

The Fundamentals of Medicare Demonstrations

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OVERVIEW — *Demonstrations are experiments that test Medicare policy changes without permanently changing the Medicare program. They allow policymakers to learn about the potential impact and operational challenges of a proposed modification to Medicare, but in a more controlled environment and on a limited basis. Since demonstrations can affect hundreds of thousands of beneficiaries and providers and involve millions of dollars, they are often controversial. This paper describes the basics of Medicare demonstrations, including what they are, how they are initiated, and why they are undertaken. The paper also explores the relationship between demonstrations and other research projects. The primary challenges in designing and implementing demonstrations and how the results of demonstrations are incorporated into Medicare are examined. Finally, this document highlights key demonstrations in Medicare history and their impact on the Medicare program.*

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Medicare Demonstrations: Planning for the Future

Demonstrations are real-world tests of new ways of delivering health care services, paying health care providers, or designing benefits under Medicare. They act as laboratories for the Centers for Medicare & Medicaid Services (CMS), the federal agency that runs Medicare, to experiment with potential changes to the Medicare program. If these innovations prove their worth, Congress and the administration can make informed decisions about whether or not to add them to the Medicare program as a regular part of ongoing operations. (*The Medicaid program uses waivers to allow for innovation in its program as well; for more information, see Cynthia Shirk, “Shaping Medicaid and SCHIP Through Waivers: The Fundamentals,” National Health Policy Forum, Background Paper 64, July 22, 2008, available at www.nhpf.org/pdfs_bp/BP64_MedicaidSCHIP.Waivers_07-22-08.pdf.)*

AN INTRODUCTION TO DEMONSTRATIONS

Controversial aspects of Medicare demonstration projects are often in the news. By their very nature, demonstrations change the status quo of this very large federal program, affecting beneficiaries, providers, and Medicare expenditures. There is fodder for controversy in what policies are tested, how demonstrations are designed, which health care providers or beneficiaries are included or excluded, how much providers are paid, or how the demonstration results are interpreted and when they are made available. In many respects, demonstrations are a microcosm of the larger Medicare program—replete with influential stakeholders, political interests, taxpayer dollars, and beneficiary protection issues.

Demonstrations and the public interest that seems to follow them are not new to Medicare. Since the demonstration waiver authority was granted in 1967, hundreds of demonstrations have been undertaken. Some have never gotten off the drawing board and others have failed to reveal better ways to administer the program. But many have led to some of the most important changes in Medicare payment and service delivery. The method Medicare uses to pay hospitals for inpatient care—the inpatient prospective payment system, or IPPS—is a prime example. Others include the skilled nursing facility and home health prospective payment systems; the Medicare managed care program, including preferred provider organizations and special needs plans; durable medical equipment competitive bidding; programs to improve care for dual-eligible beneficiaries, such as the Program for All-inclusive Care for the Elderly, or PACE, and social health maintenance organizations, or SHMOs; the hospice benefit; and Medicare coverage for heart transplants. Demonstrations can also have an impact beyond the

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Medicare program, as other payers follow Medicare's lead in adapting their payment and coverage policies. The IPPS concept, for example, is now used by many insurers to pay for inpatient hospital services.

Most demonstrations are undertaken for one of two reasons. The first is to test ideas about potential broad changes to Medicare. The ability to undertake smaller, controlled, experiments before making permanent changes in a program as large as Medicare helps ensure smoother transitions for both providers and beneficiaries. A second reason is to evaluate changes that are targeted to a subgroup of beneficiaries or providers who are not well served by the current program. In this case, a program-wide change may not be the right solution. A more targeted approach can be tested and refined through a demonstration.

Over the years, as Medicare has faced major changes in health care delivery, financing, or benefits, the results of demonstrations have very often informed the way the program is updated. Research and demonstrations have provided Congress and the administration with a better understanding of the policy tools available to address accelerating growth in health care spending, more information on how those tools actually work in the Medicare program, and an estimate of the potential results of implementing those tools program-wide. As policymakers nervously eye the depletion of the Medicare Part A Trust Fund as soon as 2019, the hope is that the demonstration and research programs being designed and implemented now will yield policy approaches that can help slow the rate of growth in health spending.

DEMONSTRATION BASICS

A demonstration is applied research that tests the effects of a new policy approach on Medicare beneficiaries, providers, or program expenditures. Demonstrations are often limited to one or several geographic areas, or to a particular subgroup of Medicare providers or beneficiaries. They are generally time-limited, commonly two years. New policy approaches most often involve paying for Medicare-covered services in a different way, but may also involve paying for items or services not otherwise paid for by Medicare, or allowing health care providers not otherwise providing a particular Medicare-covered service to do so.

Demonstrations rely on basic research studies to develop the concepts to be tested, the payment mechanisms to achieve them, and the measures by which success is evaluated. However, unlike a research project that does not require gathering data in the field, demonstrations actually affect the services provided to beneficiaries and adjust the payments to providers. Demonstrations allow CMS to gain real-world experience with the proposed changes, but in a controlled manner that provides, at their best, clear information on which to evaluate the innovations being tested. The geographic area, the providers, the beneficiary population, and/or the time period involved can be controlled and changes can be assessed before larger-scale adoption. They can provide insight into the impact of

a particular change as well as provide operational knowledge that may inform the agency's implementation of other policy changes.

The focus of Medicare demonstrations tends to reflect the policy concerns of the day. In the 1970s, many demonstrations focused on controlling health care cost growth, including the largest component of costs at the time, inpatient hospital services. In the 1980s, the majority of projects addressed either long-term care issues or alternative delivery mechanisms, such as prepaid health plans.¹ More recent demonstration activity has focused on refinements of existing payment systems. Table 1 (next two pages) highlights examples of recent and upcoming demonstrations grouped into four categories: health care quality, alternative payment methods, expansion of the program to cover new provider types or benefits, and care coordination and prevention. Quality of care demonstrations are projects that test methods of collecting data on the quality of care provided to beneficiaries, including investments in health information technology, and evaluate ways to incorporate incentives to meet quality goals into the Medicare payment systems. Alternative payment methodology demonstrations test new ways to pay providers for services to Medicare beneficiaries. Demonstrations that expand Medicare benefits or provider types evaluate the impact on the program of covering services that are not currently part of the Medicare benefit package. Finally, care coordination and prevention projects assess ways to better manage the care provided to beneficiaries (usually those with chronic conditions) to achieve better outcomes and control spending. While some recent or upcoming demonstrations may not fall into one of these categories, they are illustrative of current demonstration themes.

For simplicity, the demonstrations in Table 1 are listed by primary focus. However, demonstrations can, and very often do, test more than one concept. For example, the Hospital Gainsharing Demonstration and the Physician Hospital Collaboration Demonstration are both quality demonstrations testing the impact of allowing hospitals to create incentives for physicians to provide more efficient and higher-quality care. (See text box.) While focused on quality, these projects must also consider alternative methodologies that would combine payments for hospitals and physicians.

