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Shaping Public Programs through Medicare, Medicaid, and SCHIP Waivers: The Fundamentals

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OVERVIEW — *This paper examines the use of research, demonstration, and program waiver authorities to test new approaches to the delivery of and payment for health care services in federally financed health coverage programs such as Medicare, Medicaid, and the State Children's Health Insurance Program. This background paper examines the mechanics of waivers as well as their history and political context in shaping public programs. It also explores the ways the changing state-federal relationship and the ever-growing demand for state flexibility have driven waiver policy.*

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Shaping Public Programs through Medicare, Medicaid, and SCHIP Waivers: The Fundamentals

Research, demonstration, and program waiver authorities are important vehicles for testing innovative strategies in public programs. The Web site of the Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration, or HCFA) lists more than 600 active research and demonstration projects and more than 350 other programs approved through waivers. The sheer number of projects is an indication of their importance in shaping and evaluating the way services are delivered.

AN INTRODUCTION TO WAIVERS

The Social Security Act (SSA) provides the authority to “waive” certain provisions of the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) statutes that enable states and the federal government to explore new approaches to providing health care services. Waiver authority in Medicaid and Medicare plays several roles: it permits states and the federal government to test new, innovative, and more cost-effective approaches to delivering and financing health care services; it can be a vehicle for advancing an administration’s policy and political priorities; and it gives Congress an opportunity to direct the Department of Health and Human Services to test promising new payment and delivery mechanisms. The flexibility provided through waivers has enabled many states to fundamentally reshape their Medicaid programs, to the point that, in many states, the demonstrations have effectively *become* the Medicaid programs. Research and demonstration projects have also brought major changes to Medicare, particularly in the 1980s. The Medicare program, for example, used demonstration authority to test the prospective payment system for hospitals that is used widely today, not only by Medicare but also by many private insurers. Congress has also mandated a number of specific research and demonstration projects, such as social health maintenance organizations (S/HMOs) and competitive pricing projects to test alternative payment systems and innovations in health care delivery. While there are many provisions that cannot be waived (such as Medicare eligibility and freedom of choice), use of these authorities over the years has changed the face of the Medicaid, Medicare, and welfare programs by permitting innovation.

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Medicaid: The Basics

The Medicaid program uses waiver authority to alter provisions of the statute that otherwise prevent states from implementing certain types of programs. The program is structured around several fundamental principles that act as guidelines for states. While the rules provide a great deal of flexibility, there are also protections in place to ensure that Medicaid beneficiaries are treated fairly and appropriately. These program standards are known, in policy shorthand, as *amount, duration, and scope; comparability; and statewideness*:

■ **Amount, duration, and scope**—The statute requires that each Medicaid service category must be “sufficient in amount, duration, and scope to reasonably achieve its purpose.” States may vary the amount, duration, and scope of services they cover, within general limits. For example, although the law permits states to impose day limits on services, a state would not be permitted to limit coverage for inpatient hospital care to only one day per year.

■ **Comparability**—Medicaid benefits must also be comparable across the eligible population, meaning that states may not discriminate by providing different services to specific groups or limit services based on diagnosis, type of illness, or condition.

■ **Statewideness**—States are generally required to make Medicaid benefits available to all eligible individuals, regardless of where in the state they live. For example, a state that covers prescription drugs must make that coverage available in both its rural and urban areas.¹

While these principles are a key aspect of the Medicaid program structure, the federal government is authorized to waive these and other statutory provisions for purposes of research and to permit states to demonstrate new and innovative service delivery and financing strategies. Medicaid waivers can be divided into two categories: *research and demonstration projects* and *program waivers*.

Research and demonstration projects are authorized under Section 1115 of the Social Security Act (SSA). Section 1115, enacted in 1962, gives broad authority to the secretary of the Department of Health and Human Services (DHHS) to authorize “any experimental, pilot or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives” of the programs covered by the SSA. These projects are usually innovative and their designs require greater flexibility from the federal government, in terms of the types and numbers of rules that are altered, than program waivers. In addition, Section 1115 research and demonstration projects are required, by policy and practice, to include a research or evaluation component, at least for the initial approval period.² While Section 1115 authority today is primarily associated with Medicaid, it also applies to several other titles of the SSA, including Supplemental Security Income (SSI), Temporary Assistance for Needy Families (TANF, formerly Aid to Families with Dependent Children, or AFDC),³ and SCHIP.

Medicaid program waivers are more limited in the types of projects that can be implemented. Two types of program waivers were enacted in 1981 and are currently in use. Section 1915(b) authorizes states to implement delivery models, such as mandatory enrollment in managed care, that require eligible beneficiaries to use certain providers to receive services. Section 1915(c) authorizes states to provide home and community-based services as an alternative to institutional care in hospitals, nursing homes, and intermediate care facilities for persons with mental retardation (ICFs/MR).⁴

Medicare: The Basics

The Medicare program also relies on research and demonstration authority to test new payment and delivery mechanisms. Section 402 of the 1967 Social Security Amendments, as amended by Section 222(b) of the 1972 Social Security Amendments, provides broad authority to research Medicare provider reimbursement mechanisms (other than prospective payment) and to cover a variety of services that are not normally covered and to measure their effectiveness. It provides authority to waive the Medicare reasonable cost and reasonable charge requirements,⁵ and it is this section that is most commonly used today for Medicare research and demonstration initiatives. Section 222(a) of the Social Security Amendments of 1972 authorizes the secretary to conduct experiments and demonstrations that test alternative prospective payment methodologies.

Congress can also mandate that certain types of research and demonstration projects are conducted. Congress usually takes such action for promising approaches that it believes should be given immediate priority or should be tested before they are implemented on a broader scale. For example, over the years, Congress has used its authority to direct the DHHS secretary to experiment with approaches to coordinating the delivery of acute and long-term care in demonstration programs such as the Program of All-Inclusive Care for the Elderly (PACE) and the S/HMO program.

Medicare research and demonstration projects differ from Medicaid demonstrations in several important ways. Beneficiaries are treated differently in that the Medicare program has no demonstration authority to waive freedom of choice of providers; therefore, enrollment in managed care arrangements is purely voluntary. There is also no ability under Medicare demonstration authority to expand eligibility, whereas Medicaid has several mechanisms for coverage expansion. Another important difference is that Medicare is a national program, which leads to the expectation that the same benefits and services will be offered nationwide to its beneficiaries. This expectation makes changes to the Medicare program more challenging because of the complexity of making changes on a national level. Medicaid, on the other hand, essentially offers the potential of 50 very different states as laboratories for experimentation. Finally, Medicare also generally relies on voluntary participation of providers, which can make it difficult to obtain their participation in demonstrations that could significantly affect their revenues.

The Medicare program has no demonstration authority to waive freedom of choice of providers.

Financing

An important aspect of all research and demonstration projects and program waivers is the requirement for budget or cost neutrality. Although applied somewhat differently in each waiver type, the principle is that programs conducted under a demonstration project should not cost the federal government more than would have been spent under program rules without the demonstration. *Cost neutrality* for 1915(b) waivers and *cost effectiveness* for 1915(c) waivers are statutory requirements that have been in place since the first program waivers were proposed. *Budget neutrality* has been mandated by federal policy since 1983 and applies to both Medicaid Section 1115 demonstration projects and Medicare demonstration projects.

