

Accountability for Reasonable Limits to Care

CAN WE MEET THE CHALLENGES?



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All health systems, whether public or private or rich or poor, limit access to medical care. Occasionally, this limit setting takes the form of a public melodrama focused on the “heartless” denial by an “evil” insurer or bureaucrat of a “last-chance” treatment for a dying patient. Such drama leaves little room for the limit setter to claim moral authority. For example, when Medicaid denied coverage for a bone marrow transplant to young Coby Howard in Oregon, the script of the public drama barely mentioned the fact that he was not in remission from his leukemia and therefore was not even eligible for a transplant.

The backlash against this case propelled the state to evaluate its Medicaid coverage through a process that attracted international attention. Yet most lightning-rod cases yield no such positive, if unintended, side effects. In *Fox v. Health Net* (Sup. Ct. 219692 [1993]), for example, a California jury decided that a private insurer’s initial denial of an unproven bone marrow transplant contributed to the patient’s death. The resulting \$89 million judgment, combined with lobbying by interest groups, helped make bone marrow transplant the standard of care for advanced breast cancer—delaying discovery that such treatment was ineffective.

Public melodramas generally mislead people about efforts to set limits on health care, for most such efforts do not involve last-chance rescues. Avoiding these dramas—and viewing extreme situations more critically and dispassionately—requires that we learn how to set limits fairly and well in more typical settings.

Consider a case that entailed more established treatments and no life-saving rescue. When Massachusetts Medicaid recently faced cuts owing to steep declines in state revenue, the high cost of psychiatric drugs became a target (Sabin and Daniels 2003a). The agency established a process through which key stakeholders would develop a cost-reducing coverage policy acceptable to psychiatrists and patient advocates. Despite opposition by the American Psychiatric Association (APA) to limits on drug coverage, including requirements that providers obtain prior approval, the decision-making process secured acceptance of the plan among local psychiatrists and patient advocates.

Kaiser Permanente, the giant nonprofit, California-based HMO, also won general acceptance for a generics-first policy for prescribing antidepressants, this time after a careful internal review process (Sabin and Daniels 2003b). In contrast, when the Michigan legislature targeted Medicaid drug coverage for cost savings in 2001, a panel developed a preferred-drug list replete with forty-four categories requiring prior approval. The panel did not consult important stakeholders or conduct follow-up outreach efforts (Bernasek et al. 2003). This limit-setting process provoked considerable resistance and even litigation from patients and providers.

In another case in the mid-1990s, the Centers for Medicare and Medicaid Services (CMS) faced extreme pressure to approve coverage for lung volume reduction surgery for advanced cases of emphysema, even while private providers were making contradictory decisions on whether to cover the procedure. Medicare successfully delayed a decision until the National Emphysema Treatment Trial—a randomized clinical trial—produced clearer evidence on the procedure’s effectiveness. CMS recently decided to cover the procedure only for limited groups of patients in controlled settings.

Why do some attempts to set limits on health care coverage win legitimacy and moral authority, while others convince patients and clinicians that their interests are taking a back seat to cost-cutting efforts? As I recount below, these cases support a model for ensuring accountability and fair decision making in health care coverage while also revealing unresolved policy challenges.

Legitimacy and Fairness Problems

Limit setting creates winners and losers, and thus conflict. These outcomes reflect not only competing interests but also the fact that reasonable people often disagree on how to weigh competing values. Should we refrain from giving a dying child or a woman with cancer a last chance with an unproven therapy because of concern about scarce resources? How much weight should limit setters give to reducing drug costs versus allowing individual patients to escape policies that might force them to accept less-than-optimal drugs? In the Medicare decision regarding lung volume reduction surgery, should decision makers approve only carefully selected patients and providers for an unproven therapy?

Fundamental issues regarding human well-being force decision makers to wear a mantle of moral authority. Under what conditions do those affected by the decisions appropriately grant that moral authority? I refer to this as the legitimacy problem (Daniels and Sabin 1997, 2002).