Gainsharing Demonstrations

The Hospital Gainsharing Demonstration and the Physician Hospital Collaboration Demonstration are testing

incentives for physicians to provide high-quality and efficient care. The incentives can include allowing physicians to share in the savings that may accrue to the hospital, a practice referred to as "gainsharing." Physicians have significant control over the services provided in a hospital, but Medicare pays the physician and the hospital separately and on different bases for those services: hospitals are paid a fee per case, but physicians are paid per service. Consequently, the financial incentives for the two players seem to work in opposition to one another: hospitals can maximize profits by reducing the length of patient stays, while physicians can maximize payments by providing more services such as patient visits. These two demonstrations are testing whether models can be developed that will better align incentives for both hospitals and physicians. The goal is to improve efficiency while providing high-quality care to beneficiaries.

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TABLE 1
Examples of Demonstrations by Subject

QUALITY OF CARE	
Demonstration Title	Description
Home Health Pay for Performance	Tests impact of incentive payments funded by savings from reduced use of higher-cost services on outcome-based quality improvement measures.
Care Management Performance	Experiments with giving financial incentives to physician practices to report clinical quality data, meet performance standards, and provide preventive services, with additional incentives to implement an electronic health record and report the performance data electronically.
Physician Hospital Collaboration	Evaluates the intermediate and longer-term impact of allowing physicians to share in the savings from providing more efficient inpatient care.
Health Care Quality	Tests major changes implemented by physician practices, integrated delivery systems, or regional health consortia intended to improve patient safety, enhance quality, increase efficiency, and reduce scientific uncertainty and the unwarranted variation in medical practice.
Premier Hospital Quality Incentive	Tests impact on quality of care of providing financial incentives to hospitals that demonstrate high quality in five acute care areas: heart attack, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacements.
Physician Group Practice	Tests impact on quality measures of providing incentive payments to physicians that are allocated based on cost efficiency and performance and are generated from coordinating care under Parts A and B of Medicare.
ALTERNATIVE PAYMENT METHODS	
Demonstration Title	Description
Part D Payment	Provides alternative methods of receiving reinsurance for drug costs above the “catastrophic” level for Part D plans offering enhanced coverage.
Evaluation of Payment Demonstrations for Medicare Part D	Uses alternative weighting methods for calculating the regional low-income benchmark.
Demonstrations Serving Those Dually Eligible for Medicare and Medicaid	Evaluates impact of combining Medicare and Medicaid funding pools at the health plan level and different approaches to managing care on expenditures and quality of care for dual-eligible beneficiaries.
Recovery Audit Contractors	Tests the cost-effectiveness of additional resources to ensure that correct payments are made by Medicare.
Rural Community Hospital	Tests whether reasonable cost reimbursement for certain small rural hospitals enhances the ability of those hospitals to meet the needs of their communities.

Table 1 — continued >

Table 1 — Examples of Demonstrations by Subject > *continued*

NEW PROVIDER TYPES AND / OR BENEFITS	
Demonstration Title	Description
Low Vision Rehabilitation	Allows for coverage of vision rehabilitation services by additional types of practitioners, such as low-vision therapists, orientation and mobility specialists, and vision rehabilitation specialists.
Frontier Extended Stay Clinic	Allows payment for treatment in nonhospital settings of patients who need inpatient care but cannot be transferred to an inpatient facility because of weather or other circumstances.
Frequent Hemodialysis Network Clinical Trials	Evaluates impact of covering hemodialysis six times a week rather than the conventional frequency of three times a week.
Medical Adult Day Care Services	Allows for coverage of services provided in an adult day care center as a substitute for some home health services.
Rural Hospice	Evaluates the impact of waiving certain requirements for Medicare-approved hospice providers on access to hospice care in rural areas.
CARE COORDINATION AND PREVENTION	
Demonstration Title	Description
Medicare Health Support	Tests the impact of disease-management/care-improvement programs on quality, beneficiary satisfaction, health outcomes, and cost of fee-for-service Medicare beneficiaries with chronic conditions.
Senior Risk Reduction	Tests the effect on Medicare beneficiaries of health promotion and health management approaches used in the private sector.
Cancer Prevention and Treatment Demonstration for Racial and Ethnic Minorities	Evaluates the impact on racial disparities in the screening, diagnosis and treatment of cancer of providing patient navigator services, such as care coordination, transportation assistance, and translation services.
Care Management for High-Cost Beneficiaries	Tests care coordination and management techniques targeted specifically at high-cost fee-for-service beneficiaries.
ESRD* Disease Management <i>(*End-Stage Renal Disease)</i>	Tests the effectiveness of disease management models and quality incentive payments on care for ESRD beneficiaries enrolled in Medicare Advantage plans that have partnered with dialysis facilities.
Coordinated Care	Tests the impact on the number of hospitalizations, health status, and health care costs of different case and disease management approaches to coordinating care for beneficiaries with complex chronic conditions.
Informatics for Diabetes Education and Telemedicine	Evaluates use of telemedicine sessions with case managers to improve primary and preventative care for diabetes in underserved inner-city and rural areas of New York.

Source: Centers for Medicare & Medicaid Services (CMS), "Demonstration Projects and Evaluation Reports: Medicare Demonstrations," available at www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list.asp#TopOfPage; and CMS, "Medicare Health Support," available at www.cms.hhs.gov/CCIP.

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Demonstrations that do not achieve their primary goals also can be instructive. Indeed, sometimes more can be learned from failure than success, since avoiding costly mistakes is as important as finding solutions that clearly work. Ideas that do not produce expected results encourage policymakers to seek other solutions or to reassess how a policy could be implemented. For example, by the end of 2008 CMS will complete a high-profile pilot, Medicare Health Support, that has been testing methods of managing care for chronically ill beneficiaries.² Preliminary evaluations of the project found that the Medicare program was not saving money, the opportunity for long-term Medicare savings was not evident, and there were only modest effects on clinical quality indicators, beneficiary compliance, and self care activities.³ Despite the apparent lack of the hoped-for results, the final evaluation likely will yield useful insights for future work.

Responsibility for overseeing demonstration projects within CMS is handled primarily by the Office of Research, Development, and Information.⁴ This office also is responsible for developing and implementing the agency's broader research agenda. CMS relies on research funding to help design, implement, and evaluate demonstration projects. It also uses research contracts for other purposes, including gathering and interpreting data and providing analytical, actuarial, or technical support for CMS activities. A report listing the hundreds of research, demonstration, and evaluation projects CMS manages each year is available on the the agency's Web site.⁵

THE CONNECTION BETWEEN DEMONSTRATIONS AND RESEARCH

When considering how to evaluate a potential policy option, CMS or Congress may choose to conduct research, undertake a demonstration, or both. Research is generally a data-driven enterprise: data are analyzed to shed light on the policy being evaluated. In general, if sufficient data exist to examine an issue, policymakers will choose research over a demonstration since it can be less expensive, less complicated, quicker, and avoids changing the status quo for beneficiaries and providers.