The concept of budget neutrality has become a major driver in the negotiation and approval process for research and demonstration projects. During the 1970s and early 1980s, the only budgetary restriction placed on projects was that the overall operating budget for research and demonstration activities—the funds apportioned to HCFA⁶ to staff and evaluate projects—could not exceed the amount specified in the president's budget. The Office of Management and Budget (OMB) originally implemented this restriction through the budget process in response to concerns that some projects, especially hospital prospective payment system (PPS) demonstrations, were significantly increasing program costs and involved significant portions of the Medicare trust fund.

Over a period of several years, the OMB became increasingly concerned about the large amount of program service costs that were tied to research and demonstration projects.⁷ In 1983, an agreement between the OMB and DHHS gave the OMB clearance authority for demonstration projects and established the budget neutrality policy. Following that agreement, the OMB used its authority to reject or delay a number of demonstration projects and program expansions that it viewed as fiscally undesirable in the tight budget atmosphere of the time. The more extensive review that was necessary to assure budget neutrality also may have had a dampening effect on the number of projects being initiated. The OMB's entry into the approval process coincided with a sharp decline in the level of demonstration project activity and, shortly thereafter, an increase in congressionally mandated projects.⁸

The budget neutrality requirements for Medicaid Section 1115 demonstrations have led states to pursue to a number of creative financing approaches in order to expand coverage or services that would not usually be eligible for federal matching funds. They have also led to many contentious negotiations between states and DHHS. (See further discussion below.) In Medicare, the budget neutrality analysis of costs with and without the waiver is done in a similar manner; however, the process is less contentious because providers are not usually at risk for cost overruns unless, for example, a managed care demonstration using capitated payments is being tested.

The OMB became increasingly concerned about the large amount of program service costs that were tied to research and demonstration projects.

Process and Politics

Another important aspect of demonstration projects and program waivers is that they often reflect the policy priorities of the administration in office at the time the proposal is approved. Precedents set through approval of a project, though frequently difficult to negotiate initially, can clear the path for similar projects in the future. Administration policy can be influenced by a variety of interest groups, and priorities are often based on the leading health care delivery and financing concepts of the day. For example, managed care has come in and out of favor over the years, and demonstration approvals reflect those trends. The current enthusiasm for moving away from institutional care and toward community-based services for the elderly and those with disabilities is illustrated by a tremendous amount of program waiver activity in this area.

Waiver proposals are initiated in several different ways. In Medicaid, proposals are most often generated by states looking for flexibility to try new approaches to program administration and service delivery. CMS also encourages projects by providing written guidance and suggestions for certain types of proposals that would be of interest. For example, in its guidance for the Health Insurance Flexibility and Accountability (HIFA) demonstration initiative, CMS strongly encouraged states to integrate premium assistance programs with Medicaid/SCHIP. CMS also issues more formal requests for research and demonstration proposals, usually related to Medicare, that are published in the *Federal Register*. These solicitations set out criteria for participation in specific research and demonstration or evaluation projects.

No matter how proposals are initiated, all go through negotiations between the proposers and DHHS during which the design features of the proposals may be significantly changed. Medicare demonstration proposals that respond to specific solicitations may be somewhat more straightforward because the solicitation has laid out the parameters for the proposal. Nonetheless, the negotiation and approval process for research and demonstration projects has often been criticized for its difficulty and the amount of time it takes. However, it is important to note that the internal review process can include a large number of federal staff representing various parts of the administration—from the CMS regional office all the way to the OMB and the White House—and each component must agree with the terms of approval. The majority of time is often spent on reviewing whether the proposal meets the budget neutrality test. Alterations to the budget neutrality formula can affect the project design, the size of the expansion, the funding mechanism, and even the list of covered services. Even after the project has been approved, however, the proposer and DHHS must work out a host of design and implementation issues (such as enrollment, marketing, evidence of coverage contracts, provider contracts, and grievance and appeals systems) before the program can get under way. Nonetheless, research and demonstration projects

Precedents set through approval of a project can clear the path for similar projects in the future.

and program waivers provide the best vehicle currently available to test new approaches to expanding coverage, controlling costs, and improving quality of care.

Evaluation

Most demonstration projects are evaluated to determine the success of the project in achieving its research and policy objectives. DHHS may contract with independent research organizations to evaluate a specific project or group of projects. In recent years, as its research budget has decreased, DHHS has placed its priority on evaluating its Medicare demonstrations and has required some Medicaid and SCHIP agencies to produce their own evaluations. Because these evaluation efforts, particularly in Medicaid, are sometimes hampered by a lack of adequate data, their effectiveness has been questioned. In addition, demonstrations that have been widely replicated have been criticized for moving away from the original research nature of the waiver authority that initially used a more limited experimental design.⁹ However, one could argue that the experience gained from the more liberal use of demonstrations and program waivers has permitted the program to develop at a much more rapid pace than would have otherwise been possible, especially given the lack of congressional willingness to “open up” the Medicaid statute.

Theoretically, successful programs could be adopted by Congress and made permanent. In practice, however, the interaction between the legislative and executive branches has not always been smooth. Congress has acted in some instances before DHHS has fully evaluated a project’s results, as was the case with the legislation that created a hospice benefit in the Medicare program. Time lags in completing evaluations have also been an issue. At other times, Congress has been slow to legislate changes for seemingly successful programs. For example, the PACE program operated under demonstration status for 11 years before Congress acted to make it a permanent part of the Medicare and Medicaid statutes.

It is important to note that statutory changes often do not include all of the elements that are needed in order for a demonstration project to continue to operate without waivers, in some cases resulting in low state and provider participation rates. For example, because provisions of the new state plan option do not provide as much flexibility as is available under the waiver authority, only 15 states have converted their Section 1915(b) waivers into state plan amendments in the six years since enactment. Demonstration results may also be difficult to generalize to the nation as a whole due to unique features within a particular project or area of the country. Moreover, no matter how successful the demonstrations might appear, members of Congress may continue to disagree with certain approaches to service delivery.

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MEDICAID SECTION 1115 DEMONSTRATIONS IN DEPTH

Statutory Provisions

Section 1115 permits the DHHS secretary to approve projects consistent with objectives of certain programs authorized under the SSA. Section 1115 may be used to waive certain sections of several titles of the SSA, including Titles I (Old-Age Assistance), X (Aid to the Blind), XIV (Aid to the Permanently and Totally Disabled), XVI (SSI for Aged, Blind, and Disabled), XIX (Medicaid), or part A or D of Title IV (TANF/AFDC). Section 1115 authority has rarely been used in relation to the Social Security program. It has been used most extensively to alter Medicaid and, prior to welfare reform in 1996, the AFDC program. Section 1115 authority also applies to SCHIP, which was enacted as part of the Balanced Budget Act (BBA) of 1997, and demonstration projects are underway in seven states.¹⁰

The first provision of Section 1115, Section 1115(a)(1), allows the secretary to waive provisions of Section 1902 of the Medicaid statute, the key section that contains the state plan requirements. (Each state operates its Medicaid program under a plan that is approved by CMS.) Section 1902 outlines the information that must be included in the state plan and sets the federal parameters within which states must operate. The state plan describes the states' Medicaid eligibility criteria and the services that will be offered, as well as the service delivery and payment methodologies the state uses in administering Medicaid. For example, under an 1115 demonstration proposal, a state might propose to use income as the sole criterion in determining eligibility. (Historically, states have considered an individual's assets or have disregarded certain types of income, such as child care, in calculating financial eligibility for the program). States have also proposed modifying the benefit package to provide certain benefits to one group, such as pregnant substance abusers, and not to others.

