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Unhealthy Determinations: Controlling "Medical Necessity"

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**UNHEALTHY DETERMINATIONS:
CONTROLLING “MEDICAL NECESSITY”**

Janet L. Dolgin *

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The notion of medical necessity has been the operative tool through which healthcare coverage determinations in the United States have been rendered and justified. Now, for most people, decisions about coverage translate into decisions about healthcare since few people can afford to pay for their own healthcare. The notion of medical necessity constitutes a necessary component of any healthcare system that is committed to providing high-quality healthcare at a sustainable cost. In practice, however, reliance on medical necessity to determine healthcare coverage is only as productive as the larger health care system within which medical necessity determinations occur. Definitions of both “medical” and “necessity” are flexible and interpretations are varied. As a result, the value of medical necessity determinations depends on the character of a nation’s healthcare delivery and payment structure and on the identity of those rendering medical necessity determinations.

INTRODUCTION

THE notion of “medical necessity” sits at the center of cost containment efforts in the healthcare arena.¹ Reasonable on its face, the notion can be used to serve population health, or to serve the interests of those in control of health care. It can be used to justify decisions that protect the population from wasteful spending, as well as decisions that serve commercial or ideological interests. In fact, the notion of medical necessity is less a tool for rendering fair and efficient decisions about the provision of health care than a lens through which to view the underside of prevailing healthcare delivery and payment systems in the United States through the last century.² The shifting interests that have shaped U.S. health care can be delineated through an examination of the uses to which the notion of medical necessity has been put over time. This is notable in that medical necessity – who determines it and how – has not generally been at the forefront of debate about reforming the nation’s healthcare system. The notion facilitates decision-making about

¹ William M. Sage, *Managed Care’s Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 597 (2003).

² Before the passage of Medicare in 1965, medical necessity determinations were of comparatively insignificant moment. See *infra* Section II.A. That is suggestive of the character of the nation’s healthcare system before the 1960s. See PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 3–29, 61–63, 291–310 (1982).

healthcare payments and thus about healthcare delivery (since very few people can afford to pay out-of-pocket for health care). Yet, the notion and its uses are rarely invoked in analyses of health care in the United States.

In fact, healthcare payers in the United States have relied on medical necessity since the nineteenth century to assess healthcare claims submitted by patients and clinicians.³ Yet, this reliance should not be taken to suggest a consistent vision of healthcare payment or delivery, of who should receive care for which medical interventions, and of who should benefit financially. This Article explores reliance on the notion of medical necessity in U.S. healthcare systems over time and suggests that, despite reasonable presumptions, the notion does not shape healthcare coverage decisions. Rather, it is powerful precisely because it bends to shifting visions of how health care should be delivered and financed. Analysis of the notion thereby offers a framework within which to outline and interpret the history of the nation's healthcare system, and within which to assess the strength of the nation's current commitment to increasing access to healthcare coverage.

Part I of this Article reviews definitions of medical necessity constructed by physicians' groups, the insurance industry, and the government. Almost all seem reasonable on their face, yet both the term "medical" and the term "necessity" defy definitional precision. Accordingly, virtually all definitions of medical necessity are open to discrepant interpretations. Further, Part I suggests that the risk that such definitions will fall prey to economic and ideological interests not connected with, or even in conflict with, patients' interests is magnified because of the enormity of the claims-review system(s) and the absence of transparency in the review process.

Part II then outlines the role of medical necessity determinations in shaping health care in the United States between the end of the nineteenth century and the present. In that history, medical necessity determinations offer an accurate reflector of shifts in the nation's system for delivering and paying for health care. By the last decades of the twentieth century, medical necessity determinations had emerged clearly as the operative concept around which healthcare coverage decision-making was entertained and justified. Yet, the force of the notion lies in its openness to diverse interpretations that, variously, can serve patient health or partisan interests.

Finally, Part III suggests two sets of reparative responses to the inconsistency and unfairness that can mark medical necessity determinations. One set rests on the assumption that health-insurance companies will continue to play a central role in structuring healthcare payments and delivery in the United States. The second assumes a healthcare sys-

³ See *infra* Section II.A.

tem less dependent on serving the interests of the health-insurance industry than that now in place in the United States.

I. MEDICAL NECESSITY – A TERM IN SEARCH OF AN AGENDA

Specific definitions of medical necessity are less important than the overarching framework within which coverage determinations occur. Individual determinations about healthcare coverage reflect the particular decision-maker, and the social and economic frame within which he or she is rendering coverage determinations, far more than they reflect formal definitions of medical necessity.⁴ In fact, a review of extant definitions shows most to be sensible efforts to provide care if “necessary,” but such definitions have been open to heterogeneous interpretations.⁵ In practice, understandings of “medical” care vary as widely as understandings of “necessary” care.

A. Definitions of Medical Necessity

The notion of medical necessity as a means of assessing healthcare claims is distinct from the notion as it may relate to coverage decisions. The latter involves broad-based policy decisions about coverage, implicates large categories of conditions and modes of care, and thus carries direct, and comparatively clear-cut consequences for the coverage of large populations.⁶ In contrast, the notion of medical necessity is applied to individual claims for coverage. This has entailed thousands upon thousands of decisions, each largely dependent on the facts of individual claims.

Validation of the notion of medical necessity and development of methods for implementing the notion would seem basic to any healthcare system that is anxious both to provide adequate care and contain costs.⁷ Many professional, private, and governmental definitions of medical necessity support those presumptions. But various stakeholders assume different interpretations of the phrase.⁸ In 2003, William Sage noted a consistent discrepancy in clinicians’ and insurers’ perspectives on medical necessity:

To many physicians, the phrase “not medically necessary” means “not clinically indicated,” which makes

⁴ Sara J. Singer & Linda A. Bergthold, *Prospects for Improved Decision Making About Medical Necessity: A Group Process Approach to Demystifying Decisions of Medical Necessity in Managed Care Plans*, 20 HEALTH AFF. 200, 202 (2001).

⁵ See *infra* text accompanying notes 6–26.

⁶ Singer & Bergthold, *supra* note 4, at 200.

⁷ Edward B. Hirshfeld & Gail H. Thomason, *Medical Necessity Determinations: The Need for a New Legal Structure*, 6 HEALTH MATRIX 3, 19–20 (1966).

⁸ Sage, *supra* note 1.

them question why a seemingly nonprofessional party such as a health plan has the right to challenge their professional opinion. To many health plans, it means “not covered even though not expressly excluded from coverage,” which gives them a degree of comfort issuing denials based on established insurance practice even though such decisions outrage physicians.⁹

A 2011 Institute of Medicine (IOM) report described “medical necessity reviews” as shaping the context within which “the tough decisions on coverage are made.”¹⁰ On its face, the notion of “medical necessity” as a tool for assessing requests for coverage of recommended or provided medical care is straightforward and reasonable. Medically necessary care would seem to be coincident, as a theoretical matter, with good care.¹¹ Again, in theory, medical necessity reviews should be able to limit costs in a reasonable manner, even improving a population’s health status as it cuts healthcare costs.¹² Indeed, it can no longer be assumed that limiting costs undermines care.¹³ In the 1980s, studies demonstrated clearly that different rates of care do not necessarily result in differences in population health status (assuming, of course, that basic healthcare needs are met).¹⁴ Ethics and finances alike suggest that health

⁹ *Id.* at 601.

¹⁰ INST. OF MED., ESSENTIAL HEALTH BENEFITS: BALANCING COVERAGE AND COST 9 (Cheryl Ulmer et al. eds., 2011), <http://www.nap.edu/catalog/13234/essential-health-benefits-balancing-coverage-and-cost>.

¹¹ Coverage decisions are generally distinguished from medical necessity decisions. Yet, there is some variation in how the difference is understood. The first are usually understood as involving broad policies describing the types of care that are available to a specific population (for instance, pursuant to a particular health insurance plan). The second are usually understood as involving applications of covered benefits to individuals (decisions about how to implement covered care in light of a wide variety of factors, like medical need and cost). See Singer & Berghold, *supra* note 4, at 200. In 1998-1999 in California, however, provider groups and health plans distinguished medical necessity decisions and coverage decisions differently. INST. OF MED., *supra* note 10, at 23; Sage, *supra* note 1, at 603.

¹² See 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 (2014) (noting that an estimated 750 billion dollars is wasted each year on unnecessary health care).

¹³ See Susan Dentzer, Editorial, *The ‘Triple Aim’ Goes Global, and Not a Minute Too Soon*, 32 HEALTH AFF. 638 (2013) (noting that coverage and payment policies can result in cost containment without undermining good care). The “triple aim” looks to “better health, better care, and lower costs.” *Id.*

¹⁴ Hirshfeld & Thomason, *supra* note 7, at 19 (citing Lucian L. Leape, *Practice Guidelines and Standards: An Overview*, 16 QUALITY REV. BULL. 42, 42 (1990)).

care should not be provided if unnecessary – that it should not be used wastefully.

Various definitions – some crafted by professional groups, others by insurance companies, courts, or government commissions – generally reflect similar concerns. A 2005 definition of medical necessity offered by the American Medical Association described the notion in the context of a “prudent” physician’s provision of medical care aimed at “preventing, diagnosing[,] or treating an illness, injury, disease or its symptoms.”¹⁵ The definition further specified that the care provided should be:

- (a) in accordance with generally accepted standards of medical practice;
- (b) clinically appropriate in terms of type, frequency, extent, site, and duration;
- and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.¹⁶

Another definition, crafted by a group of researchers at Stanford at the end of the twentieth century, proposed that care should be deemed medically necessary if recommended by a patient’s doctor and found by the patient’s insurer to meet factors linked to “medical purpose, scope, evidence, and value.”¹⁷

Still another definition of medical necessity, developed as part of a settlement agreement in *In re Managed Care Litigation*,¹⁸ harmonizes with the Stanford definition’s focus on purpose, scope, evidence, and value as well as the one offered by the AMA.¹⁹ The suit – a class-action, initiated in the early 2000s by over 900,000 healthcare providers²⁰ – was

¹⁵ H-320.953: *Definitions of “Screening” and “Medical Necessity”*, AM. MED. ASS’N, <https://www.ama-assn.org/ssl3/ecommm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=/resources/html/PolicyFinder/policyfiles/HnE/H-320.953.HTM> (last visited May 20, 2015).

¹⁶ *Id.*

¹⁷ INST. OF MED., *supra* note 10. “Medical purpose” involves an “intervention for the purpose of treating a medical condition,” “scope” refers to “the most appropriate supply or level of service, considering potential benefits and harms to the patient,” “evidence” relates to knowledge that an intervention is “effective in improving health outcomes,” and “value” allows for consideration of whether an intervention is “cost-effective for this condition compared to alternative interventions, including no intervention . . .” *Id.* at 97 tbl. 5-7. The Stanford definition was used by some state’s Medicaid programs and in a few insurance contracts. *Id.* at 96.

¹⁸ *In re Managed Care Litig.*, 298 F. Supp. 2d 1259 (S.D. Fla. 2003).

¹⁹ *See supra* notes 15–17 and accompanying text.

²⁰ Mark H. Gallant & Kevin D. Gordon, *Two Ps in a Pod Emerging Issues in Provider-Plan Litigation*, AHLA-PAPERS P06240707 (2007).

commenced in a federal district court in Florida and involved claims against 13 insurance companies.²¹

The settlement agreement defined medical necessity to mean:

[H]ealth care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: a) in accordance with generally accepted standards of medical practice; b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and c) not primarily for the convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease. For these purposes, “generally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.²²

Additionally, Medicare's website for patient-viewers defines “medically necessary” as “[h]ealth care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.”²³ Finally, Medicaid, a joint federal-state program, does not offer a national definition of medical necessity (or medically necessary); instead, it leaves that task to the states.²⁴

On their face, none of these definitions is objectionable. Each provides, more or less explicitly, for a patient's clinician and insurer to determine coverage for care in light of a set of factors (such as the purpose of the care and its likely benefit or harm to the patient). Yet, medical necessity determinations are ultimately made at the level of the individual

²¹ *Managed Care Litig.*, 298 F. Supp. at 1249. The insurance companies included Aetna, CIGNA, Health Net, Prudential, Anthem/Well Point, and Humana. *Id.* at 1271 n. 2, 1272 n. 4.

²² INST. OF MED., *supra* note 10, at 228.

²³ *Glossary-M*, MEDICARE.GOV, <http://www.medicare.gov/glossary/m.html> (last visited May 20, 2015).

²⁴ INST. OF MED., *supra* note 10, app. G at 229; see also 42 U.S.C.A. § 1369d (West 2014).

patient, and the definitions noted here allow for wide interpretive berth as they are applied to particular cases.²⁵

Soon after passage of the Patient Protection and Affordable Care Act (“Affordable Care Act”)²⁶ in 2010, the IOM explored the possibility of designing a national definition of medical necessity and interpretive guidelines to use in making such determinations.²⁷ If developed and implemented as a set of interpretive guidelines – far more crucial than another effort to define the phrase²⁸ – the effort might have mitigated some of the frustrations flowing from the current methods – largely ad hoc – for determining medical necessity. Even more, if the many stakeholders with conflicting views of medical necessity determinations could collaborate in developing a consistent approach, the nation’s healthcare system and thus its population would benefit. But the IOM found that stakeholders continue to adhere to sharply divergent visions of how best to define and interpret medical necessity in coverage contexts. Essentially, clinicians and the public favor development of national standards.²⁹ But private insurers, who have long sat at the center of medical necessity determinations of both private and public healthcare plans, favor preservation of the present system.³⁰ In justifying that view, they invoked a provision in the Affordable Care Act that allows “insurers ‘flexibility to employ appropriate medical review and determination of medical necessity.’”³¹

As long as the insurance industry sits at the center of the delivery and coverage of health care in the United States – a reality reinforced by the Affordable Care Act – it will be difficult, if not impossible, to create an efficient, comprehensive set of guidelines for determining the necessity of care and thus the obligation of payers to cover it.³² Even more, it will be difficult, though not impossible, to demand transparency in the

²⁵ In defining the terms of coverage for children and adolescent patients, Medicaid has noted that medical necessity determinations “must be made on a case-by-case basis.” U.S. DEP’T OF HEALTH & HUMAN SERVS., EPSDT—A GUIDE FOR STATES: COVERAGE IN THE MEDICAID BENEFIT FOR CHILDREN AND ADOLESCENTS 23 (2014), http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Downloads/EPSDT_Coverage_Guide.pdf.

²⁶ Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010), *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152 (2010) (West 2012) (codified in scattered sections of 26 U.S.C. and 42 U.S.C.) [hereinafter Affordable Care Act].

²⁷ INST. OF MED., *supra* note 10, at 5–23.

²⁸ *See supra* notes 6–26 and accompanying text.

²⁹ INST. OF MED., *supra* note 10, at 5–23.

³⁰ *Id.*

³¹ *Id.*

³² Other nations have developed a more consistent and comprehensive understanding of medical necessity as well as procedural methods that allow changes in understanding over time. *See infra* Section III.B.

process through which insurers reach medical necessity decisions.³³ At present, the definition of medical necessity remains in the hands of those with commercial interests. Most operative definitions of medical necessity in the United States stem from within the insurance industry and are included in industry contracts.³⁴

Still more important, at the level of medical necessity determination, whether coverage is extended or denied in particular cases continues to depend on a slew of factors including, most importantly, the name, position, and motives (both express and implicit) of the decision-makers, as well as the shifting economic and political choices of payers (by whom the decision-makers are usually employed, either directly or indirectly). In short, medical necessity determinations depend on the knowledge, politics, motives, and inclinations of those who render them far more than they depend on objective truths.³⁵ In Daniel Skinner’s phrase, determinations of medical necessity “can just as easily be deployed to help people gain access to care as to limit it.”³⁶ Empirical evidence is too often displaced in medical necessity determinations by the motives, express and implicit, of those with the authority to make the determinations.³⁷ In other words, formal definitions of medical necessity can mask a slew of individual determinations that do not serve particular patients or the population of which those patients are part.

B. Who Decides, Why, and at What Cost?

Since the creation of Medicare in 1965, the insurance industry has occupied a privileged position in rendering medical necessity determinations – the rationale in terms of which health care is apportioned.³⁸ This has been consequential in shaping the nation’s healthcare system.³⁹ The key role insurance companies play in determining who gets health care and under what circumstances is a product of Congress’s decision, in

³³ See *infra* Part III (recommending a need for greater transparency).

³⁴ SARA ROSENBAUM ET AL., CTR. FOR MENTAL HEALTH SERVS., MEDICAL NECESSITY IN PRIVATE HEALTH PLANS: IMPLICATIONS FOR BEHAVIORAL HEALTH CARE 1 (2003), http://publichealth.gwu.edu/departments/healthpolicy/DHP_Publications/pub_uploads/dhpPublication_3A45C497-5056-9D20-3DAA24F165B5678A.pdf (last visited May 20, 2015).