Demonstrations are applied research: they change how Medicare operates in a geographic area or for a particular group of beneficiaries. Demonstrations most often require some level of research to support their development and to evaluate their results. Indeed, research can be undertaken without conducting a demonstration, but a demonstration cannot be undertaken without supporting it with research. Before implementing a demonstration, CMS uses research to develop and test the methodology and measures to be used. After a demonstration is completed, an evaluation assesses the impact of the project.

The combination of research and demonstrations has been vital to past Medicare reforms. One of the most fundamental changes in the Medicare

program's history was the shift from cost-based payment to prospective payment for inpatient hospital services. In developing the IPPS, CMS (then the Health Care Financing Administration, or HCFA) engaged in research studies on many technical aspects of the payment system, including measures of patients' severity of illness and differences in hospital wages and other costs. The agency also conducted multiple demonstrations of key concepts (see text box below for a history of the use of demonstrations in the development of the IPPS). The development

Development of the Hospital Inpatient Prospective Payment System (IPPS)

The development of the IPPS is classic Medicare demonstration work. The prospective payment demonstration projects identified viable alternatives to cost-based reimbursement and winnowed out unworkable approaches.

From 1965 until October 1983, hospitals were paid based on their stated costs of providing care. This methodology encouraged hospital participation in the Medicare program but gave providers little incentive to increase efficiency or reduce costs. If a hospital's costs increased, Medicare's payments to that hospital went up. Projects to identify alternative approaches to cost reimbursement began in 1974. The first demonstrations were budget review programs conducted in Rhode Island, Pennsylvania, and South Carolina that allowed payers to prospectively negotiate hospital budgets. While these projects encouraged payers to focus on cost differences between hospitals, they quickly showed that each side in the negotiations had a different understanding of the meaning of prospective payment, and both payers and hospitals sought retroactive payment adjustments to reduce their own risk. Within a year, budget review programs were rejected as impractical for the Medicare program as a whole.

Pursuit of other alternatives continued through the

late 1970s and early 1980s. A request for proposal (RFP) released in 1975 resulted in awards to various state agencies and Blue Cross organizations to test different approaches. These projects were undertaken in Washington, New York, Massachusetts, Georgia, and New Jersey. The project with the most significant impact was in New Jersey. It experimented with prospectively set payment rates for patients classified with clinically similar patients into diagnosis-related groups (DRGs). The IPPS adopted in 1983 closely resembled the New Jersey model in that both used payments based on DRGs, and both were systems in which the payment rates were indexed for future inflation.

By 1983, more than 10 years of research and demonstrations related to hospital prospective payment allowed HCFA to identify features it wanted to include as well as to avoid in a prospective payment system. Demonstration experience showed that the system needed to account for differences in patient severity or case-mix, minimize the need for retroactive adjustments, and maximize incentives to control costs. The DRG-based system was determined to best meet these needs, and within the first year it exceeded expectations for reducing length of stay and extended the solvency of the Hospital Insurance Trust Fund by a decade.

Source: Alfonso Esposito, "Medicare's Prospective Payment Demonstration Program," in Diagnosis-Related Groups: The Effect in New Jersey, The Potential for the Nation, HCFA Pub. No. 03170, proceedings of a conference sponsored jointly by the New Jersey Department of Health and the Health Care Financing Administration, U.S. Department of Health and Human Services, Atlantic City, NJ, November 30–December 2, 1983, pp. 18–24; Allen Dobson et al., "The Future of Medicare Policy Reform: Priorities for Research and Demonstrations," Health Care Financing Review, 1986 Annual Supplement, pp. 1–3.

of the prospective payment systems for skilled nursing facilities and home health agencies also relied on both research and demonstrations. In contrast, development of the physician fee schedule involved research studies on key aspects of the system, but the fee schedule methodology as a whole was not tested under a demonstration project.⁶ Although not always tested under demonstrations, research funding was used to develop essential elements of most Medicare payment systems, including the patient classification systems such as resource utilization groups for skilled nursing facilities and ambulatory payment classifications for hospital outpatient departments; the risk-adjustment model for Medicare Advantage; and the resource-based relative value scale for physician services.

In order to respond rapidly to research needs, CMS establishes base contracts with firms able to perform analyses of Medicare, Medicaid, and SCHIP issues. These contracts are generally for research, analysis, demonstration evaluation and survey activities, and are activated through “task orders”—competitive procurements for specific projects that are open only to firms that have been awarded base contracts—as CMS identifies specific research requirements.

CMS’s research budget must accommodate both research studies and contracts to design and evaluate demonstrations. While the number of payment systems and Medicare expenditures continues to grow, the CMS research budget has declined in recent years, from a high of \$138 million in fiscal year (FY) 2001 to a low of roughly \$47 million in FY 2008.⁷ (See Figure 1 on next page and Appendix on p. 26.) Some have suggested that current funding is insufficient to ensure that policymakers have an adequate stock of tested ideas for the future.

INITIATION OF MEDICARE DEMONSTRATIONS

Both Congress and the Department of Health and Human Services (HHS), usually acting through CMS, may initiate Medicare demonstration projects. The distribution of congressionally mandated and CMS-initiated projects has varied over time. In the early 1980s, few projects were mandated by Congress. This changed over the next decade and congressionally mandated demonstrations became the majority.⁸ In January 2008, about 60 percent of the 31 current or upcoming demonstrations listed on the agency’s Web site were legislated by Congress.⁹

Congressional Mandates

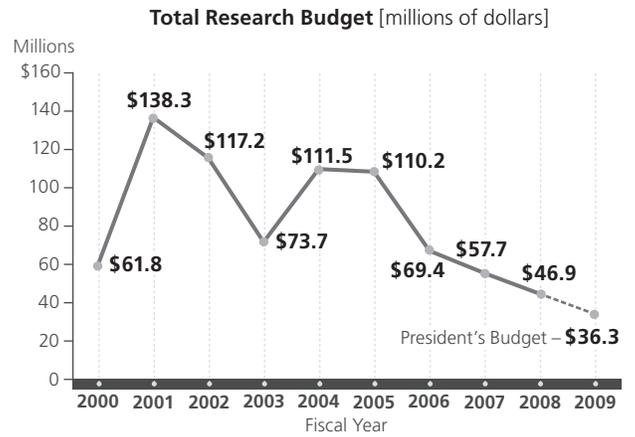
Congress may mandate particular projects or studies when it enacts legislation. By mandating a research study or demonstration, Congress can test a policy approach or idea that may be premature or inappropriate to implement on a program-wide basis. Requiring demonstrations or other research projects signals congressional interest in an area and specifies