Perhaps more significantly, Section 1115(a)(2) permits the secretary to provide federal matching payments for state costs that would not otherwise be matched under Section 1903, the section that contains funding requirements. It is this "costs-not-otherwise-matchable" authority that has been widely used for statewide health care reform demonstrations that expand coverage to new populations—such as childless adults—and services that Medicaid does not normally cover. Another common use, prior to enactment of the BBA, was to permit states to contract with health maintenance organizations (HMOs) that did not meet the Medicaid participation requirements¹¹ and, therefore, would not usually be eligible to receive Medicaid reimbursement. Because covering new populations and services has the potential to greatly increase state and federal costs of the program, budget neutrality is often a major point of contention.

Section 1115 research and demonstration projects are, theoretically, approved for a limited period of time—generally five years. However, in

practice, many demonstrations have operated for far longer and to date, demonstrations have only been terminated at a state's request. For example, Arizona's Medicaid program has operated under Section 1115 authority since its initial approval in 1982. In addition, the BBA included a provision for one three-year renewal period after the first five years of operation. The ability to extend approvals for these demonstrations was affirmed in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which permitted the secretary to continue granting three-year extensions to existing Section 1115 demonstration projects.

Financing Options

States have always had the ability to provide health coverage to any and all of their residents, above and beyond the federal Medicaid guidelines. However, if states choose to cover populations that are not eligible for Medicaid services under federal rules (such as nondisabled adults without children), they must do so with state-only funds, unless they are granted demonstration authority that allows them to receive federal Medicaid matching funds (known as federal financial participation, or FFP) for these populations. The financing of these types of expansions is often the most complex part of the application process, because of the requirement for budget neutrality.

As described earlier, for a demonstration project to be considered budget neutral, federal expenditures over the life of a demonstration must be no greater than they would have been without the demonstration. In order to maintain budget neutrality, states need to identify savings in their programs to offset the cost of any program expansion. There are several sources of savings that states have used to fund Medicaid program expansions:

Managed Care Savings — Existing statewide Section 1115 demonstrations have most commonly projected savings through the use of managed care. Requiring Medicaid beneficiaries to enroll in managed care plans has been an effective strategy to limit federal and state expenditures. However, use of this source of savings is more limited now than in early demonstrations due to rising premium costs and the fact that most states are already using managed care to the maximum extent feasible.

Redirecting Medicaid Disproportionate Share Hospital (DSH) Payments¹² — States have proposed the use of allotted DSH funding on the premise that the need to pay hospitals for services to indigent patients is reduced when health insurance is provided for expansion populations. Some states have successfully used DSH as a financing mechanism, but others have been deterred by concerns regarding reduced DSH funding from the provider community. In addition, states' proposals may not have a clear impact on hospital costs, so DSH is not always a logical funding source.

Benefit and Cost-Sharing Savings — To the extent a state offers more limited benefits than would normally be provided under Medicaid or increases cost sharing to existing populations, the projected savings can

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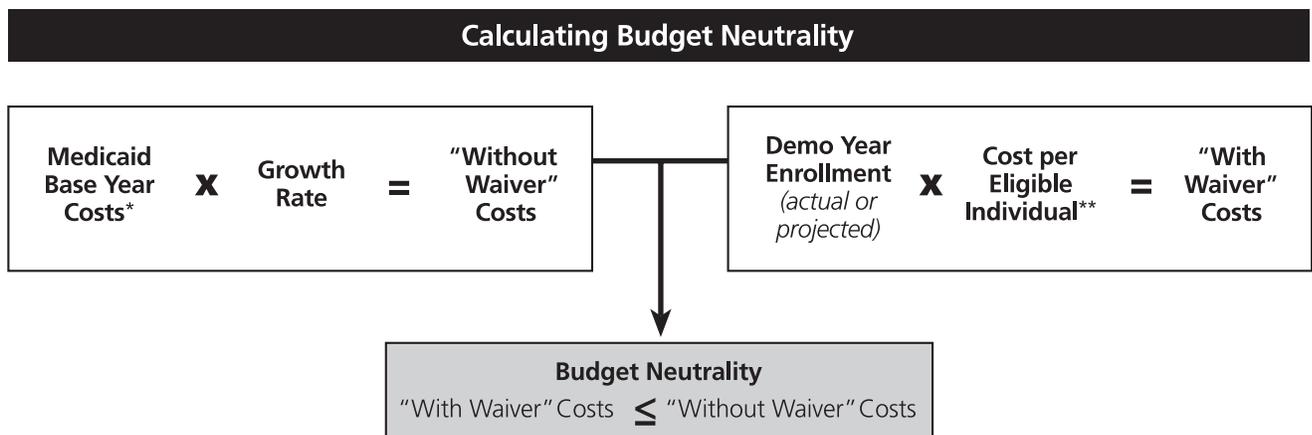
be used to finance the expansion of services to new populations. For example, Oregon’s demonstration, approved in 1993, established a priority list of health services, which replaced the Medicaid benefit package for all beneficiaries in the state. The resulting reduction in benefit costs, combined with cost sharing and the use of managed care, permitted the state to cover many uninsured individuals who had not previously been eligible for Medicaid. This financing strategy has also been used more recently under the HIFA initiative (see discussion below).

Calculating Budget Neutrality

The expenditure limit, or budget-neutrality cap, for research and demonstration projects is based on projections of what federal costs would have been had there been no demonstration—sometimes called the *without waiver costs*. The budget neutrality cap may apply to some or all of the project’s service expenditures and may also include DSH expenditures.

Budget neutrality is calculated by first determining a state’s Medicaid costs in a base year. The base year is usually the 12-month period for which the most recent, complete program data are available. *Growth rates* are then applied to the base year data to project future expenditures to create the without waiver baseline. The growth rates are determined by using historical caseload and expenditure data over the prior five-year period. The lower of either this historical growth rate or the Medicaid growth rate in the president’s budget is used to set the budget-neutral expenditure limit for the demonstration. The *with waiver costs*, including any new populations or services, are then compared to the without waiver costs to establish that the project is budget-neutral. (See Figure 1 for a simplified illustration of how the budget neutrality cap may be calculated.)

FIGURE 1



* Base year costs include the number of enrollees (in member months) and costs per eligible individual for a given year.

** The cost per eligible individual is fixed based on the base-year costs and growth rate that have been negotiated for the “without waiver” costs.

