Section A begins by describing health plans' varying approaches to incorporating rules of medical necessity into their formal contracts and legal documents. Section B explores the extent to which health plans treat rules of medical necessity as binding on the health plan personnel who are charged with making coverage and utilization review decisions. Finally, Section C turns to the methods by which health plans and third parties develop and update rules of medical necessity.

A. GOVERNING DOCUMENTS AND RULES OF MEDICAL NECESSITY

Health plans' legal obligations to insureds are predominantly defined in their insurance policies and, in the case of employer-sponsored plans, their ERISA plan documents, which we refer to collectively as a plan's governing documents.⁸¹ Drawing from multiple sources, this Part first outlines four different approaches that health plans use to describe rules of medical necessity in their governing documents. It then attempts to gauge the prevalence of these four different approaches by examining health insurers' filings of insurance policies with state regulators.

78. See, e.g., Julia R. Trosman, Stephanie L. Van Bebber & Kathryn A. Phillips, *Coverage Policy Development for Personalized Medicine: Private Payer Perspectives on Developing Policy for the 21-Gene Assay*, 6 J. ONCOLOGY PRAC. 238, 238 (2010) (describing different payers' development of internal policies on coverage for personalized medicine); Andrew Hresko & Susanne B. Haga, *Insurance Coverage Policies for Personalized Medicine*, 2 J. PERSONALIZED MED. 201, 202 (2012) (reviewing the coverage policies of the largest U.S. insurers for genomic and pharmacogenomics tests).

79. See Michael D. Graf, Denise F. Needham, Nicole Teed & Trisha Brown, *Genetic Testing Insurance Coverage Trends: A Review of Publicly Available Policies from the Largest US Payers*, 10 PERSONALIZED MED. 235, 235 (2013) (noting that, as of 2013, "[a]pproximately one-third of insurers had at least one genetic testing policy").

80. See Henry M. Kuerer, et al., *Current National Health Insurance Coverage Policies for Breast and Ovarian Cancer Prophylactic Surgery*, 7 ANNALS SURGICAL ONCOLOGY 325, 325 (2000) (reporting that, in 2000, "44% of private plans ha[d] specific policies for coverage of prophylactic mastectomy for a strong family history of breast cancer and 38% of plans for a BRCA mutation").

81. When a health plan is purchased in the individual insurance market, the governing document is simply the health insurance policy, which constitutes a legal contract between the insurer and the policyholder. By contrast, when an individual is insured through an employer sponsored plan, then the governing documents are the ERISA plan documents, which, depending on the plan, may include the group insurance policy, the summary plan description, the certificate of coverage, or other documents prepared by the employer.

1. Four Strategies for Deploying Rules of Medical Necessity in Governing Documents

There is significant variation in how health plans' insurance policies and ERISA plan documents describe or reference rules of medical necessity. Broadly speaking, though, these approaches can be split into four categories, which are not all mutually exclusive. In particular, health plans may: (i) define rules of medical necessity in lengthy documents that are incorporated by reference into their governing documents, (ii) include specific rules of medical necessity directly within their governing documents, (iii) authorize plan personnel to base coverage determinations on rules of medical necessity that are distinct from the governing documents or (iv) make no mention of separate rules of medical necessity in their governing documents.

i. Governing Documents that Incorporate by Reference Rules of Medical Necessity Contained in Separate Medical Policies

Health insurance policies and ERISA plan documents increasingly specify that certain types of care are covered only to the extent provided in separate documents that contain rules of medical necessity.⁸² These separate documents often have names like “medical policies,” “clinical bulletins,” “utilization review procedures” or “medical criteria.” In many cases, health plans' governing documents explicitly incorporate by reference these separate rules of medical necessity. In other cases, the incorporation by reference is implicit, consisting of the governing document's declaration that benefits are only covered to the extent specified in the plan's separate policies, procedures, or criteria. Either way, the governing documents purport to replace the traditional standard-based approach to determining when care is medically necessary or experimental with rules of medical necessity that are contained in separate writings.

Health plans vary in how extensively they use this approach. Many health plans incorporate by reference rules of medical necessity only with respect to various specific categories of care. For instance, a health plan's governing documents may specify that its medical policies define the plan's coverage obligations with respect to organ transplants,⁸³ residential treatment

82. This result contrasts with the conclusion that at least in some settings, property/casualty insurers retain policy language that courts have found to be ambiguous because that very finding provides the language with a fixed (albeit pro-coverage) meaning that insurers can price. See Michelle E. Boardman, *Contra Proferentem: The Allure of Ambiguous Boilerplate*, 104 MICH. L. REV. 1105, 1106 (2006); cf. Daniel Schwarcz, *The Role of Courts in the Evolution of Standard Form Contracts: An Insurance Case Study*, 46 BYU L. REV. 471, 477 (2021) (finding that the ambiguity rule has played a major role in the evolution of the ISO homeowners insurance policy). By contrast, health insurers have apparently found the cost of the ambiguity rule sufficient to induce them to redraft their policies.

83. See, e.g., *Hyde v. Humana Ins. Co.*, 598 So. 2d 876, 877-79 (Ala. 1992). Large group policy contains “Major Transplant Benefit Rider,” which states approval

facilities,⁸⁴ durable medical equipment,⁸⁵ radiation therapy,⁸⁶ and a variety of other discrete categories of care. The specific language that plans use to accomplish this result also varies. Illustrative language might provide that “[w]e cover oral amino acid based elemental formula if it meets our medical coverage criteria.”⁸⁷

Other health plans more aggressively use this approach of incorporating by reference their rules of medical necessity, extending it to all covered care, rather than specific subsets of care. For instance, Blue Cross of Alabama provides in all of its insurance policies that “[i]f a service or supply is not medically necessary according to one of our published medical criteria policies, we will not pay for it.”⁸⁸ Parallel language applies with respect to whether medical care ordered by a provider is experimental.⁸⁹ Similarly, all Minnesota Blue Cross policies as of 2020 provide that:

Covered benefits will be determined in accordance with Blue Cross’ policies in effect at the time treatment is rendered or, if applicable, prior authorization may be required. Our medical policies can be found at www.bluecrossmn.com and are hereby incorporated by reference.⁹⁰

[f]or a major transplant procedure . . . will be based on written criteria and procedures established by our Medical Affairs Department. . . . One of three exclusions to that rider reads: “No benefit is payable for or in connection with a major transplant if . . . Our Medical Affairs Department does not approve coverage for the procedure, based on established criteria for *medical necessity* or based on a determination that the procedure is *experimental* for the condition involved.”

Id. The insurer denied coverage because its internal medical criteria—contained in a document entitled “HUMANA HEALTH CARE DIVISION TRANSPLANT COVERAGE CRITERIA”—specified that company “provides liver transplant benefits only for biliary atresia and certain congenital metabolic disorders,” and Hyde did not fall in these categories. *Id.*

84. See, e.g., *Wit v. United Behav. Health*, No. 14-CV-02346, 2019 WL 1033730, at *14 (N.D. Cal. Mar. 5, 2019) (describing ERISA plan participant whose plan explicitly “excludes ‘services which are not consistent with [UBH’s] level of care guidelines or best practices as modified from time to time[.]’” where “Level of Care Guidelines” determine the covered mental health and substance use disorder benefits).

85. See HEALTHPARTNERS INS. CO., HEALTH PARTNERS INDIVIDUAL MARKET POLICY MARKUP, MGC-200.1 ICM 7-11, at 12 (“We cover oral amino acid based elemental formula if it meets our medical coverage criteria.”).

86. See *Linn v. BCBSM, Inc.*, 905 N.W.2d 497, 504 (Minn. 2018) (describing an insurance policy that incorporated by reference rules regarding coverage for a highly specific type of radiation treatment needed by Plaintiff).

87. HEALTHPARTNERS INS. CO., *supra* note 85, at 12.

88. See, e.g., BLUECROSS BLUESHIELD ALA., UNIVERSITY OF ALABAMA STUDENT HEALTH PLAN 58 (2020).

89. See *id.*

90. BLUECROSS BLUESHIELD MINN., GROUP HEALTH CARE CERTIFICATE 9 (2015) [hereinafter BCBSM CERTIFICATE]; see also *Creative Care, Inc. v. Conn. Gen. Life Ins. Co.*, No. CV 16-9056, 2018 WL 10072259, at *2 (C.D. Cal. Oct. 15, 2018) (according to Cigna’s own

Health plans that incorporate by reference their complete set of rules of medical necessity purport to convert virtually all of their coverage obligations into a detailed set of complex rules. This is because these health plans typically maintain an immensely lengthy and detailed set of rules of medical necessity, which span virtually every major type of care. To illustrate, Blue Cross of Minnesota maintains medical policies that are organized into seven categories on: (1) Ancillary Services; (2) Behavioral Health; (3) Laboratory; (4) Medicine; (5) Miscellaneous; (6) Radiology; and (7) Surgery.⁹¹ There are 171 separate medical policies under the “Medicine” section with names such as “Hematopoietic Stem-Cell Transplantation for Autoimmune Disease” and “Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting.”⁹² Most individual medical policies are at least several pages long and contain detailed, statute-like criteria regarding when treatments are considered medically necessary or experimental.

This approach of incorporating by reference separate rules of medical necessity in health plans’ governing documents has several key advantages over attempting to include rules of medical necessity within these documents directly. For instance, it makes the underlying contract more readable, if less transparent. But by far the most important benefit of this approach is that it allows health plans to update their rules of medical necessity in a coordinated and timely fashion simply by altering the cross-referenced document containing these rules, rather than by attempting to update or amend all of their policies and/or plan summaries.⁹³ This flexibility to alter rules of medical necessity is often essential, as medical knowledge can sometimes change dramatically in a short period of time.⁹⁴ By contrast, there would be innumerable practical difficulties associated with updating individual health

counterclaim, the insurer’s “medical necessity determinations are in a document called ‘Cigna Standards and Guidelines/Medical Necessity Criteria for Treatment of Mental Health and Substance Use Disorders’ (‘Guidelines’), which are publicly available on Cigna’s website and incorporated by reference into each plan administered by Cigna”); *Potter v. Blue Shield of Cal. Life & Health Ins. Co.*, No. SACV 14-0837, 2017 WL 1334289, at *4 (C.D. Cal. Apr. 7, 2017) (“The Plan defines ‘medically necessary’ as ‘includ[ing] only those [Services] which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by the Plan, are: . . . Consistent with the Plan’s medical policy[.] . . .’” (alteration in original)).

91. *BlueCross Blue Shield of Minnesota Medical Policy*, BLUECROSS BLUESHIELD MINN., <https://securecms.bluecrossmnonline.com/content/medpolicy/en/minnesota/core/all/search.html> [<https://perma.cc/FNU3-AUVW>].

92. *See id.* As of September 2021, there are also 95 surgery medical policies, 13 radiology policies, 5 miscellaneous policies, 33 laboratory policies, 7 behavioral health policies, and 26 ancillary services policies.

93. *See* Robert Whitman, *Incorporation by Reference in Commercial Contracts*, 21 MD. L. REV. 1, 1 (1961); Royce de R. Barondes, *Side Letters, Incorporation by Reference and Construction of Contractual Relationships Memorialized in Multiple Writings*, 64 BAYLOR L. REV. 651, 652–53 (2012).

94. *See, e.g.,* Morreim, *supra* note 30, at 1025–28 (describing the advantages of being able to change clinical guidelines rather than plan documents).

insurance policies or ERISA plan documents whenever medical science or medical community standards advanced with respect to any particular treatment or medical intervention, particularly when that update needs to be made in the middle of a plan year or contract term.⁹⁵

ii. Governing Documents that Directly Include Rules of Medical Necessity

Virtually all health plans contain numerous exclusions or limitations of coverage aside from the ubiquitous requirements that care must be “medically necessary” and non-“experimental.” But as explained in Part II, these coverage restrictions were historically categorical in nature, meaning that they excluded coverage for treatments or services under all circumstances, irrespective of whether they were medically necessary, non-experimental, or the most appropriate treatment for the patient.

Some health plans, however, include rules of medical necessity directly in their plan documents or insurance policies with respect to specific types of care. Consider, for instance, the group health plan at issue in *Hawaii Medical Service Association v. Adams*, which involved a plan participant whose doctors had recommended an allogeneic stem-cell transplant (“allo-transplant”) to treat a recurrence of his multiple myeloma.⁹⁶ In the section of the plan documents entitled “Services Not Covered,” the plan specifically excluded coverage for all transplant services and supplies other than those described in a separate section of the plan entitled “Description of Benefits under Organ and Tissue Transplants.”⁹⁷ That Section of the plan listed a number of conditions for which allo-transplant was covered but did not include multiple myeloma.⁹⁸ On the basis of these plan provisions, the plan’s administrator denied coverage.⁹⁹ Unlike traditional categorical coverage exclusions, this plan limited coverage for a specific treatment to a pre-specified subset of insureds based on a judgment regarding the treatment’s medical and scientific appropriateness for different types of insureds.¹⁰⁰

Plans vary in what specific types of medical care they single out in their governing documents with rules of medical necessity. Examples include not just organ transplants, but also weight loss surgery,¹⁰¹ hyperbaric oxygen

95. See, e.g., Korobkin, *supra* note 13, at 29 (noting the impossibility of keeping health care contracts updated for changes in medical technology and knowledge).

96. *Hawaii Med. Serv. Ass’n v. Adams*, 209 P.3d 1260, 1263–65 (Haw. Ct. App. 2009).

97. *Id.* at 1265.

98. *Id.* at 1270.

99. *Id.* at 1263.

100. The fact that this exclusion was based on a medical judgment was clear in the case, as the plan’s medical guidelines—which were separate from the Plan itself—specifically described the use of allo-transplants for multiple myeloma as investigational.

101. See UNITED HEALTHCARE, UNITEDHEALTHCARE SELECT PLUS: UNITEDHEALTHCARE INSURANCE COMPANY CERTIFICATE OF COVERAGE 21 (2020) (“Obesity - Weight Loss Surgery[:] Surgical treatment of obesity when provided by or under the direction of a Physician when you

therapy,¹⁰² acupuncture,¹⁰³ infertility treatment,¹⁰⁴ osteoporosis detection and prevention,¹⁰⁵ and genetic testing.¹⁰⁶ Few governing plan documents directly contain detailed rules of medical necessity for major categories of medical care like cancer or heart disease.

There are several potential reasons why health plans may choose to include rules of medical necessity directly in their governing documents, rather than incorporating them by reference. First, doing so may increase the chances that third-party reviewers, like courts and external reviewers, will deem these rules to constitute formal plan terms that cannot be avoided. Second, including rules of medical necessity directly in governing documents, rather than in centralized rules that are cross-referenced by numerous plans, more easily allows a health insurer to maintain different rules of medical necessity for different plans.¹⁰⁷ Although insurers generally rely on a single set of rules of medical necessity across all of their policies,¹⁰⁸ we have heard anecdotal reports that insurers acting as third-party administrators for self-insured employers are often willing to modify their standard rules of medical necessity at the employer's request in order to increase plan generosity.¹⁰⁹ Third, the explanation for including these rules of medical necessity directly in governing documents may simply be historical: They may have started off

have a body mass index (BMI) equal to or greater than 40 or greater than 35 with complicating coexisting medical conditions or diseases (such as sleep apnea or diabetes) directly related to, or made worse by, obesity.”).

102. See, e.g., *Rodarte v. Presbyterian Ins. Co.*, 371 P.3d 1067, 1070 (N.M. Ct. App. 2016) (describing a health insurance policy that listed “certain conditions for which [hyperbaric oxygen therapy] was available, and excluded ‘any clinical condition not listed above,’ specifically naming seven such excluded conditions”).

103. See AMERIHEALTH INS. CO. OF N.J., EXCLUSIVE PROVIDER ORGANIZATION HEALTH BENEFITS PLAN 44, 63 (on file with publisher); AETNA, COVERAGE AND EXCLUSIONS HO COC000040 05 1 (on file with publisher).

104. See UNITEDHEALTHCARE INS. CO., CERTIFICATE OF COVERAGE COC20.INS.2018.LG.FL 17 (2020) (on file with publisher); CAREFIRST BLUECHOICE, INC., 2020 AMENDMENT MD/CFVC/LG/2020 AMEND 12-16 (2020) (on file with publisher).

105. See CAREFIRST BLUECHOICE, INC., IN-NETWORK DESCRIPTION OF COVERED SERVICES 6 (2019) (on file with publisher).

106. See BLUECROSS BLUESHIELD OF KAN. INC., BLUECARE EPO BRONZE CHOICE NON-GROUP CONTRACT 22 (on file with publisher); CIGNA HEALTH & LIFE INS. CO., EXCLUSIVE PROVIDER ORGANIZATION (EPO) POLICY 65 (on file with publisher).

107. Incorporating rules directly into plan documents helps to assure insurers that doing so has no impact on the other plans administered or provided directly by the insurer. An alternative approach is for a single insurer to have different approaches to how it references rules of medical necessity in their governing legal documents, though this approach does not seem common.

108. See *infra* Section III.A.2.

109. *But see* *Wit v. United Behav. Health*, No. 14-CV-02346, 2019 WL 1033730, at *47-48 (N.D. Cal. Mar. 5, 2019) (“UBH maintains a uniform set of Guidelines for fully insured and self-funded plans,” even though its Clinical Policy Committee recommended developing different standards for these two types of plans, because UBH’s in-house counsel determined that from a “legal perspective we cannot deny some commercial requests and approve others based on our financial arrangements.”).

as categorical exclusions (as suggested by their focus on care that is at the borderline of medical and non-medical care), but then may have been converted to rules of medical necessity as insurers recognized specific scenarios in which the categorically excluded care was both medically necessary and important to provide to insureds for market-based or ethical reasons.

iii. Governing Plan Documents that Authorize the Development and Use of Rules of Medical Necessity

In some cases, governing plan documents simply authorize plans to develop and use rules of medical necessity, but do not make these rules part of the plan or insurance policy. Unlike governing documents that purport to define the substance of coverage by cross-referencing or directly reproducing rules of medical necessity, this approach describes rules of medical necessity merely as a procedural tool that the plan uses to implement a more traditional standard-based approach to defining medically necessary and non-experimental care.¹¹⁰ Rules of medical necessity in these cases function more as interpretive guidance than as binding contract terms.