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FIGURE 1: CMS Research and Demonstration Funding, FY 2000 – FY 2009

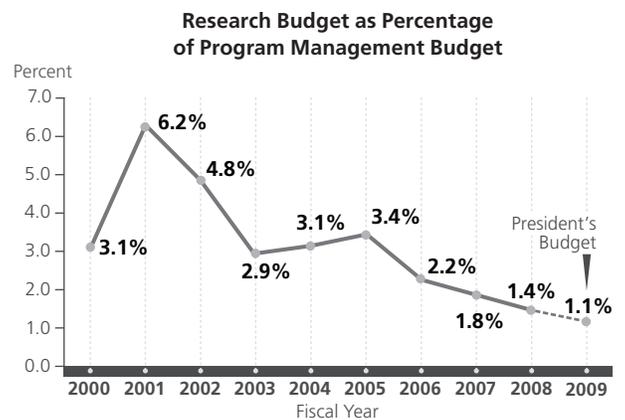
CMS Research Budget FY 2000 – FY 2009

CMS’s total research budget has lacked stability over the years, making planning for future research projects challenging. The research budget has been cut from a high of \$138.3 million in FY 2001 to \$46.9 million in FY 2008. The President’s FY 2009 budget proposed a further reduction.



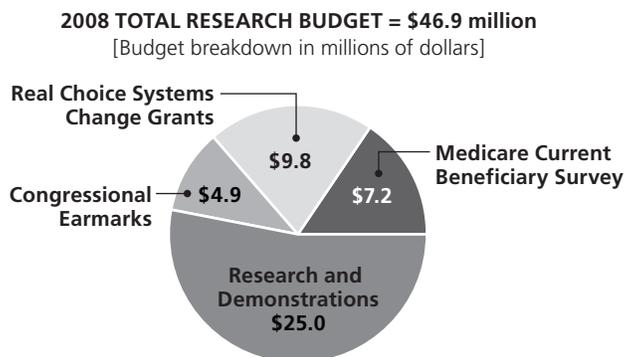
CMS Research Budget as a Percentage of Program Management Budget FY 2000 – FY 2009

Since FY 2001, the CMS research budget has been declining as a percentage of CMS’s program management budget, from a high of 6.2 percent in FY 2001 to a low of 1.4 percent in FY 2008. The President’s FY 2009 budget proposed lowering the percentage to 1.1 percent. Note: The program management budget is appropriated annually to carry out the day-to-day management of CMS functions.



FY 2008 CMS Total Research Budget: Breakdown of Spending

Only about half of the total research budget is actually available for new or ongoing projects. For FY 2008, about half of the total research budget was reserved for congressional earmarks, Real Choice Systems Change grants, and execution of the Medicare Current Beneficiary Survey.



Note: See Appendix (p. 26) for more information on research and demonstration funding.

Source: U.S. Department of Health and Human Services, “Justification of Estimates for Appropriations Committees,” available at www.hhs.gov/budget/docbudget.htm; Centers for Medicare & Medicaid Services, staff communication with author, April 2008.

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topics on which members believe they need more information. In particular, mandated projects can reflect the concerns and future agenda of the Senate Finance, House Ways and Means, and House Energy and Commerce Committees, the three authorizing committees that have specific jurisdiction over the Medicare program. Congressional appetite for demonstrations and reports is great. For example, in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Congress mandated 14 demonstrations and requested over 100 reports to Congress on specific research, implementation of various initiatives, and evaluations of required demonstrations from HHS, the Government Accountability Office (GAO), the Medicare Payment Advisory Commission (MedPAC), and the Institute of Medicine.

Rather than enacting discrete legislation for demonstrations, the Medicare authorizing committees most often include them in bills that incorporate more extensive changes to the program. Since the authorization for many demonstrations specifies budget neutrality (that is, they cannot increase Medicare spending), they typically do not increase the cost of the overall bill and, therefore, spark little opposition by the members. Also, because the demonstrations are not permanent parts of the program, the language authorizing them is often not incorporated into the Social Security Act; it is found only in the statute that is being enacted (the MMA, for example). Tracking congressional action on demonstrations and any changes to the statutory authority can be difficult, since not all of the language related to a particular demonstration can necessarily be found in one place.

Congressionally mandated demonstrations are sometimes the result of a political compromise when not all parties can agree on a particular legislative provision. Demonstrations also can jumpstart interest in a policy solution, sometimes moving forward a compelling but yet unproven approach.¹⁰ They can also act as a pressure valve for controversial ideas that are argued to have merit but may lack widespread support or evidence of their effectiveness for Medicare nationally. For example, some members of Congress have advocated introducing more competition into the determination of Medicare payment rates, especially when the program purchases discrete goods and services, such as durable medical equipment (DME) and clinical laboratory services. However, legislators are far from agreement on this proposal. A demonstration testing competitive bidding in limited markets for DME showed it could result in program savings, and the MMA mandated competitive acquisition of DME in more areas. Still, the concept remains a topic of debate, and the MMA did not require its use for additional services. Instead, the legislation mandated another demonstration applying the same techniques to clinical laboratory services and creating a voluntary competitive acquisition program

Congressionally mandated demonstrations are sometimes the result of political compromise.

for certain prescription drugs delivered in physician offices and paid for under Medicare Part B. Most recently, Congress delayed implementation of competitive acquisition for DME and repealed the clinical laboratory competitive bidding demonstration in the Medicare Improvements for Patients and Providers Act of 2008.

Congress also mandates demonstrations in response to the needs of particular constituencies. For example, many members of Congress represent rural areas and are interested in supporting access to care for rural beneficiaries. Reflecting this interest, the MMA included three demonstrations on rural health issues. The Rural Hospice project evaluates the impact of waiving particular requirements for Medicare-approved hospice providers on access to hospice care in rural areas; the Rural Community Hospital Demonstration tests whether reasonable cost reimbursement for certain small rural hospitals enhances the ability of those hospitals to meet the needs of their communities; and the Frontier Extended Stay Clinic Demonstration allows payment for care of patients in nonhospital settings who need inpatient care but cannot be transferred to an inpatient facility because of weather or other circumstances.