The budget neutrality cap is usually calculated on a per member per month, or per capita, basis, eliminating financial exposure should enrollment growth exceed projections. However, aggregate caps have occasionally been used.¹³ In a budget-neutrality agreement with a per capita cap, the cost per eligible individual is fixed during negotiations; however, total expenditures over the life of the demonstration will vary based on actual enrollment. In a budget-neutrality agreement with an aggregate cap, the total expenditures as determined during negotiations form an overall cap on expenditures for the demonstration. Once established through negotiations between the state and DHHS, the cap on demonstration costs generally is not changed during the approval period of the demonstration. Negotiations around budget neutrality are often lengthy and contentious, since the outcome is critical to a state's ability to fully fund the demonstration and receive federal matching payments, as well as to the federal government's ability to contain its costs.

Hypothetical Expansions — Since the mid-1990s, CMS and the OMB have permitted *hypothetical program expansions* to be included in the without waiver baseline. These hypothetical program expansions are program elements that states have the authority to adopt under current law but which are not currently part of the state's Medicaid program. For example, a state may propose to provide health coverage to children up to 185 percent of the federal poverty level, which is above the mandated Medicaid eligibility levels and can be accomplished through the use of existing law. In a demonstration proposal, the hypothetical expenditures for these as yet uncovered children may be included in the base-year calculations, effectively raising the expenditure limit for the demonstration. States have been using this creative method of calculating budget-neutrality expenditure limits to pursue their program expansions since the mid-1990s. This approach to financing has been criticized by the General Accounting Office (GAO) almost from the moment of its inception because the GAO believes that this methodology artificially inflates the amount the federal government would pay in the absence of the waiver.¹⁴

1115s, SCHIP, and Allotment Neutrality

As mentioned earlier, Section 1115 demonstration authority also applies to the SCHIP program. Because of its unique funding formula that provides a higher, enhanced federal matching rate, states have shown great interest in utilizing the demonstration authority to shape SCHIP programs in ways that better meet states' needs and maximize the use of available federal funds.

The advent of SCHIP and the ability to use monies from the state's SCHIP allotment¹⁵ for demonstration expansions has altered the budget neutrality equation. When SCHIP funds are used, *allotment neutrality* rather than budget neutrality applies. Instead of obtaining savings to finance coverage expansions, a state may use the unspent portion of its SCHIP allotments up to the annual allotment cap, as well as currently redistributed

When SCHIP funds are used, allotment neutrality rather than budget neutrality applies.

funds.¹⁶ One advantage to this interpretation is that states can receive the SCHIP enhanced federal matching payments for covering expansion populations—including parents, pregnant women, and childless adults—using the SCHIP allotment, rather than the state’s usual Medicaid matching rate. However, the statutory funding formula includes a reduction in allotments to states, known as “the SCHIP dip,” that began in 2002. This decrease, in combination with continued increases in SCHIP enrollment and the state fiscal crisis, has significantly compromised the program’s viability as a funding source for states.

The GAO also has criticized this financing mechanism, particularly with regard to program expansions that have used SCHIP funds to cover childless adults.¹⁷ The GAO argues that the use of SCHIP funding in this manner does nothing to advance the primary objective of the program—providing health coverage for children. In January 2003, the GAO placed Medicaid for the first time on its list of programs at high risk for fraud, waste, abuse, or mismanagement, and Congress has launched an investigation of state program integrity practices.¹⁸

Although CMS’ use of its waiver authority is only one of several reasons for the GAO designation, it reflects the tension that historically has existed between the executive branch (including DHHS, the OMB, and the White House) and the legislative branch (of which the GAO is an investigative arm). At issue is the appropriate locus of control for program changes. Demonstration projects are viewed by some as a mechanism for states to make changes that are intended to be a permanent part of their programs, thereby circumventing the federal legislative process and, arguably, increasing Medicaid outlays outside of the federal budget process. On the other hand, many of the advances in knowledge about health care delivery and payment over the years have occurred through innovative Medicaid research and demonstration projects.

SECTION 1115 DEMONSTRATIONS DRIVING POLICY CHANGE

The ability to waive certain aspects of the SSA has given states significant flexibility to experiment with new and innovative approaches to program operation, service delivery, and financing. The outgrowth of these demonstrations, in several cases, has been major legislative and policy change that has altered the face of the programs forever.

Welfare Reform

During the late 1980s and early 1990s, many states began applying for Section 1115 waivers in the AFDC program. These waivers were used to broaden eligibility in AFDC and to extend Medicaid coverage beyond the 12 months of transitional benefits normally provided to welfare recipients who returned to work. They also streamlined and expanded eligibility in the Food Stamp Program. The demonstrations—which eventually numbered more

At issue is the appropriate locus of control for program changes.

than 40—were states' efforts at reforming the welfare system in the absence of federal legislation. In addition, the demonstrations illustrated the administration's willingness to permit, even encourage, significant replication across states and confirmed a significant movement away from the "research" nature of Section 1115 demonstrations.

The eventual enactment of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) obviated the need for states to seek waivers to accomplish welfare reform.¹⁹ Many of the features of PRWORA were based on the experience and design elements from the welfare reform demonstrations, and states were able to use the funds provided by a new TANF block grant to continue pursuing their welfare reform goals.

Medicaid in the 1990s: Statewide Health Care Reform

The use of the Section 1115 demonstration authority to alter the Medicaid program has grown dramatically over the past ten years. While there were many approved demonstrations prior to the 1990s, they tended to be small in scope, have a limited number of participants, or take place only in limited geographic areas. The waiver movement gained momentum when the Clinton administration signaled its willingness to provide states with more flexibility to design and operate public programs. Through negotiations with the National Governors Association, the Clinton administration publicly indicated its intent to provide more flexibility in designing and financing Section 1115 demonstrations shortly after the president was inaugurated in 1993. Then, on September 27, 1994, DHHS published a *Federal Register* notice outlining its policy with regard to Section 1115 research and demonstration projects.²⁰ This notice was significant because DHHS articulated its intent to grant similar waivers to multiple states and to allow projects to be carried out on a statewide basis. It also allowed budget neutrality to be calculated over the life of the demonstration rather than on an annual basis. The ability to conduct such large-scale projects in multiple states, combined with states' desire to contain what were viewed as unsustainable increases in health care costs and significant levels of uninsurance, generated a new outpouring of health system reform efforts.

The demonstrations that were approved in the 1990s effectively became the vehicle for statewide health care reform (in the absence of national health reform). Perhaps the most significant mechanism for statewide reform was the shift toward managed care as a delivery system for the Medicaid population. Concerns about rising health care costs are not a new phenomenon—states had begun looking to managed care as a means to control spiraling health care costs in the early 1980s. In the 1990s, many states began to turn to managed care on a large-scale basis as a means of improving access to care, decreasing health care costs, and using the savings to expand coverage. Through Section 1115, states were able to obtain

The demonstrations approved in the 1990s effectively became the vehicle for statewide health care reform (in the absence of national health reform).

waivers of Medicaid requirements relative to freedom of choice of provider, statewide program implementation (statewideness), and comparable services for all recipients (comparability). These waivers permitted states to require Medicaid-eligible individuals to enroll in managed care networks that operated in limited geographical areas of the state and in which enhanced benefits were often offered. While these requirements could also be waived under Section 1915(b), as discussed later, an important advantage of Section 1115 was the ability to expand coverage to new populations and to alter payment mechanisms to certain providers such as federally qualified health centers (FQHCs).²¹

By 1997, CMS had approved 14 statewide health care reform demonstrations, 9 of which included expansions to previously uninsured populations; all of the demonstrations used some form of mandatory managed care. Today, 16 statewide demonstration projects continue to operate,²² covering over 8 million enrollees and accounting for about one-fifth of Medicaid spending.²³ (See Table 1). In fact, the popularity and perceived success of mandatory managed care, both under Section 1115 authority and under Section 1915(b), led to legislation in 1997 allowing states to mandate enrollment in managed care by amending the state Medicaid plan rather than through the waiver process.