As above, plans vary in the specific language they use when adopting this approach. This variation is most evident in the extent to which plans describe the processes they use to develop and update their rules of medical necessity. Some insurance policies and ERISA plan documents say very little about these matters. For instance, some UnitedHealthcare policies provide simply that “[w]e develop and maintain clinical policies that describe the *Generally Accepted Standards of Medical Practice* scientific evidence, prevailing medical standards and clinical guidelines supporting our determinations regarding specific services.”¹¹¹ Other health plans contain some more detail about the principles that undergird the development of their rules of medical necessity. Thus, certain Blue Cross policies provide:

Internally developed policies are subject to approval by our Medical Policy Committee, which is made up of independent community Physicians who represent a variety of medical specialties. The remaining policies are approved by other external specialists. For all

110. For cases involving plans with this type of language, see, e.g., *Julie L. v. Excellus Health Plan, Inc.*, 447 F. Supp. 3d 38, 47 (W.D.N.Y. 2020) (The underlying plan contained broad standard for medically necessary care, but specified that “Excellus [the administrator] ‘may develop or adopt standards which describe in more detail when payments will or will not be made under the [Plan]’”) (second alteration in original); *Krauss v. Oxford Health Plans, Inc.*, 517 F.3d 614, 622 (2d Cir. 2008) (describing plan that specifies that the administrator “may adopt reasonable policies, procedures, rules, and interpretations to promote the orderly and efficient administration of this Certificate”); *Benjamin v. Oxford Health Ins.*, No. 16-CV-00408, 2018 WL 3489588, at *6 (D. Conn. July 19, 2018) (expressing the same idea, borrowing language from *Krauss*).

111. See UNITEDHEALTHCARE INS. CO., UNITEDHEALTHCARE CHOICE PLUS, CERTIFICATE OF COVERAGE FOR THE PLAN BCFC (MOD) OF AIMS BENEFIT TRUST 83 (2019) (on file with publisher).

policies, Blue Cross' goal is to find the right balance between making improved Treatments available and guarding against unsafe or unproven approaches. From time to time, new medical policies may be created or existing medical policies may change.¹¹²

This approach of procedurally authorizing the development of rules of medical necessity can co-exist with the two approaches described earlier of incorporating medical policies by reference or including them directly within plan documents. In particular, some health plans' governing documents both authorize the development and use of a full suite of rules of medical necessity while simultaneously incorporating by reference specific rules for certain types of care or simply including such rules directly within the governing document itself.¹¹³

iv. Governing Plan Documents that Do Not Authorize or Incorporate by Reference Rules of Medical Necessity

The governing documents of some health plans neither contain any rules of medical necessity nor authorize the development or use of such rules. Instead, they simply recite traditional standard-based definitions of "medically necessary" and "experimental" care, and perhaps cite a variety of potential sources that the plan may look to when applying these standards. Notably, we include plans in this category if their governing documents lay out multiple sources that the plan can consider when making determinations regarding medical necessity or experimental care, even if one of these sources consists of the plan's internal rules of medical necessity: relegating these rules simply to one relevant source in the broader consideration of whether care is medically necessary or experimental is consistent with the traditional standard-based approach to this inquiry.

Some health plans' governing documents do not mention rules of medical necessity but do contain discretionary clauses. Discretionary clauses purport to provide health insurers or plan administrators with special authority to interpret the terms of the underlying policy or plan. Under well-established federal law, discretionary clauses are generally enforceable when they are contained within employer-sponsored plans that are governed by ERISA.¹¹⁴ Although many states ban health insurers from using discretionary clauses in their insurance policies,¹¹⁵ these laws are preempted by ERISA with

112. BLUECROSS BLUE SHIELD MINN., HEALTH CARE PLAN X21920-R1 168 (on file with publisher).

113. See for example, UnitedHealthcare policies, which authorize development of rules and include specific rules in policy itself for weight loss surgery. *UnitedHealthcare Commercial Medical & Drug Policies and Coverage Determination Guidelines*, UNITEDHEALTHCARE, <https://www.uhcprovider.com/en/policies-protocols/commercial-policies/commercial-medical-drug-policies.html> [<https://perma.cc/P56W-2A8X>].

114. See *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989).

115. As of spring 2020, 22 states have some sort of prohibition on the use of discretionary clauses. See the appended materials to NAT'L ASS'N INS. COMM'RS, PROHIBITION ON THE USE

respect to self-insured plans (but not fully insured group plans). As is explored further in Part IV, discretionary clauses are highly relevant in this context, as many courts have understood a plan's development and use of rules of medical necessity as constituting a plan's exercise of its authority pursuant to a discretionary clause.

2. Empirically Examining the Frequency of Health Insurers' Use of Rules of Medical Necessity in Governing Documents

In order to gain a rough sense of how common it is for private health plans to rely on each of the four strategies described above for referencing rules of medical necessity in their governing documents, we systematically examined health insurers' filings with state regulators. Virtually every state requires that health insurers file with their state insurance department all of the insurance policies that they sell within that jurisdiction, though this requirement does not apply to self-insured health plans, which are exempt from state law due to ERISA.¹¹⁶ Many, though not all, states make these regulatory filings publicly available through a system known as SERFF, or System for Electronic Rate and Form Filing.¹¹⁷

We initially took an intensive look at health insurers' regulatory filing in five states, examining all of the regulatory filings containing insurance policy forms over the last five years for each of the three top health insurers in the three primary insurance markets: individual market plans, small group plans, and large group plans.¹¹⁸ We selected Minnesota, Texas, Alabama, Illinois and Oregon for this preliminary inquiry.¹¹⁹ Based on this initial "deep dive" into health insurers' regulatory filings in these five states, we reached several preliminary conclusions that informed our subsequent empirical strategy.

First, we found that virtually all insurance policies issued by a single health insurer in a single state included identical language with respect to rules of medical necessity, irrespective of whether the policy was sold in the

OF DISCRETIONARY CLAUSES MODEL ACT ST-42-3-42-6 (2006) [hereinafter PROHIBITION ON DISCRETIONARY CLAUSES MODEL ACT], <https://content.naic.org/sites/default/files/inline-files/MDL-042.pdf> [<https://perma.cc/4FK6-78K8>].

116. See KENNETH S. ABRAHAM & DANIEL SCHWARCZ, *INSURANCE LAW AND REGULATION* 150-54 (7th ed. 2020).

117. *Id.* at 154. For most states, individual filings can be retrieved online via the SERFF system. See, e.g., *SERFF Filing Access*, NAT'L ASS'N INS. COMM'RS, <https://filingaccess.serff.com/sfa/home/MN> [<https://perma.cc/G36V-E968>].

118. See *Market Share and Enrollment of Largest Three Insurers – Large Group Market*, KAISER FAM. FOUND. (2018), <https://www.kff.org/other/state-indicator/market-share-and-enrollment-of-largest-three-insurers-large-group-market/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> [<https://perma.cc/2TUF-BN8B>].

119. We selected these states not only because they made health insurers' regulatory filings over the past five years publicly available (a criteria that, for instance, excluded both New York and California), but because they represented a broad range of sizes and political dispositions.

large group, small group, or individual market or was one of several different filed policies.¹²⁰ However, we also found that health insurers' approach to this issue often did vary substantially across different states.

Second, we found that the vast majority of health insurers' policies within an individual state were consistent with respect to their treatment of rules of medical necessity over the prior five years. The only exceptions to this trend that we identified involved insurers shifting towards more aggressive incorporation-by-reference of rules of medical necessity. For instance, in 2018 Bright Health of Alabama moved from a traditional standard-based definition of medical necessity to explicitly incorporating by reference its rules of medical necessity in its insurance policy.¹²¹ Similarly, in 2015 Blue Cross of Minnesota shifted from selectively incorporating by reference its rules of medical necessity for specific subsets of care to incorporating by reference the entirety of its medical policies.¹²²

In light of these findings, we subsequently examined the most recent filings of all health insurers that were one of the top three insurers in one of the three primary markets in the 45 states that made their most recent regulatory filings publicly available through SERFF.¹²³ Thus, for every state that made health insurers' regulatory filings available, we examined the most recently filed health insurance policy of any insurer that was a top-three writer of business in the individual, small group, or large group markets.¹²⁴ In total, we examined 180 policies in this second stage of review. Given that insurers' policies within a single state are typically consistent across market and plan types with respect to their treatment of rules of medical necessity and that they are also largely consistent across the last five years, we are confident that this procedure yielded a roughly accurate sample for assessing how health insurance policies currently treat rules of medical necessity.

120. In a small number of instances, some filings suggested the possibility that different language was used by different groups because they contained bracketed variations in policy language.

121. *Compare generally* BRIGHT HEALTH INS. CO., INDIVIDUAL POLICY BHAL0001-0317 (2017) (no language referencing insurer's medical policies), *with* BRIGHT HEALTH INS. CO. ALABAMA, INDIVIDUAL POLICY BHAL0001-0518 at 94 (2019) ("If a service or supply is not Medically Necessary according to one of our published medical criteria policies, We will not pay for it.").

122. *Compare generally* BLUECROSS BLUESHIELD MINN., GROUP CONTRACT X20784-R3 (2014) (no language referencing insurer's medical policies), *with* BCBSM CERTIFICATE, *supra* note 90, at 9) ("Covered benefits will be determined in accordance with Blue Cross' policies in effect at the time treatment is rendered or, if applicable, prior authorization may be required. Our medical policies can be found at www.bluecrossmn.com and are hereby incorporated by reference.").

123. We were unable to locate policies on SERFF for the following states: Alaska, California, Massachusetts, Mississippi, and Washington.

124. In isolated instances where a top-three writer of coverage only issued specialty policies rather than general health insurance policies in the individual, small group, or large group markets, we substituted that insurer with the fourth largest insurer in the state. We did not look at plan language on preventative care. Additionally, we did not treat plan requirements of approval by FDA as incorporation by reference of rules of medical necessity.

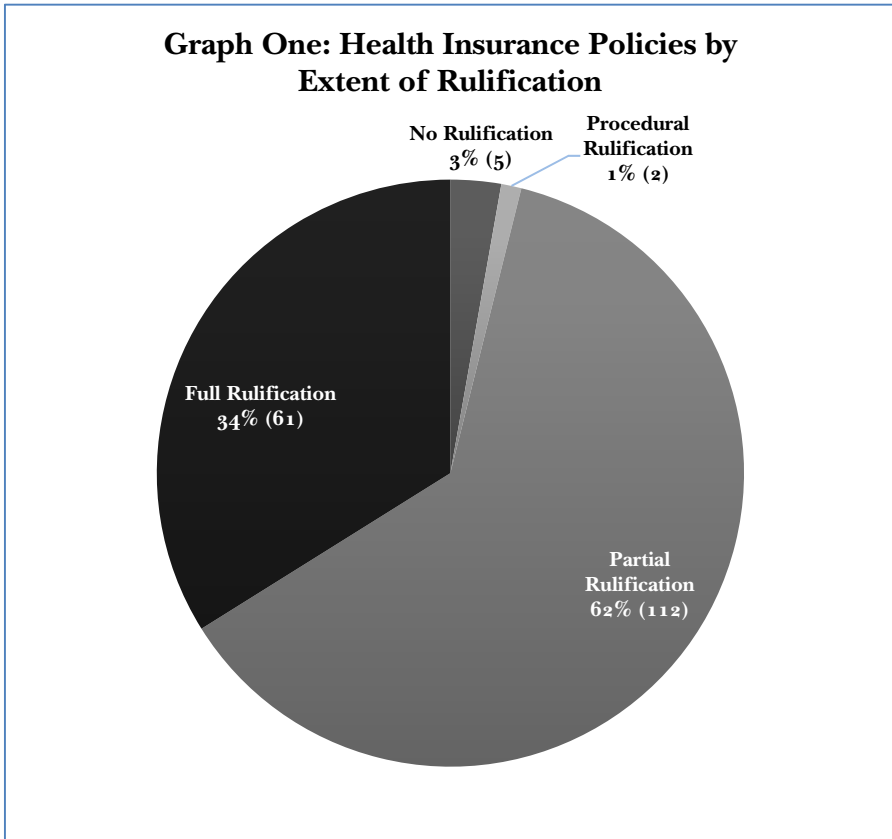
We then coded each insurance policy for various factors related to rules of medical necessity. Graph One breaks down the resulting data, by grouping the insurance policies we examined into four broad subcategories:

*No Rulification: Insurance policies that do not contain any rules of medical necessity or authorize the development of such rules;

*Procedural Rulification: Insurance policies that authorize the development of rules of medical necessity but do not otherwise contain such rules;

*Partial Rulification: Insurance policies that contain some rules of medical necessity for specific types of care, either by directly including such a rule or by referencing a separate rule of medical necessity for a specific type of care;

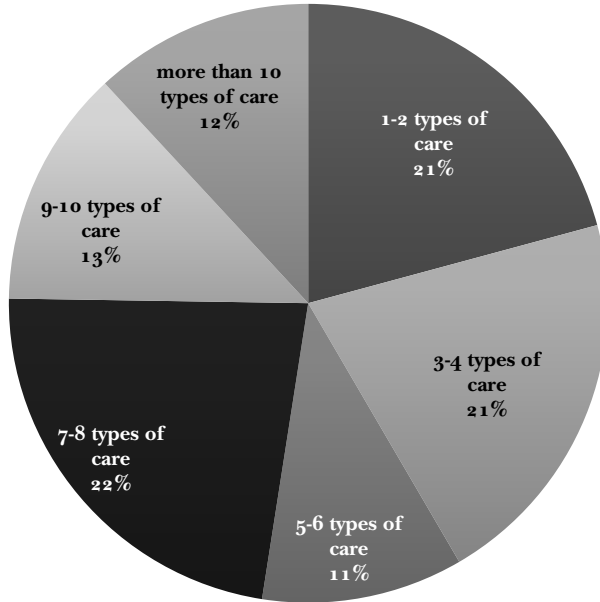
*Full Rulification: Insurance policies that substantively limit coverage by explicitly incorporating by reference a full suite of rules of medical necessity that are applicable to a broad range of care types.



As suggested by the data presented in Graph One, substantive rulification is becoming ubiquitous in most health insurance policies. Approximately 1/3 of examined policies contained “full rulification” because they attempted to incorporate by reference separate rules of medical necessity that applied across a broad range of care types. Virtually all of the remaining health insurance policies contained “partial rulification” because they included substantive rules of medical necessity for a discrete number of specific types of care.

Because such a large percentage of insurance policies included partial rulification and that category is rather broad, Graph Two presents some additional data about the degree of rulification for insurance policies fitting into this category. To do so, Graph Two breaks down the sampled policies falling into the “partial rulification” category based on how many specific types of care were subject to a rule of medical necessity. As it suggests, health insurance policies falling in the partial rulification category varied significantly as to the number of care types that were subject to rules of medical necessity.

Graph Two: Number of Care Types Subject to Rules of Medical Necessity for Health Insurance Policies with "Partial Rulification"



B. THE EXTENT TO WHICH RULES OF MEDICAL NECESSITY BIND INTERNAL HEALTH PLAN DECISIONS

Virtually all health plans maintain rules of medical necessity that they rely on to process claims and prior authorization requests when they are first made.¹²⁵ This is true not only of health plans whose governing documents explicitly incorporate by reference these rules or authorize their use and development, but also of health plans whose governing documents make no mention of any rules of medical necessity.¹²⁶ By training personnel to rely on

125. See, e.g., *Wit v. United Behav. Health*, No. 14-cv-02346, 2019 WL 1033730, at *8 (N.D. Cal. Mar. 5, 2019) ("While the Guidelines allow for some exercise of clinical judgment, they are the criteria against which UBH Peer Reviewers make clinical coverage determinations, and they are mandatory.")

126. Numerous cases report that plans rely on specific rules of medical necessity in this way, even when their formal governing documents do not incorporate by reference or authorize the development or use of such rules. See, e.g., *id.* at *15 (insurer relied on rules of medical necessity

rules of medical necessity to process initial claims and implement utilization review procedures, health plans can promote consistent treatment of different claims across time and insureds.¹²⁷ They can also substantially increase their ability to operate efficiently while limiting the need for medical professionals to be involved in routine claims determinations.¹²⁸

Health insurers' reliance on rules of medical necessity at the initial claims stage is well-illustrated by the claims-handling procedures of United Behavioral Health ("UBH"), which are described in detail in *Wit v. United Behavioral Health*.¹²⁹ When an initial claim is submitted to UBH by an insured or a provider, it is assigned to a "Care Advocate." The Care Advocate determines whether any categorical exclusions apply and, if not, whether the care ordered by a provider is consistent with UBH's rules of medical necessity, which are contained in two documents denominated "Level of Care Guidelines" and "Coverage Determination Guidelines."¹³⁰ If a Care Advocate determines that the requested care is covered or categorically excluded, then that decision is communicated to the insured.¹³¹ By contrast, if the Care Advocate determines that the requested care should be denied because it is inconsistent with UBH's rules of medical necessity, then that determination is reviewed by a "Peer Reviewer," who is a doctor or PhD psychologist.¹³² Like the initial Care Advocate, the Peer Reviewer is required to adhere to the rules of medical necessity contained in UBH's guidelines when reviewing the claim.¹³³ UBH internally audits its Peer Reviewers' determinations for "Inter-Rater Reliability" to ensure consistent application of its rules of medical necessity (which often require some application of clinical judgment).¹³⁴ This process facilitates UBH's capacity to make prompt coverage determinations while enabling Peer Reviewers to write up complete explanations for any denial of care relatively quickly, typically in about 30 minutes.¹³⁵

Although health insurers typically rely on rules of medical necessity to process initial claims, the extent to which they rely on these rules to resolve

for mental health and substance abuse treatment that, for most plans, were not mentioned in ERISA plan documents); *Weiss v. Banner Health*, 416 F. Supp. 3d 1178, 1182 (D. Colo. 2019) (insurer relied on Milliman Criteria to deny coverage even though these criteria were not mentioned in policy, which contained a non-exclusive list of sources plan might consult to make medical necessity determinations); *Michael P. v. Blue Cross & Blue Shield of Tex.*, 459 F. Supp. 3d 775, 778 (W.D. La. 2020).

127. See, e.g., *HEALTH CARE PLAN X21920-R1*, *supra* note 112, at 168. ("Blue Cross applies medical policies in order to determine benefits consistently for its members.")

128. See *infra* Section IV.A.

129. See *Wit*, 2019 WL 1033730, at *10-13.

130. See *id.* at *1, *12.

131. *Id.* at *12.