The House and Senate appropriations committees also seek to influence the selection and implementation of Medicare projects. The appropriations committees may encourage CMS to undertake certain projects by indicating their support in the conference report accompanying the Labor, Health and Human Services, and Education Appropriations bill. Although report language does not have the same weight as a statutory mandate, CMS pays careful attention to recommendations on the use of research funding included in any appropriations bill report. Appropriators can be extremely specific in identifying their preferred projects, commonly referred to as “earmarks.” Appropriations bills have also included language that prohibits CMS from spending money to implement certain demonstrations, thereby delaying or possibly ending a demonstration. Such action can be seen as infringing on the jurisdiction of the authorizing committees, which, by the rules of the House and Senate, have responsibility for handling the substantive policy issues facing the program.¹¹

In addition to requiring new projects or studies, Congress may choose to extend existing projects (whether statutorily mandated or initiated by CMS) beyond their original time frame. In particular, Congress may act when a demonstration enjoys strong support from the providers or beneficiaries involved but expansion of the concept being tested is unlikely because, for example, savings goals were not reached. In the case of the Municipal Health Services Demonstration, Congress acted eight times to extend the project. This demonstration tested whether or not elimination of copayments and deductibles, and offering incentives such as eyeglasses and prescription drugs)

CMS pays careful attention to recommendations on the use of research funding included in any appropriations bill report.

at municipal health centers could reduce utilization of hospital inpatient and emergency department services. Begun in 1978, the demonstration ran through 2006, well beyond its original timeframe of five years.¹²

HHS Initiatives

HHS has authority to initiate demonstration projects under section 402 of the Social Security Amendments of 1967. The section 402 authority allows the Secretary of HHS to determine whether efficiency or economy of health services is increased if changes are made in the method of payment or if services are covered other than those for which payment may already be made under Medicare.¹³ Statutory authority limits CMS-initiated demonstrations to changes in methods of payment.

CMS can use its demonstration authority to signal the administration's intent to pursue a particular approach without waiting for the legislative process to produce a congressional mandate. For example, using demonstration projects that gathered voluntarily provided performance data, CMS laid the groundwork for quality incentive programs that reward physicians and providers for meeting performance goals. Congress then built on those initiatives and provided for payment adjustments to hospitals and physicians who participated.¹⁴

Since they lack a congressional directive, projects initiated under this authority may be subject to more intense scrutiny by Congress and other observers such as MedPAC and GAO. Questions may be raised as to whether such demonstrations appropriately exercise the section 402 authority and whether the program and administrative resources needed to administer the demonstration were properly used. Recent CMS demonstrations under Part D and for oncology services under Part B are not limited to a specific geographic area but rather adjust payments nationally for certain plans or services. Under the Part D demonstrations, CMS changed the methodology for calculating the Part D premium for low-income beneficiaries and allowed all prescription drug plan sponsors who intended to offer supplemental drug benefits to choose an alternative to the standard method for determining when a beneficiary would qualify for catastrophic coverage. Under the oncology demonstration, Medicare made an additional payment to oncologists for submitting quality of life or patient care data. CMS has been criticized for these atypical demonstrations, which are seen as attempts to use the demonstration authority to make widespread payment or policy adjustments without intending to gather data to explore a particular policy option.¹⁵

In addition to the demonstration authority, section 1110 of the Social Security Act provides the Secretary with the authority to make grants that pay for research projects to improve the administration and effectiveness of CMS programs, including Medicare. Grants CMS has funded in the past include unsolicited projects that are suggested by the public. However, the agency

notes that there has been a sharp reduction in research grants in recent years, and unsolicited proposals are unlikely to be funded.¹⁶

KEY ISSUES

There are a number of key issues to consider in designing, implementing, and evaluating Medicare demonstrations.

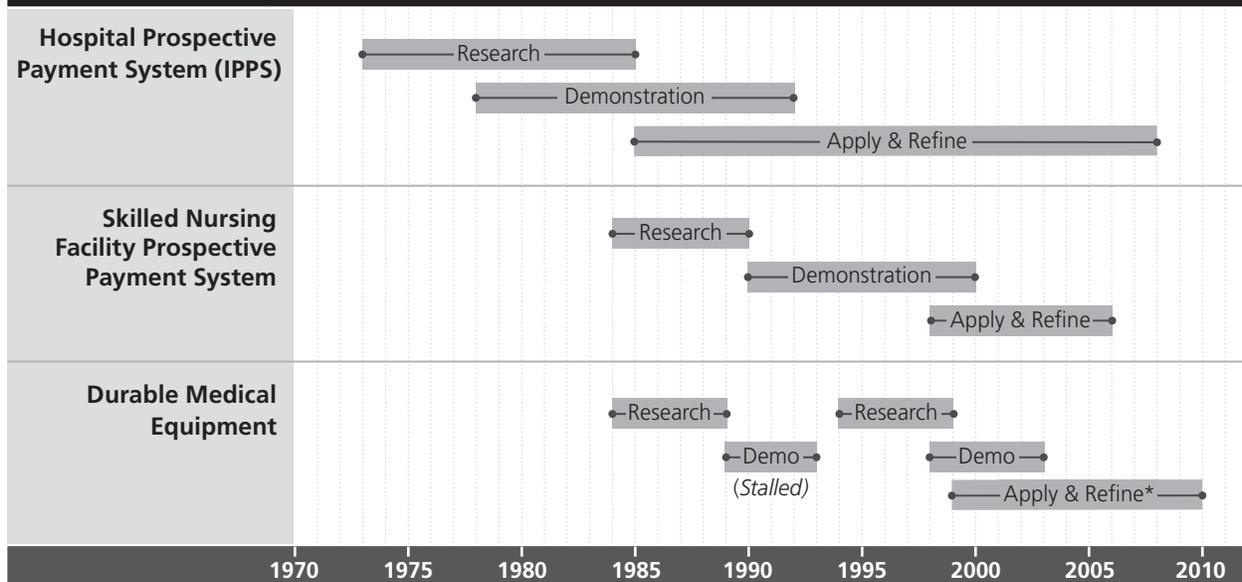
Time Required

Designing and implementing demonstrations is a multistep process that can take from months to years to complete. First, a demonstration model is developed by CMS staff with input from experts on the relevant subject. The input may be through informal consultation, advisory panels, or a formal federal contract for development design. The design must incorporate the data needs of the project's evaluation as well as address how the Medicare claims processing systems will be able to identify and correctly process claims under the demonstration model. CMS must work with HHS and OMB staff to get approval for the proposed project. The public is then notified of the demonstration and participants recruited through a notice in the *Federal Register* and on the CMS Web site, a press release, outreach to relevant provider organizations, or mailings to potential applicants. Demonstration participants (health care providers and/or beneficiaries) are selected, consistent with the requirements of the demonstration, and the participants are given adequate lead time to plan for and implement the demonstration. The demonstration then is operational for a period of between one and five years, depending on the mandate and study design. Interim evaluations may be conducted during the demonstration, and an overall evaluation is conducted after the demonstration is completed. A one-year demonstration typically takes at least three years to complete, with one year for design and solicitation of participants, one year for operation, and one year for evaluation.¹⁷ Many demonstrations also involve a refinement stage, in which results are used to refine policies or operational aspects to further hone the policy or how it is implemented. Figure 2 (next page), highlights the life cycle of three major demonstrations: IPPS, skilled nursing facility prospective payment system, and competitive bidding for durable medical equipment.