Other Medicaid Initiatives

Beginning in the late 1990s, two other types of Medicaid demonstrations emerged as a result of changes that were occurring in the health care arena.

Cash and Counseling Demonstrations — Three states (Arizona, Florida, and New Jersey) received approval for *cash and counseling demonstrations* in 1997. Driven by the demand for consumer-directed care that grew out of the disability rights and independent living movements, these demonstrations test direct payment of cash benefits to individuals with disabilities to purchase their own personal assistance services. The Oregon Independent Choices demonstration approved in November 2000 follows a similar model. These demonstrations are significant in that it is the first time that the Medicaid program has permitted cash allowances to be paid directly to beneficiaries rather than providers. The current administration's Independence Plus Initiative has grown out of these demonstrations.

HIV/AIDS Demonstrations — These projects expand Medicaid coverage to individuals with HIV/AIDS and are approved in three states—Massachusetts, Maine, and the District of Columbia.²⁴ With the introduction of

TABLE 1
Section 1115 Statewide
Health Care Reform Demonstrations
Operating in 2003

State	Date Awarded
Arizona	07/13/1982
Arkansas	09/01/1997
Delaware	05/17/1995
Hawaii	07/16/1993
Kentucky*	10/06/1995
Maryland	10/30/1996
Massachusetts	04/24/1995
Minnesota	04/27/1995
Missouri	04/29/1998
New York	07/15/1997
Oklahoma	04/01/1996
Oregon	03/19/1993
Rhode Island	11/01/1993
Tennessee	11/18/1993
Vermont	07/28/1995
Wisconsin	01/22/1999

* Kentucky's demonstration was originally approved as a statewide project; however it has been implemented only in selected areas of the state.

Source: Centers for Medicare and Medicaid Services.

antiretroviral therapies in the mid-to-late nineties, states and the administration became interested in providing coverage to individuals with HIV/AIDS who usually would not qualify for Medicaid. They theorized that proving treatment early in the course of the disease would reduce health care costs by delaying the onset of disability and decreasing the use of more expensive hospitalization. These programs will be monitored and evaluated over the next few years to compare actual results with those proposed in the demonstration.

SCHIP: A New Era of Expansion

Almost from the date of the enactment of SCHIP in 1997, states were interested in obtaining waivers to operate their programs, either to cover groups of individuals that the statute excluded or to change other features of the program, such as benefits and cost sharing. DHHS initially delayed approval of SCHIP waivers because the department believed that it could not determine what types of projects were appropriate without first having experience with the new program. However, three states—Missouri, New Mexico, and Wisconsin²⁵—received approval for Section 1115 demonstrations to permit cost sharing and, in the case of Missouri, a slight alteration of the benefit package. The rationale was that these SCHIP programs were actually expansions of Medicaid, a program with which HCFA did have experience.

In July 2000, HCFA issued long-awaited guidance on SCHIP demonstration projects that signaled additional flexibility for both Medicaid expansion states and states with separate child health programs. This guidance indicated that HCFA would consider projects that expanded coverage to parents of children being served under SCHIP and pregnant women. It was believed that expansions of this nature would assist in improving enrollment of children, as well as providing much needed coverage for uninsured adults. The guidance also outlined that the principle of *allotment neutrality*, rather than budget neutrality, would apply. States were particularly interested in this feature since it enabled them to use more of their annual SCHIP allotments and receive the higher SCHIP matching rate for their expansions. Four states were approved in 2001 to use SCHIP funds to cover parents—Minnesota, Wisconsin, Rhode Island, and New Jersey—and today a total of seven states provide parental coverage and use SCHIP allotments to finance the expansions.²⁶

MEDICAID PROGRAM WAIVERS

After protracted debate over ways to reform Medicaid early in the Reagan administration, the Omnibus Budget Reconciliation Act of 1981 (OBRA 1981) enacted a new type of waiver authority in the Medicaid program. The authority for Medicaid program waivers, found at Sections 1915(b) and (c) of the SSA, was intended to give states more administrative flexibility to operate their programs based on experience that had been gained

It was believed that SCHIP demonstrations would assist in improving enrollment of children, as well as providing much needed coverage for uninsured adults.

from research and demonstration projects in the areas of managed care and long-term care. At the same time, the federal government retained some additional control over states' use of these new programs by requiring that they be approved through a waiver process, and therefore subject to greater scrutiny, rather than through the usual state plan amendment process.

Freedom of Choice Waivers

Before the addition of Section 1915(b) to the Medicaid statute, beneficiaries could be enrolled in managed care organizations only on a voluntary basis. In June 1980, 16 states and the District of Columbia had contracted with HMOs or other types of prepaid plans, covering approximately 1 percent of all Medicaid recipients.²⁷ So, as part of the following legislative session, Congress agreed that mandatory enrollment in managed care should be an optional service delivery mechanism for states. Today more than 57 percent of the Medicaid population is served through some type of managed care arrangement, either through Section 1915(b) waivers or Section 1115 demonstrations. As of March 2003, 29 states had 49 approved 1915(b) program waivers.²⁸

The Medicaid statute guarantees enrollees freedom of choice of providers in order to ensure access to services. Section 1915(b) of the SSA permits states to use primary care case management systems (PCCMs)²⁹ or managed care organizations (MCOs) that restrict provider choice other than in emergency circumstances. This section of the statute gives the secretary authority to waive certain provisions of Section 1902 as necessary. The provisions that are most commonly waived are those that require freedom of choice of providers, statewide implementation (statewideness), and comparable services to be offered to all beneficiaries (comparability). The secretary is specifically precluded, however, from waiving the provisions that establish payments to rural health clinics and FQHCs and payments to DSH hospitals for infants and young children. The secretary also may not restrict freedom of choice for Medicaid family planning services. In addition, there is no authority to expand eligibility, which is the reason that many states pursued Section 1115 waivers in the 1990s rather than using the Section 1915(b) program authority. By law, approvals of 1915(b) waivers are for two years and these programs must be "cost-effective and efficient." States can also provide additional services using managed care savings under these programs.

The types of managed care programs established may provide either comprehensive medical services or may be a carve-out to manage specialty services such as behavioral health or dental care. As a result, many states have more than one waiver program. For example, a state may provide managed primary and acute care services to families and children, as well as providing specialty managed care services to other targeted populations. Selected provider arrangements in which beneficiaries are restricted

Today more than 57 percent of the Medicaid population is served through some type of managed care arrangement.

to receiving covered services from only a contracted facility, such as a hospital, have also been approved under Section 1915(b) authority.

