gram in order to reduce spending will only increase. Proposed reforms are typically evaluated on the basis of how they affect the bottom line — the exhaustion date of Medicare's hospital insurance trust fund or the share of the gross domestic product devoted to Medicare. They are also evaluated on whether their burden is borne, on average, by providers or by beneficiaries. These metrics are not enough. Reforms must also be evaluated in terms of how they affect beneficiaries' risk of being exposed to high expenditures — and whether they strike a better balance between financial protection and preserving incentives to consume care wisely.

Technological innovation raises the stakes. Many new technologies are crucial for extending life and improving well-being but also create even greater uncertainty about health care spending both for individuals and for the health care system overall. Medicare's balance between financial protection and incentives for efficient use of care would require continual adjustment even if budgetary pressures were not creating an imperative for reform.

Medicare was always intended not just to increase access to care but to protect the elderly from financial ruin. As President Lyndon Johnson said when signing Medicare into law in 1965, "No longer will illness crush and destroy the savings that [older Americans] have so carefully put away over a lifetime so that they might enjoy dignity in their later years." Indeed, the introduction of Medicare reduced out-of-pocket spending among the top quartile of spenders by 40%.[5] Will Medicare continue to fulfill this promise in decades to come? Medicare reforms that strike a balance between financial protection and incentives for efficient use of care will help to ensure that the program will be solvent for future generations without undermining the fundamental insurance value of this public insurance program.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Department of Health Policy and Management, Harvard School of Public Health, Boston (K.B.); and the Institute for Social Research, University of Michigan, Ann Arbor (H.L.).

1. Kelley AS, McGarry K, Fahle S, Marshall SM, Du Q, Skinner JS. Out-of-pocket spending in the last five years of life. J Gen Intern Med 2012 September 5 (Epub ahead of print).
2. Medicare and the health care delivery system: report to the Congress. Washington, DC: Medicare Payment Advisory Commission, June 2012.
3. Newhouse JP, The Insurance Experiment Group. Free for all? Lessons from the RAND Health Insurance Experiment: a RAND study. Cambridge, MA: Harvard University Press, 1993.
4. Finkelstein A. The aggregate effects of health insurance: evidence from the introduction of Medicare. Q J Econ 2007;122:1-37.
5. Finkelstein A, McKnight R. What did Medicare do? The initial impact of Medicare on mortality and out of pocket medical spending. J Public Econ 2008;92:1644-68.

DOI: 10.1056/NEJMp1210789

Medicare's Enduring Struggle to Define "Reasonable and Necessary" Care

Peter J. Neumann, Sc.D., and James D. Chambers, Ph.D.

> No payment may be made . . . for any expenses incurred for items or services, which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.
>
> — Sec. 1862(a) of the Social Security Act

The Medicare program, among its many functions, serves as the country's preeminent organization for the assessment of health technology. Its decisions to cover and pay for medical technology can have profound consequences for patients' access to therapies, physicians' treatment options, and the fiscal well-being of the program.

Since its inception in 1965, Medicare policy has been guided by legislation mandating that the program not pay for items and services that are not "reasonable and necessary." Over the years, amid escalating costs and the medical community's embrace of evidence-based medicine, the Centers for Medicare and Medicaid Services (CMS) has struggled to interpret and apply the "reasonable and necessary" criteria. At key junctures, CMS has been thwarted by political pressure or the courts. As Medicare spending takes center stage in the country's budget debates, "reasonable and necessary" warrants a closer look.

Defining "reasonable and necessary" has proven an enduring challenge. Determinations of what

is necessary care generally turn on the strength of the medical evidence, as encapsulated, for example, in clinical guidelines. Such determinations, however, are rarely straightforward, given the complexity of individual cases. Moreover, the influence of various interest groups has challenged Medicare's attempts to stick closely to the data. For example, in 2008, CMS was pressured to reverse its proposed decision to limit coverage of coronary computed tomographic angiography, despite the conclusions of an external evidence review and an independent advisory committee that the technology's benefits and harms were uncertain.[1] In 2011, Medicare chose to continue paying for bevacizumab for metastatic breast cancer, despite the fact that the Food and Drug Administration had removed this indication from the label on the basis of studies showing no benefit and possible harms.

Determining "reasonableness" has presented even more difficulty. The word implies moderation, suggesting that the resources expended should not be excessive. The issue is not simply whether care is essential, but whether it is advisable given a delicate balance of benefits, risks, and costs.

In 1989, Medicare published a proposed regulation defining "reasonable and necessary" as safe, effective, noninvestigational, appropriate, and *cost-effective*. Adding "cost-effectiveness" required a small leap of imagination, but it seemed defensible given the opening provided by "reasonable," and it seemed justifiable — as the proposal noted — in light of "the explosion in the cost of new medical technology." The idea, however, sparked criticism from external stakeholders, including the medical device industry and some medical professional societies, on the grounds that it would lead to denials of needed care. The proposal was eventually withdrawn.

In making coverage determinations, Medicare should be guided by the available clinical evidence. Beyond that principle, a legislative fix for the "reasonable and necessary" clause would help.