132. *Id.*

133. *Id.*

134. See *id.* at *10.

135. See *id.* at *12.

internal appeals of coverage denials is less clear. There are no legal impediments to an insurer continuing to use such rules as the basis for internal appeals. Not surprisingly, doing so appears to be particularly common when rules of medical necessity are formally made part of the plan's governing legal documents, either through incorporation by reference or direct inclusion in these documents.¹³⁶ However, some plans rely exclusively on their rules of medical necessity to resolve internal appeals even when those rules are not formally made part of their governing legal documents.¹³⁷ For instance, the *Wit* court found that UBH applied the same rules of medical necessity contained in its guidelines to decide initial claims and internal appeals, even though these guidelines were not part of the insured's formal plan documents.¹³⁸

The justification for relying on rules of medical necessity to resolve internal appeals is more tenuous than the justification for relying on these rules to process initial claims. First, an appeal of a coverage denial that was premised on a rule of medical necessity provides some indication that the relevant rule may be problematic, perhaps because it does not fully account for unusual individual circumstances, has become out-of-date with scientific knowledge or medical practice, or is systemically out-of-step with prevailing medical and scientific standards. Additionally, because such appeals are much less common than initial requests for coverage or prior authorization, insurers can reasonably be expected to devote more resources to the resolution of these coverage disputes. Finally, predictability of results is arguably less important during appeals of initial coverage denials, as the insured and their provider are already on notice that the claim may ultimately be denied.

136. See, e.g., *Linn v. BCBSM, Inc.*, 905 N.W.2d 497, 500 (Minn. 2018) (noting that insurer relied on rules of medical necessity during internal review where plan explicitly incorporated by reference these rules in its insurance policy); *Haw. Med. Serv. Ass'n v. Adams*, 209 P.3d 1260, 1265 (Haw. Ct. App. 2009) (noting that insurer's internal review denied coverage because rules of medical necessity were incorporated directly into plan documents); *Hyde v. Humana Ins. Co.*, 598 So. 2d 876, 879 (Ala. 1992) (noting that internal appeal denied coverage solely based on rules of medical necessity, which were IBR in insurance policy).

137. See, e.g., *Julie L. v. Excellus Health Plan, Inc.*, 447 F. Supp. 3d 38, 47-48 (W.D.N.Y. 2020) (alleging that a "determin[ation] that BlueFire and BCA services were not medically necessary was in error" because they were based on InterQual Criteria that the plan had adopted rather than plan language, and where "undisclosed external medical necessity criteria are at odds with the actual terms of the Plan, the language of the Plan documents must prevail"); Class Action Complaint at 3, *Cole v. United Healthcare Ins. Co.*, No. 19-CV-21258 (S.D. Fla Apr. 3, 2019) (alleging that even though the underlying plan documents use broad standards for medical necessity and experimental, in both internal review and external review, UH relied entirely on its proton beam therapy internal policy, refusing to even consider evidence provided by treating doctor, including references to peer reviewed literature); *Weiss v. Banner Health*, 416 F. Supp. 3d 1178, 1183 (D. Colo. 2019) ("As to the findings relevant to the determination, Banner stated that 'Banner Health Plan utilizes Milliman Guidelines . . . in making decisions,' and that this was 'a non-covered service' under the Milliman Guidelines."); *Michael P. v. Blue Cross & Blue Shield of Tex.*, 459 F. Supp. 3d 775, 778 (W.D. La. 2020).

138. See *Wit*, 2019 WL 1033730, at *50.

C. THE DEVELOPMENT, MAINTENANCE, AND PUBLIC AVAILABILITY
OF RULES OF MEDICAL NECESSITY

Many large national health insurers rely on rules of medical necessity that they internally develop and maintain. Other insurers, however, rely on rules drafted by third-party organizations like non-profits, medical societies, or private companies. Still others rely on a mix of these two strategies, developing internal rules of medical necessity for some types of care while relying on external rules for other types of care.

Most states have utilization review laws that govern the creation and maintenance of rules of medical necessity. These state laws are generally procedural in nature and, for example, require a physician's involvement in rule creation and require that such rules be reviewed at least annually.¹³⁹ These laws do not typically impose significant substantive restraints on the rules, often requiring only that they reflect "sound clinical evidence."¹⁴⁰ Only one state prohibits the consideration of cost in crafting such rules.¹⁴¹ In some states, insurers can satisfy state utilization review laws by receiving accreditation through one of the independent non-profit organizations that seek to foster the development of high-quality, objective rules of medical necessity.

The two leading such organizations are the National Committee for Quality Assurance ("NCQA") and the Utilization Review Accreditation Commission ("URAC"). Both organizations base accreditation on health insurers following specific procedures when developing their rules of medical necessity. These include requirements similar to those imposed under state law—that health insurers consult with independent providers, consider clinical evidence, annually review rules, update rules when appropriate, and rely on clinical directors to facilitate this process.¹⁴²

1. Internally Drafted Rules of Medical Necessity

Health plans that produce their own rules of medical necessity typically rely on committees consisting of some combination of internal and external medical experts to oversee the development, maintenance, and updating of these rules.¹⁴³ These committees are generally charged with developing rules based on the traditional standards of "medically necessary" and "non-experimental" care. Thus, the ostensible goal of the committees and individuals charged with crafting insurers' rules of medical necessity is, as Blue Cross puts it,

139. See, e.g., NAT'L ASS'N OF INS. COMM'RS, UTILIZATION REVIEW & BENEFIT DETERMINATION MODEL ACT § 12 (2012) [hereinafter NAIC MODEL UTILIZATION REVIEW ACT] (adopted by three states).

140. *Id.* § 8(A).

141. See *infra* note 145 and accompanying text.

142. While the full accreditation criteria for NCQA and URAC are not publicly available, their basics have been described in judicial decisions. See *Wil*, 2019 WL 1033730, at *46.

143. See, e.g., HEALTH CARE PLAN X21920-R1, *supra* note 112, at 168.

“to find the right balance between making improved [t]reatments available and guarding against unsafe or unproven approaches.”¹⁴⁴ Cost considerations are not typically mentioned explicitly, although state utilization review laws do not generally prohibit their use.¹⁴⁵ One of the largest accrediting organizations for utilization review, URAC, explains that their accreditation process “[e]nhances [the plan’s] ability to improve the quality and effectiveness of patient care while eliminating unnecessary treatment and expense”—a clear indication that cost can play a role in crafting these rules.¹⁴⁶

The mechanics of this drafting and development process for one insurer, United Behavioral Health (“UBH”), are extensively detailed in *Wit*.¹⁴⁷ According to *Wit*, UBH updated its rules of medical necessity annually.¹⁴⁸ To do so, it first solicited feedback on these rules from various providers and professional societies.¹⁴⁹ It then relied on one or more employees to draft initial revisions to its rules based on this feedback, as well as any relevant developments in the medical or scientific literatures.¹⁵⁰ These drafts were then forwarded to an internal working group that included UBH’s chief medical officers and senior clinicians, who developed and revised the initial set of recommended updates.¹⁵¹ Once this work was complete, the proposed revisions were forwarded to a UBH Committee for review and approval.¹⁵² That committee was chaired by UBH’s Senior Vice President of Behavioral Medical Operations, and included various other UBH medical professionals, such as its Senior Behavioral Medical Director.¹⁵³

Perhaps not surprisingly, these types of procedures do sometimes cause health insurers’ rules of medical necessity to fall short of generally accepted standards of care due to cost considerations. The *Wit* court, for instance, concluded that UBH’s internal rules of medical necessity displayed “an excessive emphasis on addressing acute symptoms and stabilizing crises while

144. *Id.*; see, e.g., *Wit*, 2019 WL 1033730, at *10 (“UBH’s Guidelines state that they are ‘objective,’ ‘evidence-based’ and ‘derived from generally accepted standards of behavioral practice.’”).

145. We did not identify any state utilization review laws that prohibit considerations of cost, although a 2001 survey indicated that one state (Minnesota) prohibited plans from directly considering cost in medical necessity determinations. CTR. FOR HEALTH POL’Y, STANFORD UNIV., STATE-BY-STATE COMPENDIUM OF MEDICAL NECESSITY REGULATION: SURVEY OF STATE MANAGED CARE REGULATORS 19 (2001); see also *Weiss v. CIGNA Healthcare, Inc.*, 972 F. Supp. 748, 755 (S.D.N.Y. 1997) (permitting medical necessity determinations based on actuarial guidelines).

146. *Health Utilization Management Accreditation*, UTILIZATION REV. ACCREDITATION COMM’N, <https://www.urac.org/accreditation-cert/health-utilization-management-accreditation> [<https://perma.cc/SD3G-QGS9>].

147. *Wit*, 2019 WL 1033730, at *45-49.

148. *Id.* at *46.

149. *Id.* at *45-46.

150. *Id.* at *45.

151. *Id.* at *46.

152. *Id.*

153. *Id.* at *8.

ignoring the effective treatment of members' underlying conditions."¹⁵⁴ The resulting "defect" in UBH's rules was "pervasive . . . result[ing] in a significantly narrower scope of coverage than is consistent with generally accepted standards of care."¹⁵⁵ The principal explanation for these conclusions, the court found, was that the insurer directly and indirectly infused cost considerations into the rule development process.¹⁵⁶ For instance, UBH "placed representatives of its Finance and Affordability Departments in key roles in the [rules] development process."¹⁵⁷ It also briefed members of its rule-development committees who were not located within these Departments on the financial implications of the rule-development process.¹⁵⁸

Courts have hardly been the only entities to criticize health insurers' rules of medical necessity; numerous organizations of medical professionals have claimed that health insurers' utilization review processes unreasonably restrict access to medically necessary care due to cost considerations. For instance, in 2017, the American Medical Association joined with numerous healthcare organizations to draft a document urging health plans to reform their utilization review practices.¹⁵⁹ Key reforms, the medical groups urged, required these decisions to "be based on accurate and up-to-date clinical criteria and never cost alone" and to allow for "timely overriding of step therapy requirements," which typically require patients to first try relatively inexpensive forms of care before they are provided coverage for more costly forms of care.¹⁶⁰ Similarly, the American Society for Clinical Oncology recently criticized insurers for "often" relying on incorrect "assumptions regarding the availability of clinically equivalent oncology drugs" when making coverage determinations.¹⁶¹ The result, the statement suggested, was "to incentivize, force, or coerce patients to accept anti-cancer therapy alternatives that are not recommended by their oncologist [and] can threaten

154. *Id.* at *22 (footnote omitted).

155. *Id.*

156. *Id.* at *24.

157. *Id.* at *47, *9 ("UBH communications involving Mr. Niewenhaus make it crystal clear that the primary focus of the Guideline development process, in which Mr. Niewenhaus played a critical role, was the implementation of a 'utilization management' model that keeps benefit expenses down by placing a heavy emphasis on crisis stabilization and an insufficient emphasis on the effective treatment of co-occurring and chronic conditions.").

158. *See id.* at *47.

159. AM. MED. ASS'N, PRIOR AUTHORIZATION AND UTILIZATION MANAGEMENT REFORM PRINCIPLES 1 (2017), <https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf> [<https://perma.cc/2qYT-LT2Z>].

160. *Id.* at 2.

161. AM. SOC'Y OF CLINICAL ONCOLOGY, AMERICAN SOCIETY OF CLINICAL ONCOLOGY POLICY STATEMENT ON THE IMPACT OF UTILIZATION MANAGEMENT POLICIES FOR CANCER DRUG THERAPIES 1 (2017), <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2017-ASCO-Utilization-Management-Statement.pdf> [<https://perma.cc/UT4C-W8KM>].

both the outcomes for patients and the well-being of their families or caretakers.”¹⁶²

Health plans vary in the extent to which they make their internal rules of medical necessity available to insureds or the public more generally. Many insurers, like United Health, Anthem, and Medica make their rules publicly available online to anyone.¹⁶³ Some insurers, however, resist such transparency, only making specific policies available to insureds upon request.¹⁶⁴

2. Rules of Medical Necessity Produced by Third Parties

Some health plans partially or completely outsource their development and maintenance of rules of medical necessity to third parties. The third parties that supply these rules can be split into two broad categories. The first consist of government agencies and non-profits that drafted and maintain rules of medical necessity. For instance, health plans sometimes rely on Medicare’s rules of medical necessity, which are contained in various sources, including national and local coverage determinations.¹⁶⁵ Other health plans use subject-specific rules of medical necessity that are published and periodically updated by societies of medical providers, such as the American Society of Addiction Medicine Criteria or the American Association of Community Psychiatrist’s Level of Care Utilization System.¹⁶⁶

Second, private companies also develop detailed rules of medical necessity that health plans can rely on when making coverage determinations. For instance, a company known as Change Healthcare produces and updates rules of medical necessity known as the InterQual Criteria, which are widely

162. *Id.*

163. *See, e.g., Coverage Policies*, MEDICA, <https://www.medica.com/providers/policies-and-guidelines/coverage-policies> [<https://perma.cc/K8N7-S62K>]; *UnitedHealthcare Commercial Medical & Drug Policies and Coverage Determination Guidelines*, *supra* note 113; *Medical Policies & Clinical UM Guidelines: Full List*, ANTHEM, <https://www.anthem.com/provider/policies/clinical-guidelines/updates> [<https://perma.cc/3P4F-DDYQ>].

164. This practice has been criticized by the AMA and other provider groups:

Utilization review entities should publically [sic] disclose, in a searchable electronic format, patient-specific utilization management requirements, including prior authorization, step therapy, and formulary restrictions with patient cost-sharing information, applied to individual drugs and medical services. Such information should be accurate and current and include an effective date in order to be relied upon by providers and patients, including prospective patients engaged in the enrollment process.

AM. MED. ASS’N, *supra* note 159, at 4.

165. *See supra* Section III.C (discussing Medicare’s national and local coverage determinations).

166. *ASAM Criteria*, AM. SOC’Y OF ADDICTION MED., <https://www.asam.org/asam-criteria/about> [<https://perma.cc/FZ42-JGWQ>]; *Level of Care Utilization System for Psychiatric and Addiction Services*, AM. ASS’N FOR CMTY. PSYCHIATRY, <https://www.communitypsychiatry.org/resources/locus> [<https://perma.cc/R4FA-GNJJ>].

used by health insurers and providers to “[a]ssess the safest, most efficient care level”¹⁶⁷ and to “help improve clinical outcomes in a cost-effective manner.”¹⁶⁸ These criteria were drafted by a panel of over a thousand doctors, and rely on approximately 16,000 medical sources.¹⁶⁹ Another commonly-used set of rules of medical necessity are the Milliman Care Guidelines, which, according to its developer, provide “[e]vidence-based care guidelines” “across the continuum of care” “in strict accordance with the principles of evidence-based medicine.”¹⁷⁰ To do so, Milliman employs teams of clinical directors who review and rank “thousands of references” annually.¹⁷¹

Public access to rules of medical necessity that are developed by third parties is significantly more limited than public access to insurer-specific rules of medical necessity. Even where state utilization review laws otherwise require such rules to be publicly available, guidelines purchased from private third parties are exempt from these requirements.¹⁷² This is because private third parties sell access to their rules of medical necessity, meaning that they have good reason for not making these rules publicly available. Thus, neither the Milliman nor the InterQual criteria are available to the public without paying a substantial fee.¹⁷³ By contrast, the rules used by government insurers like Medicare are freely accessible online.

IV. THE LEGAL IMPLICATIONS OF RULIFICATION

The law has long recognized that insurers cannot be given unfettered discretion to determine when health care will be covered given their financial incentive to limit coverage. Historically, litigation operated as the primary legal constraint on coverage determinations. Over recent decades, however, federal and state lawmakers have developed various additional approaches to constraining health insurers’ coverage determinations in an attempt to prevent insurers from unduly prioritizing profitability over covering medically and scientifically appropriate care. For instance, state and federal laws now require all health plans to provide a mechanism for insureds to appeal a coverage denial, first internally within the insurer and then externally to an

167. *InterQual*, CHANGE HEALTHCARE, <https://www.changehealthcare.com/clinical-decision-support/interqual> [<https://perma.cc/3QC8-ZHWT>].

168. *InterQual Level of Care Criteria*, CHANGE HEALTHCARE, <https://www.changehealthcare.com/solutions/interqual/level-of-care-criteria> [<https://perma.cc/2R8C-2V7Z>].

169. *Norfolk Cnty. Ret. Sys. v. Cmty. Health Sys., Inc.*, 877 F.3d 687, 690 (6th Cir. 2017); *Stephanie C. v. Blue Cross Blue Shield of Mass. HMO Blue, Inc.*, 852 F.3d 105, 114 (1st Cir. 2017).

170. *See Industry-Leading Evidence-Based Care Guidelines*, MCG HEALTH, <https://www.mcg.com/care-guidelines/care-guidelines> [<https://perma.cc/323H-G5RQ>].

171. *Id.*

172. *See, e.g.*, MASS. GEN. LAWS ch. 176O, § 12 (2016) (specifying that “a carrier shall not be required to disclose licensed, proprietary criteria purchased by a carrier or utilization review organization”).

173. In some states, such criteria must be disclosed to insureds and prospective insureds upon request. *See, e.g., id.*

independent medical expert. Similarly, state and federal laws now require many health plans to provide a broad range of mandated benefits. Finally, most states regulate the processes insurers must use when developing and implementing their utilization review procedures.

This Part demonstrates how the rulification of health insurance described in Part III is gradually altering the impact and, in many cases, the effectiveness of these legal tools for constraining health insurers' coverage determinations. Not surprisingly, given the immensely fragmented nature of health insurance law and regulation, the details regarding how this plays out vary based on the legal tools at issue, the specific strategies that an insurer uses to embrace rulification, the details of the operative state laws, and the extent to which ERISA preempts relevant state laws. The bottom line, however, is that health insurers' move from standards to rules to define their coverage obligations tends to limit the capacity of law to meaningfully constrain insurers' coverage determinations. This is particularly true when insurers incorporate their rules of medical necessity into their health insurance contract, thereby converting what were traditionally interpretative aids for internal use into contractual terms that are not subject to oversight.

As suggested in Part II, at least with respect to litigation, this result was both anticipated and encouraged by some prior commentators. But this Part illustrates that the impact of rulification goes far beyond controlling overly sympathetic judges. Instead, it gives insurance companies immense discretion to limit coverage through their utilization review and claims determinations. In many cases, this is because legal constraints on health insurers like external review and mandated benefits were implicitly premised on the assumption that health insurers relied on standards rather than rules to define their coverage responsibilities. Insurers' rulification of medical necessity has increasingly allowed insurers to define their coverage responsibilities as they see fit, subject only to the limited constraints of market forces.

A. INTERNAL REVIEW

Both individual and group health plans are required to provide covered individuals with the opportunity to internally appeal an "adverse benefit determination."¹⁷⁴ Internal review is designed to serve a variety of functions, such as allowing insureds to correct claims denials that were based on technical issues like a missing date of service or an incorrect procedure code.