Cost-Neutrality — Cost-effectiveness review for these programs traditionally has been based on comparison with what fee-for-service costs would have been in absence of the waiver. CMS has recently implemented an alternative method due to erosion of the fee-for-service base in areas where there has been widespread use of managed care for a number of years. Under the new methodology, renewals of Section 1915(b) waivers use expenditures in the previous two-year period as the base costs. These costs are then trended forward using adjustments (such as for inflation) to determine the cost-effective amount for the current two-year approval period. This methodology is intended to reduce the amount of negotiation needed for CMS to determine cost-neutrality in order to approve the waivers.³⁰

From Waiver to State Plan — The Balanced Budget Act of 1997 amended the SSA to include a new Section 1932 state plan option as an alternative to seeking waivers under Section 1915(b) and Section 1115. The new authority permits states to implement mandatory managed care without waivers and with no cost-neutrality provision.³¹ Approval is obtained through a state plan amendment and there is no time limit on the approval. The managed care state plan provisions require that enrollees in urban areas be offered a choice between at least two MCOs or between a PCCM system and an MCO. In rural areas, there may be one MCO or PCCM as long as there is choice of physicians or case managers. Enrollees may be required to stay enrolled in an MCO or PCCM for up to 12 months. Children with special needs, Medicare beneficiaries who are dually eligible for Medicare and Medicaid, and American Indians who are members of federally recognized tribes are exempt from mandatory enrollment.

Although Congress intended for Section 1932 to negate the need for waivers under Section 1915(b); that has not proven to be the case. As of August 2003, six years after the enactment of Section 1932, only 15 states have used the state plan option to implement mandatory managed care. While for some states, Section 1932 has been an effective means of avoiding the waiver process, it has not worked for others. In part, this is due to the states' familiarity with Section 1915(b) and the process for obtaining approval. However, the restriction on the populations that may be included, particularly children with special needs, has also discouraged many states from using Section 1932 as an alternative to 1915(b). Consequently, the number of 1915(b) waivers has remained fairly constant over time.

Home and Community-Based Services Waivers

OBRA 1981 also enacted Section 1915(c), which permits states to provide a set of home and community-based services (HCBS) to individuals who would otherwise be institutionalized in hospitals, nursing homes, or ICFs/MR. Before enactment of Section 1915(c), comprehensive long-term care services were available only in institutional settings. Although mandatory

The Section 1932 authority permits states to implement mandatory managed care without waivers and with no cost-neutrality provision.

home health services and optional personal care services were available Medicaid benefits, states had largely restricted their use, allowing only medically oriented types of services, such as skilled nursing care, to be provided in the home. States also placed limits on the amounts of services furnished. In enacting the legislation for HCBS waivers, Congress hoped that long-term care costs could be contained if services were provided in settings, such as the home or community, that were less expensive than institutions.

As with other waivers, while the Medicaid statute usually requires that comparable services be provided to all enrollees statewide, the secretary may waive these Medicaid requirements for statewideness and comparability. For home and community-based services, the secretary may also waive certain Medicaid income and resource rules. This permits states to use more liberal income criteria for determining eligibility for these programs than they would use in regular Medicaid. The statute identifies services that may be made available as home and community-based services, including case management, homemaker/home health aide services, personal care services, adult day health, habilitation services, and respite care. It also permits the secretary to approve other services that are cost-effective and needed to avoid institutionalization, which leads to great diversity in the program. Waivers under Section 1915(c) are approved for three years with an unlimited number of five-year extensions.

The statute requires that Section 1915(c) waivers be cost-effective. Cost-effectiveness is determined by comparing the average per capita HCBS costs to average per capita costs under the state plan without the waiver. In addition, states use enrollment caps, made possible through waivers of statewideness and comparability requirements, to help limit expenditure growth in HCBS waiver programs. Enrollment caps help guard against the “woodwork effect” which occurs because some eligible individuals prefer not to apply for institutional services but will apply for and use community-based services

While six states had waivers approved by 1982, the overall growth in the use of home and community-based services was gradual.³² In order to encourage states to apply for the new HCBS waivers, HCFA developed a *model waiver* system that was intended to expedite the review process by limiting the federal government’s financial risk. Program size in model waivers was limited to no more than 50 enrollees (later increased to 200). Model waivers are still being used today, but many states have converted them into traditional HCBS waivers as a means of increasing the numbers of individuals that can be served. There is now virtually no difference between model waivers and other HCBS waivers, other than the size of the population served.

Another factor, the “cold bed” requirement, actually deterred states from submitting waiver proposals in the first decade of the program. The cold bed rule required states to demonstrate that an institutional bed

Congress hoped that long-term care costs could be contained if services were provided in settings that were less expensive than institutions.

was available for each individual to be enrolled in the HCBS waiver. In many states where there were restrictions on building new nursing home beds, this test was a serious impediment to HCBS waiver growth. Removal of the cold-bed requirement in 1994 gave states more flexibility to determine how much waiver programs could grow. At the same time states' commitment to reducing their institutional populations increased as a result of legal challenges, skyrocketing institutional costs, and pressure from the advocacy community. By 1999, every state except Arizona (which offers similar services in its statewide Section 1115 demonstration) had at least one waiver serving persons with mental retardation or developmental disabilities and one waiver for aged or physically disabled persons. There are currently 261 HCBS waiver programs in operation.³³

States have used home and community-based services to serve a wide variety of populations, including seniors, people with physical disabilities or HIV/AIDS, individuals with mental retardation and developmental disabilities, and people with traumatic brain injury. Because of the diversity of the populations served, as well as other factors, such as unique state delivery systems, payment structures, and consumer-driven service models, it is difficult to generalize about the programs that have been implemented under the authority of Section 1915(c). They represent a diverse group of programs that all use the same statutory waiver authority.

The GAO released a report in June 2003 examining federal oversight of HCBS waiver programs under Medicaid that included strong criticism of CMS and its regional offices in failing to consistently review the waiver programs for quality assurance and compliance with federal and state regulations. The GAO found that, in some regions, waiver programs were rarely, if ever, reviewed and that several programs had been extended without conducting an evaluation. CMS pointed out in its response to the GAO that HCBS waiver reviews require a significant amount of resources for which there is no line-item budget appropriation and that funding for quality assurance activities must come from the operating budget. In addition, CMS asserted that the combination of the agency's intensive involvement in the program design, state quality assurance activities, and organizational changes within the agency to place a greater emphasis on quality confirm the importance of and commitment to the integrity of home and community-based services.³⁴

(b)/(c) Combination Waivers

In the late 1990s a new twist on program waivers was introduced when the Section 1915(b)/(c) combination waiver came into existence. States wanted to use managed care to provide long-term care services or to designate a limited pool of providers to deliver certain services. This approach could not be accomplished using Section 1915(b) alone because there is no authority under 1915(b) to cover individuals who are eligible for Medicaid only through the more liberal income requirements in a HCBS waiver,

There are currently 261 HCBS waiver programs in operation.

nor is there authority to provide the types of services that are available under Section 1915(c). At the same time, 1915(c) does not have authority to restrict freedom of choice of providers, and states were leery of the more rigorous approval process associated with Section 1115 demonstration projects. Therefore, CMS agreed to consider “combination proposals” that incorporate features from both types of program waiver authorities.

