

STATE OF THE ART AND SCIENCE

Are Medicaid Closed Formularies Unethical?

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Abstract

State Medicaid programs have proposed closed formularies to limit spending on drugs. Closed formularies can be justified when they enable spending on other socially valuable aims. However, it is still necessary to justify guidelines informing formulary design, which can be done through a process of decision making that includes the public. This article examines criticisms that Medicaid closed formularies limit deliberation about decisions that affect drug access and unfairly disadvantage poor patients. Although unfairness to poor patients is a risk, it is not a problem unique to Medicaid, since private insurance programs have also implemented closed formularies.

Closed Formularies

As health care costs increase, state Medicaid programs are looking for ways to limit spending. In 2017, both Massachusetts and Arizona submitted waiver requests to the Centers for Medicare and Medicaid Services (CMS) for closed Medicaid formularies that would allow them to select drugs for coverage based on price and effectiveness rather than providing, as is currently required, all drugs covered by the CMS Medicaid Drug Rebate Program, which includes nearly all new US Food and Drug Administration (FDA)-approved drugs.^{1,2,3} Because all government programs must pay for the public goods and services they provide out of finite budgets, access to health care services for Medicaid enrollees must be balanced against other social goals that public resources could support. Massachusetts and Arizona saw closed formularies as one way of achieving this balance, although some drug manufacturers and patient organizations have criticized the Massachusetts policy as unfairly limiting treatment options.³

How can [closed formularies](#) achieve ethical acceptability? We argue in the first section that a minimum ethical requirement for a closed formulary is that savings be put to socially valuable uses. Once that condition is met, 2 ethical issues remain: (1) Which values and procedures inform access choices? (2) Do closed formularies unfairly disadvantage poor patients? In response to the first question, the next section argues that policymakers who propose closed formularies should consider a broader range of social values and discuss procedural approaches for making drug inclusion decisions. In response to the second question, the concluding section argues that even if a Medicaid

closed formulary is less generous than private formularies, it is not necessarily unjust. In sum, rather than rejecting closed formularies outright, we argue that policymakers should apply ethical principles in considering whether and how to implement closed formularies.

Social Values and the Ethics of Saying No

A closed formulary enables a payer to say no to some pharmaceuticals. Specifically, the payer has the power to say no both to pharmaceutical firms selling a given drug and to patients who would like that drug. Saying no can enable savings both directly and indirectly. Directly, it can reduce or eliminate spending on costly drugs whose benefits either do not exceed those of cheaper alternatives or do not justify their costs. Indirectly, it can enable payers to negotiate more effectively with pharmaceutical firms by allowing payers to credibly threaten to refuse to pay high prices.³

Both saying no to firms and saying no to patients present ethical issues. But saying no to firms presents ethical issues only indirectly—saying no to a drug signals that firms should lower prices (in the short term) or refocus their research and development efforts on other drugs or drug classes (in the longer term). In contrast, saying no to patients directly presents ethical issues, because doing so—depending on what other options are available—can limit patients' treatment options and potentially the quality and length of their lives. Norman Daniels has famously argued that the structure of the United States health care system makes saying no difficult to justify, because the savings from saying no to some patients could end up serving socially unproductive purposes.⁴

The first step in justifying a closed formulary, therefore, is to explain how the savings from the closed formulary will be used. The more socially valuable the purpose, the easier a closed formulary is to justify. What it means for a purpose to be socially valuable is, of course, debatable. Many things other than health care—early childhood education or even direct cash transfers—can promote health,⁵ and, in any event, social value encompasses more than health promotion. Similarly, social value encompasses more than the interests of current beneficiaries. Social programs like Medicaid are justified by their contribution to the common good and are not the private property of current beneficiaries. Although current beneficiaries should not be given veto power over formulary restructuring, decisions about formulary design should include their perspectives, as we argue next.

Deliberative Procedures and Public Decisions

Assuming the savings from a closed formulary are used for socially valuable purposes, the question becomes what drugs to include and how to make these decisions, which can involve numerous ethical considerations. Although the goal of a closed formulary—reduced spending on drugs—implies an emphasis on cheaper alternatives, other goals such as improving effectiveness or benefiting the least advantaged are also relevant.

The recent Massachusetts proposal for a CMS waiver, mentioned earlier, illustrates the need for clarity about values or reasons informing formulary design. In 2017, Massachusetts submitted a Medicaid 1115 waiver request for the Medicaid program, MassHealth,² which CMS rejected in 2018.⁶ Among the proposed changes to MassHealth was the introduction of a closed formulary with the explicit intention of reducing overall spending on drugs. There were 2 requirements for the formulary: (1) at least one drug per therapeutic class would be included and (2) for each drug included there should be adequate evidence demonstrating its effectiveness.² Arizona submitted a similar proposal, which CMS has not yet decided on,⁷ although the Arizona Health Care Cost Containment System suggested 2 drugs per therapeutic class would be covered unless one is "clinically superior."¹ Both waivers claim that access to medically necessary care will be maintained since minimum access across therapeutic classes is required. Including at least one drug per class is also a politically smart move that avoids excluding patient groups. However, this requirement might conflict with the goal of reduced spending and the further requirement that included drugs have demonstrated effectiveness. Recently approved drugs, such as eteplirsen for Duchenne muscular dystrophy or nivolumab for some cancers, are [new classes of drugs](#) with limited evidence and very high costs.^{8,9} Including these drugs in the closed formulary goes against its 2 aims of reducing costs and encouraging the use of more effective drugs.