As Figure 2 indicates, significant lead time often is necessary to adequately research, design, implement, and evaluate a demonstration. The time required to carry out a demonstration may offset the usefulness of the lessons learned through the project. For example, Section 623 of the MMA mandated a report to Congress on a bundled payment system for end-stage renal disease as well as a three-year demonstration of the concept. In its report, CMS noted the delay the demonstration would cause in implementing a national bundled payment system and cited reasons that running the demonstration concurrent with implementing a bundled system would be

Designing and implementing demonstrations is a multistep process that can take from months to years to complete.

FIGURE 2: Life Cycle of Demonstrations: Research, Demonstration, and Refinement Phases



* Durable Medical Equipment was originally scheduled to be implemented July 1, 2008 but was delayed 18 months by the Medicare Improvements for Patients and Providers Act of 2008.

Source: Centers for Medicare & Medicaid Services, Master Demonstration, Evaluation and Research Studies System of Record Project List found at www.cms.hhs.gov/DemoProjectsEvalRpts; and CMS staff communication with the author, July 2008.

inappropriate. As an alternative, the agency has suggested going ahead with a national system without the demonstration and monitoring the experience of beneficiaries and providers.¹⁸ Given the need for tested ideas as policymakers consider proposals to avoid exhaustion of the Medicare Part A Trust Fund in 2019 and the relatively long lead time necessary to undertake demonstrations, some experts believe that current investments in research and demonstrations are insufficient.

Changes to the Status Quo

There is no disputing that demonstrations upset the status quo. CMS uses its demonstration authority to waive specific provisions of law or regulation to pay a subset of providers or organizations differently from other like providers or organizations in order to test a program innovation and evaluate the results. Although the Medicare waiver authority has not generally been used to make the broad changes that are permitted under the Medicaid waiver authority,¹⁹ by their very nature Medicare demonstrations require payment policies that are different from the Medicare standard.

Demonstrations may cause controversy because, while some providers or beneficiaries may benefit from the approach being tested, others may be adversely affected (or fear being adversely affected). In some instances, Congress has put additional requirements on or even prevented implementation of controversial demonstrations. For example, in the BBA, Congress mandated a competitive bidding demonstration for managed care plans

after unsuccessful attempts to implement HCFA-initiated demonstrations in Baltimore and Denver. Following objection by local plans and providers in Kansas City and Phoenix, the two sites selected for the mandated demonstration, Congress delayed the project and placed additional requirements for its implementation, effectively ending the demonstration.²⁰ In other instances, the courts have been asked to intervene to determine whether a demonstration is an appropriate use of CMS or congressional authority or whether processes for awarding contracts are correct. For example, a permanent injunction in April 2004 halted activity on a gain-sharing demonstration in New Jersey after the court determined that CMS did not have authority to waive civil monetary penalties as needed to permit gainsharing.²¹ Congress later provided explicit authority for a similar demonstration in the 2005 Deficit Reduction Act. More recently, in April 2008, a federal court issued a preliminary injunction halting implementation of the clinical laboratory competitive bidding demonstration in San Diego because HHS had not gone through the rulemaking process in designing the demonstration.

CMS attempts to mitigate the negative impact of demonstrations on beneficiaries, if possible. For example, in the DME competitive bidding demonstration, CMS included an ombudsman who responded to questions and investigated complaints from beneficiaries, physicians, and suppliers. In the hospital gainsharing demonstration, CMS has instituted continuous monitoring to ensure that the quality of care provided to beneficiaries under the demonstration is not compromised.

Whatever the difficulty of incorporating change through a demonstration project, it pales in comparison to upsetting the status quo in the Medicare program as a whole. By identifying necessary refinements to or limitations of an approach before it affects beneficiaries and providers nationwide, CMS hopes to reduce the inevitable turmoil associated with such change.

Budget Neutrality

Congress requires most mandated demonstrations to be budget neutral, which means that the demonstration must be designed so that total benefit payments under the demonstration are expected to be no more than expenditures would be under the existing payment or coverage requirements. The Office of Management and Budget (OMB) has approval authority for both mandated and CMS-initiated demonstrations and requires CMS-initiated projects to be budget neutral.²² Some demonstrations are actually required to show a reduction in program expenditures. For example, participating organizations in the Disease Management Demonstration mandated by Section 121 of the Benefit Improvement and Protection Act of 2000 (BIPA) were required by law to reduce Medicare spending, although no specific savings target was mandated. CMS also sought program savings under the Medicare Health Support projects but revised the targets to be budget neutral when anticipated savings did not occur.

The method of reaching budget neutrality varies from demonstration to demonstration, depending on design, and must be approved by OMB. In some cases, the participating health care providers or organizations agree to put a portion of their payments at risk to ensure that the project does not increase spending. The BIPA Disease Management demonstration covered both disease management services and prescription drug costs (prior to the existence of Medicare Part D), and participating organizations had to assume the risk if the project did not reduce Medicare expenditures.²³ Such an approach is relatively rare and can be a disincentive for providers or organizations to participate.

Demonstrations are typically designed to offset anticipated costs with anticipated savings. Assumptions of costs and savings are based on available evidence, which may be limited, particularly for the savings assumptions. The implication of failing to achieve assumed savings varies among demonstrations. In some cases, such as the Physician Group Practice Demonstration and the Home Health Pay for Performance Demonstration, incentive payments included in the demonstration design are not awarded if the participating organization does not generate sufficient savings. In other cases, increased payments under the demonstration are offset by reducing payments for the type of provider nationally. The Expansion of Coverage of Chiropractic Services Demonstration mandated by Section 651 of the MMA allowed coverage in four sites for services that chiropractors could provide under their licensure but which had not previously been covered by Medicare. The demonstration tested whether coverage of such services would reduce Medicare spending on other services, such as hospital or physician care. The law requires that expenditures under the demonstration not exceed what expenditures would have been without the demonstration. If the demonstration is shown to increase spending over its two-year duration, payments for all chiropractor services nationally will be reduced to make up the difference.²⁴

In many instances, though, higher-than-expected costs or lower-than-expected savings under a demonstration are not recouped. Instead, such experience is considered during the evaluation of the project and the decision about whether to adopt the proposed approach more widely. In developing the Medicare Health Support program, for example, CMS established a five percent savings threshold for participating organizations in the pilot phase of the program. As noted, participants had difficulty achieving the target savings and asked that the standard be adjusted to be budget neutral. Ultimately though, according to CMS, costs for the projects were between 5 percent and 11 percent greater than they would have been, absent the intervention. CMS is ending the current projects as scheduled and will determine whether to exercise its authority to implement a second phase of the project following completion of the Phase I evaluation.²⁵

When estimating budget neutrality for a demonstration, CMS typically looks at total expenditures, not just payments for a certain type of provider. Additional expenditures on a specific provider or supplier type may be

Demonstrations are typically designed to offset anticipated costs with anticipated savings.

expected to be offset by reduced expenditures in other areas, allowing the demonstration to meet the requirements for budget neutrality. Such a calculation cannot occur under most Medicare payment systems, which are required to be budget neutral within the payments for a specific type of provider. For example, increased spending on physicians for certain services that may reduce expenditures on inpatient hospital care must be offset by reduction in payment for other services under the physician fee schedule, without consideration of the reduced inpatient spending. However, the current application of budget neutrality has also been criticized for its narrowness. The calculation of whether a project is budget neutral is determined from results over the relatively short duration of the demonstration and therefore does not account for potential long-term savings from some interventions. In addition, budget neutrality does not generally recognize savings to other federally funded programs, including Medicaid, and it does not take into consideration the quality of the services being purchased.²⁶

Demonstrations are collaborations between CMS, providers, suppliers and organizations, and Medicare beneficiaries.