Although combined waivers have been extremely complex for states to achieve, three states have received approval for combination waivers:

■ The **Texas STAR+PLUS** program was approved in January 1998. This mandatory program serves disabled and elderly beneficiaries in Houston and uses three MCOs and a PCCM to deliver both acute and long-term care services. The majority of enrollees are dually eligible for Medicaid and Medicare and, although Medicare freedom of choice is not restricted under this program, an enhanced drug benefit is provided as an incentive for enrollment in the same MCO for both Medicare and Medicaid services.

■ **Michigan’s** combination waiver, approved in June of 1998, serves individuals with developmental disabilities. It provides mental health, substance abuse, and developmental disability services under a prepaid shared-risk arrangement.

■ **Wisconsin** converted an existing Section 1115 demonstration for dually eligible adults with long-term care needs to a combination waiver in June 2001. This demonstration manages only Medicaid-financed long term care services.

Program waivers and demonstration projects are prevalent features of almost all states’ Medicaid programs. As discussed earlier, approximately 20 percent of Medicaid expenditures are devoted to statewide demonstration costs. Over 57 percent of the Medicaid population is enrolled in managed care, mostly through either Section 1115 demonstrations or Section 1915(b) program waivers. In addition, home and community-based services waivers have changed the nature of service delivery for the elderly and people with disabilities. However, since enrollment in most of these programs is capped, institutionalization remains a significant part of state programs. Taken as a whole, the combination of Medicaid Section 1115 demonstration projects and Section 1915(b) and (c) waivers have dramatically altered the way in which program eligibility is determined, services are delivered, and payment is made in the Medicaid program.

MEDICARE RESEARCH AND DEMONSTRATION PROJECTS IN DEPTH³⁵

The Medicare program has primarily used research and demonstration authority to test new ways to pay for and deliver services. As noted earlier, the most commonly used statutory authority is found in Section 402 (as amended by Section 222 of the Social Security Amendments of 1972). Section 222(b) authorizes demonstrations to experiment with the Medicare

Program waivers and demonstration projects are prevalent features of almost all states’ Medicaid programs.

payment methodology and to cover services that are not normally covered, in order to demonstrate the effectiveness of these new services. Section 222(a) authorizes the secretary to conduct experiments and demonstrations that test alternative prospective payment methodologies. Medicare's payment system was established initially as a cost-based reimbursement system; over time, Congress and Medicare administrators have made changes to it in order to control growth of program costs. Many Medicare payment system changes and alternative delivery approaches adopted by Congress (especially in earlier days) have had their origins in research and/or demonstration projects (Table 2).

Alternative Payment Systems

One area of the Medicare program that has been dramatically changed by research and demonstration projects is payment policy. As with Medicaid, Medicare was initially established as a program that reimburses hospital and other facilities for their incurred costs and physicians for the charges they billed. Today, under the traditional fee-for-service program, Medicare sets predetermined payment amounts for the majority of Medicare providers and for most covered services. Nearly all of the payment systems in place today were initially tested as research and demonstration programs. These include the inpatient hospital prospective payment, a PPS for skilled nursing facilities (SNFs), a PPS for home health, and a PPS physician payment system that replaced the Medicare retrospective, charge-based system.

■ Inpatient hospital prospective payment reform moved Medicare from cost-based reimbursement to a prospectively determined per case payment based on diagnosis. Research studies and demonstration projects on case-mix measures, inflation factors, and rate setting resulted in legislation requiring use of a system of diagnosis-related groups (DRGs) as the method of Medicare payment for most hospital care.³⁶ Implemented in Medicare in 1983, the DRG system is also used by half of the state Medicaid programs and many private insurers. It is the most common form of hospital payment today.

■ A prospective payment system for skilled nursing facilities (SNFs)³⁷ was mandated by the BBA in 1997. Based largely on research projects using resource utilization groups (RUGS)—a system that classifies patients on costs associated with their medical, functional, and personal characteristics and their use of staff time—the system was implemented in 1998. Previously, payment was a uniform amount per resident based on each facility's average cost. The new system pays different amounts for residents of the same facility based on their resource needs, with higher reimbursement for patients with more intense medical and therapy needs.

■ Home health is another area in which rapidly escalating costs stimulated the need for a prospective payment system. As directed by the

Nearly all of the payment systems in place today were initially tested as research and demonstration programs.

TABLE 2
Examples of Medicare Research and Development Projects Leading to Health System Reforms, 1978–present

Major Reform	Research Studies	Demonstrations
HMO Risk Contracts (passed in 1982; effective 1985)	<ul style="list-style-type: none"> ■ AAPCC payment ■ Biased selection ■ HMO quality 	<ul style="list-style-type: none"> ■ 8 sites—Medicare capitation (1978–1983) ■ 26 sites—Medicare competition (1982–1985)
Hospital PPS (passed in 1983; effective 1985)	<ul style="list-style-type: none"> ■ Classification system ■ Inflation factors ■ Case-mix measures ■ Payment methodologies ■ State infrastructure ■ Case-mix refinements 	<ul style="list-style-type: none"> ■ Maryland rate setting (1980–present) ■ New York PPS per diem (1983–1985) ■ Massachusetts all-payer system (1983–1985) ■ Rochester (N.Y.) Area Hospital Corporation (1980–1987) ■ New Jersey DRG all-payer system (1980–1984)
Nursing Home Reform (passed in 1987; effective 1992)	<ul style="list-style-type: none"> ■ Minimum data set ■ Resident assessment instrument ■ Case-mix systems ■ Improving quality of care 	<ul style="list-style-type: none"> ■ 3 states—inspection of care (1979–1984) ■ Yale RUGS (1981–1983) ■ New York RUGS (1982–1985) ■ Texas RUGS (1984–1986)
Physician Payment (passed in 1989; effective 1992)	<ul style="list-style-type: none"> ■ Harvard RBRVS ■ Allocating practice costs ■ Geographic practice cost indices ■ Visit coding ■ Malpractice premiums ■ Volume performance standards 	<ul style="list-style-type: none"> ■ No demonstrations conducted
Hospital Capital PPS (passed in 1987; effective 1991)	<ul style="list-style-type: none"> ■ Capital vs. operating cost variation ■ Capital and total cost models ■ Payment adjustment design 	<ul style="list-style-type: none"> ■ No demonstrations conducted
PACE (passed in 1997)	<ul style="list-style-type: none"> ■ No research conducted 	<ul style="list-style-type: none"> ■ On Lok demonstration—San Francisco (1983–1986) ■ PACE demonstrations (1986–1997)—25 sites in 13 states
Home Health PPS (passed in 1997; implemented in 2000)	<ul style="list-style-type: none"> ■ Home health case mix ■ Audited home health agency costs ■ Alternative reimbursement methods for home health services 	<ul style="list-style-type: none"> ■ Per-visit PPS demonstrations (1990–1994) ■ Per-episode PPS demonstrations (1995–1997)

Sources: Joe Antos, "Peer Review: Waiters, Research and Health System Reform," Health Affairs, Spring 1993, 181; Medicare Payment Advisory Commission, "Report to the Congress: Variation and Innovation in Medicare," June 2003.