³⁵ Daniel Skinner, *The Politics of Medical Necessity in American Abortion Debates*, 8 POL. & GENDER 1, 3 (2012).

³⁶ *Id.*

³⁷ *Id.*

³⁸ See *infra* Section I.B.1.

³⁹ Barbara L. Atwell, *Mainstreaming Complementary and Alternative Medicine in the Face of Uncertainty*, 72 UMKC L. REV. 593, 597–98 (2004); see *infra* Section I.B.1 (noting role given to private insurers in determining medical necessity for Medicare patients).

fashioning Medicare a half-century ago, to hire third-party contractors to review medical claims and make payments to Medicare providers.⁴⁰

1. Who Decides?

In the United States, almost all medical necessity determinations, both for patients with private coverage and for those covered through government programs, are made by insurance company employees. In the case of Medicare patients, coverage determinations are rendered pursuant to contracts between the companies and Medicare.⁴¹ Most insurance companies rely on nurses to make initial decisions about the coverage of submitted claims in light of “usual and customary” standards of practice.⁴² Denials are reviewed by physicians employed by the relevant insurance company.⁴³ A study of medical necessity determinations in California in the 1990s found that contractual definitions of medical necessity were less important than other factors in explaining particular determinations and reported significant variation in how determinations were rendered.⁴⁴

In the years immediately following Medicare’s passage, Blue Cross and Blue Shield plans were given the majority of third-party Medicare contractor positions. At the time, the “Blues” were nonprofits.⁴⁵ Soon private insurers also obtained many of the contractor positions.⁴⁶ This placed a central component of the administration of the Medicare program – the review of claims and payments or denials – with third-party contractors, primarily insurance companies (increasingly commercial entities). The Medicare model, originally passed to ease physicians’ concern about a governmental take-over of medicine, has remained in place since Medicare’s implementation. It has had far-reaching consequences. Even beyond the delegation to third parties of central administrative tasks, the model has empowered the insurance industry and limited opportunities for constructing a one-payer healthcare system in the United States.⁴⁷ Applicable definitions of medical necessity have almost invariably been susceptible to heterogeneous interpretations, largely dependent

⁴⁰ See *infra* Section I.B.1.

⁴¹ See *infra* Section II.B.

⁴² Atwell, *supra* note 39, at 598.

⁴³ *Id.*

⁴⁴ Singer & Bergthold, *supra* note 4, at 202.

⁴⁵ Laura D. Hermer, *Private Health Insurance in the United States: A Proposal for a More Functional System*, 6 HOUS. J. HEALTH L. & POL’Y 1, 9 (2005). Hermer notes that the “Blues” began to seek for-profit status once it became clear that they could not successfully compete with companies that relied on experience rating in their underwriting. *Id.* at 10–11.

⁴⁶ Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn’t Worked*, 101 GEO. L.J. 519, 527 (2013).

⁴⁷ See *infra* Part III.

on the motives – both implicit and explicit – of those responsible for reviewing medical claims. With a focus on limiting costs, insurers’ determinations cannot be expected to, and have not always, served patients.⁴⁸

2. Beyond Definitions: Other Factors Motivating Medical Necessity Determinations

The industry’s economic motives can privilege considerations about cost over those about quality of care. Further, the approval or refusal of medical claims can reflect ideological or political agendas.⁴⁹ Insurers collect premiums before care is rendered. The fewer claims that an insurance company pays, the greater the company’s profits.⁵⁰ But the flexibility of almost all definitions of medical necessity can make it difficult to discern economic motives that undermine the provision of good health care.⁵¹ Gregg Bloche has contended that insurance companies’ reliance on the notion of medical necessity in reviewing medical claims can be an opaque form of rationing, grounded not in concern for the potential advantages of the intervention at issue, but in concern for cost.⁵²

In addition to economic interests, ideological interests shape medical necessity decisions. A diverse set of groups has invoked the notion of medical necessity variously to further or to stymie various agendas. For instance, anti-abortion groups deny that abortion can be justified medically and that, accordingly, claims for covering abortions should be denied on the grounds that they are not medically necessary.⁵³ Another instance involves patients and clinicians favoring complementary and alternative (CAM) modes of care. They may face coverage denials insofar as CAM interventions may be unusual, may appear to be experi-

⁴⁸ Hermer, *supra* note 45, at 27–28.

⁴⁹ Sage, *supra* note 1, at 604.

⁵⁰ Mark A. Hall & Gerald F. Anderson, *Models of Rationing: Health Insurers’ Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1668 (1992). Self-insured claims raise different issues since insurance companies are only paid to administer such claims and not to pay them out. *Id.*

⁵¹ Sage, *supra* note 1, at 604.

⁵² M. GREGG BLOCHE, *THE HIPPOCRATIC MYTH: WHY DOCTORS ARE UNDER PRESSURE TO RATION CARE, PRACTICE POLITICS, AND COMPROMISE THEIR PROMISE TO HEAL* 11 (2011); *see also* B. Jessie Hill, *What Is the Meaning of Health? Constitutional Implications of Defining “Medical Necessity” and “Essential Health Benefits” Under the Affordable Care Act*, 38 AM. J.L. & MED. 445, 449 (2012) (considering Bloche’s claim). Within the last decade and a half, the industry has often preferred to “pass-through” coverage expenses rather than deny coverage, replacing a pattern of coverage denials with higher premiums. Mark A. Hall, *State Regulation of Medical Necessity: The Case of Weight-Reduction Surgery*, 53 DUKE L.J. 653, 671 (2003).

⁵³ *See* Skinner, *supra* note 35, at 14–16.

mental (even when they are not), and are less often approved in mainstream medical literature than more traditional forms of care.⁵⁴

Mark Hall reported on another example – grounded in different visions of the division between medical and cosmetic care more than ideology. The case at issue occurred in the early 2000s when insurance companies hesitated to cover bariatric surgery.⁵⁵ Hall identified a trend against any coverage for the procedure on the grounds that it was cosmetic, almost never medically necessary, and thus almost always deemed appropriately excluded from coverage.⁵⁶

3. Costly Duplication of Effort

The development and widespread appropriation of the Medicare model – which handed over to the insurance industry the power to make healthcare coverage decisions on the basis of flexible definitions – has resulted in an enormous group of decision-makers who render determinations notable for idiosyncratic variations.⁵⁷ These determinations have no precedential value, unless refusals are appealed. The magnitude of duplicated efforts is costly, with medical necessity determinations stemming from thousands of decision-makers. In short, the system is inconsistent and wasteful and would seem, even on its face, to elide – or even undermine – the creation of a set of rules that could restrain costs while improving the quality of the nation's health.

⁵⁴ See Atwell, *supra* note 39, at 594, 607–10. Atwell suggests that relying centrally on evidence-based medicine “overlooks the premise that medicine is not just a science, but an art. To try to impose a ‘one size fits all’ generalized standard undermines the importance of clinical evaluation.” *Id.* at 604 (citing Sara Rosenbaum et al., *Who Should Determine When Health Care is Medically Necessary?*, 340 NEW ENG. J. MED. 229, 231 (1999)).

⁵⁵ Hall, *supra* note 52, at 662. Today, bariatric surgery is often covered, if “specific criteria are met.” *Insurance FAQs*, UNIVERSITY OF IOWA HEALTH CARE, <https://www.uihealthcare.org/otherservices.aspx?id=22485> (last visited May 20, 2015). This may, in part, reflect the nation's focus on the health risks of obesity. One website describing bariatric surgery notes that insurance companies will generally cover the procedure if a patient “meets patient criteria and medical necessity is established,” requires providing a Letter of Medical Necessity from the patient's physician. *Medical Necessity*, BARIATRIC.US, <http://www.bariatric.us/medical-necessity.html> (last visited May 20, 2015).

⁵⁶ Hall, *supra* note 52, at 669.

⁵⁷ At the end of 2013, over 460,000 Medicare appeals were pending before the Office of Medicare Hearings and Appeals. As a result, the agency suspended assignments of appeals for 28 months. Christopher P. Brewer, *Hospitals File Lawsuit Over Medicare Administrative Law Judge Hearings Delays*, THE NAT'L LAW REVIEW (July 24, 2014), <http://www.natlawreview.com/article/hospitals-file-lawsuit-over-medicare-administrative-law-judge-hearings-delays> (attributing increase in number of appeals to “expanded number of Medicare contractors reviewing claims and the expanded volume of claims reviews”).

II. THE STORY OF MEDICAL NECESSITY IN THE UNITED STATES

The broad reliance of the U.S. healthcare system on private insurers to determine the medical necessity of care – and thus to determine whether particular healthcare interventions are covered by insurance – is a product of developments in the 1960s that led to the passage of Medicare.⁵⁸ This Part reviews the nation’s understanding and use of medical necessity determinations before that time, the impact of Medicare’s deference to industry in reaching medical necessity decisions, the reshaping of that deference more fully to serve industry in the 1980s and 1990s, and, finally, the effects of the Affordable Care Act on determinations of medical necessity. At each stage, the notion of medical necessity has not so much determined, as it has reflected, the nation’s approach to healthcare delivery and coverage. At each stage of this history, the nation has failed to look to the notion of medical necessity as a theoretical ground on which to contemplate how best to construct a system offering high quality, sustainable health care. Rather, the notion of medical necessity emerges, again and again, as a *deus ex machina* – a tool through which shifting approaches to healthcare delivery and coverage have been implemented and justified.

A. Early Uses of the Notion of Medical Necessity in the United States

Until the 1960s, the notion of medical necessity enjoyed a subservient role in the U.S. healthcare system. That role harmonized with a healthcare system that gave significant control to individual physicians whose medical decisions were rarely upended by anyone – including patients. It was an age that assumed a paternalistic relationship between patient and doctor in which patients rarely challenged physicians’ medical decisions.⁵⁹

Between the late 1800s and the middle of the twentieth century, courts relied on the notion of medical necessity in attempting to settle disputes involving some combination of patients, physicians, and the government. These cases involved a wide variety of issues and did not focus, in particular, on payment disputes. Although some involved questions about payment,⁶⁰ others involved disputes about the character of care provided⁶¹ or about justifications for medical interventions.⁶² In

⁵⁸ See *infra* Section II.B.1.

⁵⁹ STARR, *supra* note 2, at 235–36.

⁶⁰ See, e.g., *Dauterive v. Sternfels*, 164 So. 349 (La. Ct. App. 1935) (relieving husband of obligation to pay medical bills for wife after couple separated even though the medical care was “necessary,” and placing the obligation to pay on the patient herself).

⁶¹ See, e.g., *Commonwealth v. Minor*, 11 S.W. 472 (Ky. 1889) (involving dispute about prescription of whiskey as form of medical care).

⁶² See, e.g., *Davis v. Walton*, 276 P. 921 (Utah 1929) (reversing an order authorizing sterilization of prisoner who was convicted of robbery).

these cases, the definition of medical necessity was not always explicit, but the identity of the decision-maker was.

One of the first uses of the term “medical necessity” by a court in the United States involved questions about the right of a physician to prescribe whiskey in the face of a county rule that prohibited the sale of “spirituous, vinous, or malt liquors in said county as a beverage.”⁶³ The rule contained an exception for a physician prescribing liquor for a patient who was found to be “actually sick.”⁶⁴ In effect, the rule provided for doctors to prescribe whiskey if deemed medically necessary. Decided in 1889, *Commonwealth v. Minor* put the burden on the doctor to show that “the whiskey was needed as a medicine by the person [another doctor] for whom it was prescribed.”⁶⁵ The Kentucky court that entertained this dispute explained that “medical science” is a complicated field that “is progressing,” but that it will always elude perfection.⁶⁶ Within that framework – and sounding quite modern – the court noted that “new diseases” and new “remedies” appear with great frequency. As a result, the court opined, there could be no hard and fast rules within medicine about how best to care for patients. Kentucky law categorized whiskey as a “*necessary medicine*.”⁶⁷ “All [the Act] means,” explained the court, “is that the person must be actually sick, and, if the physician, after making a reasonably full and fair investigation of the disease, believes in good faith that his patient needed the whisky as a medical remedy, and prescribes it, he is not guilty of violating said section.”⁶⁸

Although this period preceded widespread reliance on health insurance to pay for medical care, a few other cases followed. Yet, none of the early cases framed the notion of medical necessity as an operative concept for assessing healthcare claims. In 1920, a Texas court distinguished “medically necessary” care from emergency care, concluding that medically necessary care to a child required parental consent, but emergency care did not.⁶⁹ Thus, in 1920 in Texas, medical necessity could offer a defense to the “offense” of performing an abortion. A year later, a Missouri court invoked the notion of medical necessity in a case involving abortion. “The production of abortion,” wrote the court, is “the intent to produce a miscarriage or abortion by administering drugs, using instru-

⁶³ *Minor*, 11 S.W. at 473.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.* (emphasis added).

⁶⁸ *Id.*

⁶⁹ *Moss v. Rishworth*, 222 S.W. 225 (Tex. Comm’n App. 1920) (distinguishing medically necessary care from emergency care).

ments, etc., where the act is not a medical necessity. The intent constitutes the gravamen of the offense.”⁷⁰

Between the end of World War II and 1965, the year in which Congress established the Medicare and Medicaid programs, U.S. courts only infrequently entertained the notion of medical necessity. Of those cases that have been reported, a few involved tax issues⁷¹ or questions about the legitimacy of abortions.⁷² Two reported cases, both decided in Massachusetts during this period, concerned questions about payments for medical care. In one, a Boston hospital sought reimbursement for patient care pursuant to a state law that made towns liable for the unpaid hospital expenses of residents “in need of public assistance” in the event that hospitalization was medically necessary.⁷³ The determination of medical necessity was to be made by the hospital itself.⁷⁴ In the second case, a Massachusetts court concluded that the Department of Public Welfare did not owe a Boston hospital extra compensation for special nursing care provided to four patients even if the department conceded the medical necessity of the care provided.⁷⁵ However payment decisions were resolved, courts seemed simply to assume that providers determined medical necessity.

Even near the end of this period, some courts seemed perplexed by the notion that insurers should second-guess physicians’ medical determinations. *Mount Sinai Hospital v. Zorek*, decided by a New York trial court in 1966, is illustrative.⁷⁶ The case involved a dispute about whether an insurer was obligated to pay for the hospitalization of Jane Zorek at Mount Sinai Hospital, in 1963. The hospitalization was deemed neces-

⁷⁰ *State v. Keller*, 229 S.W. 203 (Mo. 1921) (holding defendant was “improperly convicted” of carrying out an abortion on woman who died from the effects); *see also State ex rel. Gaston v. Shields*, 130 S.W. 298 (Mo. 1910) (noting that intent to produce abortion was a felony unless it was a “medical necessity”); *State v. De Groat*, 168 S.W. 702 (Mo. 1914) (noting that legality of abortion procedure depended on whether it was medically necessary to preserve life of pregnant woman).

⁷¹ *See, e.g., Carasso v. Comm’r*, 34 T.C. 1139 (1960), *aff’d*, 292 F.2d 367 (2d Cir. 1961) (denying taxpayer right to deduct cost of living expenses for convalescent care away from home); *Bilder v. Comm’r*, 33 T.C. 155, 160 (1959), *vacated*, 369 U.S. 499 (1961) (holding that petitioner’s housing expenses while in Florida in the winter were “properly deductible medical expenses”).

⁷² *See, e.g., State v. Miller*, 261 S.W.2d 103, 105 (Mo. 1953) (act done with intent to destroy fetus was manslaughter unless the “act was a medical necessity to preserve the life of the woman or that of a ‘quick child’”).

⁷³ *Mass. Gen. Hosp. v. Revere*, 191 N.E.2d 120, 121 (Mass. 1963).

⁷⁴ *Id.* at 224–25.

⁷⁵ *Mass. Gen. Hosp. v. Comm’r of Pub. Welfare*, 347 Mass. 24 (1964).

⁷⁶ *Mount Sinai Hosp. v. Zorek*, 271 N.Y.S.2d 1012, 1014 (N.Y. Civ. Ct. 1966). *Zorek* was decided in the year following the promulgation of Medicare in 1965, but the events in question preceded the Medicare legislation’s passage. *See id.*

sary by Zorek's physician in order to treat her obesity. While in the hospital, Zorek was placed on a zero-calorie diet, consisting only of fluids, mixed with vitamins and minerals.⁷⁷ Although Zorek's insurer – Blue Cross – had paid for hospitalization for the same purpose in 1962, it refused to pay in 1963.⁷⁸ The Blue Cross contract⁷⁹ provided for hospital coverage for a “condition” if the patient's physician had concluded that hospitalization was “necessary and consistent with the diagnosis and treatment of the Condition for which hospitalization is required.”⁸⁰

The court in *Zorek* further explained that the insurer's assertion that it did not cover hospital care for obesity was misplaced insofar as the test for coverage did not look to the patient's diagnosis but to the necessity of hospitalization for “proper treatment.”⁸¹ Remarkably, in contrast with a present-day perspective, the *Zorek* court noted the rarity of precedents addressing questions about defining medical necessity:

The words “necessary for proper treatment” call into play the exercise of judgment. “Proper” in whose eyes? The patient's, the treat[ing] physician's, the hospital's, an [insurance] administrator, or a court's looking back on the events sometime afterwards? Although no cases have been brought to the court's attention directly dealing with this problem, this court concludes that the applicable standards of judgment as to the treatment prescribed must be those of the treating physician.⁸²

In the court's view, permitting insurers to refuse payment for care recommended by an insured's physician could serve no useful end:

Only the treating physician can determine what the appropriate treatment should be for any given condition. Any other standard would involve intolerable second-guessing . . . The diagnosis and treatment of a patient are matters peculiarly within the competence of the treating physician . . . Can a hospitalization insurer rightfully decline to pay for the expenses incurred, on the theory that subsequent events may have proved the diagnosis or the recommended treatment to have been wrong? . . . Once the treating doctor has decided on a course of

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ Jane Zorek's Blue Cross coverage was through a policy with Associated Hospital Service of New York. *Id.* at 1014–15.