Legitimacy might be less important if the fairness problem had a straightforward, principled solution that was clear to all. Unfortunately, no such consensus exists. Instead, as the examples suggest, controversy over unproven technologies reflects the competing values of human compassion versus stewardship of scarce resources. There is similar controversy about the fair distribution of burdens and benefits in the drug management cases. Society also lacks consensus on how much priority to give the sickest patients, and on whether modest benefits for large numbers of people should outweigh significant benefits for a few.

In the absence of consensus on such principles, we must develop a decision-making process whose outcomes all who participate in the process and are affected by it will accept as just. The process must eliminate obvious sources of bias and conflict of interest and recognize the values and interests of different stakeholders. This is a classic appeal to procedural justice, wherein a fair process yields a just outcome in the absence of prior agreement on criteria and principles (Rawls 1971).

Some market advocates would claim that my appeal for procedural justice is unnecessary, as consumers can set limits by choosing different health plans. What could better legitimize limits than people's choices? Choice brings consent, and consent brings legitimacy.

Both theoretical and practical problems undercut this appeal to market accountability, however, even if we were to rely entirely on private insurance. Uncertainty about people's needs, the performance of health care plans, and the effectiveness of treatments make the purchase of medical services very different from the purchase of computers or cars. What's more, half of all workers with insurance have no choice of plans, and those who do have choices usually do not understand the limits that affect them until they have medical problems, at which point switching plans is difficult or impossible. Thus, I propose a process—accountability for reasonableness—for resolving disputes over scarce health care resources.

Accountability for Reasonableness

Four general conditions can ensure accountability for reasonableness. If met, they should lead health plan enrollees, patients, and the public to respect the fairness and legitimacy of decisions by managed care organizations and public officials regarding coverage of new technologies and treatments:

Publicity: Decisions and their underlying rationales must be publicly accessible.

Relevance: These rationales must rest on evidence, reasons, and principles that plan managers, clinicians, patients, and consumers agree are pertinent to deciding how to meet diverse needs under resource restraints.

Revisability and appeals: A mechanism must allow challenges to limit-setting decisions, help resolve those challenges, and allow revisions in light of further evidence and arguments.

Enforcement: A voluntary or public regulatory process must ensure that decision makers fulfill the first three conditions.

These four conditions can convert behind-the-scenes deliberations by public agencies and private health plans into a public—and ultimately democratic—deliberation concerning how limited resources might best be used to maintain the health of populations with diverse service needs. A culture of openness would also facilitate learning among clinicians and enrollees about the need for limits on health care coverage. Many people claim that the litigious public will accept no limits;

changing that culture requires a concerted educational effort both outside and inside the institutions that deliver and finance care. Education begins with openness about the reasons for decisions by public and private health providers and insurers. Over time, this process can spur broader deliberation by a public better educated to think about how to share medical resources fairly and its elected officials.

Though some, and perhaps many, health plans proceed carefully and thoughtfully when deciding which procedures to cover, private plans generally fail to make their rationales public. Rationales would make it crystal clear to patients and clinicians alike why the plan's cost and quality controls lead to its criteria for coverage. A public record of a plan's decisions, like case law in legal judgments, provides a basis for judging their coherence and consistency. Such a record enables those affected by those decisions, who often have no real ability to seek alternatives, to understand why they face the restrictions they do. The publicity condition thus satisfies a fundamental requirement of justice.

Participants in a health plan—patients, their clinicians, and plan managers—pursue a common goal: they aim to meet their diverse needs under resource constraints on terms they can justify to each other. Since hard decisions must be made about how to meet those needs fairly, the grounds that decisions are based on must be ones that fair-minded people can agree are relevant. (Being fair-minded means being willing to play by rules of the game they accept and can justify to each other.) The relevance condition imposes constraints on the rationales supporting coverage decisions, thus narrowing the range of disagreement. Involving diverse stakeholders is one way to secure greater agreement.