Voluntary Provider and Beneficiary Participation

Generally voluntary in nature, demonstrations are collaborations between CMS, health care providers, suppliers and organizations, and Medicare beneficiaries. CMS designs a project and hopes that practitioners, providers, and plans as well as beneficiaries will want to participate. In some instances, such as the disease management demonstrations, the demonstration organizations recruit from pools of eligible beneficiaries to identify participants. In other cases, such as the Acute Care Episode Demonstration, selected hospitals are paid under the demonstration for all beneficiaries treated at the hospital who meet the demonstration qualifications and must only notify beneficiaries of the hospital's participation in the demonstration. Competitive bidding demonstrations, such as those for health plans, durable medical equipment, and laboratory services, are the exception to the voluntary nature of demonstrations. These typically require that beneficiaries within the geographic area of the demonstration purchase items or services only from the suppliers selected for participation in the project. Some demonstrations have not been fully implemented because plans or providers have not wanted to offer the services provided under the demonstration or because beneficiary enrollment has been limited. For example, the Medical Savings Account demonstration was designed to test a new product that would combine a high-deductible health plan with a personal health account to be used for out-of-pocket costs, but organization initially was willing to offer the product.²⁷ The Lifestyle Modification Demonstration sought to test the impact of programs including intense nutrition and stress-reduction interventions on beneficiaries with moderate to severe coronary artery disease. Although the project included 16 sites, fewer than 600 beneficiaries enrolled over six years.²⁸

Evaluation

Most mandated demonstrations require an evaluation and report to Congress on recommendations regarding the proposed approach. CMS also evaluates agency-initiated demonstrations. The agency contracts out evaluation reports through task order contracts with research firms, and the evaluation design is often developed at the same time the demonstration itself is being developed.

Evaluators strive for the highest quality research design in assessing demonstrations, with comparability between experimental and control groups and sufficient data to control for other factors that may affect outcomes. However, designing and implementing such a study can be expensive and time-consuming.²⁹ The dynamic nature of demonstrations can also complicate such an evaluation, which is designed to gather data from a specific experiment with a particular design. If the demonstration is adapted to respond to unanticipated events, the data gathered change and the evaluation must adapt, potentially causing further delays in analyzing and reporting on the effects of the demonstration.³⁰

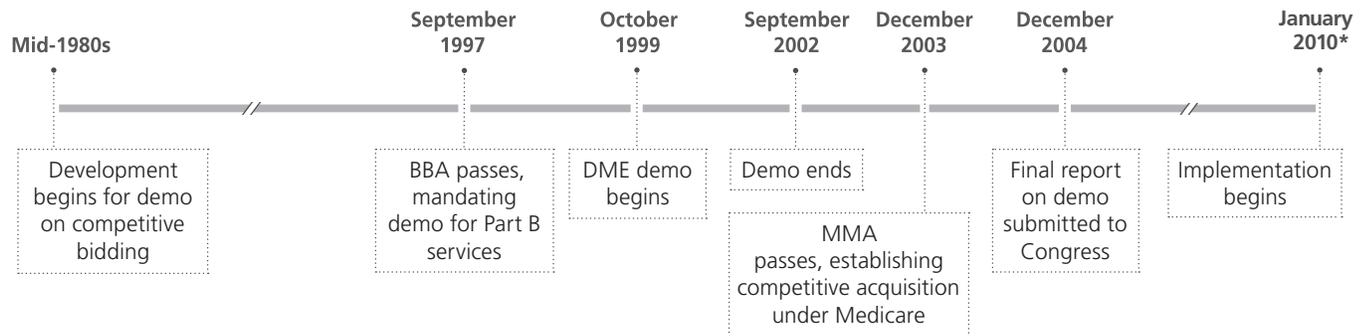
Not all demonstration evaluations reach this exacting standard in their design. Isolating the specific impact of multiple (and often simultaneous) interventions can be difficult, if not impossible. There is also a tension between the desire for comprehensive evaluations that take into consideration a range of impacts, including the long-term effects of a change, and the need to produce timely and meaningful results. Observers have suggested ways to accelerate the evaluation process, including continuous monitoring of demonstration projects or use of alternative models that allow rapid-cycle feedback on change to expedite incorporation of demonstration findings into consideration of policy changes.³¹ CMS has recently incorporated some of these approaches into its evaluation of the disease management demonstrations.

INCORPORATION OF RESULTS INTO MEDICARE

While designing, implementing, and evaluating demonstrations often can be a challenge for CMS, providers, and beneficiaries, few contest that the research, policy, and operational knowledge gained is worth the effort. Former HCFA officials have bluntly stated the value of demonstrations in an article on the agency's experience with the competitive bidding demonstration: "We know that it is difficult to change Medicare, but it is worse to do so without testing new ideas."³² A major hurdle in modifying Medicare can be the lack of a mechanism, other than a change in the statute, for incorporating successful demonstration approaches into the program nationwide.

In some instances, the demonstration project provides evidence that can be utilized in the Medicare coverage process to determine what treatments are medically reasonable and necessary. These instances,

FIGURE 3
Adopting Change Under Medicare: Years in the Life of Competitive Acquisition of Durable Medical Equipment



such as the Lifestyle Modification Demonstration, are relatively rare, however, since the treatment being evaluated must be coverable under existing Medicare law. There is often no mechanism that allows CMS to apply more broadly many of its findings from demonstrations. While the administration can include proposals in the President’s budget to incorporate successful approaches into the program, Congress must act for most payment or coverage changes to be adopted. An exception is Medicare Health Support, which Congress authorized the Secretary to implement in two phases. Although it appears unlikely from preliminary indications, if the evaluation following the first phase indicates that the program met the conditions of improving quality of care and beneficiary satisfaction and reached savings targets, the Secretary is required to expand geographic implementation of the program and could implement it on a national basis without further action from Congress.