⁸⁰ *Id.* at 1015 (quoting patient's Blue Cross policy).

⁸¹ *Id.* at 1016.

⁸² *Id.*

treatment for which hospitalization is necessary, his judgment cannot be retrospectively challenged.⁸³

In fact, the court did consider the reasonableness of Zorek’s physician having hospitalized her for treatment of obesity, and concluded that the decision was within the parameters of sound medical care: “a busy metropolitan hospital complex . . . was not going to make one of its much sought-after-beds available for three weeks for a person who merely was seeking a ‘rest cure’ . . . It was medical necessity and not cosmetic vanity which dictated the hospital stay.”⁸⁴

Zorek reflects a healthcare world that has largely vanished. Now, physicians’ recommendations are routinely questioned and overridden by patients, insurers, and courts. And the certainty of the *Zorek* court’s conclusion that physicians’ decisions cannot be “retrospectively challenged” by payers reminds one of a healthcare system that focused on physicians and their patients in a universe before health care became big business.⁸⁵ A decade after *Zorek*, assumptions that had defined health care for over a century were being vociferously challenged, elided, and replaced.

In the set of cases considered in this subsection, all decided between the late nineteenth century and the middle of the twentieth century, no one questioned the notion of medical necessity. The term was open to flexible application, but it was assumed that those applications rested on the notion of care deemed important for a patient’s health by his or her clinician. Only later, after commercial and governmental mediators reshaped the character of medicine, did health insurers begin to include “medical necessity” limitations in their contracts.⁸⁶

B. Medicare

Congress created Medicare⁸⁷ and Medicaid⁸⁸ in 1965. The first (promulgated as Title XVIII of the Social Security Act) provides coverage to almost all of those over 65 (as well as some others), and the second (promulgated as Title XIX of the Social Security Act) provides coverage to certain low-income people.⁸⁹ Medicare is a federal program;

⁸³ *Id.*

⁸⁴ *Id.* at 1018.

⁸⁵ This is not to suggest that that universe was without problems. Among other things, patients were often given no choice about their medical care, and medicine was able to do far less to treat a wide variety of conditions.

⁸⁶ Hall & Anderson, *supra* note 50, at 1645–46.

⁸⁷ 42 U.S.C. §§ 1395 to 1395b-10 (West 2014).

⁸⁸ §§ 1396–1396w-5 (West 2014).

⁸⁹ MARK A. HALL ET AL., HEALTH CARE LAW AND ETHICS 1025 (8th ed. 2013).

Medicaid is a joint federal-state program.⁹⁰ This section focuses on the development of Medicare and its consequences for visions of health care in the United States. It has proved more consequential than Medicaid in offering broad models for reforming the nation's healthcare system. Further, Medicare has become a testing ground under the Affordable Care Act for models of health care that may limit costs and sustain or improve the quality of care.⁹¹

The enormity of the Medicare program suggests the scope of its likely effects on the nation. In the decade following Medicare's promulgation, expenditures for health care rose from \$39 billion to \$119 billion.⁹² The program is now responsible for about twenty percent of spending for health care in the United States.⁹³ In early 2014, Medicare expected its contractors to handle approximately 1.2 billion claims submitted in its fee-for-service program during the year.⁹⁴ At that time, the program covered about 50 million people at an estimated annual cost of almost \$600 billion.⁹⁵

1. Passage of Medicare

In the years leading up to passage of the legislation that created Medicare, physicians' groups and hospitals voiced adamant opposition to both Medicare and Medicaid. They saw these programs as a direct threat

⁹⁰ This article focuses on changes relevant to Medicare, not Medicaid. Because the federal government alone runs Medicare, the program has a much broader effect than Medicaid on the nation's healthcare systems.

⁹¹ For instance, the option of Accountable Care Organizations (ACOs) created the Medicare Shared Savings Program to encourage Medicare providers, working as part of integrated provider networks, to develop methods of limiting spending while offering good care. 42 C.F.R. § 425.10–20 (Medicare's final regulations for the ACO program). ACOs are paid set amounts for each patient as well as incentive payments for meeting certain healthcare targets. Marc Steinberg & Michealle Gady, *Implementing Accountable Care Organizations*, FAMILIES USA: THE VOICE FOR HEALTH CARE CONSUMERS (Jan. 2012), <http://familiesusa.org/product/implementing-accountable-care-organizations>. Private insurers soon began to experiment with the ACO model of paying for health care. Susan Adler Channick, *Health Care Cost Containment: No Longer an Option but a Mandate*, 13 NEV. L.J. 792, 807 (2013).

⁹² Harvey V. Fineberg, Editorial, *The State of Health in the United States*, 310 JAMA 585, 585 (2013).

⁹³ Bagley, *supra* note 46, at 554.

⁹⁴ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-102, MEDICARE PROGRAM INTEGRITY: GREATER PREPAYMENT CONTROL EFFORTS COULD INCREASE SAVINGS AND BETTER ENSURE PROPER PAYMENT 6 (2012) [hereinafter GAO REPORT]; *Medicare Fraud Protection: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 113th Cong. (2014) (testimony by Kathleen M. King, Health Care Director, U.S. Gov't Accountability Office) [hereinafter Testimony by Kathleen M. King].

⁹⁵ Testimony by Kathleen M. King, *supra* note 94.

to the medical profession, which had been largely free from governmental intrusion.⁹⁶ In the 1930s, Franklin Roosevelt had abandoned his support for a national program to provide healthcare coverage, in light of the strength of physicians’ opposition.⁹⁷ And later, during the Truman administration, the AMA continued strenuously to oppose national healthcare coverage, associating it, during the middle of the Cold War years, with socialism.⁹⁸

In the effort to placate physicians and hospital groups, Congress drafted the Medicare legislation to declare, “nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided.”⁹⁹ Congress designed Medicare on the model of the commercial insurance companies, with which physicians and hospitals were familiar and comfortable. Even more, and ultimately of still greater consequence, the legislation authorized insurance companies to render coverage determinations and to administer Medicare payments.¹⁰⁰

In the years immediately following the creation of Medicare, the majority of hospitals in the nation relied on Blue Cross to administer hospital Medicare claims.¹⁰¹ For purposes of administering Part B (the part of Medicare relevant to clinician’s services), the nation was divided into 64 areas.¹⁰² Contracts were given to forty-nine carriers, including Blue Shield not-for-profit plans and a number of for-profit insurers.¹⁰³ This design reflected a system with which clinicians and medical institutions were familiar.

Despite these provisions, aimed at comforting physicians’ groups and hospitals, by the 1970s, Medicare began openly to gainsay physi-

⁹⁶ David Orentlicher, *Rights to Healthcare in the United States: Inherently Unstable*, 38 AM. J.L. & MED. 326, 328 (2012).

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ 42 U.S.C. §§ 1395 to 1395b-10 (West 2014).

¹⁰⁰ Sylvia A. Law & Barry Ensminger, *Negotiating Physicians’ Fees: Individual Patients or Society? (A Case Study in Federalism)*, 61 N.Y.U. L. REV. 1, 12–13 & n.67 (1986). The Medicaid statute gave states responsibility for developing a payment system for reimbursing physicians treating Medicaid patients. *Id.* at 13 n.67.

¹⁰¹ Susan Bartlett Foote, *The Impact of the Medicare Modernization Act’s Contractor Reform on Fee-for-Service Medicare*, 1 ST. LOUIS U. J. HEALTH L. & POL’Y 67, nn.15–18 (2007).

¹⁰² *Id.* at nn.19–21.

¹⁰³ *Id.* The number of fiscal intermediaries and carriers fell over time, leaving only 25 fiscal intermediary contractor organizations and 18 carrier contractor organizations by 2005. *Id.* at nn.22–24.

cians' decisions about medically necessary care.¹⁰⁴ By the early 1980s, Congress provided for Peer Review Organizations (PROs) to supervise the kind and quality of care provided to Medicare patients.¹⁰⁵ PROs increased payer supervision over physician decision-making.¹⁰⁶ And three-and-a-half decades after the creation of Medicare, the Second Circuit – even as it paid verbal homage to the significance of a treating physician's "informed opinion"¹⁰⁷ – expressly declared that a Medicare coverage refusal could "not be set aside simply because it is at variance with the joint assessment of the attending physician and the utilization review committee at the hospital."¹⁰⁸ It thus became clear that the model put in place at Medicare's start to administer the program's claims and payments has had lasting consequences and has created significant challenges for the nation's healthcare system.

2. Administration of Medicare Claims

This subsection reviews the model for reviewing claims that developed with the implementation of Medicare and considers some of its more problematic features. Those reviewing and paying Medicare claims were initially referred to either as "fiscal intermediaries" (those who reviewed hospital claims under Part A) or "carriers" (those who reviewed providers' claims under Part B).¹⁰⁹ In 2006 the Centers for Medicare and Medicaid Services (CMS) renamed its claims and payment contractors,

¹⁰⁴ Phyllis G. Coleman & Ronald A. Shellow, *Independent Contracting Under Medicare and Implications for Expansion Into Managed Care*, 16 J. LEGAL MED. 509, 509 n.2 (1995).

¹⁰⁵ Hall & Anderson, *supra* note 50, at 1651 (citing KAREN DAVIS ET AL., HEALTH CARE COST CONTAINMENT 104–29 (1990)).

¹⁰⁶ *Id.* at 1652–53.

¹⁰⁷ New York *ex rel.* Holland v. Sullivan, 927 F.2d 57, 60 (2d Cir. 1991).

¹⁰⁸ *See id.* The Secretary of Health and Human Services contended that coverage was denied to the patient, Theresa Holland, because the in-patient care provided to her was not "reasonable and necessary." *Id.* at 58. The Utilization Review Committee, an "in house" committee, acted, like others responsible for reviewing Medicare claims, "on behalf of" the Secretary of Health and Human Resources. *See* Michael Neeley-Kvarme, *Administrative and Judicial Review of Medicare Issues: A Guide Through the Maze*, 57 NOTRE DAME LAW. 1, 7–16 (1981). The Social Security Amendments of 1965 require hospitals receiving Medicare funds to have utilization review committees. Pub. L. 89-97, § 102(a), 79 Stat. 286, 313 (codified as amended in scattered sections of 42 U.S.C.); *see also* Eleanor D. Kinney, *The Affordable Care Act and the Medicare Program: The Engines of True Health Reform*, 13 YALE J. HEALTH POL'Y L. & ETHICS 253, 269 (2013).

¹⁰⁹ HALL ET AL., *supra* note 89, at 1025; JONATHAN OBERLANDER, THE POLITICAL LIFE OF MEDICARE 111 (2003).

calling them “Medicare Administrative Contractors” (MACs).¹¹⁰ Congress expected that this design – one putting insurers, and especially Blue Cross and Blue Shield at the center of claims’ determinations – allowed hospitals and providers to work with groups with which they were already comfortable. The plan openly gave private insurance companies – some, such as the “Blues” were not-for-profits and others were for-profits – administrative control over “provider reimbursement, claims processing, and auditing.”¹¹¹ Significantly, until the last decade, the process of bidding to become a Medicare contractor was not competitive,¹¹² and contractors’ pay did not reflect the quality of service rendered.¹¹³ CMS’s contracts with intermediaries and carriers renewed automatically, by their terms.¹¹⁴

Under this system for determining claims, Medicare coverage determinations have suffered from inconsistency, in part because the system has not been monitored, the justification for individual determinations is rarely public and transparent, and, even in theory, many coverage determinations hold no precedential value outside particular geographic areas.¹¹⁵

Since 2003, CMS has provided for both “national” and “local” coverage determinations.¹¹⁶ National coverage determinations (NCDs) are expected to pertain to Medicare participants¹¹⁷ throughout the country and to be used as precedents by Administrative Law Judges overseeing claim appeals.¹¹⁸ In contrast, local coverage determinations (LCDs)¹¹⁹

¹¹⁰ MACs administer Medicare Parts A and B claims as well as durable medical equipment claims. See GAO REPORT, *supra* note 97.

¹¹¹ OBERLANDER, *supra* note 109, at 111; Foote, *supra* note 101, at 68. This administrative structure gave a significant role to Blue Cross and Blue Shield, because they controlled the largest part of the American health insurance industry when Medicare was implemented. OBERLANDER, *supra* note 109, at 111. The “special status” of the Blues as “voluntary nonprofits made [them] an excellent fit for federal policymakers looking to alleviate concerns over federal power by contracting out administration to the private sector.” *Id.* at 112.

¹¹² Testimony by Kathleen M. King, *supra* note 94.

¹¹³ *Id.*

¹¹⁴ *Patients First: A 21st Century Promise to Ensure Quality and Affordable Care Health Coverage: Hearing Before the Subcomm. on Health and the Subcomm. on Oversight & Investigations of the H. Comm. on Commerce*, 107th Cong. (2001) (testimony of Michael F. Mangano, Acting Inspector Gen., U.S. Dep’t of Health and Human Servs.).

¹¹⁵ CTRS. FOR MEDICARE & MEDICAID SERVS., DEP’T HEALTH & HUMAN SERVS., *Local Coverage Determinations*, in MEDICARE PROGRAM INTEGRITY MANUAL § 13.1.2 (2014) [hereinafter INTEGRITY MANUAL], available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf>.

¹¹⁶ *Id.* § 13.1.3.

¹¹⁷ GAO REPORT, *supra* note 94.

¹¹⁸ INTEGRITY MANUAL, *supra* note 115, § 13.1.1.

assess the reasonableness of, and need for, particular services but apply only within specific geographic regions.¹²⁰ Medicare contractors reaching LCDs are not required to – and often do not – inform providers about the character and scope of interpretations relied on in processing particular claims.¹²¹ This has built opacity into the center of the system. Now, both local and national coverage determinations are reported in Medicare’s Coverage Database.¹²² However, Medicare places the burden on providers to review the database and expects that “health care providers [will] know Medicare coverage requirements so that they can anticipate payment denial”.¹²³

Only in 1986, did Congress establish any guidelines for national determinations.¹²⁴ And LCDs continue to result in different Medicare coverage policies in different geographic regions of the country. Further, there has been no systematized effort to analyze the precedential value of medical necessity determinations.¹²⁵ In part, that has been a product of Congress’s broad grant of authority to Medicare contractors to determine the legitimacy of charges for care without effective national guidelines.¹²⁶

a. Promises and Developments

The initial promise that Medicare would protect providers’ independence proved short-lived. Soon, contractors’ medical necessity determinations¹²⁷ began openly to disempower physicians.¹²⁸ And three

¹¹⁹ *Id.* § 13.1.3 (noting that the term “local coverage determinations” was created by the Benefits Improvement and Protection Act).

¹²⁰ GAO REPORT, *supra* note 94; INTEGRITY MANUAL, *supra* note 115, § 13.1.1. Before 2003, LCDs were also authorized to make decisions about benefit categories. *See supra* note 115, § 13.1.1.

¹²¹ Timothy P. Blanchard, *Medicare Medical Necessity Determinations Revisited: Abuse of Discretion and Abuse of Process in the War Against Medicare Fraud and Abuse*, 43 ST. LOUIS U. L.J. 91 (1999).

¹²² *How to Use the Medicare Coverage Database*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedicareCvrgeDatabase_ICN901346.pdf.

¹²³ *Id.*

¹²⁴ Timothy P. Blanchard, “Medical Necessity” Determinations—A Continuing Healthcare Policy Problem, 37 J. HEALTH L. 599, 610 (2004) (citing Pub. L. 99-509, § 9321(e), 100 Stat. 1874, 2017 (1986)).

¹²⁵ GAO REPORT, *supra* note 94.

¹²⁶ *See* Blanchard, *supra* note 124, at 611. Congress did not define “reasonable” or “necessary” in the legislation providing that Medicare would pay for “reasonable and necessary” care “for the diagnosis or treatment of illness or injury.” 42 U.S.C. § 1395y(a)(1) (West 2014).