The relevance condition does not mean that all parties will agree with specific decisions; parties may agree on which reasons are relevant but still weight them differently. As long as fair-minded parties who make the decision and are affected by it can accept that the grounds are relevant, however, even those who do not agree cannot complain that it is unreasonable. Desperate parents and spouses who demand last-chance treatments for loved ones may not behave as fair-minded people interested in mutually justifiable rationales, but a public with experience in limit setting may resist unreasonable demands (Edgar 2000).

Fair-minded people will accept many kinds of evidence and reasons as relevant to decisions regarding health care coverage. These can include scientific evidence on a treatment's effectiveness and safety and even information on its cost-effectiveness, especially when a less-costly approach delivers equal or superior benefits. Controversy occurs when decision makers must sacrifice achievable benefits for some people in favor of greater overall cost-effectiveness. The situation becomes even more controversial when the cost-effectiveness comparison weighs treatments for patients with different conditions. Decision makers must carefully explicate their choices in these cases.

Except for some decisions concerning drug coverage, health plans do not seem to evaluate treatments as competitors within an overall budget for new technologies. If such comparative budget-driven judgments do become common, decision makers will have to pay even more attention to distributive fairness.

Because accountability for reasonableness is intended to apply in various

public and private settings, consumer participation itself is not essential to fairness. Yet such participation, when properly supported, enhances legitimacy. Because such a process does not select consumer participants democratically, they do not make it more democratic, nor do they act as proxy consenters on behalf of other consumers. Rather, consumer participation reassures stakeholders that decision makers are addressing their arguments, broadens stakeholders' perspectives on which rationales are relevant, and ensures transparency.

Coverage decisions often rest on specific evidence about efficacy and cost. Because such evidence can change over time, and because decisions that apply to most patients with a condition may not apply to all, plans must make provision for revising decisions when new evidence emerges or when patients or doctors feel they should be exceptions to coverage rules. Enforcement of the publicity, relevance, and revisability conditions might be achieved by building them into accreditation requirements for health plans, or this may require some legislative mandates, as in the case of state laws regarding independent review of coverage decisions.

Accountability for Reasonableness in Practice

An ideal test of the effectiveness of accountability for reasonableness in solving the legitimacy problem would compare situations that implemented its central tenets and those that did not. Such an evaluation would measure outcomes such as stakeholder perceptions of legitimacy (represented by fewer appeals and complaints), consistency and coherence of decisions, and equitable access to services. This ideal test is not yet feasible, however, as no significant part of the U.S. health care system has explicitly adopted such an approach, and serious obstacles often prevent decision makers from pursuing it. Still, if we examine the narratives cited above in closer detail, we can find explicit use of such principles as well as situations where skilled managers implement those ideas on their own.

Weighing Pharmacy Benefits

In the late 1990s, James Sabin and I worked with executives at Merck-Medco (now Medco Health Solutions), one of the nation's two largest for-profit companies managing pharmacy benefits, to analyze limit setting in a broad range of designs for pharmacy benefits. These executives wanted to make the ethical rationales underlying their decisions available to practitioners, pharmacists, and patients. Consulting with Medco's clients, including large purchasers of pharmacy benefits, clinical managers, pharmacists, and marketing personnel, we developed an "ethical template" for many different pharmacy benefits (Daniels, Teagarden, and Sabin 2003).

This template maps the decisions entailed in designing such benefits onto types of ethical rationales appropriate for each. These decisions include which drug categories a plan will cover, which drugs each category will include, which symptoms each drug can address, and what limitations the plan will impose on the use of a drug. We found that officials based the first two decisions largely on need,

while cost considerations drove decisions on the latter two criteria. The ethical rationale for covering certain drugs, for example, weighs the overall cost advantage of using a cheaper drug against the need to protect patients for whom the cheaper drug does not work.