174. 29 C.F.R. § 2560.503-1 (2020); 26 C.F.R. § 54.9815-2719 (2020). While the appeal procedure requirements for group health plans and individual policies are contained in separate sets of regulations, their substance is nearly identical. Group health plans are subject to Department of Labor regulations promulgated under ERISA, while individual plans are subject to Health & Human Services regulations promulgated under the Public Health Services Act. The individual market regulations incorporate the ERISA regulations by reference, subject to a few modifications. *See* 29 C.F.R. § 2560.503-1; 26 C.F.R. § 54.9815-2719. Grandfathered individual plans are exempt but may be subject to state law requirements.

One of the most important intended functions of internal review, however, is to allow insureds who were denied coverage due to the insurer's medical or scientific judgment to attempt to convince a medical expert at the insurer why, in their individual circumstances, the care that their physician had recommended was indeed appropriate. But insurers' embrace of rules of medical necessity is fundamentally altering this latter function of internal review, converting it into an administrative mechanism by which the insurer simply confirms that a particular rule was properly applied to an insured's case without questioning the medical or scientific appropriateness of that rule for the particular insured who has filed an appeal.

Federal regulations evince a clear intent that internal review affords insureds the opportunity to explain to their insurer why, as their treating doctor concluded, their unique medical circumstances make denied health care medically and scientifically appropriate in their specific circumstances.¹⁷⁵ Under these rules, insurers must provide covered individuals with a notice of any "adverse benefit determination" that includes, among other things, the reasons for the determination, including the specific plan provisions and scientific or clinical judgment relied upon.¹⁷⁶ Covered individuals have a right to "a full and fair review of" this determination, with no deference to be afforded to the initial denial of coverage.¹⁷⁷ Importantly, where an appealed decision was "based in whole or in part on a medical judgment, including" a determination regarding "experimental" or medical necessity determinations, the plan is required to "consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment."¹⁷⁸ This medical expert must not

175. See 29 C.F.R. § 2560.503-1(h) (specifying that claimants must be provided the opportunity for a "full and fair review" of their claim, including the requirement that the plan take into account "all comments, documents, records, and other information submitted by the claimant relating to the claim").

176. "If an internal rule, guideline, protocol, or other similar criterion was relied upon [when] making the" benefit determination, such rule or other criterion must either be disclosed, or the claimant must be informed that she has a right to receive a copy of such rule or other criterion free of charge upon request. *Id.* § 2560.503-1(g)(v)(A). Similarly, if the "determination is based on a medical necessity or experimental treatment or similar exclusion or limit," the notice must contain "an explanation of the scientific or clinical judgment" underlying the determination that applies the terms of the plan to the individual's medical circumstances, or a statement that such explanation will be provided upon request. *Id.* § 2560.503-1(g)(v)(B). In both cases, individual plans must provide the explanation in the notice itself and may not require the participant to request it.

177. *Id.* § 2560.503-1(h)(3). After receiving the required notice of an adverse benefit determination, the covered individual has 180 days to file an appeal. *Id.* § 2560.503-1(h)(3)(i). Individual market plans may require only one level of internal appeal, while group plans may require no more than two levels of internal appeal, before an individual is permitted to file a lawsuit. See *Id.* § 2560.503-1(c)(2). As with the initial claim decision, the health plan is required to decide an appeal within certain timeframes that vary with the type of claim involved. *Id.* § 2560.503-1(h)(2).

178. *Id.* § 2560.503-1(h)(3)(iii).

be the same medical expert consulted regarding the initial claims determination, and must not be subordinate to that expert.¹⁷⁹ Additionally, the claimant must be permitted to submit additional information and comments for consideration in the appeal, and must be given access to all documents and other information relevant to their claim.¹⁸⁰

With certain forms of rulification, health plans are converting internal review from an opportunity to convince an insurer's medical experts about appropriate care in an individual case into a procedural review of whether the plan followed its own rules. This is because rules of medical necessity, by definition, require adjudicators to employ only limited medical judgment when applying those rules in individual cases. The more rule-like a rule of medical necessity is, the less opportunity there is for an internal reviewer to consider whether a covered individual's unique medical circumstances warrant a particular treatment. Instead, internal review of a denied claim involves a simple determination of whether or not the objective criteria contained in the relevant rule of medical necessity were satisfied.

Such internal reviews that mechanistically apply rules of medical necessity to individual cases are very different than internal reviews in which medical experts are largely free to evaluate the full range of relevant considerations. Internal reviews based on rules of medical necessity do not provide a covered individual with an opportunity to explain why an insurer's decision is inconsistent with new scientific evidence, or to explain why the patient's clinical presentation is unique. In a very real sense, covered individuals have no opportunity to make *medical* arguments at all during such internal reviews.¹⁸¹ Instead, they are reduced to making procedural and lawyerly arguments about whether the insurer properly interpreted and applied its own rule. As a result, the claims processors who handle these internal appeals need not employ any medical judgment at all. For that reason, they also need not consult with a medical expert regarding the appropriate treatment of the covered individual's case.

179. *Id.* § 2560.503-1(h)(3)(v). The plan must disclose the identity of any medical expert who provided advice in connection with the determination, even if the advice was not relied upon in making the ultimate decision. *Id.* § 2560.503-1(h)(3)(iv). In addition to the consulting medical expert, the individual who decides the appeal cannot be the same individual who decided the initial claim and cannot be subordinate to that person. *Id.* § 2560.503-1(h)(3)(ii). Individuals making claims and appeals decisions may not be rewarded based on their likelihood of supporting the denial of benefits. 26 C.F.R. § 54.9815-2719(b)(2)(ii)(D).

180. 29 C.F.R. § 2560.503-1(h)(2)(ii)-(iii).

181. *See, e.g.,* Bechtold v. Physicians Health Plan of N. Ind., 19 F.3d 322, 327-28 (7th Cir. 1994). In that case, the plan at issue defined "experimental" treatment by reference to the Medicare Coverage Issues Manual. *Id.* at 325. That manual very clearly stated that high dose chemotherapy with autologous bone marrow transplant was considered experimental for the treatment of breast cancer. *Id.* at 326. The court upheld the insurer's decision to deny coverage for that treatment, noting that where contractual language is clear it must be enforced and that a participant's right to a "full and fair review" does not include the right to challenge the underlying medical judgment of a clear contractual exclusion. *Id.* at 327-28.

A simple example illustrates these points. Imagine an individual who seeks coverage for weight loss surgery to address diabetes and high blood pressure and whose health plan relies on the broad standard of medical necessity rather than rules of medical necessity to determine coverage for weight loss surgery. If the claim is initially denied, the individual has a right to appeal wherein the plan must consult with a medical professional with expertise in the treatment of obesity with comorbidities so as to fully evaluate the clinical situation in light of the individual's particular circumstances.

Now suppose that the plan has incorporated by reference a detailed rule regarding coverage of weight loss surgery into its formal plan documents. That rule might be that "weight loss surgery shall be a covered expense only where the individual has a body mass index ("BMI") of 40 or greater for at least one year." Based on this rule, the insurer can now decide the individual's internal appeal without reliance on medical judgment, but instead simply by confirming that the individual's BMI was less than 40 at some point in the last year. Because no medical judgment is involved, there is no requirement to consult a relevant medical professional. Arguments by the insured that weight loss surgery is appropriate in their particular case because of their comorbidities, weight history, or family history, would simply be irrelevant. By adopting a rule of medical necessity, the insurer fundamentally alters the meaning of the "full and fair" review promised by the internal review regulations.

To be fair, not all rules of medical necessity eliminate all use of medical judgment, nor do all insurers treat these rules as dispositive during internal appeals, particularly if they are not formally made part of the plan language. For example, some rules of medical necessity use factors that do indeed require the application of medical discretion, such as rules that require "the least intensive" level of care that will be effective for the patient,¹⁸² or that turn on whether a patient is at risk of harming herself or others.¹⁸³ Even with these types of rules, however, a patient would not receive a full clinical review of her claim, because that review would be constrained by the rule's guideposts. At the same time, there would be at least some role for judgement and discretion during an internal appeal. When insurers do mechanically apply rules during internal review that are not included directly in their plan language, there remains some possibility of successfully challenging those determinations through litigation, as discussed in more detail below.

B. EXTERNAL REVIEW

External review laws are intended to provide individuals who are denied coverage based on their insurer's medical judgment with the right to

182. *Wit v. United Behav. Health*, No. 14-cv-02346, 2019 WL 1033730, at *18 (N.D. Cal. Mar. 5, 2019) (noting clinical care guidelines that are based on "the least intensive" care setting that is safe and effective).

183. *Id.* at *16 (describing care guidelines that take into account the "risk of serious harm to self or others").

challenge that determination before an independent medical expert. As with internal review, however, the rulification of health insurance has the potential to significantly undermine the ability of external review to serve this intended purpose. Fundamentally, this is because external reviewers typically do not have the legal authority to order insurers to provide care when doing so is inconsistent with any rules of medical necessity that are contained within their insurer's governing legal documents. And even when rules of medical necessity are not part of an insurer's governing legal documents, these rules may unduly influence external review under some of the procedures governing these adjudications.

Understanding these conclusions requires first appreciating the evolution and purpose of external review. As with internal review, external review laws were designed to limit insurers' discretion to determine the level of care or course of treatment that was appropriate for patients. Such limits were necessary, state legislatures reasoned, given the inherent financial conflict of interest that exists when insurers make coverage decisions.¹⁸⁴ Starting in the 1990s, states began enacting statutes that provided individuals with the right to appeal claim denials premised on medical necessity or experimental care judgments to an independent, external medical expert.¹⁸⁵ These laws proved popular, with nearly every state enacting some type of external review law by the early 2000s.¹⁸⁶ Because of ERISA preemption, these state laws applied only to insured plans—individually purchased health insurance policies and employer-sponsored plans that purchased a group insurance contract. Starting in 2010, however, nearly all health plans were legally required to provide external review as a result of the Affordable Care Act (“ACA”).¹⁸⁷

While federal law now requires virtually all group health plans and health insurance issuers to provide enrollees access to external review, the rules governing this review can vary significantly.¹⁸⁸ Under federal law, external

184. See, e.g., Kesselheim, *supra* note 8, at 878; see also Sage, *supra* note 10, at 622 (noting that the first external review processes were voluntarily adopted by insurers “to ensure trust” in the insurers).

185. Leatrice Berman-Sandler, Note, *Independent Medical Review: Expanding Legal Remedies to Achieve Managed Care Accountability*, 13 ANNALS HEALTH L. 233, 235–36 (2004).

186. See MARK SCHERZER, NEW YORKERS FOR ACCESSIBLE HEALTH COVERAGE, IMPLEMENTING HEALTH CARE REFORM: EXTERNAL REVIEW OF HEALTH PLAN DECISIONS 4 (2011), <https://www.cidny.org/wp-content/uploads/2017/07/Implementing-Health-Care-Reform-External-Review.pdf> [<https://perma.cc/SW4J-36EE>] (noting “the vast majority of . . . states” enacted external review statutes prior to 2003); see also Wade S. Hauser, Note, *Does Iowa’s Health Care External Review Process Replace Common-Law Rights?*, 99 IOWA L. REV. 1401, 1405–06 (2014) (noting that 43 states and Washington, D.C. enacted external review laws prior to the ACA).

187. 42 U.S.C. § 300gg-19(b) (2018). The ACA’s external review requirements do not apply to “grandfathered” plans. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1251, 124 Stat. 119, 161 (2010).

188. We know relatively little about how external review works in practice. There have been a handful of small studies of the process, but the process remains opaque. See, e.g., Berman-

review can be provided through a state process that meets certain minimum protections, an accredited independent review organization contracting process, or the HHS-administered federal external review process.¹⁸⁹ All of these pathways must contain core features and specific consumer protections drawn from the National Association of Insurance Commissioner's ("NAIC's") Uniform Health Carrier External Review Model Act.¹⁹⁰ Generally speaking, external review must be available for an "adverse benefit determination" that "involves medical judgment," including but not limited to decisions concerning medical necessity, appropriateness, health care setting, level of care, or effectiveness of a treatment.¹⁹¹ An individual whose claim is denied after internal appeal may elect external review if their claim qualifies, or they may skip external review and proceed to litigation.

Although they vary in their specificity and clarity, the rules governing external review generally prohibit a reviewer from ordering coverage of a treatment that is excluded in the insurer's governing plan documents. Many state laws on external review are explicit on this point.¹⁹² Meanwhile, both the NAIC Model Act and various state laws that mirror this model suggest that external reviewers should not order coverage that is "contrary to the terms of coverage under the covered person's health benefit plan with the health carrier," though these laws arguably allow external reviewers to depart from this principle when doing so is "appropriate."¹⁹³ These instructions are quite

Sandler, *supra* note 185, at 296–97; Katherine T. Vukadin, *Hope or Hype?: Why the Affordable Care Act's New External Review Rules for Denied ERISA Healthcare Claims Need More Reform*, 60 BUFF. L. REV. 1201, 1225–33 (2012) (finding that evidence suggests that external review is relatively rarely used); Sage, *supra* note 10, at 623–25. See generally Hall, *supra* note 33 (discussing the types of cases brought to external review).

189. *Affordable Care Act: Working with States to Protect Consumers*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 16, 2018), https://www.cms.gov/CCIIO/Resources/Files/external_appeals [<https://perma.cc/WCS7-URKT>]. CMS reports that, as of May 16, 2018, 44 states have processes that satisfy the federal standards, with only six states utilizing a federal external review procedure (Alabama, Florida, Georgia, Pennsylvania, Texas, and Wisconsin). *Id.* Self-insured plans use federal procedures unless a state has expanded its external review process to include such plans.

190. Internal Claims and Appeals and External Review Processes, 26 C.F.R. § 54.9815-2719 (2020).

191. *Id.* § 54.9815-2719(c)–(d); see also NAT'L ASS'N OF INS. COMM'RS, UNIF. HEALTH CARRIER EXTERNAL REV. MODEL ACT (2010) [hereinafter NAIC MODEL ACT].

192. See, e.g., KY. REV. STAT. ANN. § 304.17A-625 (West 2020) ("The independent review entity shall not be permitted to allow coverage for services specifically limited or excluded by the insurer in its health benefit plan."); DEL. CODE ANN. tit. 15, § 6417 (West 2020) ("The independent review entity shall promptly review the pertinent medical records of the covered person to determine whether the carrier's denial, reduction or termination of benefits deprived the covered person of medically necessary services covered by the person's health benefits plan." (emphasis added)).

193. NAIC MODEL ACT, *supra* note 191, § 8(H)(4). The NAIC Model Act provides that the review organization shall consider, among other things, "[t]he terms of coverage under the covered person's health benefit plan with the health carrier to ensure that the independent review organization's decision is not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier," but only to the extent the review organization determines that it would be "appropriate" to do so. *Id.* Some states mirror this NAIC language,

ambiguous, though one straightforward interpretation is that it would never be “appropriate” for external reviewers to order coverage that is contrary to the terms of coverage, at least when those terms are clearly relevant to the dispute at hand. Regulations governing the federal external review process also appear to provide that an external reviewer’s decision may not be contrary to the terms of the plan, but the language is similarly unclear.¹⁹⁴ Our research identified only a single state, Minnesota, which clearly authorizes external reviewers to require coverage of medically necessary and non-experimental care even when such care is explicitly excluded in the governing legal documents of the insured’s health benefit plan.¹⁹⁵

Under a traditional health insurance contract—which covers a broad set of services subject to medical necessity and experimental treatment exclusions that are defined by standards—these external review rules respect contractual terms while offering an independent check on clinical judgment calls. But insurers’ rulification of medical necessity fundamentally alters this balance. The extent of this alteration depends critically on whether an insurer formally includes its rules of medical necessity in its governing legal documents, either directly or by incorporating them by reference, or instead merely uses these rules to implement traditional definitions of medical necessity and experimental care.¹⁹⁶

When health plans make their rules of medical necessity part of their governing legal documents, they can, and often do, fundamentally undermine the capacity of external review to check insurers’ clinical judgments. Because applicable state and federal laws generally prohibit external reviewers from ordering coverage when doing so is inconsistent with an insurer’s governing legal documents, insurers can use rulification to convert clinical judgments that would historically have been subject to external review into contractual issues that are completely outside the ambit of external review. To return to our previous example, if an insurance policy specified that weight loss surgery was only covered for individuals with a BMI above 40 for at least one year,

while others removed the “appropriate” modifier. *See e.g.*, IOWA CODE § 514J.107 (2021) (adopting NAIC language); LA. STAT. ANN. § 22:2436 (2020) (adopting language similar to the NAIC model act but removing the “appropriate” modifier); *see also* Frank A. Sloan & Mark A. Hall, *Market Failures and the Evolution of State Regulation of Managed Care*, 65 L. & CONTEMP. PROBS. 169, 196 (2002) (“[T]he core purpose of external review should be to enforce the actual terms of the contract.”).

194. The regulations provide that the external reviewer shall consider, to extent deemed “appropriate,” a number of items, including “[t]he terms of the claimant’s plan or coverage to ensure that the [independent review organization’s] decision is not contrary to the terms of the plan or coverage.” 26 C.F.R. § 54.9815-2719(d) (iii) (B) (5) (iv). One obvious interpretation is that the reviewer must consider the plan language where it bears on the claim’s decision, but the apparent grant of discretion to the reviewer creates some uncertainty.

195. *See* Linn v. BCBSM, Inc., 905 N.W.2d 497, 503 (Minn. 2018) (interpreting Minn. Stat. § 62Q.73 to establish “an independent determination of medical necessity, not a legal interpretation of a contract’s definition of medical necessity” as part of the state external review process).

196. *See supra* Part III.

external reviewers would not generally have authority to order coverage for someone who did not meet this requirement, even if they believed that weight loss surgery was indeed medically and scientifically appropriate for that individual. This is true even though the insurer obviously made a medical judgment in adopting its rule of medical necessity on weight loss surgery.

In fact, under many external review regimes, coverage disputes like this example—which involve a clearly applicable rule of medical necessity contained in an insurer’s governing legal documents whose application does not require the use of clinical judgment—might not even be eligible for external review in the first place. Despite the importance of this issue, there is very little guidance regarding when a claim involves medical judgment and is therefore eligible for external review, and no guidance on the extent to which rules of medical necessity should be considered in making that determination. The regulations governing the federal external review process specify that it is the external reviewer who determines when an adverse benefit determination involves “medical judgment.”¹⁹⁷ But aside from offering two examples of claims that involve medical judgment, there is no specific guidance in the regulations regarding how a reviewer should make the determination.¹⁹⁸ The statutory language and regulations on state external review processes are even more ambiguous, as they often do not specify who determines whether a claim involves medical judgment and is therefore eligible for external review.¹⁹⁹

197. 26 C.F.R. § 54.9815-2719(d)(1). The preamble to amendments to the interim final rules explained the scope as claims “involv[ing] . . . medical judgment (excluding those that involve only contractual or legal interpretation without any use of medical judgment), as determined by the external reviewer.” 76 Fed. Reg. 37,208, 37,216 (June 24, 2011). We also reviewed consumer-oriented materials of external review and found no additional clarification of eligibility. For example, Healthcare.gov describes appealable claims as “[a]ny denial that involves medical judgment where you or your provider may disagree with the health insurance plan.” *External Review*, HEALTHCARE.GOV, <https://www.healthcare.gov/appeal-insurance-company-decision/external-review> [<http://perma.cc/7ZL5-N42F>].