¹²⁷ The term “contractor” is used to refer to “fiscal intermediaries,” “carriers,” and Medicare administrative contractors (MACs); however, use of the term

decades after the language of the Medicare legislation appeared to leave decisions about medical care to patients’ physicians,¹²⁹ the Secretary of the U.S. Department of Health and Human Services (HHS) asserted openly that agency determinations should outweigh provider determinations.¹³⁰ That position – not always accorded deference in Medicare claim appeals¹³¹ – has contrasted with the “treating physician rule” that pertains in disability cases within the Social Security Administration.¹³²

Even more, by the mid-1990s, hearings before the House Subcommittee on Human Resources and Intergovernmental Relations suggested that often only a thin line separated physicians’ determinations of medical necessity from fraud.¹³³ Whatever the accuracy of that assess-

“administrative contractors” refers to MACs (the label that replaced the terms fiscal intermediaries and carriers in 2006). See GAO REPORT, *supra* note 94.

¹²⁸ Blanchard, *supra* note 124, at 604–07.

¹²⁹ Bagley, *supra* note 46, at 526. Medicare’s “chief architect” Wilbur Cohen asserted that “[t]he sponsors of Medicare, including myself, had to concede in 1965 that there would be no real controls over hospitals and physicians. I was required to promise . . . that the Federal agency would exercise no control.” *Id.* (quoting RICK MAYES & ROBERT A. BERENSON, *MEDICARE PROSPECTIVE PAYMENT AND THE SHAPING OF U.S. HEALTH CARE* 17 (2006)). Blanchard notes that the statute itself states that “[n]othing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided.” Blanchard, *supra* note 124, at 605 (citing 42 U.S.C. § 1395 (2004)).

¹³⁰ Blanchard, *supra* note 124, at 605.

¹³¹ See *State of New York on Behalf of Holland v. Sullivan*, 927 F.2d 57 (2d Cir. 1991). The case involved a denial of Medicare coverage by HHS, and the agency argued that in-patient care for Holland was not “reasonable and necessary.” *Id.* at 58. Holland’s doctor authorized care in a NYS rehabilitation hospital. The admission was approved by the admitting hospital’s Utilization Review Committee. *Id.* HHS, an administrative law judge, and the Appeals Council refused to approve or order payment for Holland’s rehabilitation care on the grounds that the admitting hospital should have been aware that Medicare would not cover that care. *Id.* The district court agreed with the magistrate’s recommendation that the medical care be covered, because the treating physician and the hospital’s Utilization Review Committee had approved the care in question. *Id.* The Second Circuit remanded the case because neither the administrative law judge nor the Appeals Council offered any findings in the case. *Id.* at 59–60.

¹³² Ann K. Wooster, Annotation, *Determination and Application of Correct Legal Standard in Weighing Medical Opinion of Treating Source in Social Security Disability Cases*, 149 A.L.R. FED. 1 (1998).

¹³³ *Screening Medicare Claims for Medical Necessity: Hearing Before the Subcomm. on Human Res. & Intergovernmental Relations of the H. Comm. on Gov’t Reform & Oversight*, 104th Cong. 4 (1996) (statement of Sarah F. Jaggard, Director, Health, Education, and Human Services Division, U.S. Gov’t Accountability Office) [hereinafter Statement of Sarah F. Jaggard].

ment,¹³⁴ it legitimizes skepticism about the good faith of physicians submitting claims for payment. During 1990 House hearings, Sarah Jagggar, Director of the Health Financing and Policy Issues at the General Accounting Office, focusing on how best to limit Medicare payments for “unnecessary services,”¹³⁵ revealed significant suspicion of physicians’ claims and attributed overspending by Medicare to a “lack of financial incentive for physicians or patients to resist unnecessary diagnostic tests and routine services” within Medicare’s “fee-for-service” payment system.¹³⁶

b. Costs and Complexity

At least as problematic has been the uncertainty and enormity of Medicare’s claims determination efforts. The process involves thousands of people making determinations. Local coverage determinations – permissible in the absence of a relevant national coverage determination¹³⁷ – have almost no precedential value and do not become public unless appealed.¹³⁸ Appeals can be difficult to bring and are expensive for everyone.¹³⁹ Further, the scope Medicare has given to individual contractors to reach coverage determinations at the local level has stymied development of a robust and effective national policy.¹⁴⁰

Decisions about healthcare coverage were – and in significant part still are – grounded on a flexible, almost amorphous, understanding of both “reasonable” and “necessary,” but particular determinations seemed to leave no room for alternative approaches, such as partial coverage. Many determinations – either approving or denying coverage – have

¹³⁴ Assessing the claim is an important task but one beyond the scope of this Article.

¹³⁵ Statement of Sarah F. Jagggar, *supra* note 133, at 4.

¹³⁶ *Id.* at 8. Jagggar downplayed the notion that patients can act as watchdogs, monitoring physicians’ tendency to over-treat patients, noting that patients often lack the necessary knowledge to serve in that role. *Id.*

¹³⁷ *Medicare Coverage – General Information*, CMS.GOV: CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Coverage/CoverageGenInfo/index.html?redirect=/CoverageGenInfo/> (last modified Mar. 6, 2015, 1:15 PM).

¹³⁸ Blanchard, *supra* note 124, at 609.

¹³⁹ *See id.* at 609, n.43.

¹⁴⁰ Timothy Blanchard noted: “The Medicare program continued to delegate important coverage, documentation and coding rules to individual contractors through the ‘local medical review policy’ (LMRP) process, despite what appeared to be the obvious benefits of national policymaking: efficiency, uniformity, and equity.” *Id.* at 612. After December 2003, all LMRPs “were converted to LCDs.” INTEGRITY MANUAL, *supra* note 118. Blanchard further reported: “Providers and the Medicare regional offices develop LMRPs after a notice and circulation of proposed policy for comment.” Blanchard, *supra* note 124, at 612–13.

lacked nuance. Many claims have been approved or denied depending on contractors’ individual views about the medical necessity of the care at issue.¹⁴¹ Ryan Abbott and Carl Stevens have suggested re-fashioning the existing system on the model of a “variable co-pay approach”¹⁴²:

Validated, multilevel ratings of medical necessity based on clinical circumstances for a majority of commonly performed, costly diagnostic and therapeutic procedures could be deployed in a variety of ways to ensure that patients who stand to benefit substantially retain access to these procedures, while those who might benefit more from alternative, less complex interventions are offered both an opportunity and an incentive to select them [A] woman desiring hysterectomy for bleeding prior to a trial of conservative treatment would not be denied coverage based on a failure to meet a medical necessity threshold. Instead, she might be offered the procedure with a 30-40% co-pay prior to undergoing the surgery, perhaps amounting to several thousand dollars. However, the same patient, after failing an adequate trial of alternative non-operative treatments might receive the surgery with a low or even no co-pay, since the failure of alternative therapy increases the appropriateness of a surgical intervention.¹⁴³

The system for determining medical necessity should be restructured to encourage decisions based around compromises. More generally, the plethora of Medicaid contractors, the room given to contractors to reach local determinations, and the complications and expense of appealing Medicare determinations have resulted in uncoordinated, costly, replicated efforts that do not serve patients or providers as they should.¹⁴⁴

One study undertaken by the American Hospital Association (AHA) in 2007 explored the consequences for hospital patients of the Medicare system for reviewing claims.¹⁴⁵ The study looked only at denials of re-

¹⁴¹ Abbott & Stevens, *supra* note 12, at 6–7.

¹⁴² *Id.*

¹⁴³ *Id.* at 17. Abbott and Stevens acknowledge the challenge of delineating “multi-level medical necessity ratings” – called “Matrices of Appropriateness” – for a wide variety of conditions in a manner that would avoid conflicts of interest. *Id.*

¹⁴⁴ Jennifer E. Gladieux & Michael Basile, *Jimmo and the Improvement Standard: Implementing Medicare Coverage Through Regulations, Policy Manuals and Other Guidance*, 40 AM. J.L. & MED. 7, 8–9, 24–25 (2014).

¹⁴⁵ *Limiting Access to Inpatient Medical Rehabilitation: A Look at Payment Denials for Medicare Patients Treated in Inpatient Rehabilitation Facilities*, AM. HOSP. ASS’N (Oct. 2007), http://www.aha.org/content/00-10/071003_rehablcd.pdf [hereinafter *Limiting Access*].

habilitation care submitted by seventy-two inpatient rehabilitation hospitals.¹⁴⁶ The AHA reported that Medicare's fiscal intermediaries rejected the vast majority of claims submitted for that care.¹⁴⁷ Eighty percent resulted in denials of coverage.¹⁴⁸ The consequences for hospital patients – and ultimately for Medicare – were unfortunate:

Uncertainly about whether [claims] will be paid for care, coupled with the high administrative costs associated with increased payment denials and the lengthy appeals process, has led many IRFs [inpatient rehabilitation facilities] to restrict the types of patients that they admit for care, reduce clinical and support staff and decrease the number of available beds. This reduces patient access to medical rehabilitation services, despite the fact that these patients need this level of specialized care to be able to return to everyday activities.¹⁴⁹

Most of the denials rested on restrictive interpretations of Medicare's guidelines for rehabilitative care¹⁵⁰ or on policies reflecting local coverage determinations.¹⁵¹ Both approaches create inconsistent responses to claim submissions.

Determinations can be appealed, but as noted, the appeals process is burdensome, costly, and time-consuming.¹⁵² The process can involve many stages and multiple reviewing platforms. Medicare appeals are made to the responsible Medicare contractor (through a request for reconsideration); then appeals are taken, in this order, to a "qualified independent contractor;" an administrative law judge; a Medicare appeals council; and a federal court.¹⁵³ The process, if followed only to level three (a hearing before an administrative law judge) may take a year and a half.¹⁵⁴ Relying on data collected from the first seven months of 2007 from 72 rehabilitation facilities in 20 states, the AHA researchers found that 80% of claims submitted had been denied.¹⁵⁵ Importantly, by level

¹⁴⁶ *Id.* at 1.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* at 3. The "Criteria for Medicare Coverage of Inpatient Rehabilitation" include, among other things: need for "intensive rehabilitation," need for physician and nurses specialized in rehabilitation, and expectation that rehabilitation will lead to "significant improvement in a reasonable period of time." *Id.*

¹⁵¹ LCD policies are permissible, but Medicare rules preclude their use to limit coverage for which Medicare's Guidelines provide. *Id.*

¹⁵² *Id.* at 4.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at 1.

three of the appeals process – the stage of review managed by an administrative law judge – 63% of the appeals were successful.¹⁵⁶

In these cases, contractors’ medical necessity determinations were often based on limited interpretations of Medicare guidelines and on idiosyncratic local considerations.¹⁵⁷ These determinations, many of which were appealed, resulted in considerable expense for the facilities. Further, some facilities were refusing to accept patients whom they believed were eligible for in-hospital Medicare coverage but whose claims seemed likely to be denied by Medicare contractors¹⁵⁸:

Uncertainly about whether [claims] will be paid for care, coupled with the high administrative costs associated with increased payment denials and the lengthy appeals process, has led many IRFs [inpatient rehabilitation facilities] to restrict the types of patients that they admit for care, reduce clinical and support staff and decrease the number of available beds. This reduces patient access to medical rehabilitation services, despite the fact that these patients need this level of specialized care to be able to return to everyday activities.¹⁵⁹

Several years later (in 2014 and after passage of the Affordable Care Act), the Office of Inspector General within HHS expressed concern that LCDs result in inconsistencies among states regarding which items and services Medicare covers.¹⁶⁰ A one-week study concluded in late 2011 showed that LCDs were generally not linked with “cost and utilization of items and services.”¹⁶¹ Accordingly, the Inspector General recommended to CMS that Medicare Administrative Contractors create “a single set of coverage policies.”¹⁶²

For years, Medicare has continued to rely on LCDs by many thousands of individual decision-makers whose assessments have not been

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 4–8.

¹⁵⁸ *Id.* at 7–8.

¹⁵⁹ *Id.* at 1.

¹⁶⁰ DANIEL R. LEVINSON, DEP’T OF HEALTH & HUMAN SERV., LOCAL COVERAGE DETERMINATIONS CREATE INCONSISTENCY IN MEDICARE COVERAGE (2014), *available at* <http://njssahq.org/wp-content/uploads/2014/02/LCDs-create-inconsistency-in-Medicare-coverage-Jan2014.pdf>.

¹⁶¹ *Id.* at 2.

¹⁶² *Id.* at 2. The Independent Payment Advisory Board will recommend changes to some payment categories in the Medicare system. RICHARD S. FOSTER, OFFICE OF THE ACTUARY, CTRS. FOR MEDICARE & MEDICAID SERVS., ESTIMATED FINANCIAL EFFECTS OF THE “PATIENT PROTECTION AND AFFORDABLE CARE ACT” (2010), *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/downloads/PPACA_2010-04-22.pdf.

adequately guided by national policies: “The Medicare program continued to delegate important coverage and documentation and coding rules to individual contractors through the ‘local medical review policy’ (LMRP) process, despite what appeared to be the obvious benefits of national policymaking: efficiency, uniformity, and equity.”¹⁶³ (LMRPs have since been replaced by LCDs.)¹⁶⁴

3. The Medicare Modernization Act of 2003: Some Changes in Approach

Congress has tried several times to reform Medicare with an eye toward sustaining or even improving quality while lowering costs.¹⁶⁵ None of the reforms has been particularly effective – in significant part because none of the reform efforts upended the program’s dependence on private organizations to administer and supervise Medicare claims and payments.¹⁶⁶ Moreover, for decades, Congress did not respond to the problems inherent in a claims processing system that depended on many thousands of administrators, most affiliated with private insurance companies. Serious efforts to develop a national policy did not emerge until the early twenty-first century.¹⁶⁷ Congress instituted some – though inadequate – changes in 2003 with the passage of the Medicare Prescription Drug Improvement, and Modernization Act (“Medicare Modernization Act”).¹⁶⁸ That law, known for creating Medicare Part D and extending prescription drug benefits to seniors, also effected changes to other parts of the Medicare program.¹⁶⁹

The Medicare Modernization Act replaced fiscal intermediaries (responsible for Part A determinations) and carriers (responsible for Part B determinations) with a newly labeled category of contractors – the so-called Medicare Administrative Contractors.¹⁷⁰ Fiscal intermediaries and

¹⁶³ Blanchard, *supra* note 124, at 612.

¹⁶⁴ INTEGRITY MANUAL, *supra* note 115.

¹⁶⁵ Bagley, *supra* note 46, at 521.

¹⁶⁶ Bagley, *supra* note 46, at 533–34.

¹⁶⁷ *See infra* Subsection II.B.3.

¹⁶⁸ *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066 (codified in scattered sections of 26 and 42 U.S.C.).

¹⁶⁹ *See id.*

¹⁷⁰ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, § 911(a)(1), § 1874A, 117 Stat. 2066, 2378 (codified at 42 U.S.C. § 1395kk-1) [hereinafter Medicare Modernization Act]; U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-14-417T, MEDICARE CONTRACTORS AND PRIVATE PLANS PLAY A MAJOR ROLE IN ADMINISTERING BENEFITS 4 (2014), available at <http://www.gao.gov/assets/670/661317.pdf> [hereinafter MEDICARE CONTRACTORS].

carriers are now referred to as “legacy contractors.”¹⁷¹ In addition, CMS reduced the number of organizations responsible for hiring contractors and broadened the geographical area within which groups of contractors worked.¹⁷² The Medicare Modernization Act also provided for a significant transformation in the selection process for organizations that would enter into Medicare contractor agreements with the federal government. For the first time, the process became competitive, with Medicare considering price, quality, and a number of other relevant factors, in selecting among companies bidding to serve as contractors.¹⁷³ Moreover, the Act did away with restrictions on the type of contractors with which CMS could enter into Medicare contractor agreements, and it provided for payment of incentives linked to the quality of service.¹⁷⁴

In the same period, private insurers and Medicaid plans followed Medicare’s model and developed procedures requiring prospective utilization review of care.¹⁷⁵ This approach significantly undermined the power of patients and their individual physicians to choose among options for care.¹⁷⁶ These changes were exacerbated by protections that the Employee Retirement Income Security Act (ERISA) afforded to some managed care organizations during the same decades.

C. Managed Care Organizations and Medical Necessity

Ironically, Medicare – fashioned so as to offer comfort to anxious and disgruntled physicians and other healthcare providers – facilitated the increasingly powerful hold of the commercial insurance industry on coverage determinations.¹⁷⁷ By the 1980s, the augmented control of the industry facilitated developments in the structure of American health care that altered traditional medicine dramatically. Further, Medicare’s continuing efforts, despite consistent failure, to limit healthcare costs resulted in models that were appropriated by private insurers, particularly in the context of the explosion of managed care organizations during the last decades of the twentieth century. These organizations – special-

¹⁷¹ Testimony by Kathleen M. King, *supra* note 94. Within a decade of the passage of the Medicare Modernization Act, Medicare Administrative Contractors were handling virtually all claims-processing. LEVINSON, *supra* note 160, at 4; *see also* Foote, *supra* note 104, at 76 (reporting that very different aims inspired Medicare Advantage Preferred Provider Organization regions and “free-standing prescription drug plans . . . regions” and noting that the differences could interfere with quality improvements).