All the while, CMS was employing a "least costly alternative" policy to provide reimbursement for durable medical equipment (such as wheelchairs) and some Part B (non–self-administered) drugs. The idea was that if two alternative interventions were equivalent, Medicare should not pay more for one of them.[2]

In 2008, this policy was challenged when it was applied to a drug for treating chronic obstructive pulmonary disease. The government argued that the "reasonable and necessary" clause provided sufficient legal authority for the policy. The plaintiff countered that the clause in the original statute (quoted above) modified "items and services," rather than "expenses," and thus CMS could determine only whether the drug was reasonable and necessary (a binary choice); if so, Medicare must reimburse according to the statutory payment formula (106% of the drug's average sales price).[3] The court agreed with the plaintiff. The appeals court affirmed the decision, stating that the broad interpretation of "reasonable and necessary" embraced by the secretary of health and human services was unambiguously foreclosed.[4]

Medicare has also used the "reasonable and necessary" clause to support its "coverage with evidence development" (CED) policy, under which the program provides conditional coverage for medical technology while it collects additional evidence on its safety and efficacy. CMS has used the CED designation in more than a dozen cases for technologies ranging from implantable cardioverter–defibrillators to positron-emission tomography.

The CED policy has proved challenging to implement, in part because of the costs and complexities of data collection. However, the program's reliance on the reasonable and necessary criteria has also presented problems. As Tunis et al. observe, CMS has defined "reasonable and necessary" to mean there is "adequate evidence to conclude that the item or service improves health outcomes." But if the purpose of a CED decision is to require that such "adequate evidence" be generated, then the item or service cannot yet be considered reasonable and necessary under the statutory authority.[2] Medicare is currently revising its CED policy, and legal issues involving "reasonable and necessary" remain concerns.

It is unfortunate, if not unexpected, that Medicare's attempts

to implement evidence-based decisions have been influenced by politics. It's ironic that as CMS launches value-based purchasing programs for providers, it is unable to apply value-based purchasing for technology.[5] Moreover, circumstances have forced the program into a disingenuous conversation about medical technology as it attempts to address its fiscal predicament while pretending that costs do not matter.[5]

Above all, in making coverage determinations, Medicare should be guided by the available clinical evidence. Beyond that principle, a legislative fix for the "reasonable and necessary" clause would help. Legal scholar Jacqueline Fox argues that amending the original statute so that it prohibits payment "for any expenses which are unreasonable and which are incurred for items and services" would provide CMS authority and legitimacy to consider costs openly (because reasonable would then modify expenses rather than items and services).[5] Another option is for Congress to rewrite the "reasonable and necessary" clause borrowing language from the 2008 Medicare Improvements for Patients and Providers Act, which permits CMS, in covering preventive services, to account for "the relation between predicted outcomes and expenditures" and thus to consider costs in coverage decisions pertaining to prevention.

Making such changes will be challenging in the current political climate, but the urgency of the situation — Medicare is projected to become insolvent in a decade — and postelection budget talks provide an opening. In the meantime, Medicare will continue its peculiar dance over technology policy, in which it intensely scrutinizes clinical evidence and emphasizes outcomes and subgroups, while cost considerations lurk offstage.

It may be tempting to believe that the matter will be rendered moot by payment reform and premium-support policies. That is, some may hope that the federal government can simply delegate coverage decisions to other parties, such as accountable care organizations, while forcing patients to consider the value of technologies through increased cost sharing. Such reforms are needed, since they will help move CMS out of the business of micromanaging coverage policy, though the details will be crucial. Offloading financial risk, however, does not absolve Medicare. Although it will shield CMS from certain controversies, questions will persist over how much geographic and socioeconomic variation in technology coverage the country will tolerate in a federal program. Moreover, the steady march of big-ticket, high-profile technology, such as cancer therapies, will demand a single response from Medicare regarding the adequacy and reasonableness of the evidence base.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Center for the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, Boston.

1. Redberg RF, Walsh J. Pay now, benefits may follow — the case of cardiac computed tomographic angiography. N Engl J Med 2008;359:2309-11.
2. Tunis SR, Berenson RA, Phurrough SE, Mohr PE. Improving the quality and efficiency of the Medicare program through coverage policy: timely analysis of immediate health policy issues. Urban Institute, 2011 (http://www.urban.org/url.cfm?ID=412392).
3. Hays v. Leavitt, 583 F. Supp. 2d 62, 69, 72 (D.D.C. 2008).
4. Hays v. Sebelius, 589 F.3d 1279, 1280 (D.C. Circuit 2009).
5. Fox J. The hidden role of cost: Medicare decisions, transparency and public trust. Univ Cinci Law Rev 2010;79(1):1-51.

DOI: 10.1056/NEJMp1208386

The Taxing Power and the Public's Health

Michelle M. Mello, J.D., Ph.D., and I. Glenn Cohen, J.D.

Many observers feared that the Supreme Court decision on the challenge to the Affordable Care Act (ACA)[1] would endorse a breathtaking expansion of the role of the federal government in regulating health matters. And it did — but not in the anticipated way. While enunciating limits on the commerce and spending powers, the Court opened the door for Congress to use its taxing power to achieve myriad policy objectives. The federal government may now increasingly join state and local governments in making creative use of taxes to pursue public health goals, though political obstacles may block immediate action.

Chief Justice John Roberts surprised pundits by joining the four liberal justices in upholding the individual insurance mandate in the ACA as an exercise of Congress's power to "lay and collect