198. The first example involves a situation in which an interpretation of the plan’s definition of medical necessity is relied upon in deciding a claim. In the second example, the claim turns “on whether a [specific] service can effectively be provided in network,” which, the regulations explain, involves medical judgment. 26 C.F.R. § 54.9815-2719(c)(2)(i). Interestingly, in promulgating the final rule on external review, HHS explicitly acknowledged receiving comments “that the description of medical judgment was ambiguous and that it was unclear how to determine whether a claim involved ‘medical judgment.’” 80 Fed. Reg. 72,192, 72,209 (Nov. 18, 2015). Commentators also criticized the substance of the description of medical judgement and argued that “the examples did not fall within what was normally considered medical judgment.” *Id.* Despite these comments, no changes were made to either the description of medical judgment or the examples provided in the final regulations. *Id.* at 72,210.

199. The statutory language in some states does specify the decisionmaker, which is often the state department of insurance. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1374.30 (West 2020). In Ohio, the insurer makes the initial determination of whether an appeal involves an issue of coverage or medical judgment. In either case, it gets sent to the administrative official, who either undertakes the review himself (for issues involving coverage) or appoints an independent review organization (for issues involving medical judgment). OHIO REV. CODE § 3922.11 (West 2020).

Even when the rules of medical necessity that an insurer incorporates into its plan documents require the exercise of some clinical judgment in their application, these rules can still limit external reviewers' discretion in determining whether or not care should be covered. Building on our previous example, suppose that an insurer has incorporated into its plan documents a rule that weight loss surgery is only covered for individuals with a BMI between 35 and 40 if they have a "substantial co-morbidity." A coverage dispute involving an individual with a BMI of 38 would require an external reviewer to determine whether the insured had a "substantial co-morbidity," but would preclude the reviewer from considering other potentially relevant factors regarding the advisability of weight-loss surgery that might be suggested by the full body of relevant clinical literature and practices. The upshot is that an insurer's rules of medical necessity can shift the external reviewer's task from determining whether the insurer reached the correct clinical result to simply assessing whether the insurer followed its own rules.

Health insurers' rulification of medical necessity can undermine external review's capacity to act as an independent check on clinical determinations even when those rules are not part of the insurers' governing legal documents. This is because the procedures governing external review can, in many cases, be understood to direct external reviewers to place meaningful weight on an insurer's rules of medical necessity when reviewing coverage disputes. For instance, the NAIC Model Act, on which both state and federal processes are based, provides that the reviewer shall, to the extent considered appropriate, take into account "[a]ny applicable clinical review criteria developed and used by the health carrier or its designee utilization review organization."²⁰⁰ The federal regulations use substantially similar discretionary language, with the additional caveat that such criteria shall be considered "unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law."²⁰¹ This language strongly suggests that any rule of medical necessity, whether embedded in the contract or merely adopted through informal practice, should be afforded weight in the external review process. As above, however, this language is qualified by the ambiguous instruction that the reviewer should consider these rules only to the extent deemed "appropriate," and there is simply no guidance on how a reviewer is to exercise this discretion.

Insurers certainly have an incentive to argue in external review that their rules of medical necessity must govern the outcome of external review, or even preclude it altogether. Even if unsuccessful in pressing this argument, the insurer has little to lose as external review decisions are not binding on it beyond the specific case at issue and have no precedential effect. The insurer would remain free to continue to rely on its rules of medical necessity not only

200. NAIC MODEL ACT, *supra* note 191, at § 8H(6).

201. 26 C.F.R. § 54.9815-2719(d)(2)(iii)(B)(5)(vi).

in making initial claims decisions and deciding internal appeals, but also in contesting coverage in future external reviews.²⁰² Future claimants would need to take the issue to external review and again convince a reviewer to disregard the insurer's rule of medical necessity in order to overturn a claim denial on the same issue.

From a broader policy perspective, rulification may seriously undermine the primary goal of external review, which is to allow patients to have a neutral medical expert review their insurer's medical judgment.²⁰³ By shifting medical judgment to the crafting of rules instead of the broad application of standards in individualized decisions, insurers avoid this scrutiny. A patient who can establish that a certain treatment is highly efficacious in her specific circumstance may nonetheless be prevented from making that argument in external review by a rule of medical necessity.

Not only does the rulification of medical necessity undermine the purpose of external review, it has a very practical effect on a patient's chance of having an insurer's claim denial overturned. External review typically represents a patient's best chance at reversal because it is conducted without any deference to the plan's internal claims decision. In contrast, many patients who pursue litigation face a standard of review that is highly deferential to the plan's claims decision, which must be "arbitrary and capricious" for a court to overturn it.²⁰⁴ By effectively curtailing the power of an external reviewer, rulification greatly improves an insurer's chances of successfully defending a claim denial.

C. COVERAGE LITIGATION

As described in Part II, health plans were motivated to rely on rules of medical necessity at least in part to limit the risk that sympathetic courts would overturn coverage denials.²⁰⁵ To a large degree, this strategy has proven successful. As with internal and external review, courts routinely deny attempts to challenge coverage denials that are premised on the application of a plan's rules of medical necessity, particularly when the insurer has formally made its rules of medical necessity part of its governing legal documents. Even in the handful of cases where courts have found ways around such rules of medical necessity, they have relied on reasoning that health

202. See Hall, *supra* note 33, at 663 (with respect to insurer reactions to external review losses regarding coverage for weight loss surgery "[m]ost insurers said they have made no changes to the substance of their medical management policies based on external review decisions, even after losing. . . . [I]nsurers consider themselves free to make essentially the same decision in future cases").

203. See Sage, *supra* note 10, at 623 (noting that external review can allow "the best scientific evidence to bear on individual cases" and help the treating physician come to the right treatment decision); Kesselheim, *supra* note 8, at 875 (noting that external review ensures the "scientific basis" for insurer decisions).

204. See *supra* Section IV.C.1.

205. See *supra* Part II.

plans can easily address through relatively straight-forward alterations to their insurance policy or ERISA plan documents. Insurers and plan administrators are also typically successful in relying on their rules of medical necessity to fend off legal challenges even when they do not formally incorporate those rules into their governing legal documents, so long as these coverage disputes are subject to a deferential standard of review, as is the case for the vast majority of employer-sponsored plans, whether insured or self-insured.

1. Cases Involving Deferential Review

Not surprisingly, courts are more likely to affirm coverage denials premised on a health insurer's rules of medical necessity when the dispute is subject to deferential, rather than *de novo*, review. Such deferential review is the norm in coverage disputes involving employer-sponsored plans subject to ERISA.²⁰⁶ Under long-standing Supreme Court precedent, ERISA requires courts to review coverage denials using a deferential standard of review when so required by plan documents.²⁰⁷ Even in the absence of such explicit plan language, some courts confronting coverage disputes under ERISA hold that plan terms authorizing the development of rules of medical necessity themselves trigger deferential review.²⁰⁸ Consequently, the central issue in most coverage disputes involving an employer-sponsored plan's denial of coverage pursuant to its rules of medical necessity is whether the plan administrator acted without substantial evidence, or in an arbitrary and capricious manner.

In answering these questions, courts typically interpret a health plan's development and implementation of rules of medical necessity as a legitimate exercise of that plan's discretion, at least when these rules are consistent with the general standards contained in the plan's governing legal documents. The

206. Maria O'Brien Hylton, *Post-Firestone Skirmishes: The Patient Protection and Affordable Care Act, Discretionary Clauses, and Judicial Review of ERISA Plan Administrator Decisions*, 2 WM. & MARY POL'Y REV. 1, 1 (2010); Katherine T. Vukadin, *On Opioids and ERISA: The Urgent Case for a Federal Ban on Discretionary Clauses*, 53 U. RICH. L. REV. 687, 697-98 (2019).

207. *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989). An employer's conflict of interest in deciding claims is, however, a factor that should be taken into account when reviewing whether the employer acted arbitrarily and capriciously. *Metro. Life Ins. Co. v. Glenn*, 554 U.S. 105, 115 (2008).

208. See, e.g., *Krauss v. Oxford Health Plans, Inc.*, 517 F.3d 614, 622-23 (2d Cir. 2008) (denying benefits under the arbitrary and capricious standard of review where the plan allowed the Administrator to "adopt reasonable policies, procedures, rules, and interpretations to promote the orderly and efficient administration of [the] Certificate"); *Benjamin v. Oxford Health Ins.*, No. 16-CV-00408, 2018 WL 3489588, at *6 (D. Conn. July 19, 2018) (applying the arbitrary and capricious standard where the plan allowed the Administrator to "develop or adopt standards that describe in more detail when [to] make payments under [the] Certificate" and "develop administrative rules pertaining to enrollment and other administrative matters"); *Dorato v. Blue Cross of W. N.Y., Inc.*, 163 F. Supp. 2d 203, 210 (W.D.N.Y. 2001) (stating the arbitrary and capricious standard applies where the Administrator "reserved for itself complete discretion to make benefit eligibility decisions and to construe the terms of the contract").

very process of developing rules of medical necessity, courts reason, involves a reasoned, evidence-based inquiry that is guided by the traditional standards of “medically necessary,” “non-experimental” care.²⁰⁹ So long as this is the case, plan administrators’ reliance on these rules to make coverage determinations constitutes a reasonable exercise of the discretion that is granted to them by plan documents.²¹⁰ Rules of medical necessity that are widely-used and developed by third parties, such as the InterQual and Milliman criteria, are often presumed by courts to be consistent with standard-based definitions of “medically necessary,” “non-experimental” care without further inquiry.²¹¹

In the small handful of cases that reverse a coverage denial premised on an insurer’s rules of medical necessity notwithstanding the presence of an enforceable discretionary clause, courts usually reason that the insurer’s rules were inconsistent with the standard-based definition of “medically necessary,”

209. See *supra* Part III (describing the process of developing and maintaining rules of medical necessity).

210. See *Julie L. v. Excellus Health Plan, Inc.*, 447 F. Supp. 3d 38, 48 (W.D.N.Y. 2020) (“InterQual Criteria help interpret what treatment is ‘appropriate and consistent’ and ‘in accordance with community standards.’”); *Bonanno v. Blue Cross & Blue Shield of Mass., Inc.*, No. 10-11322, 2011 WL 4899902, at *11 (D. Mass. Oct. 14, 2011) (reasoning that the plan’s reliance on InterQual criteria was itself evidence of the rationality of the coverage decisions); *Weiss v. Banner Health*, 416 F. Supp. 3d 1178, 1186 (D. Colo. 2019) (“Courts have long recognized that an administrator may establish and rely on procedures or guidelines so long as they reasonably interpret the plan.”); *Michael P. v. Blue Cross & Blue Shield of Tex.*, 459 F. Supp. 3d 775, 782–83 (W.D. La. 2020) (upholding denial of coverage based on Milliman Care Guidelines because these guidelines constituted a reasonable interpretation of the plan document’s definition of “medical necessity”); *E.R. v. UnitedHealthcare Ins. Co.*, 248 F. Supp. 3d 348, 361 (D. Conn. 2017) (upholding coverage denial based on rules of medical necessity because grants of discretionary authority have been held to afford the insurer “the right to establish guidelines . . . to assist with benefit determinations”); *Krauss*, 517 F.3d at 628 (upholding the claims administrator’s reliance on a coverage rule not contained in the plan on grounds that it was consistent with the general language contained within the plan’s Supplemental Certificate of coverage, which gives it discretion to interpret that Certificate’s language); *Berdeau v. Schaeffler Grp., USA Inc.*, No. 17-cv-02744, 2019 WL 2137474, at *9 (D.S.C. May 16, 2019) (“[T]he Plan clearly gave BCBSSC discretion to determine medical necessity and authorized the use of standards, policies, guidelines, and criteria, including, but not limited to, CAM policies to determine clinically appropriate health care services and generally accepted standards of medical health practice.”); *Neal v. Christopher & Banks Comprehensive Major Med. Plan*, 651 F. Supp. 2d 890, 893, 910 (E.D. Wis. 2009) (affirming denial of coverage for liver transplant that was based on internal rule that “candidates for transplants have six months of sobriety and be in treatment for substance abuse,” as this rule was based on sound medical judgement and entitled to deference due to discretionary clause); *Jon N. v. Blue Cross Blue Shield of Mass.*, 684 F. Supp. 2d 190, 204–05 (D. Mass. 2010) (affirming denial of coverage that was based on insurer’s use of InterQual Behavioral Health Criteria in light of plan’s discretionary clause, which requires arbitrary and capricious review); *Weiss v. CIGNA Healthcare, Inc.*, 972 F. Supp. 748, 753–54 (S.D.N.Y. 1997) (affirming denial of coverage based on insurer’s use of the Milliman & Robertson guidelines in light of discretionary clause in underlying ERISA plan documents); *Smith v. Health Servs. of Coshocton*, 314 F. App’x 848, 859 (6th Cir. 2009) (insurer did not abuse its discretion in relying on internal medical policies that were consistent with plan documents).

211. See, e.g., *Julie L.*, 447 F. Supp. 3d at 48; *Michael P.*, 459 F. Supp. 3d at 782–83.

“non-experimental” care in its governing legal documents.²¹² For instance, in the *Wit* case,²¹³ the insurer’s governing legal documents across numerous ERISA plans defined “medically necessary” care using broad standards that, while varying in their specific language, encompassed services that were “consistent with generally accepted standards of care.”²¹⁴ As discussed in Part III, the *Wit* court found that UBH’s rules of medical necessity pervasively and significantly restricted coverage in ways that flouted generally accepted standards of care.²¹⁵ The insurer’s reliance on its rules of medical necessity could not, therefore, be understood as a reasonable exercise of its discretion to interpret its health plan language, the court held.²¹⁶

Because the relevant inquiry in cases involving discretionary review is whether the insurer’s rules of medical necessity are plausibly consistent with its governing legal documents, the analysis generally does not turn on whether these documents explicitly reference or describe the relevant rules of medical necessity. So long as an insurer’s rules of medical necessity “do not ‘change the definition of a term within a plan or effectively add requirements to that definition,’” courts understand these rules merely to interpret with greater specificity than the governing legal documents when specific types of care meet the broad standards of “medically necessary” and “non-experimental” care contained within those documents.²¹⁷ This is precisely what discretionary clauses appear to contemplate, meaning that courts consistently reject plaintiffs’ objections that their insurer relied on rules that were never mentioned in the governing plan documents.²¹⁸

For similar reasons, courts adjudicating disputes involving discretionary clauses have consistently rejected arguments that an insurer’s reliance on

212. See, e.g., *Arnold v. Blue Shield of Cal.*, No. C 12-02115, 2012 WL 5904735, at *3 (N.D. Cal. Nov. 26, 2012) (refusing to grant summary judgment in case involving discretionary clause because there was insufficient evidence of whether Milliman guidelines that insurer relied on were consistent with plan language); *Egert v. Conn. Gen. Life Ins. Co.*, 900 F.2d 1032, 1036–38 (7th Cir. 1990) (rejecting a denial of coverage as arbitrary and capricious when an insurer relied on internal guidelines that were inconsistent with plan terms); *Baker v. Physicians Health Plan of N. Ind. Grp. Health Plan*, No. 05-CV-348, 2007 WL 1965278, at *9–10 (N.D. Ind. July 3, 2007) (holding that health plan relied on guidelines that were inconsistent with the terms of its plan, meaning that its denial of coverage was arbitrary and capricious); *Evans v. W.E.A. Ins. Tr.*, 361 N.W.2d 630, 636–38 (Wis. 1985) (similar).

213. See *supra* Part III.

214. See *Wit v. United Behav. Health*, No. 14-cv-02346, 2019 WL 1033730, at *13 (N.D. Cal. Mar. 5, 2019).

215. *Id.* at *22.

216. *Id.* at *38.

217. *Michael P. v. Blue Cross Blue Shield of Tex.*, 459 F. Supp. 3d 755, 782 (W.D. La. 2020) (quoting *Weiss v. Banner Health*, 416 F. Supp. 3d 1178, 1186 (D. Colo. 2019)).

218. See *id.* at 782; *E.R. v. UnitedHealthcare Ins. Co.*, 248 F. Supp. 3d 348, 361–62 (D. Conn. 2017). See generally *Reimann v. Anthem Ins. Cos.*, No. 08-cv-0830, 2008 WL 4810543 (S.D. Ind. Oct. 31, 2008) (holding that insurer appropriately relied on internal rules of medical necessity, even though they were more specific than the language of the Health Certificate, as the two sources of information were still consistent with one another).

rules of medical necessity was inappropriate because those rules were not made available or disclosed to insureds prior to the coverage determination. Because rules of medical necessity merely detail how a plan administrator will exercise the discretion granted to it by the underlying plan documents, there is no requirement that they be disclosed or even made available to insureds before a claim is made.²¹⁹ Consistent with this conclusion, the documents that ERISA requires plans to make available to participants do not include rules of medical necessity.²²⁰ Instead, Department of Labor regulations implementing ERISA require that an insurer that denies coverage must at the time of the denial disclose any internal rules of medical necessity upon which it has relied,²²¹ with the clear implication that such rules “need not be disclosed earlier.”²²² The bottom line is that rules of medical necessity, even if not considered part of the plan’s governing documents, are extremely likely to be followed in cases involving a deferential standard of review.

2. Coverage Disputes Involving De Novo Review

Courts approach coverage denials premised on rules of medical necessity quite differently when the standard of review is de novo. Most coverage disputes involving health insurance plans purchased on the individual market are subject to do novo review, as a significant number of states ban discretionary clauses in health insurance policies.²²³ Even in the absence of an explicit statutory ban, health insurers in many individual markets do not include discretionary clauses in their policies, presumably because they are concerned that courts would not enforce them or regulators would not approve them.²²⁴ State laws banning discretionary clauses also apply to

219. See *Weiss v. Banner Health*, 416 F. Supp. 3d 1178, 1187 (finding that insurer’s reliance on Milliman guidelines was not arbitrary and capricious even though they were not mentioned by plan documents are made available to insured, as plan grants administrator discretion and “the plan administrator, exercising its discretion, effectively determined that the Milliman Guidelines were ‘reliable evidence’ that ACI is ‘Experimental’ within the meaning of the plan language”).