¹⁷² MEDICARE CONTRACTORS, *supra* note 170, at 4.

¹⁷³ Medicare Modernization Act, *supra* note 170.

¹⁷⁴ Testimony by Kathleen M. King, *supra* note 94.

¹⁷⁵ Hall & Anderson, *supra* note 50, at 1652–53.

¹⁷⁶ *See Wickline v. State*, 239 Cal. Rptr. 810, 812 (Cal. Ct. App. 1986).

¹⁷⁷ By the start of the twenty-first century, following the development of the managed care movement, insurance policies routinely specified that the insurer controlled necessity determinations. Atwell, *supra* note 39, at 598.

ly those with ERISA-protections – placed significant controls on the use and costs of health care.¹⁷⁸

1. The Development of Managed Care Organizations and ERISA Protection

Managed care first appeared in the United States after World War I.¹⁷⁹ It did not emerge as an important mode of delivering health care until the 1970s. That happened with passage of the Health Maintenance Organization Act (FHMO Act).¹⁸⁰ The Act promoted managed care organizations by offering funding and other support to, as well as regulation of, groups that obtained certification pursuant to the law.¹⁸¹ The development of managed care organizations gained significant momentum in the 1980s as a joint effort of insurers and employers to control the costs of health care.¹⁸² Managed care altered the physician-patient relationship, especially insofar as the development of managed care involved the amalgamation of those paying for health care and those providing health care.¹⁸³ In particular, managed care organizations (MCOs) – offering bundles of care at a pre-determined cost through provider networks¹⁸⁴ – compelled physicians to consider costs when making healthcare decisions for patients.

ERISA, passed a year after the FHMO Act, effectively protected self-insured employer health plans from state laws applicable to insurers.¹⁸⁵ ERISA has safeguarded these plans from state insurance laws and from many suits by patients anxious to dispute denials of care to which they believe they were entitled.¹⁸⁶ These results stem from ERISA's

¹⁷⁸ Eleanor D. Kinney, *Resolving Consumer Grievances in a Managed Care Environment*, 6 HEALTH MATRIX 147, 148 (1996).

¹⁷⁹ Benjamin Saunier, Note, *The Devil Is in the Details: Managed Care and the Unforeseen Costs of Utilization Review as a Cost Containment Mechanism*, 35 OKLA. CITY U. L. REV. 483, 489 (2010).

¹⁸⁰ See 42 U.S.C. § 300e (1996). Various terms are used to refer to organizations called MCOs in this Article. For present purposes, the term health maintenance organization is synonymous with managed care organization.

¹⁸¹ See *id.*

¹⁸² Kinney, *supra* note 179, at 148, 150.

¹⁸³ *Id.* at 152–53.

¹⁸⁴ Brian Wilson, *Tough Love: The Emergence of Criminal Statutes and Disciplinary Actions Against Managed Care Plans for Inadequate Care*, 18 J. CONTEMP. HEALTH L. & POL'Y 53, 53 n.2 (2001) (quoting RAND ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 551-52 (1997)).

¹⁸⁵ See § 29 U.S.C.A. § 1001b (noting that one goal of the Act was to safeguard the interests of people enrolled in “employee benefit plans”); Hirshfeld & Thomason, *supra* note 7, at 42; Sharon Reece, *The Circuitous Journey to the Patients' Bill of Rights: Winners and Losers*, 65 ALB. L. REV. 17, 20 (2001).

¹⁸⁶ § 1144(a) (“Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any

preemption of state insurance laws relating to self-funded employer group health plans. Such plans are subject only to federal law. Ironically, however, ERISA resulted in a legal vacuum within which plans with ERISA status could operate since neither the statute itself nor federal common law offered any guidelines that might have replaced preempted state laws.¹⁸⁷

Within a decade of ERISA’s passage, this legal vacuum encouraged large employers to self-insure.¹⁸⁸ Rather than paying a health insurance company to provide coverage for employees, employers funded their own plans, hiring insurers to implement the plans and preserve ERISA’s preemption protections from state laws.¹⁸⁹ Beginning in the 1980s and continuing, unabated, through much of the 1990s, judicial interpretations of ERISA granted disconcerting protection to managed care organizations with ERISA-status to operate outside state insurance laws.¹⁹⁰ By the 1990s, health plans with ERISA-status covered approximately 44 million people in the United States.¹⁹¹ ERISA freed these plans from a significant part of state liability laws that applied to non-ERISA plans.¹⁹²

and all State laws insofar as they may now or hereafter relate to any employee benefit plan . . .”); *see also* Wilson, *supra* note 185, at 53–55.

¹⁸⁷ Timothy Cahill, Comment, *Keeping the Saving Clause Safe from Judicial Annihilation: The Status of ERISA Preemption Jurisprudence Following Moran v. Rush Prudential HMO, Inc.*, 71 U. CIN. L. REV. 611, 612 (2003).

¹⁸⁸ Curtis D. Rooney, *States, Congress, or the Courts: Who Will Be First to Reform ERISA Remedies?*, 7 ANNALS HEALTH L. 73, 74 (1998).

¹⁸⁹ BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 710 (7th ed. 2013) (noting that in addition to hiring plan administrators, employers typically buy stop-loss insurance policies). “[C]ourts have overwhelmingly held that employer plans remain self-insured even though they are reinsured through stop-loss plans, and have prohibited states from attempting to impose requirements on self-insured plans through regulation of stop-loss coverage.” *Id.*

¹⁹⁰ *See, e.g.*, *District of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125 (1992) (strictly interpreting ERISA’s “relate to” language); *Mass. Mut. Life Ins. v. Russell*, 473 U.S. 134 (1985) (precluding insured from suing disability insurer’s fiduciary for damages due to improper cancellation of coverage); *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724 (1985) (providing for exemption of self-insured plans from state mandate that health insurers provide coverage for mental health); *Shaw v. Delta Airlines, Inc.*, 463 U.S. 85 (1983) (interpreting “relate to” language in ERISA statute literally).

¹⁹¹ Rooney, *supra* note 189, at 78 (citing U.S. GEN. ACCOUNTING OFFICE, HEHS-95-167, EMPLOYER-BASED HEALTH PLANS: ISSUES, TRENDS AND CHALLENGES POSED BY ERISA 9 (1995), <http://www.gao.gov/assets/230/221489.pdf>).

¹⁹² Thomas R. McLean & Edward P. Richards, *Health Care’s “Thirty Years War”*: *The Origins and Dissolution of Managed Care*, 60 N.Y.U. ANN. SURV. AM. L. 283, 283–84 (2010).

In consequence, plans gained enormous leeway to deny coverage requests. Thomas McLean and Edward Richards suggest the breadth of the control that these cases gave to managed care organizations.

After *Russell* [decided in 1985], many assumed that states could not individually regulate an ERISA MCO's prospective utilization review. Unfortunately, prospective utilization can be easily manipulated by creating incentives for physicians to misclassify a patient's conditions so that expensive care is not classified as medically necessary under the plan's guidelines. Such incentives became commonplace because MCOs are not required to disclose provider incentive packages, and because physicians had little power to bargain over these incentives once MCOs captured a majority of insured lives where the physician practiced.¹⁹³

ERISA preemption has had particularly fateful consequences for patients facing coverage denials. Preemption of state law does not, of course, preclude plaintiffs from moving cases to federal court. However, ERISA provided no substantive law through which plaintiffs would have been able to define their claims pursuant to federal laws.¹⁹⁴ Despite the theoretical possibility of a federal common law that would have brought justice to patients covered by plans with ERISA status, for over a century before the passage of ERISA, the "business of insurance" was regulated only at the state level.¹⁹⁵ As explained by one law professor, ERISA preemption, compounded by the absence of relevant federal laws or rules, lead to an untoward development:

The "void" or "absence of regulation" [created with ERISA's preemption provisions] was quickly filled by corporate America, the ERISA Plans and the insurance industry. Now, the rules are unilaterally written and implemented without any regulation. Plan documents are drafted and amended without approval or supervision. Extremely harsh provisions are implemented, leaving the consumer without any input or protection. And the federal courts are put into the position of being simple enforcement tools of corporate policy.¹⁹⁶

¹⁹³ *Id.* at 300.

¹⁹⁴ See Meridith H. Bogart, Note, *State Doctrines of Substantial Compliance: A Call for ERISA Preemption and Uniform Federal Common Law Doctrine*, 25 CARDOZO L. REV. 447, 449–52 (2003).

¹⁹⁵ Roger M. Baron, "Consumer Protection" and ERISA, 56 S.D. L. REV. 405, 405–06 (2011) (citing *Paul v. Virginia*, 75 U.S. (8 Wall.) 168 (1868) for conclusion that regulation of insurance was for the states).

¹⁹⁶ *Id.* at 406.

In some real part, during ERISA’s heyday for self-funded employer health coverage plans, reasonable understandings of medical necessity fell victim to the interests that filled the vacuum created by ERISA’s preemption of state laws – those of the commercial players, especially large employers and the insurance companies with which they entered into contracts to administer and protect their self-funded plans.¹⁹⁷

a. Corcoran v. United Healthcare

A case decided by the Fifth Circuit in 1992 illustrates the potentially dire consequences for patients receiving healthcare coverage through a self-funded employer plan protected by ERISA’s preemptions clauses.¹⁹⁸ The case, *Corcoran v. United Healthcare*,¹⁹⁹ was commenced by Florence Corcoran, who worked for South Central Bell Telephone Company and received healthcare coverage through the employer’s self-funded plan. The plan was administered by Blue Cross and Blue Shield of Alabama. Part of the plan (known as the “Quality Care Program”) was administered by UnitedHealth Care (“United”).²⁰⁰ In 1989, Corcoran became pregnant.²⁰¹ Because the pregnancy was high-risk, her obstetrician recommended hospitalization as the pregnancy approached its due date.²⁰² The part of Corcoran’s plan known as the Quality Care Program required pre-certification from United for hospital stays and for certain medical procedures.²⁰³ Florence Corcoran’s physician sought pre-certification for the hospital stay he thought necessary for the success of Corcoran’s pregnancy. The plan’s definition of the Quality Care Program suggests a level of troubling opacity – almost subterfuge:

The Quality Care Program (QCP) administered by United HealthCare, Inc., assists you and your covered dependents in securing quality medical care according to the provisions of the Plan while helping reduce risk and expense due to unnecessary hospitalization and surgery. They do this by providing you with information which will permit you (in consultation with your doctor) to evaluate alternatives to surgery and hospitalization when those alternatives are medically appropriate. In addition,

¹⁹⁷ *Id.*

¹⁹⁸ *Corcoran v. United HealthCare, Inc.*, 965 F.2d 1321 (5th Cir. 1992).

¹⁹⁹ *Id.* at 1321.

²⁰⁰ *Id.* at 1323. The self-funded plan was administered, in the main, by Blue Cross and Blue Shield of Alabama. Part of the plan was administered by United HealthCare.

²⁰¹ *Id.* at 1322.

²⁰² *Id.* at 1322–23.

²⁰³ *Id.* at 1323.

QCP will monitor any certified hospital confinement to keep you informed as to whether or not the stay is covered by the Plan.²⁰⁴

The language is striking in suggesting the plans commitment to patient care and its significant value to the covered employee: it “assists [the employee] and [his or her] dependents” in receiving “quality care.” At the same time it “reduce[s] risk and expense due to unnecessary hospitalization and surgery.” More remarkable still, the plan summary advised the insured that “when reading [the] booklet,” he or she should “remember that all decisions regarding your medical care are up to you and your doctor.”²⁰⁵ In theory, that was the case. In fact, it was not.

United denied the request of Corcoran’s obstetrician for in-hospital care. Instead, it provided nursing care to Corcoran at home for 10-hours each day. During a period when no nurse was present, Corcoran’s fetus suffered distress and died.²⁰⁶ Florence Corcoran and her husband Wayne sued in a Louisiana state court, seeking compensation for the “wrongful death” of the fetus.²⁰⁷ The defendants relied on ERISA to move the case to federal court.²⁰⁸

The plan’s language masked the truth. Among other things, only very wealthy patients could have afforded the sort of care Corcoran needed.²⁰⁹ As with Corcoran, almost all patients in Corcoran’s situation would have been compelled to accept alternative modes of care in light of the insurer’s denial. Most of the language quoted above from the plan’s summary must be characterized as a “public relations” stunt rather than a straightforward description of a healthcare plan – as Corcoran’s case shows.

The district court granted summary judgment to the defendants, and the Fifth Circuit affirmed:²¹⁰

Ultimately, we conclude that United makes medical decisions – indeed, United gives medical advice – but it does so in the context of making a determination about the availability of benefits under the plan. Accordingly, we hold that the Louisiana tort action asserted by the

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.* at 1324.

²⁰⁷ *Id.*

²⁰⁸ *Id.* at 1324–25.

²⁰⁹ The plan summary further explained: “United Health Care, an independent professional medical review organization, has been engaged to provide services under QCP. United’s staff includes doctors, nurses, and other medical professionals knowledgeable about the health care delivery system. Together with your doctor, they work to assure that you and your covered family members receive the most appropriate medical care.” *Id.* at 1324.

²¹⁰ *Id.* at 1331.

Corcorans for the wrongful death of their child allegedly resulting from United's erroneous medical decision is pre-empted by ERISA.²¹¹

b. Corcoran's Protection

In effect, the breadth of the protection afforded to insurers in cases such as *Corcoran* placed benefit denials for health plans governed by ERISA outside the purview of state review. The court lamented aspects of its decision, while re-affirming that the law gave it no choice:²¹²

The result ERISA compels us to reach means that the Corcorans have no remedy, state or federal, for what may have been a serious mistake. This is troubling for several reasons. First, it eliminates an important check on the thousands of medical decisions routinely made in the burgeoning utilization review system. With liability rules generally inapplicable, there is theoretically less deterrence of substandard medical decision-making. Moreover, if the cost of compliance with a standard of care (reflected either in the cost of prevention or the cost of paying judgments) need not be factored into utilization review companies' cost of doing business, bad medical judgments will end up being cost-free to the plans that rely on these companies to contain medical costs. 20 ERISA plans, in turn, will have one less incentive to seek out the companies that can deliver both high quality services and reasonable prices.²¹³

Corcoran made it clear²¹⁴ that utilization reviews before the provision of health care provided a powerful mechanism for limiting costs – but one that could easily elide concern for good care. Medical necessity determinations were at the center of these utilization reviews, suggesting forcefully how easily the notion of medical necessity can be twisted to serve a wide variety of financial (as well as political or ideological) interests. The pre-certification process interfered in new ways – both qualitative and quantitative – with the physician-patient relationship.²¹⁵ Denials resulting from prospective and concurrent utilization reviews precluded care that physicians had recommended.²¹⁶

²¹¹ *Id.*

²¹² *Id.* at 1338.

²¹³ *Id.*

²¹⁴ See *supra* notes 204–219 and accompanying text.

²¹⁵ Linda V. Tiano, *The Legal Implications of HMO Cost Containment Measures*, 14 SETON HALL LEGIS. J. 79 (1990).

²¹⁶ See *Sarchett v. Blue Shield of Cal.*, 729 P.2d 267 (Cal. 1987) (en banc); *Wickline v. State*, 239 Cal. Rptr. 810 (Cal. Ct. App. 1986).

For several decades, ERISA offered significant protection to insurers denying prospective and concurrent claims.²¹⁷ The level of protection that *Corcoran* extended to health plans governed by ERISA seemed to free such plans from the need to buy malpractice insurance, thus offering an additional financial advantage to industry at the expense of patients.²¹⁸ At least some ERISA-governed plans may actually have denied coverage to patients that they would have provided had they not enjoyed apparent protection from liability for malpractice.²¹⁹

2. Shifts in ERISA Jurisprudence

Under the reign of pro-industry ERISA cases in the 1980s and 1990s, medical necessity determinations became an integral part of a world of managed care that aimed – though rarely explicitly – to ration care.²²⁰ The American public has remained adamant about rejecting healthcare rationing. But all insurers – and managed care organizations, in particular – have relied on medical necessity determinations to cut costs.²²¹ The loss to good health care and the cost in appealed denials has been significant.²²² Despite this, the insurance industry's attempts to limit expenditures for health care gained increasingly broad protection in the last decades of the twentieth century as courts consistently broadened the protection given to employer-funded plans administered by insurers.²²³ Managed care plans developed in the 1980s and 1990s did limit expens-

²¹⁷The history of judicial interpretations of ERISA is beyond the scope of this paper. Much or all of that history is considered in Karla S. Bartholomew, Note, *ERISA Preemption of Medical Malpractice Claims in Managed Care: Asserting a New Statutory Interpretation*, 52 VAND. L. REV. 1131 (1999); Donald T. Bogan, *ERISA: The Savings Clause, § 502 Implied Preemption, Complete Preemption, and State Law Remedies*, 42 SANTA CLARA L. REV. 105 (2001); Karen A. Jordan, *Recent Modifications to the Preemption Doctrine and Their Impact on State HMO Liability Laws*, 1 IND. HEALTH L. REV. 51 (2004); and William M. Sage, *Managed Care's Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 597 (2003).