Our work with one major Medco client, a private health plan, aims to translate the template into a Web site tool that explains the reasons for coverage limits to clinicians, pharmacists, and patients. Many decision makers remain skeptical of using such a template. Health plans often fear that transparency will open them to accusations that they are “the first rationer in town” or to litigation if they are explicit about their decision-making process. Other decision makers are simply not persuaded that such an approach adds value, even if it seems ethically justified (“business is business”).

Two policy challenges are clear. Though strong support for ethically defensible decision making sometimes emerges even in for-profit firms, overcoming skepticism requires showing that transparency yields payoffs, such as fewer patient complaints and lower turnover, or a better market image. And producing such evidence requires research on natural experiments in accountability for reasonableness as they arise. (The Canadian Priority Setting Research Network recently sponsored a workshop to develop a research agenda to measure the value of such an approach.) Overcoming these fears may require regulatory rules that put all players on the same playing field, removing the risks of early experiments. One model for such rules is the independent review processes that forty-two states now mandate.

Return now to the examples of Medicaid drug limits in Michigan and Massachusetts. To avoid the problems encountered in Michigan, Massachusetts decision makers explicitly involved all key stakeholders in the limit-setting process and aimed at transparency. Stakeholders included organized psychiatry (through the Massachusetts Psychiatric Society, MPS) as well as consumer and family groups. These groups nominated psychiatrists to participate in a Psychopharmacology Work Group; consumers chose James Sabin, my collaborator and a psychiatrist, as their representative. He provided information on the accountability-for-reasonableness approach to work group members.

To fulfill two criteria of that approach—transparency and flexibility—the state agency responsible for Medicaid mental health circulated the work group’s proposals for wider review and revised them to address stakeholder criticisms. The result was a set of policies—reinforced through an educational campaign by the MPS—designed to prevent providers from prescribing more than one selective serotonin reuptake inhibitor (SSRI), and five or more psychiatric medications, at a time. This policy curbed expensive and risky co-prescriptions.

Then, as the budget crisis in Massachusetts intensified, the Division of Medical Assistance, which administers the state’s Medicaid program, decided to develop a list of preferred drugs. This approach directly conflicted with the APA’s policy of exempting psychiatric medications from such lists and from requirements that providers obtain prior approval for prescriptions. The Psychopharmacology Work Group carefully evaluated the rationale for the national APA policy and weighed

it against the reality of state budget cuts. Local psychiatrists, many of whom wanted to ensure the widest-possible access to psychiatric drugs given budgetary limits, supported this approach.

In the end, the work group recommended generic fluoxetine as the SSRI for an initial prescription. This decision required careful education of providers throughout the state as to its underlying evidence and rationale. The policy also required reassuring consumer and family groups that people already successfully treated with other antidepressants could easily win exemptions from the policy. Decision makers further added a drug to the list whose slow release diminished the risk of seizures for some patients. Stakeholders initiated some of these consumer protections, while the template spurred the Psychopharmacology Work Group to consider others. Key elements of accountability for reasonableness—transparency, careful deliberation with stakeholder involvement, and revision in light of appeals—may well explain why the Massachusetts approach worked without conflict while Michigan's did not.

This evidence concerning the effectiveness of accountability for reasonableness suggests its potential as best practice. Solidifying and refining this approach requires meeting two policy challenges. The first is to carefully study such natural experiments to determine differences in the value they add. The second is to establish incentives and rewards for individuals and organizations that grab the limit-setting bull by its horns. For example, the state Department of Mental Health's Executive Office of Health and Human Services gave the MPS a Clinical Excellence Distinguished Service Award for its leadership in enlisting local psychiatrists to participate in the Massachusetts decision-making process.

Kaiser Permanente, which serves over 8 million members nationally, including 6 million in California, also instituted a generic fluoxetine-first policy. Its pharmacy policy board based its decision on a controlled study comparing the effectiveness of various SSRIs and on an internal survey of physicians' prescribing patterns that showed that patients switch equally among all SSRIs. Whereas Massachusetts had to secure clinician buy-in to a new policy by soliciting stakeholder involvement, Kaiser had already established such a mechanism: the organization monitors clinicians' prescribing patterns, and clinicians meet to debate the merits of different approaches.