220. See 29 U.S.C. § 1021(a)–(m) (2018); *Reimann*, 2008 WL 4810543, at *20–21.

221. 29 C.F.R. § 2560.503–1(g)(1)(v)(A) (2021) (“In the case of an adverse benefit determination by a group health plan—(A) If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request[.]”).

222. See *Reimann*, 2008 WL 4810543, at *26.

223. See *Ariana M. v. Humana Health Plan of Tex., Inc.*, 884 F.3d 246, 248 n.1 (5th Cir. 2018) (noting that 26 states have banned discretionary clauses in insurance policies and that this reflects a trend towards such prohibitions).

224. See *States Beef Up Bans on ‘Discretionary Clauses’ as Courts Rule Out ERISA Hurdle*, BLOOMBERG L. (Feb. 25, 2010, 11:00 PM), <https://news.bloomberglaw.com/daily-labor-report/states-beef-up-bans-on-discretionary-clauses-as-courts-rule-out-erisa-hurdle> [<https://perma.cc/ETE3-PAKN>].

employer-sponsored plans that are not self-insured, as such laws are not preempted by ERISA.²²⁵

When health insurers' coverage disputes are not entitled to deference, courts' approach to rules of medical necessity depends vitally on the extent to which these rules are part of the underlying insurance policy or plan documents. In cases when a plan's rules of medical necessity are not directly or indirectly made part of the governing legal documents, courts typically treat these rules merely as one source of potentially relevant evidence regarding whether an insurer breached its promise to provide "medically necessary" care that was not "experimental."²²⁶ Consequently, they typically refuse to affirm coverage denials based solely on a health plan's rules of medical necessity, instead requiring a fact-intensive inquiry into whether the denial of coverage was medically appropriate.²²⁷

By contrast, to the extent an insurer's governing legal documents directly contain or incorporate by reference rules of medical necessity, courts generally treat those rules as binding, irrespective of their advisability from a medical or scientific standpoint.²²⁸ The reason is simple: under either basic contract law (in the case of individual market plans) or the principles of

225. See, e.g., *Fontaine v. Metro. Life Ins. Co.*, 800 F.3d 883, 886–87 (7th Cir. 2015); *Standard Ins. Co. v. Morrison*, 584 F.3d 837, 849 (9th Cir. 2009).

226. See *Heasley v. Belden & Blake Corp.*, 2 F.3d 1249, 1261 (3d Cir. 1993) (holding that plan documents did not grant administrator discretion to make claims determinations and that the plan's "initial justification for its denial of benefits" could not be accepted "because the plan neither incorporates nor otherwise references the guidelines"); *Pirozzi v. Blue Cross-Blue Shield of Va.*, 741 F. Supp. 586, 591 (E.D. Va. 1990) (refusing to uphold coverage denial for HDCT-ABMT based on health plan's internal "technology evaluation criteria" because "the criteria are not part of the Plan and the Plan nowhere states that the Blue Cross criteria are determinative of a treatment's experimental status"); *K.F. ex rel. Fry v. Regence Blueshield*, No. Co8-0890, 2008 WL 4330901, at *3 (W.D. Wash. Sept. 19, 2008) (holding, after denying deferential review of coverage denial for in-home nursing services, that coverage denial based on failure to meet Milliman criteria was invalid when "[t]here is no evidence that the Milliman criteria are part of, or were incorporated into, the plan" because the plan cannot "impose coverage limitations or restrictions that are inconsistent with those set forth in the plan or that were not disclosed to participants").

227. See cases cited *supra* note 210.

228. See, e.g., *Linn v. BCBSM*, 905 N.W.2d 497, 504 (Minn. 2018) (refusing to allow plaintiff to seek damages for denial of coverage as his policy incorporated by reference a medical policy on requested treatment of PBRT, which defined such radiation as experimental if it involved a tumor that was not in "the basisphenoid region (skull-base chordoma or chondrosarcoma) or cervical spine," which was the case for plaintiff); *Haw. Med. Serv. Ass'n v. Adams*, 209 P.3d 1260, 1265 (Haw. Ct. App. 2009) (affirming insurer's denial of coverage for "allo-transplant" to treat multiple myeloma because health plan itself specified that "[y]ou are not covered for transplant services or supplies or related services or supplies other than those described in *Chapter 4: Description of Benefits* under *Organ and Tissue Transplants*," which did not include allo-transplant for multiple myeloma); *Rodarte v. Presbyterian Ins. Co.*, 371 P.3d 1067, 1071 (N.M. Ct. App. 2016) (affirming denial of coverage for hyperbaric oxygen therapy ("HBOT") for "global anoxic encephalopathy" because insurance policy only covered "'healthcare expenses that are expressly listed and described' in the agreement," and HBOT was not listed as a covered service).

ERISA (in the case of employer-sponsored plans), the health benefits that a plan owes to a beneficiary are limited to those that are specified in the governing legal documents.²²⁹ Consequently, even under a *de novo* standard of review there is typically no viable legal argument that an insured is entitled to coverage beyond that provided for in their insurer's rules of medical necessity when those rules form part of the governing legal documents.

To be sure, courts do occasionally find strategies around a health plan's rules of medical necessity even when they are arguably contained within a plan's governing legal documents, particularly if the evidence suggests that these rules unreasonably restrict coverage. To do so, courts must hold that an insurer's attempt to incorporate its rules of medical necessity into its governing legal documents was in some way faulty. This approach only works when the governing legal documents do not directly contain the relevant rules of medical necessity, but instead purport to incorporate these rules by reference. In such cases, courts have used at least two strategies for rejecting insurers' arguments that their rules of medical necessity are part of the plan's governing legal documents.

The first approach that courts have used to resist insurer efforts to incorporate by reference their rules of medical necessity into their governing plan documents is to conclude these efforts are ineffective because the identity of the cross-referenced document was not made "clear and unequivocal" in the governing legal document. This logic is well illustrated by *Potter v. Blue Shield*, which rejected an insurer's argument that its rules of medical necessity were incorporated by reference into its plan as a result of plan language stating that a service was only medically necessary if it was "consistent with the Plan's medical policy."²³⁰ This language, the court held, was not a "clear and unequivocal reference[]" to the specific "Residential Acute Behavioral Health Level of Care" guideline that the insurer claimed was part of its Plan.²³¹

A second strategy is to reject an insurer's incorporation by reference of its rules of medical necessity because those rules were not made sufficiently available to the insured at the time coverage was established. From a contract law perspective, this approach is premised on the idea that a person cannot assent to contract terms that are not made reasonably available to them at the time of contract formation. In some cases, this strategy can be buttressed by

229. The one exception to this principle is statutory mandates requiring coverage of particular treatments or services, even if not specifically named in the plan document.

230. *Potter v. Blue Shield of Cal. Life & Health Ins. Co.*, SACV 14-0837, 2017 WL 1334289, at *4 (C.D. Cal. Apr. 7, 2017).

231. *Id.* at *6; *see also* *Wit v. United Behav. Health*, No. 14-cv-02346, 2019 WL 1033730, at *30 (N.D. Cal. Mar. 5, 2019) (requiring "clear and compelling evidence"); *cf.* *Simmons v. Cal. Physicians' Serv.*, No. B235171, 2013 WL 794377, at *1 (Cal. Ct. App. Mar. 5, 2013) (upholding a plan's incorporation of "Blue Shield of California medical policy" because it was clear exactly what document this language referenced).

state insurance laws that explicitly require all insurance policy terms to be appended to the primary insurance policy.²³²

Although these strategies provide a potential avenue for resisting an insurer's efforts to elevate its rules of medical necessity into plan terms, they are also notable for how easy they are for motivated insurers to avoid. A clear statement in a health plan's governing legal documents that coverage is limited to care as specified in specific rules of medical necessity that are made available to the insured is sufficient to elevate those rules into plan terms. Perhaps not surprisingly, then, this is exactly what health insurers' policies are increasingly doing.²³³

D. MANDATED BENEFITS

Both federal and state governments regulate the content of health plans through laws that require coverage of specific medical treatments and services (known as "mandated benefit laws" or simply "mandates"). While these laws have various justifications and purposes, they are often enacted in part to legislatively override insurance company denials of treatments thought to be clinically or socially desirable.²³⁴ But as with internal review, external review, and litigation, health insurers' rulification of medical necessity has the potential to undermine the capacity of mandated benefits to achieve this intended goal.

Most states have a significant number of mandated benefit laws within their insurance codes.²³⁵ These state laws apply only to insured plans offered within the state and not to any self-insured employer plans.²³⁶ The federal government has two distinct sources of mandates. The first is ERISA, which contains a small number of specific benefit mandates that apply to all employer-sponsored plans.²³⁷ The second source is the Public Health Services Act, as amended by the ACA, which requires all individual and small group

232. *Hyde v. Humana Ins. Co.*, 598 So. 2d 876, 879 (Ala. 1992) (holding that insurance policy did not effectively incorporate by reference insurer's rules of medical policy because these rules were not physically attached to the policy, as required by an Alabama statute stating that "[n]o policy shall contain any provision purporting to make any portion of the . . . constituent document of the insurer, other than the subscriber's agreement . . . a part of the contract unless such portion is set forth in full in the policy").

233. See *supra* Part III.

234. See Amy B. Monahan, *Value-Based Mandated Health Benefits*, 80 U. COLO. L. REV. 127, 137-40 (2009).

235. See *State Insurance Mandates and the ACA Essential Benefits Provisions*, NAT'L CONF. STATE LEGISLATURES (Apr. 12, 2018), <https://www.ncsl.org/research/health/state-ins-mandates-and-aca-essential-benefits.aspx> [<https://perma.cc/V9Q6-X7V9>].

236. See 29 U.S.C. § 1144(b)(2) (2018).

237. See 29 U.S.C. §§ 1185, 1185a & 1185b (requiring coverage for minimum hospital stays following childbirth, mandating parity in mental health and substance use disorder benefits, and requiring coverage of breast reconstruction following mastectomy).

market insured plans to cover a package of “essential health benefits” or “EHBs.”²³⁸

Although coverage mandates prevent insurers from categorically excluding mandated treatments or services, they do not necessarily prevent an insurer from adopting rules of medical necessity that limit the circumstances under which the mandated benefit will be provided. A mandate’s ability to limit insurers’ discretion in this way depends, in large measure, on its structure. At one end of the spectrum are mandates that are stated broadly and with little detail, and at the other are mandates that are themselves rulified.

The mandates that insurers can most easily distort using rules of medical necessity are those that only broadly describe the type of treatment or service that insurers must cover (e.g., “every policy of insurance must cover treatment x”). Although state mandates infrequently use this approach,²³⁹ the federal essential health benefit requirements established by the ACA fit this description to a tee. Mandated essential health benefits extend to ten different categories of care, but the particular treatments and services that fall within those categories are not specified by statute. Instead, the ACA delegated the authority to define these benefits to the Secretary of HHS, who further delegated it to the states.²⁴⁰ States define EHBs by reference to a “benchmark plan” that they select from among certain plans already offered in the state.²⁴¹ Notably, federal regulations explicitly provide that health insurers may “appropriately utiliz[e] reasonable medical management techniques” with respect to EHBs, thereby permitting insurers to develop rules of medical necessity for these benefits.²⁴²

The functional result of this approach is that insurers can manipulate the availability of EHBs to their insureds using rules of medical necessity. This possibility is illustrated by one small study finding that insurers’ coverage rules for certain Hepatitis C drugs vary dramatically, even though these drugs are an EHB.²⁴³ Not surprisingly, nearly all insurers examined in the study met the basic requirement to include in their formulary at least one drug in this

238. 42 U.S.C. § 18022.

239. Our research, while not exhaustive, did not identify any state mandates that simply required coverage of a particular treatment or class of treatment without at least the qualifier that the treatment or service be medically necessary.

240. 45 C.F.R. § 156.100 (2020).

241. *Id.* Health insurance issuers within the state generally are required to cover the same package of benefits as the EHB benchmark plan, although issuers are given additional flexibility to substitute benefits within the ten categories if the substitutes are actuarially equivalent. *Id.* §§ 156.100, 156.115(b)(1)(i).

242. *Id.* § 156.125.

243. Amy B. Monahan, *The Regulatory Failure to Define Essential Health Benefits*, 44 AM. J.L. & MED. 529, 547-49 (2018).

therapeutic class and further required participants to obtain prior authorization before the plan would pay for the drug.²⁴⁴

At the same time, the publicly available prior authorization criteria for this class of drugs revealed wide variation in the coverage rules used by insurers.²⁴⁵ In some cases, insurers' coverage rules appeared to be based on clinical considerations, such as requirements that the patient be treated with the drug best suited to their Hepatitis C genotype, or requirements that the patient be clean and sober prior to treatment.²⁴⁶ But in other cases insurers' coverage rules were simply forms of rationing access to expensive drugs, for example by requiring patients to reach an advanced level of liver disease or have a minimum life expectancy before coverage would be provided.²⁴⁷ Although only a limited example, insurers' varying coverage rules for covering Hepatitis C drugs illustrates the larger risk that health plans can use rules of medical necessity to limit the extent to which they must cover mandated benefits.²⁴⁸

A second type of mandated benefit that may be subject to manipulation through rulification are mandates that require coverage of all "medically necessary" care within a specific category, without defining medical necessity.²⁴⁹ Such mandates are not uncommon within individual states. Illinois, for example, has several mandates that use the modifier "medically necessary" but do not define that term.²⁵⁰ The common law is not much help in this regard, as litigation regarding medical necessity does not attempt to

244. *Id.* at 548.

245. *Id.* at 548–49.

246. *Id.*

247. *Id.* Coverage rules based on life expectancy are particularly surprising, given that the ACA explicitly prohibits benefit design that discriminates on the basis of life expectancy. *See* 42 U.S.C. § 18022(b)(4)(D).

248. Unfortunately, there is not any comprehensive information about how common or pervasive such efforts might be.

249. *See, e.g.*, 215 ILL. COMP. STAT. ANN. 5/356z.33 (LexisNexis 2021) (requiring coverage of "cardiopulmonary monitors determined to be medically necessary for" children and "medically necessary epinephrine injectors for" children); IND. CODE ANN. § 27-13-7-24.5 (West 2019) (requiring coverage of "medically necessary chronic pain management"); *Id.* § 27-8-14.5-4 (requiring coverage of "medically necessary treatment for diabetes, including medically necessary supplies and equipment"); TEX. INS. CODE ANN. § 1360.004 (West 2021) (requiring coverage of "medically necessary" diagnosis and treatment of temporomandibular joint disorder); *Id.* § 1355.004 (providing that insurers "must provide coverage, based on medical necessity" of certain services to treat serious mental illness).

250. Nor is there an Illinois state statute that provides a general definition of medical necessity that must be used in health insurance contracts. Illinois statute does define medical necessity for other purposes, such as a state-run insurance plan for those otherwise uninsurable and for certain purposes within the Medicaid program, but those appear clearly inapplicable to commercial insurance mandates. *See* 215 ILL. COMP. STAT. 105/2 (LexisNexis 2018) (defining medical necessity for purposes of Illinois' Comprehensive Health Insurance Plan); 305 ILL. COMP. STAT. 5/5F-15 (LexisNexis 2018) (defining medical necessity for purposes of nursing home care provided to Medicare/Medicaid recipients).

craft such a definition, but instead typically interprets a specific contractual definition.²⁵¹ As a result, courts have significant leeway to interpret the term “medically necessary.” A court might borrow other statutory definitions of medical necessity, rely on academic literature exploring common definitions of medical necessity, or allow the insurer’s contract definition and coverage rules to prevail.²⁵² While few cases confront these issues, two federal courts interpreting a California statute requiring coverage of all “medically necessary treatment” for severe mental illnesses adopted the plan’s definition of medical necessity.²⁵³ Neither court, however, provided a detailed explanation of how they determined that “medically necessary” as used in the statute meant “medically necessary” as defined in plan documents.

The very fact that caselaw is largely silent on how to interpret coverage mandates containing undefined medical necessity qualifiers suggests that insurers have a tremendous amount of leeway in implementing these mandates. Insurers can in good faith adopt their own individualized rules of medical necessity with respect to such mandated benefits and apply these rules during initial claims determinations, internal appeals, and even external appeals. Because such disputes rarely are litigated in a way that produces binding precedent, undefined statutory requirements allowing insurers to restrict mandated benefits when they are not “medically necessary” create the prospect of substantial manipulation by insurers using rules of medical necessity.

Yet a third type of mandate that insurers may be able to manipulate through rulification are those that require coverage of specific care when that

251. See, e.g., *Dallis v. Aetna Life Ins. Co.*, 574 F. Supp. 547, 551 (N.D. Ga. 1983) (discussing the lack of consensus amount courts regarding the definition of medical necessity).

252. In a small subset of cases, state mandates may explicitly allow plans to use their own definition of medical necessity. See, e.g., 215 ILL. COMP. STAT. 5/356z.18 (specifying that plans can continue to review medical necessity and engage in utilization review when applying mandate to cover prosthetic and orthotic devices, as long as their procedures for doing so are no less favorable than those used for other covered services); *Id.* 5/356z.14(g) (allowing an insurer to use its own medical necessity criteria for purposes of autism treatment mandate, so long as the insurer makes “the determination in a manner that is consistent with the manner used to make that determination with respect to other diseases or illnesses covered under the policy”). This very fact suggests that mandates that do not contain this clarification specifically contemplate that the term “medically necessary” is a statutory term rather than a reference to an insurer’s contractual term.

253. *Potter v. Blue Shield of Cal. Life & Health Ins. Co.*, No. SACV 14-0837, 2017 WL 1334289, at *7 (C.D. Cal. Apr. 7, 2017), *aff’d*, 753 F. App’x 480 (9th Cir. 2019) (“[T]he Court HOLDS that the applicable definition of ‘medically necessary’ is that found in the Plan documents . . .”); *Harlick v. Blue Shield of Cal.*, 686 F.3d 699, 720 (9th Cir. 2012) (stating that insurer “had discretion to determine whether treatment was medically necessary”). In the *Potter* case, the court explicitly rejected the use of more detailed coverage rules to determine medical necessity because those coverage rules were not properly incorporated by reference into the plan document. *Potter*, 2017 WL 1334289, at *6.

care is “medically necessary,” but define that term using a broad standard.²⁵⁴ To be sure, such coverage mandates may limit the types of rules of medical necessity that an insurer may adopt. For example, if the mandate defined “medically necessary” as any treatment in the specified category that is likely to be clinically beneficial for a patient, the insurer could not adopt a rule of medical necessity based on cost-effectiveness.²⁵⁵ But so long as an insurer’s rule of medical necessity was consistent with the statutory standard, a court would not be able to reject that rule. As a result, when it comes to these types of statutory mandates, a court’s authority to police insurers’ rules of medical necessity would be limited, but more expansive than it would be under statutes that did not define the term “medically necessary.”