²¹⁸ McLean & Richards, *supra* note 193, at 302.

²¹⁹ *Id.*

²²⁰ Frances H. Miller, *Denial of Health Care and Informed Consent in English and American Law*, 18 AM. J.L. & MED. 37, 46 (1992).

²²¹ Kristen Underhill, *Paying for Prevention: Challenges to Health Insurance Coverage for Biomedical HIV Prevention in the United States*, 38 AM. J.L. & MED. 607, 647–48 (2012).

²²² *Id.*

²²³ See, e.g., *Union Labor Life Ins. Co. v. Pireno*, 458 U.S. 119 (1982) (limiting understanding of “insurance,” resulting in wider ERISA preemption); *Group Life & Health Ins. Co. v. Royal Drug Co.*, 440 U.S. 205 (1979) (extending preemption to insurers' decisions about payment amounts).

es, but too often they sacrificed good health care in order to do that.²²⁴ In short, managed care companies often seemed focused on money making at the expense of both patients and their doctors, an approach that placed significant limitations on healthcare choices.²²⁵

The consequences of the increasingly obvious capacity of self-funded plans to elide liability for negligent claim denials, as well as to avoid state insurance laws, led eventually to rejection of managed care in the private markets, despite its initial successes in cutting healthcare expenditures. Managed care’s limitations for patient care, and thus for patients’ health, simply became too evident, too often. Increasingly, the public perceived managed care as a form of healthcare rationing.²²⁶ At first, managed care worked to disguise its capacity to, and interest in, rationing health care.²²⁷ Soon, the reality appeared beneath the mask. Professor David Orentlicher relied on explanations outlined in *Tragic Choices* by Guido Calabresi and Phillip Bobbitt to describe this process²²⁸:

Calabresi and Bobbitt explain that the difficult life-and-death choices entailed in rationing can only be made by hiding them from public scrutiny. Managed care provided a method for disguising rationing. However, write Calabresi and Bobbitt, when the hidden “tragic choices” are exposed – as they ultimately will be – the method for making those choices becomes discredited, and the public demands a new method.²²⁹

By the end of the twentieth century, this pattern emerged with regard to managed care’s excesses.²³⁰ The harsh impact of ERISA on patients denied coverage – and thus, in effect, denied care – and on patients seeking compensation for inappropriate denials of care has eased.²³¹ In 1995, the Court recognized the excesses that flowed from its ERISA cases. In that year, it began to re-shape and limit its conclusions about ERISA’s power to preempt state laws.²³²

²²⁴ See *supra* notes 184–189 and accompanying text.

²²⁵ Abbott & Stevens, *supra* note 12.

²²⁶ Orentlicher, *supra* note 96, at 411–12.

²²⁷ GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES* (1978).

²²⁸ *Id.*

²²⁹ Orentlicher, *supra* note 96, at 413.

²³⁰ See *supra* Section II.C.2.

²³¹ Some changes in interpretations of ERISA’s preemption appeared as early as the mid-1990s. See, e.g., N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995) (preserving a state law imposing a hospital surcharge tax from ERISA preemption).

²³² *Id.* (concluding that state law relating to hospital fees was not preempted by ERISA); Bogart, *supra* note 195, at 462–66.

Still, the consequences of Congress's decision, in crafting the Medicare legislation, to place medical necessity determinations in the hands of the insurance industry are felt widely. At its worst, that model undermines coverage decisions – with regard both to payments and care – that might better serve the health of the nation. And still self-funded plans enjoy some protection from ERISA status, and managed care plans, generally, have recently gained greater support from the federal government.

Both Medicare²³³ and Medicaid²³⁴ now offer managed care options, and the Affordable Care Act²³⁵ encourages the development of comparable structures. Fortunately, there has been some retreat from the period (in the late twentieth century) during which managed care organizations protected by ERISA rendered medical necessity determinations with apparent impunity, even in cases in which those determinations seemed unconnected to virtually any understanding of “medical necessity.” In large part, increasing public furor, roused by images of federal law protecting managed care organizations but not patients, and of managed care organizations as giant commercial enterprises ready to kill patients for another dollar, stimulated fledgling legal changes that now brake ERISA's peculiar and fierce protection for self-funded employer health plans.²³⁶ Unfortunately the Affordable Care Act has left most of ERISA's most troubling provisions intact.²³⁷

D. *The Patient Protection and Affordable Care Act and Medical Necessity*

The Affordable Care Act does, however, effect a large number of changes relevant to employer-provided coverage. In contrast with ERISA, which applies only to plans that have, in fact, developed health care coverage plans for employees (with no requirement that employers do so), the Affordable Care Act gives large employers a choice between providing healthcare coverage or paying a penalty if any uninsured employee uses premium tax credits to help pay for coverage through a state

²³³ Drew Altman, *Pulling it Together: Duals: The National Health Reform Experiment We Should Be Talking More About*, KAISER FAMILY FOUND. (Jun. 1, 2012), <http://www.kff.org/pullingittogether/dual-eligibles-health-reform.cfm>; see also Carolyn J. McElroy, *State Perspective on Health Care Enforcement-Medicaid Fraud Control Units*, SE34 ALI-ABA 493 (1999).

²³⁴ By the end of the twentieth century, Medicaid was relying more and more often on managed care organizations. See, e.g., Robert N. Swidler, *Special Needs Plans: Adapting Medicaid Managed Care for Persons with Serious Mental Illness or HIV/AIDS*, 61 ALB. L. REV. 1113, 1113 (1998).

²³⁵ See Christopher Smith, *It's A Mistake: Insurer Cost Cutting, Insurer Liability, and the Lack of ERISA Preemption Within the Individual Exchanges*, 62 CLEV. ST. L. REV. 75, 96–99 (2014) (noting likely expansion of managed care under Affordable Care Act).

²³⁶ Wilson, *supra* note 185, at 53–55; McLean & Richards, *supra* note 193.

²³⁷ FURROW ET AL., *supra* note 190, at 713.

exchange.²³⁸ Moreover, under the Affordable Care Act, healthcare plans, including ERISA plans, must provide binding external review of coverage denials.²³⁹ This will usually result in requiring group health coverage plans to follow the requirements set by states’ external review rules.²⁴⁰

The Affordable Care Act became law in 2010.²⁴¹ Most of its essential provisions have been implemented. It has extended access to healthcare coverage in the United States.²⁴² However, the Affordable Care Act focuses on limiting the cost of healthcare insurance far more than on limiting the cost of health care.²⁴³ Further, the nation continues to face larger per capita healthcare costs than any other nation.²⁴⁴ And most of the act’s provisions that facilitate programs aimed at reducing the costs of health care only involve Medicare.²⁴⁵ Even more concerning, the Act both re-enforces the nation’s dependence on private healthcare insurers, and it fails to facilitate reductions in the price of pharmaceuticals, medical devices, and other expensive healthcare resources.²⁴⁶

More particularly, the Affordable Care Act has expanded on Medicare’s institutionalization of the role of insurers in paying for care and has reinforced the assumption that insurers should participate actively in medical necessity determinations.²⁴⁷ That assumption, along with concern about its implications, is reflected in a letter sent to then-HHS Secretary Kathleen Sebelius in April 2012 by over 100 organizations representing people with chronic conditions and disabilities.²⁴⁸ The letter,

²³⁸ FURROW ET AL., *supra* note 190, at 739.

²³⁹ *Id.* at 743 (citing Affordable Care Act, *supra* note 26, § 2719).

²⁴⁰ *Id.* at 713.

²⁴¹ Affordable Care Act, *supra* note 26.

²⁴² Carolyn O’Hara, *An Obama Expert Tells All: What You Need to Know About the Affordable Care Act*, FORBES (Oct. 11, 2013, 2:45 PM), <http://www.forbes.com/sites/learnvest/2013/10/11/an-obamacare-expert-tells-all-what-you-need-to-know-about-the-affordable-care-act.com> (noting that the Act extends coverage opportunities but does not guarantee access to care).

²⁴³ *Id.*

²⁴⁴ Maxwell S. Thomas, Note, *A Cross-Cultural Analysis of Health Care Models—Lessons Learned on the Importance of Localized Preventative Care in Reducing Chronic Disease*, 12 J. INT’L BUS. & L. 443, 443–44 (2013) (reporting that in 2012 the United States spent more than two times as much as “other ‘rich’ countries” on health care).

²⁴⁵ Mark A. Hall, Address, *Evaluating the Affordable Care Act: The Eye of the Beholder*, 51 HOUS. L. REV. 1029, 1042 (2014) (noting that the act has virtually no provisions aimed at cutting the cost of private health insurance, and the provisions aimed at “provider payment reform” concern Medicare only).

²⁴⁶ *Id.* at 1040.

²⁴⁷ Skinner, *supra* note 35, at 2.

²⁴⁸ Letter from Adult Congenital Heart Ass’n et al., to The Honorable Kathleen Sebelius, Sec’y of the Dep’t of Health & Human Servs., (Apr. 11, 2012)

urging changes in proposed standards for Essential Health Benefits (EHBs)²⁴⁹ and prescription drug coverage, urges that HHS clearly delineate standards for medical necessity determinations²⁵⁰:

Plans must use medical necessity criteria that are objective, clinically valid, and compatible with generally accepted principles of care. A health intervention should be covered if it is an otherwise covered category of service . . . recommended by the treating health care professional recognized under state or federal law, and determined by the health plan's medical director to be medically necessary.²⁵¹

In addition to cementing the role of the insurance industry in shaping U.S. health care for the foreseeable future,²⁵² the Affordable Care Act contains specific provisions that limit the authority of HHS to interfere with insurers' coverage decisions. Importantly, the Act expressly provides for the continued use of utilization reviews by insurers.²⁵³ And it recognizes and approves of extant methods of carrying out those reviews.²⁵⁴ This significantly limits the ability of HHS to interpret the parameters of the "essential benefits" that many insurers, including those

[hereinafter Letter to Sebelius], *available at* <http://www.accc-cancer.org/advocacy/pdf/2012-EHB-Groupletter.pdf> (urging HHS to reconsider proposed standard requiring EHB plans to "only cover one drug per therapeutic category or class covered by a selected state benchmark plan"). The letter was signed by 104 organizations "on behalf of the more than 133 million Americans living with chronic diseases and disabilities and their caregivers." *Id.*

²⁴⁹ Section 1302 of the Affordable Care Act notes ten essential benefits that insurers offering plans to the individual market or the small group market must include. Affordable Care Act, *supra* note 26. Prescription drug benefits are included among those ten essential benefits. *Id.*

²⁵⁰ Letter to Sebelius, *supra* note 249.

²⁵¹ *Id.* The letter further urges that denials must be adequately explained to patients and that patients must be informed about the opportunity to appeal negative determinations.

²⁵² See Janet L. Dolgin & Katherine R. Dieterich, *Social and Legal Debate About the Affordable Care Act*, 80 UMKC L. REV. 45, 54–55 (2011).

²⁵³ Sara Rosenbaum, Joel Teitelbaum, & Katherine Hayes, *The Essential Health Benefits Provisions of the Affordable Care Act: Implications for People with Disabilities*, THE COMMONWEALTH FUND 1, 3 (Mar. 2011), http://www.commonwealthfund.org/~media/files/publications/issue-brief/2011/mar/1485_rosenbaum_essential_hlt_benefits_provisions_aca_disabilities_reform_brief_v2.pdf (noting as well that the Act does not define "utilization review").

²⁵⁴ *Id.* at 3, 5. Extant utilization review methods cannot, however, survive if they violate the nondiscrimination provisions of the Affordable Care Act. *Id.* at 13.

offering policies on the state exchanges, must include in their plans.²⁵⁵ Further, the agency largely relieved itself of the burden – or opportunity, depending on one’s perspective – of hammering out the specific details of the ten categories of essential benefits that must be included in plans offered to the individual or small group market by transferring much of that task to the states.²⁵⁶ Still, decisions must be made continuously about what services are deemed medically necessary and thus eligible for coverage. The Affordable Care Act offers no definition of medical necessity and does not explain how to distinguish between medical interventions and non-medical interventions.²⁵⁷

In short, the Affordable Care Act leaves medical necessity determinations to private insurers and will have little effect on the manner in which those determinations are rendered.²⁵⁸ The Act forfeited an opportunity to limit the role of the insurance industry in reaching medical necessity determinations for government plans such as Medicare and Medicaid and for the state exchanges. That was perhaps an inevitable consequence of the Act’s broader design – one that placed the insurance industry at the center of the system constructed for offering coverage through state exchanges.²⁵⁹

At least in theory, insurers’ medical necessity determinations in plans offered pursuant to the Affordable Care Act must abide by statutory limits, but, in fact, the Affordable Care Act delineates very few limits that might constrain such decisions.²⁶⁰ Thus, in this crucial regard – albeit one not often the focus of critique – the Obama administration buttressed the pre-existing system by which insurers made decisions about coverage.²⁶¹ The Act does provide for external independent reviews of medi-

²⁵⁵ See Letter to Sebelius, *supra* note 249 (noting delineation of essential health benefits in § 1302 of the Affordable Care Act).

²⁵⁶ CTR. FOR CONSUMER INFO. & INS. OVERSIGHT, *Essential Health Benefits Bulletin*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1, 8 (Dec. 16, 2011), http://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf (proposing that essential health benefits be defined “by a benchmark plan selected by each state”).

²⁵⁷ INST. OF MED., *supra* note 10, at xi, 75, 95; Hill, *supra* note 52, at 450.

²⁵⁸ Hill, *supra* note 52, at 461. The term “medical necessity” (or “medically necessary”) appears only three times in the Act (§§ 2707, 520K, and 9007). See Daniel Skinner, *Defining Medical Necessity Under the Patient Protection and Affordable Care Act*, 73 PUB. ADMIN. REV. S49, S50 (2013). None of these sections defines the term(s).

²⁵⁹ The so-called “individual mandate”—made necessary to protect the insurance industry from provisions in the act—required insurers to, among other things, cover everyone eligible for coverage under the Act without regard for pre-existing conditions, and required people to have healthcare coverage or pay a penalty-tax. See *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 132 S.Ct. 2566 (2012).

²⁶⁰ Hill, *supra* note 52, at 465.

²⁶¹ *Id.* at 466.

cal necessity determinations that are appealed, and that is important.²⁶² But it is not enough.

Of additional significance, the Affordable Care Act fails to provide for the development of national guidelines in light of which medical necessity determinations could be effected and assessed. Even though definitions of medical necessity are less crucial than the identity of those reaching medical necessity determinations, the absence of national guidelines defers to an already empowered industry. In this light, it is troubling that an IOM committee, responding to a request from the Secretary of HHS to define medical necessity, disfavored development of national standards.²⁶³ The committee concluded that a call for transparency in the definition of medical necessity in plans required to offer the 10 essential health benefits along with the opportunity for external reviews of medical necessity determinations offered adequate protection.²⁶⁴ And the report recommended that distinctions between medical and non-medical interventions be left to industry.²⁶⁵ Further, the IOM committee noted concern that medical necessity determinations can support discriminatory motives but concluded that the Act offered adequate protection to vulnerable populations:

Evaluations of medical necessity will have to comply with inclusion of the 10 categories of care as well as prohibitions against discrimination based on age, disability, and expected length of life in the ACA and secretarial guidance. As noted in testimony to the committee with regard to potential discrimination in the application of medical necessity to persons with disabilities, “The central question is whether the treatment is medical in nature and whether the individual can be expected to medically benefit from it.”²⁶⁶

In sum, the IOM report supported, and therein legitimized anew, the system that for a half-century has granted control of medical necessity

²⁶² John K. Iglehart, *Defining Essential Health Benefits—The View from the IOM Committee*, 365 NEW ENG. J. MED. 1461, 1463 (2011).

²⁶³ INST. OF MED., *supra* note 10. The report further considered, in response to then Secretary Sebelius’s request, more carefully defining the ten essential health benefits delineated in the Affordable Care Act. *Id.* at 96.

²⁶⁴ *Id.* at 99. The IOM further recommended that HHS interpret the “medical purpose of interventions” so as adequately to affect the ten essential healthcare benefits defined in the Affordable Care Act and that it see medical necessity in light of “clinically appropriate” care for individual patients “based on the best scientific evidence,” and most “likely to produce incremental health benefits relative to the next best alternative that justify any added cost.” *Id.*

²⁶⁵ *Id.* at 75.