The ethical template requires an easy exception for patients whose conditions do not justify use of a cheaper drug first. In Kaiser's case, all physicians retain the authority—without prior authorization (a sticking point for the APA)—to override drug restrictions whenever they feel that is medically necessary for individual patients. Because of the organization's careful education regarding its rationales for recommended practice, variations in prescribing patterns are not widespread. This kind of peer management embodies central elements of accountability for reasonableness: transparency, deliberation of rationales, and openness to revision. This approach also allows a health plan to emphasize cost-effectiveness while protecting individual patients. These two examples show how a large insurer and a state Medicaid program relied on key elements of accountability for reasonableness to arrive at similar outcomes.

Kaiser's best practice also serves as a policy challenge. Although organizations like Kaiser have a long-standing culture that encourages cost-effective practice, loosely structured physician practice organizations (PPOs) and independent practice organizations (IPOs) lack this culture. Nevertheless, such provider groups can benefit from accountability for reasonableness, at least if they operate on a level playing field.

Moving such highly decentralized health organizations in the right direction will require quantified evidence of success. States that rely on key aspects of accountability for reasonableness to produce cost-effective pharmacy benefits can provide such evidence, especially if they win broad public support for fair limits on coverage. Alternatively, such evidence may encourage regulators to compel the private sector to move toward a more cost-effective approach based on accountability for reasonableness. To propel thinking in that direction, the federal Agency for Healthcare Research and Quality sponsored a conference for senior state policymakers on how to structure cost-effective state pharmacy benefit programs. The conference featured discussions of the ethical template, limit setting for psychiatric drugs, and a case study of the activities of the Massachusetts Medicaid program.

Independent Review: The Underdeveloped Potential of Regulation

Amid growing consumer distrust of managed care organizations, in 1998 California passed the Friedman-Knowles Experimental Therapy Act, which established the first mandatory independent review of decisions by HMOs to deny coverage for care. Some forty-two states have since established such review processes. These reviews overcome the deep conflict of interest entailed when health plans rely on experts who work for them to analyze denial of coverage. The movement toward independent reviews—clearly an idea whose time had come—codifies the appeals-and-revisions condition that underpins accountability for reasonableness.

Michigan has taken the bold step of posting the denial decisions it reverses on a Web site, providing one model of transparency. Advocates overcame resistance to such public posting by arguing that it would provide a body of unofficial case law, even if it lacked legal authority. California also posts brief summaries of its case reviews online.

State-level review of health plan decisions does put all players on a common playing field and reduces barriers to transparency and revisability. Existing legislation falls short, however, of providing incentives for converting the rich body of case evidence into an effective tool for improving health care quality. For example, although Michigan posts its redacted cases, it has no mechanism for encouraging the challenged organizations to change their decision-making policies. Nor does any research mechanism examine the cases and patterns underlying overturned denials and propose the steps insurers might take to modify their practices. Existing regulation of independent review activities could be refined to require health care organizations to systematically analyze the reasons the state reverses their coverage decisions. The resulting information could become the basis for improving quality, offsetting some of the costs of such review and evaluation.

Medicare Coverage Decisions

I noted earlier that the Centers for Medicare and Medicaid Services delayed—courageously, I believe—a decision on whether to cover lung volume reduction surgery until the National Emphysema Treatment Trial (NETT) could provide better evidence on the procedure’s safety and effectiveness. To see why that delay took courage, we must look beyond the intense pressure on Medicare to the private sector, where insurers were also considering whether to cover the procedure. In a case study completed just as NETT began, James Sabin and I found that Northern California Kaiser Permanente decided to cover the procedure at “centers of excellence,” while Health Partners in Minnesota, also a nonprofit plan, decided not to provide coverage. PacifiCare and Aetna, two for-profit plans, also reached opposing decisions on coverage (Daniels and Sabin 2002).