Not all coverage mandates are as susceptible to manipulation through insurer rulification as those described above, however. For instance, some statutory mandates not only require coverage of “medically necessary” care within a specified category, but also define “medically necessary” for purposes of the mandate to include all treatment that is recommended by the covered person’s treating physician.²⁵⁶ Such mandates effectively nullify an insurer’s ability to manipulate coverage mandates by creating their own rule of medical necessity, a strategy that is reminiscent of insurers’ initial coverage design before the 1970s:²⁵⁷ any care recommended by an insured’s treating physician is “medically necessary.”²⁵⁸ In an opinion interpreting a Pennsylvania-

254. See, e.g., 5 ILL. COMP. STAT. 375/6.11A(b) (LexisNexis 2018) (defining medical necessity for purposes of a physical and occupational therapy mandate); 215 ILL. COMP. STAT. ANN. 5/356z.33(c) (LexisNexis 2021) (creating a workgroup to develop a definition of medical necessity for purposes of the mandate to cover early treatment of a serious mental illness in a child or young adult).

255. States do not always follow a consistent approach to the use of “medical necessity” in mandate statutes. In Massachusetts, for example, we see a variety of approaches. Some Massachusetts mandate statutes contain their own definition of medical necessity for purposes of the mandate. See, e.g., MASS. GEN. LAWS ch. 175, § 47GG (2016) (defining medically necessary as determined by treating physician in consultation with the patient for purpose of clinical stabilization of substance use disorder mandate). Others explicitly cross-reference the general medical necessity standards for health insurance contracts. See, e.g., MASS. GEN. LAWS ch. 176B, § 4CC (2016) (hypodermic needle and syringe mandate). Still others use the term “medically necessary” but neither define it nor cross-reference the general medical necessity requirements. See, e.g., MASS. GEN. LAWS ch. 175, § 47H (2016) (requiring coverage of medically necessary care for the diagnosis and treatment of infertility).

256. See *Ins. Fed’n of Pa., Inc. v. Commonwealth*, Ins. Dep’t, 970 A.2d 1108, 1118–19 (Pa. 2009).

257. See *supra* Section II.B.

258. While we were unable to find any cases directly litigating that issue, the Supreme Court of Pennsylvania noted in dicta that a state mandate requiring coverage for mastectomy and breast reconstruction prohibited an insurer from overruling a treating physician’s determination where the statute explicitly mandated coverage for inpatient hospitalization and home health care visits in the length and amount “that the treating physician determines is necessary.” *Ins. Fed’n of Pa.*, 970 A.2d at 1120–21 (discussing 40 PA. STAT. AND CONS. STAT. § 764d (West 2021)). The federation of insurers involved in the case conceded in their own brief that insurers could not review the necessity or appropriateness of the care ordered by a treating physician under this mandate. See *id.* at 1120.

mandated benefit for alcohol and drug abuse treatment in this way, the Pennsylvania Supreme Court explained that this approach helped ensure that the statutory mandate “remain[ed a] mandate[] in practice” otherwise, “a managed care plan may decline to provide” the state mandated benefits “under the guise of utilization review for medical necessity.”²⁵⁹

To similar effect are mandates that simply prohibit insurer tools of medical management such as utilization review with respect to the mandated treatment. For example, in recent federal legislation responding to the COVID-19 pandemic, individual and group health plans were not only required to cover COVID-19 testing with no cost sharing during a specified emergency period but were also prohibited from “impos[ing] any . . . prior authorization or other medical management requirements” in connection with this coverage.²⁶⁰

Coverage mandates that require insurers to adhere to specific rules of medical necessity can also be resistant to insurer manipulation. In a limited number of cases, coverage mandates accomplish this by including rules of medical necessity directly in their text. For example, federal law requires that health plans cover at least 48 hours of hospitalization following childbirth.²⁶¹ A more common strategy, however, is for state mandates to follow a practice used by insurers and require the use of specific rules of medical necessity that are developed by third parties,²⁶² such as provider groups or various government sources. For instance, Washington State issued an emergency order requiring insurers to cover COVID-19 testing for individuals “who meet the CDC criteria for testing, as determined by the enrollee’s health care provider.”²⁶³ Other state mandates piggyback on Medicare coverage rules.²⁶⁴ Similarly, several states mandate that insurers must make medical necessity determinations for substance use disorders based on rules established by the American Society of Addiction Medicine.²⁶⁵

259. *Id.* at 1118.

260. Families First Coronavirus Response Act, Pub. L. No. 116-127, § 6001(a), 134 Stat. 178, 201 (2020).

261. 29 U.S.C. § 1185(a)(1)(A) (2018).

262. *See, e.g.*, CONN. GEN. STAT. ANN. § 38a-518g (West 2020) (mandating coverage for prostate cancer treatment “in accordance with guidelines established by the National Comprehensive Cancer Network, the American Cancer Society or the American Society of Clinical Oncology”).

263. STATE OF WASH. OFF. OF INS. COMM’R, EMERGENCY ORDER NO. 20-01 (Feb. 29, 2020), <https://www.insurance.wa.gov/sites/default/files/documents/emergency-order-number-20-01.pdf> [<https://perma.cc/3BSE-DPCM>].

264. *See, e.g.*, MD. CODE ANN., INS. § 15-844(f) (LexisNexis 2009) (“An entity subject to this section may not establish requirements for medical necessity or appropriateness for the coverage required under this section that are more restrictive than the indications and limitations of coverage and medical necessity established under the Medicare Coverage Database.”).

265. *See* 215 ILL. COMP. STAT. § 5/370c(b)(3) (LexisNexis 2018); CONN. GEN. STAT. ANN. § 38a-591c(a)(3) (West 2017); 27 R.I. GEN. LAWS § 27-38.2-1(g) (2020); 28 TEX. ADMIN. CODE § 3.8011(1) (2021).

But even these attempts to confine insurers may not always be successful if the rules imposed by the mandates allow for the exercise of discretion. Some rules—like the federal mandate of 48 hours of hospitalization following childbirth—are nondiscretionary and therefore effective in preventing insurers from limiting care through rules of medical necessity. However, other rules of medical necessity that are required by state law continue to allow for insurer discretion. For instance, the substance abuse rules established by the American Society of Addiction Medicine require various discretionary judgments such as whether “a patient poses an imminent risk of serious harm to self or others” or “need[s] safe and stable living environments and 24-hour care.”²⁶⁶ These types of judgments are sufficiently discretionary that an insurer could conceivably adopt rules of medical necessity to apply them in individual cases.

Mandates are a legal tool used to reduce or eliminate insurer discretion in crafting coverage terms and deciding claims. Yet this subpart has illustrated that insurers can use rules of medical necessity to retain discretion to deny coverage, even when a treatment or service must ostensibly be covered by all health plans.

V. POTENTIAL RESPONSES

Part IV demonstrates that insurers’ rules of medical necessity are eroding the effectiveness of traditional legal strategies for policing private insurers’ clinical judgments. Crafting potential responses to this reality requires grappling with some of the core tensions in the U.S. healthcare system, such as the efficacy of market mechanisms in allocating health care, the proper balance between cost and access, and which individuals or entities should determine the scope of health coverage.²⁶⁷ Reform is further complicated by the fact that federal legislation would be necessary for any solution to be universally applicable, as ERISA prohibits states from regulating self-insured employer plans.²⁶⁸ While states could adopt many of the potential reforms discussed below, at best such state reforms would impact only insured plans and in some cases only individual market coverage.²⁶⁹

^{266.} *Wit v. United Behav. Health*, No. 14-cv-02346, 2019 WL 1033730, at *16 (N.D. Cal. Mar. 5, 2019).

^{267.} Compare CHARLES SILVER & DAVID A. HYMAN, *OVERCHARGED: WHY AMERICANS PAY TOO MUCH FOR HEALTH CARE* 19–22 (2018) (arguing in favor of increased market competition to better allocate health care resources), with Allison K. Hoffman, *Health Care’s Market Bureaucracy*, 66 *UCLA L. REV.* 1926, 2020–21 (2019) (expressing skepticism regarding the ability of market mechanisms to optimally allocate health care resources).

^{268.} 29 U.S.C. § 1144(b)(2)(B) (2018).

^{269.} ERISA’s “savings clause” provides that state laws regulating insurance are saved from ERISA preemption. *Id.* § 1144(b)(2)(A). As a result, state insurance laws can generally regulate the underlying group health insurance contracts purchased by employer plans. However, state insurance laws may nevertheless be preempted by ERISA where they intrude on core ERISA functions or provide duplicate or supplemental remedies. *Aetna Health v. Davila*, 542 U.S.

Rather than attempting to craft a perfect solution here, we present in this Part an initial discussion of potential responses to health insurers' increasing reliance on rules of medical necessity and outline the various factors that impact their relative desirability. We consider below requiring the use of standard-based coverage terms after the initial claims determination, reforming existing state utilization review laws, mandating the use of specific rules of medical necessity, and improving the transparency of insurers' rules of medical necessity.

A. *PROHIBITING RELIANCE ON RULES OF MEDICAL
NECESSITY AFTER INTERNAL APPEALS*

The rulification of medical necessity raises the real possibility that individuals with health insurance will have no effective legal recourse when they are denied coverage for critical care—even lifesaving care—on the basis of an insurer-drafted rule that reflects outdated science, is focused primarily on controlling cost, or simply does not account for the individual's unique presentation.

One option for limiting this risk is to prohibit reliance on an insurer's rules of medical necessity after the initial claims decision and internal appeal are completed, irrespective of whether those rules are directly contained within, or incorporated by reference in, an insurer's governing legal documents. Rules of medical necessity are undeniably valuable at the initial claims-handling stage, as they allow insurers to manage a massive volume of claims efficiently and consistently. There is also a case to be made for having an internal check on those decisions, by having an internal review that is governed by those same rules.

By contrast, applying rules of medical necessity in external review and litigation prevents patients from questioning the substance of those rules. Even if an insurer's rules of medical necessity are outdated, biased, or otherwise problematic as applied to a specific covered person's circumstances, there is currently no feasible method to challenge them when they are made part of the insurer's formal governing documents, at least outside of Minnesota.²⁷⁰

Prohibiting reliance on these rules in external review and litigation could reintroduce some accountability for insurer clinical judgments without creating a huge administrative inefficiency. After all, only a tiny fraction of all coverage denials are contested, and fewer still progress to external review or litigation, meaning that the efficiencies associated with rules are less

200, 209 (2004).

270. As discussed earlier, Minnesota law does currently appear to allow external reviewers to disregard an insurer's rules of medical necessity even if those rules are contained within the insurer's policy. *See supra* note 195 and accompanying text. This rule does not, however, apply to judicial challenges. *See supra* note 195 and accompanying text. It also does not extend to external review of self-insured plans in Minnesota, where the state law is preempted by ERISA.

important when it comes to these types of disputes.²⁷¹ As with other reforms we discuss, this change would need to be implemented at the federal level in order to include self-insured employer plans governed by ERISA.

Prohibiting reliance on rules of medical necessity during external appeals and litigation could also have a disciplining effect on insurers' development of these rules. Recognizing the reality that these rules will be carefully scrutinized externally, insurers may be more likely to embrace unbiased and reasonable rules of medical necessity for use during initial claims handling and internal appeals. They might also more carefully document the deliberative process and underlying clinical evidence that they relied on in crafting such rules.

Even if prohibiting reliance on rules of medical necessity in external review and litigation did not have an *ex ante* disciplining effect on insurer's rules, it might have such an effect *ex post*: insurers might have good reason to redraft their rules of medical necessity if those rules were found by external reviewers or courts to be inconsistent with broad standards of medical necessity or experimental care. Doing so would help to avoid future disputes that the insurer could anticipate losing while promoting more consistent and efficient resolution of claims internally.

To be sure, insurers would be more likely to redraft rules of medical necessity that were rejected by a court than any rules that external reviewers rejected. Judicial decisions, of course, are both publicly available and precedential. By contrast, under the status quo, external review decisions have no precedential effect; an insurer is under no obligation to modify rules that external reviewers reject in an individual case or even to cease denying similar claims. In addition, it is nearly impossible for patients whose claims have been denied to determine if similar denials have been overturned in past external reviews. For these reasons, insurers would not necessarily alter rules that external reviewers rejected in individual cases. Instead, insurers might simply retain these rules and require aggrieved insureds to resort to external review or litigation for a remedy, especially since so few coverage claims are challenged in this way.

Although various supplemental reforms could conceivably increase the chances that insurers would redraft rules of medical necessity that external reviewers found inconsistent with broad standards of medical necessity or experimental care, these reforms could create their own implementation challenges and unintended consequences. For instance, reforms might

271. In the most recently available data from individual market plans offered through healthcare.gov, only 0.2 percent of all denied claims were appealed to the insurer. Of those appealed claim denials that were upheld by the insurer on internal review, "fewer than 1 in 20,000 denied claims made it to external review." Karen Pollitz & Daniel McDermott, *Claims Denials and Appeals in ACA Marketplace Plans*, KAISER FAM. FOUND. (Jan. 20, 2021), <https://www.kff.org/health-reform/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans> [<https://perma.cc/3MLJ-SCK4>].

require the decisions of external reviewers to be published online in redacted format as a matter of course. Such decisions could be indexed by subject matter and searchable. When individuals were notified of their right to seek external review of a denied claim, the notice could provide the web address where prior decisions could be found. But these transparency-oriented reforms might substantially alter the nature of external review in ways that could undermine some of its value. For instance, a risk would remain that transparency reforms would only preserve a dual system of coverage, wherein relatively knowledgeable and sophisticated insureds who appealed adverse determinations ultimately received coverage, while most other insureds did not.

An alternative, and more direct, option would simply be to require insurers to modify their rules of medical necessity when those rules have been successfully challenged in external review. However, such a requirement would be difficult to implement because insurers would be likely to redraft their rules in a way that made the change as narrow as possible, perhaps only reflecting the specific clinical presentation of the individual who successfully appealed the denial in external review. Requiring insurers to alter rules of medical necessity rejected in external review could also lead insurers to confidentially settle cases that appeared likely to result in an adverse determination. Yet another problem with this proposal arises from the fact that insurers are not able to challenge the decision of an external reviewer in court under current law.²⁷² Nonetheless compelling them to alter their rules of medical necessity in response to external review decisions would thus leave them vulnerable to errant decisions. Although this concern could be addressed by allowing insurers to challenge the clinical findings of external reviewers, this mechanism would introduce further inefficiencies and costs.

Even apart from the issue of whether insurers would alter their rules of medical necessity if they were rejected in external review, there are various reasons to be skeptical of a rule prohibiting reliance on rules of medical necessity during external review or litigation even when those rules are part of the insurer's formal legal documents. For instance, this reform could potentially undermine the efficiencies created by insurers' use of rules of medical necessity. In particular, it could conceivably induce a greater proportion of covered people whose claims were initially denied to contest that determination through external review or litigation.²⁷³

Perhaps more obviously, this proposed reform would reintroduce the problems with judicially adjudicating appropriate health care decisions that triggered the development of rules of medical necessity in the first place: courts are often poorly situated to resolve disputed questions of medical

272. 42 U.S.C. § 300gg-19(b)(1).

273. The likelihood of this result would depend both on covered persons' knowledge that they could contest a rule of medical necessity through an appeal and their willingness to do so.

necessity and overly inclined to rule in favor of sympathetic insureds.²⁷⁴ Here again, while adjustments to the proposal could conceivably be made to address this concern, they would create their own problems.

For instance, one option might be to replicate the Minnesota model and to only allow external reviewers, but not courts, to disregard rules of medical necessity that are contained within an insurers' governing legal documents.²⁷⁵ This approach might limit the risk of non-expert adjudicators being overly sympathetic to patients. At the same time, however, it would exacerbate the concerns discussed above that insurers might continue to rely on inappropriate rules of medical necessity that were rejected in external review given the confidential and non-precedential nature of these decisions.

In sum, there are ultimately good reasons for lawmakers to consider prohibiting reliance on rules of medical necessity after the internal appeals stage, irrespective of whether insurers attempt to include these rules directly in their policies or to incorporate them by reference into those legal documents. This type of reform may present the best opportunity to provide patients with a meaningful ability to challenge insurers' clinical judgments without destroying the efficiency benefits of internal claims processing rules. Perhaps the most promising version of this reform would be to focus on explicitly permitting external reviewers to disregard insurers' rules of medical necessity while requiring that external review decisions be made publicly available. Even so, this approach might only partially address the potential harms associated with rules of medical necessity, while creating new distortions and inequities in the ultimate resolution of contested claims.

B. ADDING SUBSTANCE TO STATE UTILIZATION REVIEW LAWS

While most states have utilization review laws,²⁷⁶ these laws do little to ensure that insurers' rules of medical necessity are based on valid clinical considerations and not unduly influenced by insurers' financial conflicts of interest. As previously mentioned, the substantive standards applicable to insurers' rules of medical necessity under these laws are generally very vague, requiring that insurers' rules be "based on sound clinical evidence"²⁷⁷ or

^{274.} See *supra* Sections II.C & II.D (discussing the revolt against judicial decisions requiring coverage for unestablished care pursuant to broad standards of medical necessity and experimental care).

^{275.} See *supra* Part III.

^{276.} As of 2020, 44 states had some form of utilization review law. NAIC MODEL UTILIZATION REVIEW ACT, *supra* note 139, at ST-73-3-73-6. That number has grown over time. In 1991, 20 states were reported to have such laws. Michael A. Dowell, *Avoiding HMO Liability for Utilization Review*, 23 U. TOL. L. REV. 117, 126 (1991).

^{277.} NAIC MODEL UTILIZATION REVIEW ACT, *supra* note 139, at § 8(A); see also ARIZ. REV. STAT. ANN. § 20-2532 (2021) (using a similar standard that the review criteria must be "clinically valid").