²⁶⁶ *Id.* at 98 (citing CHERYL ULMER ET AL., INST. OF MED., PERSPECTIVES ON ESSENTIAL HEALTH BENEFITS: WORKSHOP REPORT (2012)).

decisions to the insurance industry. The implications of its suggestion – followed by the administration in its implementation of the Affordable Care Act – are worrisome:

[T]he IOM report noted the multiple existing definitions of “medical necessity.” Again dispensing with the necessity of fixing one particular definition for the term, the IOM report embraced the view that “[t]he central question is whether the treatment is medical in nature and whether the individual can be expected to medically benefit from it” – thus referring back to the very term (“medical”) that it had earlier declined to define. The report essentially deferred the task to private insurers, who have substantial experience in defining medical necessity, while emphasizing the values of “individualizing care, ensuring value, and having medical necessity decisions strongly rooted in evidence.”²⁶⁷

Importantly, the Affordable Care Act grants the right to de novo external review of claim denials; the Act does not echo that protection with regard to categorical denials of coverage.²⁶⁸ This may impact interpretations of the ten essential benefits mandated under the Act for insurers providing coverage for the individual and small-group markets.²⁶⁹ And it may result in denials of healthcare coverage to patients who are not assured the right – given to those challenging individual, medical necessity determinations – to de novo external review.²⁷⁰

E. Who Has Benefitted?

The power granted to the insurance industry by Medicare – a power reinforced through the Affordable Care Act – is of little, if any, value to patients and prospective patients. Industry benefits, but patients and their clinicians do not. This Section reviews the role of industry in making medical necessity determinations and suggests some of benefits that accrue to industry as a result.

²⁶⁷ Hill, *supra* note 52, 450–51.

²⁶⁸ In *Jones v. Kodak Med. Assistance Plan*, 169 F.3d 1287 (10th Cir. 1999), the Tenth Circuit upheld a decision for the plan on the grounds that the eligibility terms were part of the plan even though they were unpublished. This response is particularly hard on parties appealing coverage denials. The court explained that the denial of coverage by the Plan Administrator was acceptable because the patient denied coverage “presented no evidence that the criteria were applied in a discriminatory manner in her case.” *Id.* at 1292.

²⁶⁹ See Letter to Sebelius, *supra* note 249 (noting delineation of essential health benefits in § 1302 of the Affordable Care Act).

²⁷⁰ See Rosenbaum et al., *supra* note 254, at 6 (noting differences between denials grounded on “benefit and coverage design” and those based on utilization reviews).

1. The Role of the Insurance Industry

Medicare, by providing for third-party contractors to administer claims, erected a framework within which the nation's healthcare system has operated since its passage.²⁷¹ Especially in the last decades of the twentieth century, ERISA expanded protections for self-funded managed care plans in troubling fashion.²⁷² That development augmented the risks of reliance on insurance companies to make medical necessity decisions for private and government healthcare plans.

At the end of the last century, Congress entertained a provision, part of the Patients' Bill of Rights Act of 1998, that would have returned authority for medical necessity determinations to physicians.²⁷³ The bill, if enacted as law, would have broadly provided for patients' rights and regulated health maintenance organizations.²⁷⁴ The insurance industry opposed the bill in general and Section 151 in particular.²⁷⁵ That section provided that healthcare insurers could not "arbitrarily interfere with or alter the decision of the treating physician regarding the manner or setting with which particular services are delivered if the services are medically necessary or appropriate for treatment or diagnosis to the extent that such treatment or diagnosis is otherwise a covered benefit."²⁷⁶ The Health Insurance Association of America (HIAA), in adamant opposition to the bill and to Section 151, in particular, opined that the provision would "undermine utilization management and increase costs," "encourage fraud and abuse, especially by providers," "undermine quality and perhaps even expose patients to danger," "undermine contract law," "create a unique coverage regime for private insurance inconsistent with governmentally funded programs,"²⁷⁷ and would destroy the nation's healthcare system as a consequence of physician greed.²⁷⁸

Further, some insurance company contracts expressly gainsay the assumption that physicians' medical decisions comply with insurers' con-

²⁷¹ See *supra* Section II.B.

²⁷² See *supra* Section II.C.

²⁷³ Patients' Bill of Rights Act of 1998, S. 2529, 105th Congress § 151(a)(1) (1998). The bill, sponsored by Senator Thomas A. Daschle (D-SD), did not pass. See *id.*, 105 Bill Tracking Report S. 2529 (Lexis 1998).

²⁷⁴ See S. 2529.

²⁷⁵ Robert Pear, *Senators Reject Bill to Regulate Care by H.M.O.'s*, N.Y. TIMES, Oct. 10, 1998, at A1. The bill was opposed by the insurance industry and displaced by the Clinton-Lewinsky sex scandal that plagued President Clinton's administration. *Id.*

²⁷⁶ S. 2529 § 151(a)(1).

²⁷⁷ "Medical Necessity" and Health Plan Contracts, HIAA, http://lobby.la.psu.edu/001_Managed_Care_Reform/Organizational_Statements/HIAA/HIAA_Medical_Necessity_and_Health_Plan_Contracts.htm (last visited May 20, 2015).

²⁷⁸ *Id.* (referring to instances of provider fraud, greed, and overreaching).

tractual understandings of medical necessity.²⁷⁹ *Holl v. Amalgamated Sugar Company* involved a Blue Cross policy that provided that “the fact a Covered Provider may prescribe, order or recommend a service does not determine Medical Necessity.”²⁸⁰ Federal Magistrate Judge Candy Dale acknowledged a conflict for an insurer acting as “both the administrator and funding source” for a plan:

[W]hile the administrator is responsible for administering the plan so that those who deserve benefits receive them, the administrator also “has an incentive to pay as little in benefits as possible to plan participants because the less money the insurer pays out, the more money it retains in its own coffers.”²⁸¹

Yet, Judge Dale held for the ERISA-protected defendant, the plaintiff’s employer, and administrator of the company’s Blue Cross healthcare plan.²⁸² The court concluded that the plan’s denial of the plaintiff’s claim (for IviG infusion therapy to treat myasthenia gravis) had not violated the plaintiff’s right to coverage under the policy.²⁸³

2. Benefits to Industry

From the passage of Medicare in 1965 through the passage of the Affordable Care Act in 2010, Congress supported granting the health insurance industry a key role in the operation of the nation’s healthcare system.²⁸⁴ The industry has flourished.²⁸⁵ In 2013, the healthcare insurance industry enjoyed robust earnings and saw large increases in the price of its stock.²⁸⁶ That success followed passage of the Affordable Care Act (implemented in large part by early 2014). The centrality that the Act gives to the insurance industry in reshaping the nation’s

²⁷⁹ *Holl v. Amalgamated Sugar Co.*, No. 1:13-cv-00231-CWD, 2014 U.S. Dist. LEXIS 59257 (D. Idaho 2014).

²⁸⁰ *Id.*

²⁸¹ *Id.* at n.6 (citing *Abatie v. Alta Health & Life Ins. Co.*, 458 F.3d 955, 986 (9th Cir. 2006)).

²⁸² *Id.*

²⁸³ *Id.*

²⁸⁴ See *supra* notes 254, 259 and accompanying text.

²⁸⁵ See *infra* notes 296–308 and accompanying text.

²⁸⁶ *Health Insurance CEO Pay Sky-Rockets in 2013: Some See Their Compensation Double*, PR NEWSWIRE (May 5, 2014), <http://www.prnewswire.com/news-releases/health-insurance-ceo-pay-sky-rockets-in-2013-257974651.html> [hereinafter *Health Insurance CEO Pay*] (noting that some of the Fortune 500 Health Insurance companies reported “better-than-expected earnings in the first quarter of 2014”); see also Tom Murphy, *Insurers Aetna, WellPoint Bulk Up Executive Pay*, STL TODAY (Apr. 2, 2014, 1:47 PM), http://www.stltoday.com/business/local/insurers-aetna-wellpoint-bulk-up-executive-pay/article_54143648-0b8d-5028-bdf4-f7404234bfe9.html.

healthcare system institutionalized and, thus, strengthened a system put in place almost a half-century earlier.²⁸⁷

a. The Insurance Industry

For instance, Aetna's 2013 Annual Report noted an increase in "fees and other revenue" compared with the previous year of \$689 million; in 2012, the company reported increased "fees and other revenue" as compared with 2011 of \$132 million.²⁸⁸ Aetna's "annual operating revenue" in 2013 was \$47.2 billion, a 33 percent increase from 2012.²⁸⁹ In the same years, UnitedHealth Group reported 2013 revenues of about \$122 billion and of about \$110 billion in 2012.²⁹⁰

For the industry's CEOs, 2013 also proved to be a boon year. The compensation of Fortune 500 health insurance company CEOs rose by almost one-fifth.²⁹¹ Compensation for Aetna's CEO was \$30 million in 2013, and WellPoint's CEO received \$17 million.²⁹² During the same period – with an average annual compensation for CEO's of Fortune 500 health insurance companies of over \$11 million – Medicare paid its top administrator less than \$200,000.²⁹³ One commentator, noting this remarkable difference, commented:

“The culture of excess at these for-profit corporations is incompatible with the goals of an efficient, ethical health care system, where every dollar diverted from patient care represents a loss of access for real families . . . We face the highest healthcare costs and have among the worst health outcomes of any country in the developed world because we allow private health insurers and dozens of other intermediaries to act as for-profit middlemen in the health care system. Although many backers of the Affordable Care Act said it would rein in insur-

²⁸⁷ See *supra* Section II.B and Section II.D.

²⁸⁸ AETNA, 2013 AETNA ANNUAL REPORT: FINANCIAL REPORT TO SHAREHOLDERS 10 (2014), available at https://materials.proxyvote.com/Approved/00817Y/20140328/AR_204030/#/1/.

²⁸⁹ Letter from Mark Bertolini, Chairman, CEO and President of Aetna, to Aetna S'holders, in AETNA, *supra* note 289.

²⁹⁰ UNITEDHEALTH GROUP, 2013 ANNUAL REPORT 2 (2014), available at <http://www.unitedhealthgroup.com/2013-annual-report/Default.aspx>.

²⁹¹ *Health Insurance CEO Pay*, *supra* note 287.

²⁹² Murphy, *supra* note 287. Aetna explained its CEO's compensation, more than double his compensation a year earlier, as the result of restricted stock and options, granted as a one-time award in 2013. *Id.*

²⁹³ *Health Insurance CEO Pay*, *supra* note 287 (see, attached source, Bar Graph: 2013 Health Insurance CEO, CMS Administrator, and Average Worker Compensation).

ance company excesses, the law clearly hasn’t curtailed top executive pay.”²⁹⁴

The dramatic economic success enjoyed by the health insurance industry has benefitted a comparatively small group of exceedingly high paid officials and administrators, but not the bulk of industry employees. In the same years (2012 and 2013) that the average health insurance industry CEO had an annual compensation package worth \$11,627,188 (2012) and \$13,866,571 (2013), respectively, the average worker in the industry earned \$34,645 (2012) and \$35,239 (2013).²⁹⁵

b. Moving Money to the Top

More generally, in the United States, the lion’s share of healthcare funding goes to “the business of medicine” and not to the provision of health care.²⁹⁶ A stunningly large part goes to the pharmaceutical industry.²⁹⁷ A large part of that funding goes to the insurance industry²⁹⁸ and some part to hospitals.²⁹⁹ Some, but far less, goes to physicians. And physicians in primary care specialties such as internal medicine, pediatrics, and family medicine earn less than physicians in a set of sub-specialties such as orthopedic surgery, cardiology, and dermatology.³⁰⁰

The top-heavy business model that shapes the healthcare system in the United States precludes the nation from achieving the “triple aim” – the provision of high-quality care and better health at a sustainable

²⁹⁴ *Health Insurance CEO Pay*, *supra* note 287 (quoting Benjamin Day, Director of Organizing at Healthcare-NOW!, described as “a nonprofit group that advocates for a single-payer system”).

²⁹⁵ *Id.* During the same period, hospital executives and administrators have fared similarly well. Elisabeth Rosenthal, *Doctor’s Salaries Are Not the Big Cost*, N.Y. TIMES, May 18, 2014, at SR4. As a group, industry and hospital executives, and even many administrators, have benefitted from compensation packages that are significantly larger than the annual income of many physicians. *Id.*

²⁹⁶ Rosenthal, *supra* note 296.

²⁹⁷ In 2012, profits in the many billions of dollars were claimed by the eleven most financially successful pharmaceutical companies. Thom Hartmann, *11 Major Drug Companies Raked in \$85 Billion Last Year, and Left Many to Die Who Couldn’t Buy Their Pricey Drugs*, ALTERNET (Apr. 30, 2013), available at <http://www.alternet.org/11-major-drug-companies-raked-85-billion-last-year-and-left-many-die-who-couldnt-buy-their-pricey>.

²⁹⁸ See *supra* notes 296–305 and accompanying text.

²⁹⁹ See *supra* note 305 and *infra* note 316 and accompanying text.

³⁰⁰ In 2013, orthopedists earned an average of \$413,000; cardiologists, an average of \$351,000; dermatologists, an average of \$308,000; pediatricians, an average of \$ 181,000; and family doctors, an average of \$176,000. Leslie Kane & Carol Peckham, *Medscape Physician Compensation Report 2014*, MEDSCAPE MULTISPECIALTY (Apr. 15, 2014), available at <http://www.medscape.com/features/slideshow/compensation/2014/public/overview#2>.

cost.³⁰¹ A comparison to other nations frames the high price the United States pays for the slew of mediators at the center of its healthcare system.³⁰² The administrative costs of health care in the United States are much higher per capita than those of other rich countries.³⁰³ In other developed nations, the best hospitals have thinner administrative staffs, and pay a far smaller percent of healthcare costs for administrative support than is the case in the United States.³⁰⁴ Theodore Marmor and colleagues reported in 2009 that other nations work expressly to diminish industry's interest in increasing healthcare costs:

All other rich democracies concentrate purchasing power to counter the medical industry's efforts to increase costs. If, as in Canada and Sweden, overall medical costs are on public budgets, then officials have powerful incentives to restrain increases in medical costs to avoid reducing the funds for other public programs or having to raise taxes. In other countries, such as Germany and France, insurers are nongovernmental entities (sickness funds) that are financed through payroll contributions from employers and employees. The governments of these countries regulate insurers and help them control costs.³⁰⁵

In the United States, between one-fifth and almost one-third of the nation's spending on health care goes to supporting the "business" of medicine – the nation's healthcare industry and hospital executives and administrators.³⁰⁶ Almost none of this improves the quality of care or the population's health, and in the nature of the case, none controls healthcare costs. As Marmor, Oberlander, and White declared in the year before the passage of the Affordable Care Act:

If the United States is to control health care costs, it will have to follow the lead of other industrialized nations and embrace price restraint, spending targets, and insurance regulation. Such credible cost controls are, in the

³⁰¹ Dentzer, *supra* note 13.

³⁰² Rosenthal, *supra* note 296.

³⁰³ Theodore Marmor, Jonathan Oberlander, & Joseph White, *The Obama Administration's Options for Health Care Cost Control: Hope Versus Reality*, 150 ANNALS INTERNAL MED. 485, 487 (2009).

³⁰⁴ Rosenthal, *supra* note 296.

³⁰⁵ Marmor et al., *supra* note 304, at 487.

³⁰⁶ Rosenthal, *supra* note 296. Rosenthal reports that the U.S. insurance industry spent over \$600 per person on the costs of administrative work. That is double the cost of the next highest spender for comparable purposes and almost twice the cost for healthcare administration in many developed nations. *Id.*

language of politics, a tough sell because they threaten the medical industry’s income.³⁰⁷

III. WHAT CAN BE DONE?

It is not the fact of medical necessity determinations that undermines good health outcomes at sustainable prices in the United States. It is the larger healthcare system within which those determinations are rendered. Coverage decisions are essential and must be made on the basis of medical necessity determinations. The notion of medical necessity, in the abstract, is unproblematic. Its concretization, however, can only be as effective at producing good health care at a sustainable cost as the political and economic system within which medical necessity determinations are entertained.

In that regard, efforts at healthcare reform in the United States since the middle of the twentieth century have been wanting. In response to political exigencies, Congress granted the insurance industry a key position in implementing Medicare. That fateful decision has shaped important components of the U.S. healthcare system for the last half century.³⁰⁸ The Affordable Care Act strengthened industry’s role within the nation’s healthcare system.³⁰⁹ Although the Act has placed significant limits on insurers, it leaves the central task of rendering coverage decisions to industry. It also has created a new marketplace for insurance companies to sell their products, and, through the “individual mandate,” it requires most people without coverage to purchase insurance in that marketplace.³¹⁰

William Sage’s assessment in 2003 – that into the foreseeable future, medical necessity determinations would reflect a diverse set of clinical, ideological, economic, and political factors³¹¹ – continues to serve as an accurate assessment of medical necessity determinations today. That assessment, and its implications, are not challenged by the Affordable Care Act.³¹² Passage of the Act has re-aligned components of the U.S. healthcare system, but it has not transformed the basic framework. Medical necessity determinations will continue to be inconsistent, and sometimes hard to justify or unfair. Consequently, the risk survives that medical necessity determinations can be maneuvered by industry to move money to the top rather than distributing it through the provision of health care to the covered population.