These contrasting conclusions did not reflect differing assessments of the technology or understanding of evidence-based practice. Rather, the decisions reflected member demand for the procedure, the presence of strong internal champions, and local practice patterns and beliefs. The decisions also reflected the degree to which the organizations felt confident of their ability to implement eligibility criteria and coverage limits for the procedure, and the weight they gave to values such as stewardship of scarce resources and rescue of desperate patients.

Such conflicting pressures affect both the private and public sector, so understanding how CMS persuaded stakeholders to wait for better evidence is important. With input from the Agency for Healthcare Research and Quality, CMS established a broad partnership backing NETT, including the National Heart, Lung, and Blood Institute. The authority and prestige of these institutions, and the resulting buy-in from many clinicians, enabled the organization to withstand pressure to provide immediate coverage of the procedure.

Also crucial to managing the social tension was creating public awareness that the decision hinged not only on rising costs but also on the need for better evidence concerning which patients would benefit. In the absence of better evidence, clinicians would be unable to secure proper consent for the procedure’s benefits and risks. Thus, CMS took important steps to create transparency around reasons stakeholders can see as relevant—two key conditions entailed in accountability for reasonableness. Meeting these conditions helped avoid the rush to coverage that occurred with bone marrow transplants for advanced breast cancer.

Moving from the results of a trial like NETT to a coverage decision by both public and private plans still requires accountability for reasonableness. Unfortunately, CMS’s actual coverage decision lacks some elements of that accountability, though the failing may reflect the organization’s legislative charge more than its process.

After public input from its Medicare Coverage Advisory Commission, CMS decided to cover the procedure for several subgroups of patients despite strong warnings that evidence of benefits for those subgroups lacked statistical significance (Ware 2003). By itself, the decision may have been a case where reason-

able people disagreed about how much caution to impose in the face of results showing measurable benefit for some subgroups.

Study results also showed that the procedure was not terribly cost-effective, however (NETT Research Group 2003). Unfortunately, the legislative charge to CMS gave decision makers little room to consider the opportunity costs of covering a potentially very expensive treatment with very modest benefits. No one explicitly asked, if Medicare funds this technology, what other new procedures or services can it not afford, and which are more important? The agency would have to make such tradeoffs explicit if it had to consider novel treatments within a budget for new coverage. And given budget neutrality pressures, still larger questions would loom if adding new benefits meant that services already covered by Medicare would have to be limited further.

The possibility that further delay was not politically feasible, and that attempts to meet urgent needs took precedence over caution concerning treatments not fully proven, suggests that Medicare may find it difficult to hold the line on coverage limits. Pressure from enthusiastic clinicians and desperate patients may lead to coverage “creep.” Such an outcome not only would be costly but might bring harms whose magnitude society is not in a good position to measure. Accountability for reasonableness would require more careful deliberation premised on the convictions that health care resources are limited and that fair and legitimate decisions must evaluate a range of social effects.

Meeting the Accountability-for-Reasonableness Challenge

Efforts to secure accountability for reasonableness in setting limits on health care coverage face three main policy challenges. First, as the discussion of pharmacy benefits shows, resistance to transparency among both public and private health providers and insurers reflects a lack of clear evidence that acting virtuously will yield clear payoffs. Winning support for more transparent decisions will require research on the positive benefits of doing so.

Second, even where regulation has helped improve accountability in decision making, as in the state-level independent review processes, such accountability has not fulfilled its potential for improving quality. Meeting this challenge will require research on reviewed cases and on how incentives and sanctions can encourage health plans to put to good use the information produced by the reviews.

Third, cultural resistance to making hard choices about opportunity costs remains. I see no quick solution to this problem, but public education and broader deliberation can produce change over time. This is a bit of a chicken-and-egg problem: implementing accountability for reasonableness is one mechanism for producing that education, but boosting implementation is difficult without initial education. Perhaps, to switch metaphors, the solution requires “bootstrapping” our way from modest changes in process to modest changes in culture and so on to broader cultural and institutional change.

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