“current clinical principles and processes.”²⁷⁸ These terms are not further defined, and there is little evidence of significant enforcement of these substantive standards.²⁷⁹ Instead, the focus of state utilization review laws is primarily on the process by which insurers craft their rules of medical necessity, such as the involvement of appropriate medical professionals in the review process²⁸⁰ and the regular review of existing rules.²⁸¹

While these laws could theoretically be reformed to better regulate the substance of rules of medical necessity, any such effort would be likely to face significant political and practical hurdles. First, in order to give these laws more teeth, they would need to spell out in more detail the appropriate boundaries of coverage rules. May insurers consider cost? If insurers may consider cost, may they take into account absolute cost, or are they limited to cost-effectiveness? What counts as sound clinical evidence? How should legitimate differences of medical opinion be addressed? Even if we make the herculean assumption that we could reach political consensus on the relevant factors to be considered, to be truly effective these laws would have to reach not only non-contractual clinical review criteria, but also rules of medical necessity embedded in insurance contracts.²⁸² If such laws reach only non-contractual rules, the result would likely be to induce a shift to contract-based rulification. But subjecting contract-based rules to regulation is likely to generate even further political opposition as it would limit insurers’ use of basic tools to control costs.

Second, revised state utilization review laws that focus on the substance of insurers’ rules of medical necessity would only make a difference if they were well enforced. One way to ensure this result would be to create a private cause of action when an insurer’s reliance on outdated or errant coverage rules harmed an insured patient. Yet such a change would likely generate significant political opposition due to the probability that it would increase the amount of health plan litigation, thereby raising the costs of coverage.

278. URAC, HEALTH UTILIZATION MANAGEMENT STANDARDS, VERSION 7.3 at 94 (2016).

279. See CTR. FOR HEALTH POL’Y, STAN. UNIV., *supra* note 145, at 31 (finding only nine states self-report that they review clinical practice guidelines for compliance with statutory requirements). While we did not perform a comprehensive survey of state law, our research did not disclose any litigation involving enforcement of state utilization review laws.

280. See, e.g., MINN. STAT. § 62M.09 (2018); URAC, *supra* note 278, at 85.

281. See, e.g., URAC, *supra* note 278, at 94.

282. Most state utilization review laws appear to cover only rules of medical necessity used as contractual interpretation guidelines rather than formal contract terms. For example, Massachusetts defines “utilization review” as “a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Such techniques may include, but are not limited to 3. . . prospective review, . . . concurrent review, . . . or retrospective review.” MASS. GEN. LAWS ch. 176O § 1 (2016). This language does not appear to capture contractual terms that reflect clinical judgment; see also MINN. STAT. § 62M.02 (2018) (defining utilization review in a similar manner).

Perhaps most importantly, even if the substance and enforcement of utilization review laws could be effectively reformed, such reform would leave self-insured employer health plans untouched due to ERISA preemption. As a result, more than half of all insured individuals would be unaffected by any such reform.²⁸³ Instead, placing significant restraints on rules of medical necessity for one portion of the market and not the other would likely lead to even more employers choosing to self-insure their plans. While utilization review could theoretically be regulated at the federal level, therefore solving the ERISA preemption impediment, this would be a massive shift in the federal approach to health plan regulation and seems even less politically likely than state-based reform.

C. MANDATING USE OF SPECIFIC RULES OF
MEDICAL NECESSITY

A central concern with insurers' rulification of medical necessity is that the insurers who craft these rules may have a financial incentive to inappropriately reduce coverage. One potential solution, therefore, is to allow rulification but require insurers to rely on rules drafted by others.

Requiring insurers to use rules of medical necessity that are devised by expert third parties could limit the corrupting impact of insurers' profit motives, thus providing an alternative pathway for achieving the goals of internal review, external review, and litigation. A related, but independent, potential benefit of mandating that insurers use rules of medical necessity devised by others is that doing so could limit insurer competition on the basis of coverage rules. When all insurers are able to devise their own rules of medical necessity, as is currently generally the case, insurers may feel financial pressure to adopt the same rules as their competitors even when those rules restrict access to medically and scientifically appropriate care. Doing so not only has the direct potential benefit to the insurer of limiting payouts for that care; it also has the indirect benefit of limiting the risk that those in need of the relevant care in the future will switch their coverage to the insurer, thus producing potential adverse selection. By contrast, refusing to match competing insurers' restrictive rules of medical necessity may trigger adverse selection for the insurer if individuals who anticipate needing the relevant care are able to distinguish carriers on the basis of their rules of medical necessity or ultimate coverage determinations.

Of course, any reform mandating that insurers use rules of medical necessity drafted by others would require identifying a specific third-party rule drafter. Currently, there are two types of organizations that produce either coverage rules or clinical practice guidelines that might plausibly provide the

²⁸³. On the barriers that ERISA imposed on state health care reform, see generally Erin C. Fuse Brown & Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 168 U. PA. L. REV. 389 (2020).

basis for statutorily mandated rules of medical necessity: specialty medical societies and government agencies.²⁸⁴

The first of these options—specialty medical societies—seems well-positioned to provide expert guidance on what should or should not be considered clinically appropriate care, and therefore might be an excellent source for rules of medical necessity that insurers could be mandated to follow. As discussed in Section IV.D above, several states already take this approach in their mandated benefit laws, for example by requiring insurers to make medical necessity determinations for substance use disorders using the American Society of Addiction Medicine’s rules.²⁸⁵

There are, however, numerous potential drawbacks to mandating that insurers use rules of medical necessity devised by specialty medical societies. First, the solution is terribly incomplete as such guidelines do not come close to covering the universe of medical care. Second, many of the guidelines that specialty medical societies currently produce are framed more as standards than rules, meaning that mandating adherence to these guidelines might not meaningfully limit an insurer’s capacity to adopt unduly restrictive rules of medical necessity.²⁸⁶ Third, the need to identify which particular medical societies’ rules should be mandated would be immensely difficult and fraught, particularly because there are often competing specialty groups that have clinical guidelines on treatment of the same medical conditions. For example, in determining best practices for spinal surgery, a state would need to determine whether it should adopt the orthopedic society’s guidelines or the neurology society’s guidelines.

Finally, perhaps the most important objection to mandating the use of a specialty medical society’s rules is that these organizations are likely to have biases and incentives of their own that might not result in socially optimal

284. A third conceivable option might be to mandate adherence to the rules drafted by the private third parties that currently develop and sell these rules to insurers, like the Milliman or InterQual criteria. *See supra* Section III.C. But this option seems implausible for a number of reasons, including the fact that a mandate to require use of these guidelines would delegate authority to a private, for-profit, third party while effectively giving that party a state-created monopoly. If the law was instead drafted to allow insurers to use rules crafted by any independent third party, the monopoly concern would be eliminated, but other downsides would remain. It is not difficult to imagine that the market would produce third parties who craft insurer-favorable rules, as these third parties would be competing for insurer business. Without a significant amount of regulation and oversight, relying on private third parties to fulfill this function appears to be a non-starter.

285. *See supra* Section IV.D.

286. The standard-based nature of these guidelines is well illustrated by the fact that most begin with the caveat that every patient’s situation is unique, meaning that the physician should use their judgement in prescribing treatment. *See, e.g.,* WORLD PRO. ASS’N FOR TRANSGENDER HEALTH, STANDARDS OF CARE FOR THE HEALTH OF TRANSEXUAL, TRANSGENDER, AND GENDER-NONCONFORMING PEOPLE 33–34 (2012) (requiring a case-by-case evaluation of medical necessity). For a case involving a state Medicaid program’s unsuccessful attempt to “rulify” these standards despite the case-by-case requirement, see 44 Minn. Reg. 1308 (May 11, 2020).

rules of medical necessity. Doctor-driven organizations like the American Society of Addiction Medicine may favor rules that provide more expansive treatment than is necessary or scientifically established, as doing so may increase their individual members' compensation. Additionally, these rules may completely ignore or downplay cost considerations, which would be entirely borne by insurers (and indirectly insureds), even though it is hardly obvious that costs should be irrelevant in devising rules of medical necessity. Additionally, the very act of delegating authority to a medical society to devise rules of medical necessity that would bind insurers could exacerbate these potential distortions.²⁸⁷ For instance, such delegation might cause more or different doctors to become part of that organization, or it might trigger active lobbying of those doctors by insurers.²⁸⁸

The second plausible possibility would be to require insurers to adopt rules of medical necessity drafted by a government agency.²⁸⁹ The most obvious way to implement this would be to mandate that insurers follow Medicare's coverage determinations regarding reasonableness and medical necessity.²⁹⁰ Indeed, at least some private insurers already identify these rules as relevant to their medical necessity determinations, though the weight given to these rules varies by private plan.

287. In order to ensure that the mandated rules of medical necessity reflected the most up-to-date medical and scientific knowledge, this approach would presumably need to require private insurers to use the most current versions of these rules, even if they were adopted by the relevant medical association after passage of the mandate. See Daniel Schwarcz, *Is U.S. Insurance Regulation Unconstitutional?*, 25 CONN. INS. L.J. 191, 197–200 (2018). It would thus effectively constitute a delegation of authority to the specialized, non-profit medical associations whose rules insurers were required to use. See, e.g., IND. CODE ANN. § 12-15-5-13(a)(3) (West 2019) (requiring coverage based on “the most current edition of the American Society of Addiction Medicine Patient Placement Criteria”). See generally Jim Rossi, *Dynamic Incorporation of Federal Law*, 77 OHIO ST. L.J. 457 (2016) (evaluating methods of incorporating federal law with state separation of powers principles).

288. See Schwarcz, *supra* note 287, at 203–05.

289. As above, the constantly changing nature of medical knowledge means that this approach would have to require insurers to adhere to the latest versions of Medicare's rules, meaning that it would effectively constitute a delegation to CMS and local Medicare contractors of authority over private insurers' rules of medical necessity.

290. The Medicare statute requires that items and services be reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category). For a brief description of that process, see the introductory paragraphs of Susan Bartlett Foote, Douglas Wholey, Todd Rockwood & Rachel Halpern, *Resolving the Tug-of-War Between Medicare's National and Local Coverage*, 23 HEALTH AFFS. 108, 109 (2004); see also *Medicare Benefit Policy Manual*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673> [<https://perma.cc/M2YC-PNX3>] (providing an overview of the treatments and services that are covered, subject to review for reasonableness and necessity). An alternative, but more speculative, option would be to empower a quasi-independent government agency like the Patient-Centered Outcomes Research Institute (“PCORI”) to devise evidence-based coverage rules that bound private insurers. The creation of PCORI was authorized by the ACA. See 42 U.S.C. § 1320e (2018).

This solution is also, however, subject to numerous valid criticisms. First, there is not a single source for Medicare's rules of medical necessity. Particularly contentious and expensive items are often subject to national coverage decisions ("NCDs") made through an extensive evidence-based process that includes public participation.²⁹¹ Many more rules are contained in local coverage determinations ("LCDs") that are developed by a Medicare Administrative Contractor and apply only in the contractor's regional area.²⁹² Second, this is not a complete solution given that Medicare coverage decisions do not cover the universe of treatments and services. Under Medicare's decentralized regime, there remain many treatments or services that lack any applicable Medicare coverage decision, with the claims processor instead making the determination on a case-by-case basis.²⁹³ Third, it is hardly clear that CMS's rules of medical necessity are immune from potential distortions. For instance, the CMS staff who devise Medicare's rules may err in favor of covering treatments that are less effective or more expensive than alternatives because they are concerned about the national availability of different treatments. In addition, CMS and Medicare contractors are prohibited from taking certain factors such as cost-effectiveness into account.

These concerns may be overstated given that Medicare's coverage rules are developed through a highly bureaucratic and regulated process that is subject to federal administrative safeguards. The problem, however, is that there exists a powerful and salient movement demonizing any potential effort to entrust "government bureaucrats" with the power to determine what types of health care will be covered by private insurers. While the coverage decisions of government bureaucrats may well be preferable to those made by private insurance companies, it is not clear that such an argument could gain significant traction in the current political environment.²⁹⁴

291. 42 U.S.C. §1395y(l). These NCDs do often closely resemble the structure of the rules of medical necessity used by private insurers, in that they do not offer blanket coverage of a particular treatment or service, but specify the conditions under which a treatment will be covered for a particular patient. *See, e.g., National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 17, 2013), <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=5> [<https://perma.cc/M4WM-KCNH>] (providing coverage for certain types of weight loss surgery "for Medicare beneficiaries who have a body-mass index \geq 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity").

292. 42 U.S.C. § 1395y(l)(5). For example, there are currently seven separate local coverage decisions for blepharoplasty, which is surgery to remove eyelid skin, fat, and or muscle. *Welcome to the MCD Search*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx> [<https://perma.cc/V2WR-66AV>] (search "blepharoplasty") (figure calculated by authors).

293. Susan Bartlett Foote & Robert J. Town, *Implementing Evidence-Based Medicine Through Medicare Coverage Decisions*, 26 HEALTH AFFS. 1634, 1636 (2007).

294. There are various additional potential difficulties with attempting to require private insurers to use rules of medical necessity that are devised by third parties like public agencies or

Ultimately, then, requiring private insurers to use rules of medical necessity that are developed and maintained by third parties—either private or public—offers some potential benefits, but significant downsides as well. While requiring the use of comprehensive rules of medical necessity drafted by a government agency has theoretical appeal, such a requirement is likely a political non-starter. Requiring the use of practice guidelines developed by medical specialty groups for specific types of care may be far more politically palatable, though it constitutes an imperfect and incomplete solution.

*D. TRANSPARENCY REFORMS FOR RULES OF
MEDICAL NECESSITY*

As described in Part II, insurers vary in the extent to which they make their rules of medical necessity publicly available.²⁹⁵ Some insurers make their rules available online to anyone, while others do not. Insurers also vary significantly in the extent to which their governing legal documents are clear regarding whether these rules are binding in coverage contestations. Some insurers explicitly state that their rules constitute terms of the underlying health plan, others are explicit that these rules are superseded by broad standards of medically necessary and non-experimental care, while many others are vague or ambiguous about these issues.

This inconsistency in insurers' transparency regarding their rules of medical necessity suggests that disclosure-based reforms could be sensible. For instance, federal or state lawmakers could require insurers to make all of their rules of medical necessity publicly available online on a single public website. They could also require insurers to disclose in a standardized format the extent to which these rules are binding at the initial claims handling and internal appeal stages, as well as whether their governing legal documents purport to make these rules formal terms of coverage that would be binding in external review in most states, and in litigation in virtually all settings under current law. In many ways, these types of transparency based reforms parallel one of the major goals of the ACA's creation of insurance exchanges, which

private medical associations. First, doing so might only partially address the risk that individual insurers would inappropriately deny medically and scientifically appropriate care to the extent that these rules require discretionary judgments by insurers. Second, legislators may not be well situated to decide which third parties should be entrusted with developing different types of rules. While insurers have medical directors on staff who can evaluate the merit of various practice guidelines, legislators must typically rely on witnesses and other forms of third-party research for such information. And even if legislators can acquire accurate information at the time that they entrust a third-party organization with developing rules of medical necessity within a specific domain, it is much less clear that they would be able to effectively monitor whether changes to those guidelines are in the public interest.

295. See *supra* Section III.A.2.

were intended to make key features of private insurers' plans publicly available in a standardized format to consumers and third parties alike.²⁹⁶

This type of transparency oriented reform has several advantages over potential alternatives. In theory, it would allow potential insureds to take into account competing insurers' rules of medical necessity when selecting coverage, though it seems implausible that any significant number of insureds would consider this issue at the time of purchase given the innumerable complexities associated with selecting health insurance.²⁹⁷ A more plausible benefit of transparency is that it would allow third parties, like public interest groups, academics and reporters, to scrutinize insurers' rules of medical necessity. This could lead to reputational costs to insurers that systematically adopted relatively aggressive rules or attempted to make these rules binding even when they were contested via internal and external review or litigation.²⁹⁸ Transparency could potentially produce these benefits non-intrusively, allowing insurers to pursue their own approaches to rules of medical necessity subject to more robust market and reputational constraints.

At the same time, requiring insurers to be more transparent about the substance and effect of their rules of medical necessity would also have significant drawbacks. Perhaps most substantially, it would potentially have very little practical effect, as is the case for many transparency oriented consumer protections.²⁹⁹ If so, then this type of reform could plausibly crowd out more effective responses like those described above, while creating yet another set of non-trivial compliance costs and technical complexities for insurers.³⁰⁰ Additionally, transparency oriented reforms could possibly legitimize insurers' efforts to insist that their rules of medical necessity are legally binding, even when those rules are relatively restrictive. Yet another potential difficulty with a transparency based approach is that it would be near-impossible to implement with respect to rules that are crafted by private third parties like Milliman.³⁰¹ These companies sensibly refuse to make their rules publicly available so that they can be sold to insurers and others; requiring the disclosure of these rules could require insurers to drop their reliance on them, which might increase costs and decrease the extent to

296. See Jon Kingsdale & John Bertko, *Insurance Exchanges Under Health Reform: Six Design Issues for the States*, 29 HEALTH AFFS. 1158, 1158 (2010) (describing the transparency goals of the ACA exchanges); Tom Baker, *Health Insurance, Risk, and Responsibility After the Patient Protection Affordable Care Act*, 159 U. PA. L. REV. 1577, 1579 (2011).

297. See Hoffman, *supra* note 267, at 1953-58 (reviewing existing evidence of suboptimal health insurance choice among consumers).

298. See Daniel Schwarcz, *Transparently Opaque: Understanding the Lack of Transparency in Insurance Consumer Protection*, 61 UCLA L. REV. 394, 425-26 (2014).

299. See OMRI BEN-SHAHAR & CARL E. SCHNEIDER, MORE THAN YOU WANTED TO KNOW: THE FAILURE OF MANDATED DISCLOSURE 169 (2014).

300. See *id.*

301. Even states that otherwise require disclosure of rules of medical necessity exempt third-party rules from such requirements for this very reason. See text accompanying notes 172-73.

which insurers' rules of medical necessity are kept up to date based on the latest scientific and medical knowledge.

VI. CONCLUSION

Lawmakers have long struggled to find the optimal level of oversight for health insurers' coverage decisions. Over the last several decades, a comprehensive set of legal mechanisms has been developed that is designed to respect contractual limits while ensuring that individuals are protected against arbitrary coverage denials, particularly in cases involving the application of medical judgment. Yet, as this Article illustrates, the increasing rulification of medical necessity undermines these legal protections.

While rules of medical necessity offer the benefits of consistency and efficiency at the initial claims handling stage, they often deny individuals the meaningful review that internal appeals, external review, and litigation are intended to provide. They also have the potential to undermine mandated benefit laws. Under our current regulatory structure, insurers have wide discretion in crafting their rules of medical necessity, with no effective oversight or recourse for patients who may be harmed by outdated or otherwise flawed rules. Worse, those affected by these rules are often unaware of their existence until a claim is denied. It is long past time for lawmakers and regulators to appreciate how changes in health insurers' operations and formal legal contracts have eroded the effectiveness of traditional legal strategies to constrain health insurers' discretion.