³⁰⁷ Marmor et al., *supra* note 304, at 488.

³⁰⁸ *See supra* Section III.B.1.

³⁰⁹ *See supra* notes 254, 259 and accompanying text.

³¹⁰ 26 U.S.C.A. § 5000A(a) (West 2014).

³¹¹ Sage, *supra* note 1, at 604.

³¹² Skinner, *supra* note 259 (noting that under the Affordable Care Act “the legacies of past health care systems remain strong”).

This Part suggests two sets of responses. One assumes that the Affordable Care Act, and the healthcare system that, in large part, it inherited and reinvigorated, will continue to broadly structure the delivery of health care in the United States. The other assumes, more felicitously, that real change is still possible, and that health care in the United States need not support the interests of insurance companies and of the healthcare industry more generally.³¹³ Both responses redesign the mode through which medical necessity determinations are rendered, suggesting that the process must become transparent and access to all determinations and justification for all denials must be easily available to clinicians, patients, and the broader public.

A. Under the Affordable Care Act

The Affordable Care Act mentions medical necessity only briefly, in three places,³¹⁴ and leaves intact the insurance industry's control of these determinations. The Act fails to address the risk this structure creates – a risk that emerged clearly in the 1980s and 1990s – of decisions that serve industry's interests rather than those of population health. As was the case before passage of the Affordable Care Act, a lack of coordination and of transparency at the heart of the system for determining coverage is costly, encourages inconsistency, and does not serve the basic goals of a first-rate healthcare system.³¹⁵

The availability of external review – guaranteed by the Affordable Care Act – is essential, but not sufficient, to protect patients from unfair, inconsistent medical necessity determinations, and it will not help develop a coherent method for making coverage decisions that protect population health.³¹⁶ Most medical necessity appeals focus on the facts of spe-

³¹³ THOMAS PIKETTY, CAPITAL IN THE TWENTY-FIRST CENTURY 92 (Arthur Goldhammer trans., Belknap Press 2014) (2013) (“[I]f a private health insurance system costs more than a public system but does not yield truly superior quality (as a comparison of the United States with Europe suggests) then GDP will be artificially overvalued in countries that rely mainly on private insurance.”). Although analysis of the pharmaceutical industry's role is beyond the scope of this article, it is essential to begin seriously to limit the profits of the pharmaceutical industry. The industry is responsible for a larger movement of resources than is the insurance industry; in the decade ending in 2012, the eleven largest drug companies made \$711 billion in profits. Ethan Rome, *Big Pharma Pockets \$711 Billion in Profits by Robbing Seniors, Taxpayers*, HUFF POST POLITICS BLOG (Apr. 8, 2013, 8:00 AM), http://www.huffingtonpost.com/ethan-rome/big-pharma-pockets-711-bi_b_3034525.html.

³¹⁴ Affordable Care Act, *supra* note 26, §§ 2707, 520K, and 9007; *see also* Skinner, *supra* note 259, at S50.

³¹⁵ Dentzer, *supra* note 13.

³¹⁶ FURROW ET AL., *supra* note 190, at 743 (citing the Affordable Care Act, *supra* note 26, § 2719).

cific cases rather than broad legal concepts.³¹⁷ Sara Rosenbaum has distinguished medical necessity determinations resulting from categorical exclusions and those embedded in interpretations of particular stories. “Appealable cases,” she explained, “rest on factual questions to be resolved by a decision maker.”³¹⁸

More important still, transparency must be built into the process of reaching medical necessity determinations, and access to those determinations must be afforded to clinicians, patients, and the public.³¹⁹ Particularly, in light of the central role that the insurance industry continues to play under the Affordable Care Act, it is more important than ever that insurance companies’ medical necessity determinations are consistent and that the factors driving the decisions are open to public purview. Were the entire process to become transparent, with a report of determinations and justifications for them – especially for denials – made readily available, the risks of inconsistency, unfairness, and abuse could be controlled.

Further, physicians’ medical decisions for their patients, assuming they do not contravene the terms of a patient’s plan, should only rarely be denied by payers. Claim disputes should be restricted to situations of apparent fraud or incompetence. An efficient mode of communication between treating physicians and payers must be developed to facilitate such an approach to claim denials.³²⁰ A cogent system for electronically reporting health information might provide a mode for easy communication between the two groups. Comparative effectiveness research can provide guidelines for reasonable medical necessity determinations.³²¹ However, such standards should be taken to inform, not control, physicians’ medical decisions for patients. And the focus of the standards must be “clinical effectiveness” at least as much as “cost effectiveness.”³²²

B. *New Possibilities for Healthcare Reform in the United States*

In the first decade of this century, far-reaching reform of the nation’s healthcare system was stymied by a combination of public preferences

³¹⁷ See Skinner, *supra* note 259, at 8; See Sara Rosenbaum, *Appendix D: The Americans with Disabilities Act in a Health Care Context*, in *THE FUTURE OF DISABILITY IN AMERICA* 426 app. D at 442 (Marilyn J. Field & Alan M. Jette eds., 2007), available at <http://www.ncbi.nlm.nih.gov/books/NBK11429/>.

³¹⁸ Rosenbaum, *supra* note 318, at 442.

³¹⁹ See Skinner, *supra* note 259, at 9.

³²⁰ Singer & Bergthold, *supra* note 4, at 203–04 (noting that medical directors of California health plans claimed that physicians often did not respond to calls); Rosenbaum et al., *supra* note 254 (noting that physicians often find it difficult to contact payers to discuss coverage questions).

³²¹ Paul H. Keckley & Barbara B. Frink, *Comparative Effectiveness: A Strategic Perspective on What It Is and What It May Mean for the United States*, 3 J. HEALTH & LIFE SCI. L. 53 (2009).

³²² *Id.* at n.43.

(among a significant part of the nation's population) and industry lobbying.³²³ As a result, the Affordable Care Act, passed in 2010, has largely institutionalized existing methods of delivering and paying for health care.³²⁴

Taking that route also meant that the nation failed to take advantage of models developed elsewhere that have produced more robust healthcare systems than currently exists in the United States. Some nations, such as Sweden and Canada, control costs by incorporating health care into the national budget.³²⁵ Others, such as Germany, have combined private and public segments to create the nation's healthcare system,³²⁶ yet enjoy lower costs and better health than does the United States.³²⁷

Essential to the success of many other nation's healthcare systems has been open communication and robust, but respectful, debate among the stakeholders. For instance, in Germany, healthcare prices are negotiated among hospitals, physicians, and sickness funds. One outcome is that standard fees are set.³²⁸ In Germany, where healthcare costs are lower than in the United States,³²⁹ and the population is healthier, standard fees apply to hospitals and to other forms of health care intervention.³³⁰ National standards and open negotiation among stakeholders about coverage and costs would advance the United States along the road toward achieving the triple aim of higher quality health care, better health, and lower costs.³³¹

³²³ A more upsetting scenario still was suggested by Rick Ungar who reported that the health insurance lobby agreed to a deal with the Obama administration even as it "funnel[ed] huge amounts money [sic] . . . to be spent on advertising designed to convince the public that the legislation should be defeated." Rick Ungar, *Busted! Health Insurers Secretly Spent Huge to Defeat Health Care Reform While Pretending to Support Obamacare*, FORBES (June 25, 2012, 8:37 PM), <http://www.forbes.com/sites/rickungar/2012/06/25/busted-health-insurers-secretly-spent-huge-to-defeat-health-care-reform-while-pretending-to-support-obamacare/>.

³²⁴ See *supra* notes 264, 297 and accompanying text.

³²⁵ David Pratt, *Health Care Reform: Will It Succeed?*, 21 ALB. L.J. SCI. & TECH 493, 581 (2011).

³²⁶ Jeffrey W. Stempel, *Adam, Martin and John: Iconography, Infrastructure, and America's Pathological Inconsistency About Medical Insurance*, 14 CONN. INS. L.J. 229, 304 (2008).

³²⁷ Marmor et al., *supra* note 304, at 487.

³²⁸ Pratt, *supra* note 326, at 581–82; Michael Nelson, *Achtung! After 125 Years of Success, The German Health Care System is in Code Blue*, 44 INT'L LAW. 1045, 1050 (2010) (citing Richard Knox, *Keeping German Doctors on a Budget Lowers Costs*, NPR: HEALTH CARE INNOVATIONS (July 2, 2008, 12:05 PM), <http://www.npr.org/templates/story/story.php?storyID=91931036>).

³²⁹ Marmor et al., *supra* note 304, at 487.

³³⁰ Pratt, *supra* note 326, at 582.

³³¹ Dentzer, *supra* note 13.

More specifically, many nations that offer universal health care, at a sustainable cost, provide for the active participation of clinicians in designing and implementing the process through which coverage decisions are made. Several look, in particular, to senior, respected healthcare officials to render guidance on coverage determinations.³³² In Canada, where health care is universal and coverage is comprehensive,³³³ part of the success of the healthcare system can be attributed to the centrality of the medical profession in the operation of the healthcare structure.³³⁴

The Israeli healthcare system costs far less per capita than that of the United States and provides high quality care. Israeli law guarantees “universal health insurance coverage”³³⁵ to every resident of the nation (citizen and non-citizen).³³⁶ The government provides a “basket” of services that are paid for by premiums and taxes.³³⁷ A government committee – the so-called “Healthcare Basket Committee” is charged with determining which medical services are provided.³³⁸ In the early years, the Committee faced a variety of stumbling blocks, including dissatisfaction from the public. But over time, the Committee’s work has gained respect. A key to the comparative success of the approach is that Committee members – drawn from the ministry of health, the nation’s medical association, the budget division of the treasury, and the public – work by consensus.³³⁹ Furthermore, serving on the Committee is viewed as a

³³² Carolyn Hughes Tuohy, *Principles and Power in the Health Care Arena: Reflections on the Canadian Experience*, 4 HEALTH MATRIX 205, 208, 222, 224 (1994); see also Guy I. Seidman, *Is a Flat-Line a Good Thing?: On the Privatization of Israel’s Healthcare System*, 36 AM. J.L. & MED. 452, 454 (2010).

³³³ Tuohy, *supra* note 333, at 208.

³³⁴ Tuohy, *supra* note 333, at 208, 223–224. Dr. Steffie Woolhandler and colleagues reported about a decade ago that at the turn of the twenty-first century, the United States spent \$1,059 per capita for the administration of healthcare. In the same year, Canada spent \$307 per capita in healthcare administrative costs. Steffie Woolhandler, Terry Campbell, & David U. Himmelstein, *Costs of Health Care Administration in the United States and Canada*, 349 NEW ENG. J. MED. 768, 771 (2003).

³³⁵ Seidman, *supra* note 333; Guy I. Seidman, *Regulating Life and Death: The Case of Israel’s “Health Basket” Committee*, 23 J. CONTEMP. HEALTH L. & POL’Y 9, 21 (2006) (citing Press Release, Isr. Cent. Bureau of Statistics, Continuing Decrease in the Share of the Nat’l Expenditure on Health Our Gross Domestic Product 6 (Aug. 28, 2006)). There are some gaps in national healthcare coverage. For instance, dental care is not covered and must, therefore, be paid for privately. Seidman, *supra* note 333, at 460.

³³⁶ The National Health Insurance Act (1994) and the Patients’ Rights Act (1996) govern the Israeli healthcare system. These laws are described in Seidman, *supra* note 336, at 19–21.

³³⁷ Seidman, *supra* note 336, at 20.

³³⁸ *Id.* at 16.

³³⁹ *Id.* at 25.

“public service” but not as an enviable task.³⁴⁰ This seems to be one factor that ensures the system’s success³⁴¹: those who determine which medical interventions are covered do so for the sake of the public good, not for personal benefit or the benefit of commercial interests.

Each of these nations – Germany, Canada, and Israel – as well as many others, has forged an approach to coverage decisions that is transparent and that depends on negotiation, compromise, and the active participation of physician groups in determining the scope of healthcare coverage. None of these countries gives the sort of sweeping power to private industry to make decisions that determine the reach of healthcare coverage that the United States gives. These nations all pay significantly less per capita for health care than does the United States, and each enjoys better health outcomes than does the United States.³⁴²

CONCLUSION

In designing the Medicare program, Congress empowered the health insurance industry with far-reaching responsibility for, and control over, an essential component of the nation’s healthcare system. The legislation creating the program allowed the industry to make basic decisions about healthcare coverage and thus, in effect, about the provision of health care for Medicare participants. The result, over time, has been to place almost all of the nation’s medical necessity determinations in industry’s hands. That power is, in effect, the power to design the scope of healthcare coverage. Even more, in the half century since Medicare’s passage, Congress has several times strengthened industry’s hand. At least for a time, ERISA’s protection for self-funded healthcare plans seemed to place those plans’ medical necessity determinations virtually outside the reach of court review.³⁴³ Most recently, the Affordable Care Act, itself shaped in significant part by the health insurance industry’s effective lobby, de-

³⁴⁰ *Id.* at 29.

³⁴¹ *Id.*

³⁴² See Lenny Bernstein, *Once Again, U.S. Has Most Expensive, Least Effective Health Care System in Survey*, WASH. POST (June 16, 2014), <http://www.washingtonpost.com/news/to-your-health/wp/2014/06/16/once-again-u-s-has-most-expensive-least-effective-health-care-system-in-survey/> (describing Commonwealth Fund report finding that health care in the United States costs significantly more per capita with poorer results than in other countries); Nathan Guttman & Nathan Jeffay, *Israel’s Health Care Outpaces U.S.*, FORWARD (June 28, 2012), <http://forward.com/articles/158550/israels-health-care-outpaces-us/?p=all> (reporting that Israel enjoys universal health care coverage at a cost equal to 8 percent of its GDP, compared to 17.4 percent in the United States, and on a number of measures has better health outcomes than the United States).

³⁴³ ERISA preempted state law. ERISA did not include relevant federal laws, and no relevant federal common law existed. SARA ROSENBAUM ET AL., *LAW AND THE AMERICAN HEALTH CARE SYSTEM* 209–10 (2d ed. 2012).

signed the state exchanges as a marketplace for insurance companies.³⁴⁴ Each of these provisions granted the insurance industry, sometimes perhaps unwittingly, remarkable control over healthcare coverage decisions. The power to wield the tool that determines who gets health care for which interventions is basic to the success or failure of health care in the United States.

The Affordable Care Act has largely been implemented,³⁴⁵ and is not soon likely to be significantly amended so as to limit industry’s control. This stymies the possibility for far-reaching reform that might appropriate, and build on, the successful healthcare-payment and delivery models in effect in other nations. Several of those, if implemented in the United States, would very likely improve care while controlling costs.

Less sweeping changes are, however, possible and should be made. Most important, the process through which medical necessity determinations are entertained must become transparent. A database that is easy to access, and easy to interpret, should be developed.³⁴⁶ Simply posting all claim determinations online is inadequate. The database should contain information about each medical claim, the reviewers’ response to each claim, and the justification for all denials. Each piece of information must be easily identifiable. Medicare’s coverage database provides a start – at least for that program’s claims.³⁴⁷ But it is difficult to use the database to understand which claims are likely to be denied and what justifies categories of denials; it only provides information about national determinations; and it applies only to Medicare claims. Broad access to a national database that can be easily searched and that extends beyond Medicare claims is needed. If the information were presented in a manner that would allow patients and providers to understand the scope of and justification for claim denials, the database would significantly further fairness and consistency in medical necessity determinations.

In sum, medical necessity determinations have shaped the nation’s healthcare system for many decades. Yet, the process through which these determinations are reached has remained largely hidden from public view. That has facilitated determinations that further private economic gain and partisan ideological ends rather than the health of individual patients and the population more broadly. Increased transparency and access to information about the processes through which such determina-

³⁴⁴ John N. Maher, *The Corporate Profit Motive & Questionable Public Relations Practices During the Lead-Up to the Affordable Care Act*, 25 J.L. & HEALTH 1 (2012); *Health Care ‘Down Payments,’* ST. LOUIS POST-DISPATCH, Jan. 18, 2009, at A8 (noting Obama’s awareness of “power of the insurance lobby” as he considered healthcare reform in 2009).

³⁴⁵ FOSTER, *supra* note 162.

³⁴⁶ Medicare’s existing database is hard for providers to use. And, of course, it applies only to Medicare determinations. See *How to Use the Medicare Coverage Database*, *supra* note 122.

³⁴⁷ *Id.*

tions are reached is necessary to stop the flow of resources to commercial interests³⁴⁸ and thus to provide adequately for the health of the nation's population.

³⁴⁸ These interests include those of the insurance industry, and even more, those of the pharmaceutical industry. *See Rome, supra* note 314.