Although the one-drug-per class requirement is an easy position to take, policymakers should consider the intention of the closed formulary and the principles that guide it, its alignment with the overall program goals of Medicaid, and enrollees' values. Aiming merely to reduce costs by including only the cheapest drugs would unjustifiably ignore other relevant considerations; it also matters which drug has the greatest effect, is most effective for the greatest number of people, or best treats those who are sickest. There are many possible factors that could inform formulary design, and sometimes they will conflict. For example, the decision of whether to include a cancer drug like nivolumab in a closed formulary should require weighing a number of factors including cost, strength of evidence of effect, and the burdens experienced by patients in the final stages of cancer. People will, of course, disagree about which of these factors is most important or socially valuable and therefore justifies [exclusion of a drug](#) from the formulary.

To address the problem of conflicting values in setting limits on drugs to be included in a closed formulary, policymakers could turn to procedures that involve citizens and that are transparent. This next step presupposes that it is not enough to justify decisions about which drugs to include in a closed formulary because these choices enable socially valuable purposes; the process of making the decision about how to save money also matters. Daniels has proposed a procedure, called accountability for reasonableness, specifically to address the problem of insurers that limit health care access.¹⁰ Accountability for reasonableness requires that these limit-setting decisions and the

reasons for them be publicly available, be based on trade-offs and reasoning that the public served by the plans will find appropriate, and include an appeals process.¹⁰ Medicaid, as an institution serving the public, should use high standards of deliberation, public engagement, and transparency for its decisions.

Oregon implemented such a deliberative process for [reforming its Medicaid program](#) in the early 1990s. In order to reduce costs and extend coverage, state health planners created a ranked list of services that would be provided. The initial list, based only on cost-effectiveness calculations, resulted in coverage trade-offs considered unacceptable by the public, with minor ailments prioritized over life-threatening conditions.¹¹ A public consultation process gathered values that informed the final ranking, which continues to be updated.^{11,12,13} Although Oregon conducted a state-wide public discussion of limit-setting values, deliberation could also occur on a small scale. The Choosing Healthplans All Together (CHAT) exercise has been run in multiple settings with lay participants who have private and public insurance plans and draws out people's preferences for health care access—preferences that shift when they consider population needs rather than their own.¹⁴ These sorts of public and deliberative exercises engage people in important public policy decisions, which ensures the legitimacy of the results and increases the likelihood of their acceptance.

The MassHealth and Arizona closed formulary proposals should have considered—and future ones should consider—the example of public, deliberative procedures to inform decisions about which drugs to include in closed formularies. The process must include both the Medicaid beneficiaries and the broader public, who are the payers and have interests in how the funding serves the public good within the state.

Fairness and Singling Out Poor Patients

In addition to considering the values and processes used in formulary construction, it is worth considering whether applying closed formularies selectively to Medicaid beneficiaries would be unfair, as some have charged.¹⁵ Proposed limits—for instance, on sugar-sweetened beverages in food assistance programs—have been criticized.¹⁶ But the charge of singling out poor patients does not apply particularly well to the use of closed formularies in Medicaid programs because other public payers as well as private payers use closed formularies.³

Although the use of closed formularies is not distinctive to programs serving poor patients, specific formulary designs could be. Hypothetically, would it be fair for Medicaid closed formularies to include drugs that are cheaper but less effective than the drugs included in other closed formularies? This would conflict with the view—endorsed by 75% of US adults in a 2003 poll—that quality of health care should not depend on wealth.¹⁷ Such a proposal presents the question of whether poorer patients are owed equal access to specific pharmaceuticals rather than a decent minimum. In an article on

global health, one of us (G.P.) has argued that opting for cheaper treatments can enable more patients to receive treatments.¹⁸ However, tailoring formulary designs to include more effective treatments is likely to be less controversial than tailoring them to reduce costs. For instance, given that medication access might contribute to adherence challenges that Medicaid patients can face,¹⁹ a closed Medicaid formulary could try to include drugs that make adherence easier for people in resource-limited circumstances.

The potential for closed formularies to uniquely disadvantage poor patients is not alone reason enough to reject closed formularies in government programs. Arguments in this article—that there should be a minimum ethical requirement for justifying the reallocation of funds and that the formulary design should be guided by a procedural approach emphasizing deliberation, transparency, and engagement—do not dismiss the idea of closed formularies but rather suggest how they might be achievable in a socially just way.

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