Without a mechanism for incorporation into the larger program, demonstrations can frustrate proponents of an approach who are skeptical that their idea will be more generally utilized.³³ Even when Congress acts in a prompt fashion in response to demonstration findings, the process of incorporating input from demonstrations into the program can be lengthy. For example, more than ten years passed between the time the competitive bid demonstration was mandated by the BBA and implementation of competitive acquisition for DME (Figure 3).

As noted, the time required to complete and assess a demonstration often does not keep pace with congressional demands for making program changes. As the DME competitive acquisition timeline shows, Congress does not always wait for the demonstration evaluations to be completed before acting. In some instances, Congress has adopted approaches being tested under demonstrations before those demonstrations have even been fully operational, much less evaluated. For example, the Medicare Choices Demonstration tested methods for offering new types of managed care products under Medicare and alternative risk-based payments

BBA — *Balanced Budget Act of 1997*

DME — *Durable Medical Equipment*

MMA — *Medicare Prescription Drug, Improvement and Modernization Act of 2003*

*Originally scheduled to be implemented July 1, 2008 but was delayed 18 months by the Medicare Improvements for Patients and Providers Act of 2008.

Source: Centers for Medicare & Medicaid Services (CMS), “First Annual Report to Congress: Evaluation of Medicare’s Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,” November 30, 2000, and CMS, “Final Report to Congress: Evaluation of Medicare’s Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.” 2004; both available at www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=dual,%20keyword&filterValue=DME&filterByDID=0&sortByDID=3&sortOrder=descending&itemID=CMS063474&intNumPerPage=10.

for managed care. The earliest enrollment in a plan under the demonstration was in February 1997, with most enrollment beginning in spring and summer of that year. However, when Congress passed the BBA in August 1997, it adopted for the larger Medicare managed care program many of the methods being tested under the Choices demonstration.³⁴

Even absent an incorporating mechanism, demonstrations still provide CMS with valuable operational experience that can often be applied in other instances. And the issues faced in implementing and evaluating a project may continue to be relevant as future demonstrations are developed. For example, the Medicare Participating Heart Bypass Center Demonstration was completed in 1996 and showed that the design, which made a global payment for both hospital and physician care for coronary artery bypass graft surgery, could reduce costs and improve quality. However, participating hospitals did not see an anticipated increase in their market share and the concept was shelved. Interest in this idea has been renewed and CMS is soliciting participants for a related project, the Acute Care Episode Demonstration, that incorporates competitive bidding into the design.³⁵

Over time, demonstration projects have shifted from broad experiments in restructuring the way the Medicare program pays for services to more subtle refinements of those restructured payment systems. No matter the specific focus, the overall goal of demonstration projects is to provide congressional and administration policymakers with the tools they need to update and improve the Medicare program. Concern that projects may not be meeting this overarching goal has been fairly constant over the history of demonstrations. In 1980, the House Ways and Means Subcommittee on Oversight held a hearing on the relevance and usefulness of the Medicare research and demonstrations projects, the timeliness of reports and feedback to Congress on those projects, the quality of the evaluation of demonstration projects, and the dissemination of demonstration results.³⁶ Members emphasized that the issues in this hearing were similar to those raised in a 1976 hearing,³⁷ and similar complaints about Medicare demonstrations are heard today.³⁸

The frustration with demonstration projects occurs in part because of the complexity of the issues involved and the importance of resolving the ongoing dilemmas in Medicare. Congress needs assistance to identify solutions for these problems and expects demonstration projects to expand its knowledge in a meaningful way. However, as the saying goes, “hindsight is 20/20.” It is easier to identify projects that are not productive after the fact than before they are implemented. It can also be difficult to identify which project will be the most successful or important until many years after the project is completed and the innovations are incorporated into Medicare. The 1980 Subcommittee on Oversight hearing, for example, occurred at the same time that the demonstrations leading to the IPPS were getting under way.

The goal of demonstration projects is to provide policymakers with the tools they need to improve the Medicare program.

CONCLUSION

Medicare's coverage and payment policies not only apply to the care received by the program's 44 million beneficiaries but also are often the standard other insurers use to determine their own coverage and payment practices. Changes to Medicare policies therefore can have a significant and far-ranging impact on health care practice, payment, and administration in the United States. Changes to the program can also affect Medicare's total spending, which in turn affects the funds available for other national spending priorities. Research and demonstrations allow CMS and Congress to explore the application of new ideas to Medicare in a targeted manner. Absent these mechanisms, changes would be made on a much larger scale, and the whole program and its beneficiaries would face the ups and downs of refining the new approach. However, significant lead time is required to design, implement, evaluate, and refine demonstrations. Having results available when they are needed requires both forethought and funding. In looking for tools to sustain, update, and improve Medicare in the future, Congress will turn to the results of demonstrations to inform their deliberations. The more robust, timely, and innovative demonstration projects are, the better prepared Congress will be to consider potential changes to Medicare.

ENDNOTES

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APPENDIX
CMS Research Budget, FY 2000 to Proposed FY 2009 (in millions of dollars)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009*
Research and Demonstrations	\$ 40.3	\$ 39.6	\$ 42.3	\$ 15.5	\$ 41.5	\$ 44.7	\$ 31.1	\$ 23.4	\$ 25.0	\$ 14.4
Congressional Earmarks	10.3	37.3	22.9	5.8	17.1	12.7	0.0	0.0	4.9	0.0
Real Choice Systems Change Grants	0.0	50.0	40.0	40.0	39.5	39.7	24.7	15.9	9.8	7.5
Medicare Current Beneficiary Survey	11.2	11.4	12.0	12.4	13.4	13.1	13.6	18.4	7.2	14.4
TOTAL RESEARCH	\$ 61.8	\$ 138.3	\$ 117.2	\$ 73.7	\$ 111.5	\$ 110.2	\$ 69.4	\$ 57.7	\$ 46.9	\$ 36.3

* President's proposed FY 2009 budget.

A congressional earmark is a demonstration or research project with a funding amount appropriated in the statute. Generally, an earmarked project is unique to a particular participant or geographic area.

Note: Includes funds from the CMS Research Appropriation and selected sections of additional legislation such as the Medicare Prescription Drug, Improvement and Modernization Act of 2003; the Deficit Reduction Act of 2005; the Tax Relief and Health Care Act of 2006; and the Medicare, Medicaid, and SCHIP Extension Act of 2007. Funds in the Quality Improvement Organization budget and Informational Technology systems changes that support research and demonstration activities are not included. Medicare Current Beneficiary Survey funding is lower in FY 2008 due to forward funding in FY 2007 and partial year funding in 2008.

Source: U.S. Department of Health and Human Services, "Justification of Estimates for Appropriations Committees," available at www.hhs.gov/budget/docbudget.htm; CMS, staff communication with author, April 2008.