BBA, CMS adopted a new PPS for home health agencies (HHAs) in October 2000. It is based on demonstration projects that began in 1990, first testing a per-visit prospective payment discipline. This first phase of demonstrations found little difference in cost between treatment and control groups and no significant effects on the quality of care. A second phase that began in 1995 tested a per-episode prospective payment which provided a per-episode payment based on 120 days of care. Outlier payments were provided for episodes that were longer than 120 days. The home health PPS system in place today pays HHAs a predetermined rate for each 60-day episode of home health care. To capture differences in expected resource use, patients receiving five or more visits are assigned to 1 of 80 home health resource groups based on diagnosis, functional capacity, and service use.

■ Research projects also led to a new system for physician payments. Physicians participating in Medicare are paid using the complex resource-based relative value scale, also known as RBRVS. This mechanism is based on research studies conducted in the 1970s and 1980s that developed and refined a uniform fee schedule that incorporates data on the level of services provided for specific diagnoses along with geographic adjustments for paying physicians.³⁸ It has replaced the Medicare retrospective, charge-based system. Physician payment reform was enacted in 1989 and fully implemented in 1992. Both public and private insurers now commonly use this system.

Managed care payment reforms have also been based on research projects that tested the use of capitated amounts for each enrollee based on the average fee-for-service spending for each enrollee's demographic group. Studies in the early 1980s showed that HMO enrollees tend to be healthier than those in the fee-for-service program, indicating that capitation amounts might be too high. As a result, HCFA tested several methods for adjusting for enrollee's health risks. Risk adjustment mechanisms such as ambulatory care groups and diagnostic cost groups were developed that use diagnoses from a prior year to predict program costs in a subsequent year.

Beginning in 1992, HCFA implemented global payment demonstrations for high-cost/high-volume surgeries, such as heart bypass and cataract removal, aimed at reducing costs and providing high-quality services. Subsequent efforts to expand this concept in a larger "Centers of Excellence" demonstration (renamed Medicare Partnerships for Quality Services) covering invasive cardiovascular procedures and total joint replacement were never brought to completion. However, while evaluations have shown this concept to be successful, political opposition to selective contracting has made widespread implementation difficult. CMS is currently planning to implement a global payment demonstration for bypass surgeries that will focus on the sharing of quality data as well as the automation of claims-processing systems.

HCFA tested several methods for adjusting for enrollee's health risks.

Alternative Delivery Systems

Medicare benefits and the way they are delivered have changed over the years as a result of research and demonstration projects. For example, in the 1970s, the shortage of nursing home beds in many rural areas, along with excess hospital capacity, led to the testing of the “swing-bed” concept—the use of existing hospital resources to provide both acute and long-term care. Legislation then authorized the rural swing-bed program for small rural hospitals. The hospice benefit was also studied to determine whether hospice care could maximize patient autonomy and comfort during the last weeks of life, although legislation to add this benefit was enacted before evaluation results were available.

Medicare HMO risk contracts were enacted into law in 1982 and implemented in 1985, following an extensive research and demonstration effort.³⁹ The use of capitation was tested and HCFA developed the adjusted average per capita cost, or AAPCC, mechanism that is used to pay HMO capitation rates. The studies showed that HMO participation in Medicare was a viable option. Originally, however, Medicare restricted the development of managed care options to only those health plans that were required to be federally qualified HMOs as defined in the HMO Act of 1973. Participation in these projects was voluntary and enrollment was low. The Medicare Choices demonstration that began in the mid-1990s was designed to give beneficiaries a wider array of options among types of managed care plans, including preferred provider organizations (PPOs) and provider-sponsored networks. These projects were designed to test a number of payment arrangements incorporating new ways for adjusting payments to reflect medical risk. These demonstrations evolved into the current Medicare+Choice program (enacted in the BBA) an effort to stimulate greater participation and choices for beneficiaries. Current efforts in this area are discussed later in this paper.

Competitive Pricing

Another area that has stimulated much interest is the use of competitive bidding to price Medicare goods and services. Despite popular support for the concept, these projects have had difficulty getting off the ground. Early efforts by HCFA to implement competitive pricing demonstrations for Medicare-risk HMOs—in Baltimore in 1996 and in Denver in 1997—were met by strong opposition from health plans and political pressure at the state and national level. Both of these demonstrations were suspended before they could be implemented—in Denver as the result of a court ruling. Shortly thereafter, Congress mandated the Medicare Prepaid Competitive Pricing Demonstration Project in the BBA. The demonstration was intended to test an approach under which payments to Medicare+Choice plans would be determined through a competitive bidding process. In targeted areas, HCFA-contracted plans were to have submitted a bid price for a specified Medicare benefit package. That price

In the 1970s, the shortage of nursing home beds in many rural areas, along with excess hospital capacity, led to the testing of the “swing-bed” concept.

was then to have been compared to a set payment contribution from HCFA to all plans in the area. Plans with a price below the contribution level would have offered additional benefits, while those above the contribution level would have charged an additional premium to cover the difference. However, both health plans and beneficiaries generated bipartisan political pressure, and Congress stopped the project before the demonstration started. Health plans opposed competitive pricing because they feared lower prices, while beneficiaries opposed it because they feared that their benefits might be reduced.

CMS has conducted successful demonstrations to test the impact of two variations of competitive bidding.⁴⁰ Both demonstrations tested whether competition could lower prices without adversely affecting quality or access. CMS conducted a competitive bidding demonstration for durable medical equipment (DME) in two sites: Polk County, Florida, and San Antonio, Texas. During the three years of competition for DME goods and services, providers lowered their prices an average of 20 percent per year. Evaluations have generally characterized both the quality of the goods and services and beneficiaries' access to them as good. The demonstration ended in both sites on December 31, 2002, when congressional authority expired and was not reauthorized, but efforts are underway to expand and integrate competitive bidding for DME into the Medicare program.

A Medicare demonstration conducted between 1991 and 1996 had providers compete on price and quality to receive a bundled payment for all inpatient hospital and physician services related to coronary artery bypass grafts. HCFA selected seven provider organizations, each of which could market itself as a Medicare participating heart bypass center. An evaluation showed that the demonstration reduced costs and increased quality; however, contrary to what many had expected, it did not increase the market share for the majority of participating sites. CMS attempted to continue these demonstrations but was unsuccessful when too few providers responded to the solicitation notice.

Much interest remains in using market principles to purchase goods and services within Medicare. The Medicare prescription drug proposals currently pending in Congress place strong emphasis on the use of competition as a pricing mechanism in the future. Experiences in these earlier demonstrations could provide valuable lessons for moving forward in this regard.

SERVING THE FRAIL ELDERLY

Over the last ten years, there has been growing state, federal, and industry interest in conducting demonstration projects to test delivery systems for the frail elderly, many of whom are eligible for both Medicare and Medicaid. The population of "dual eligibles" comprises only about 15 percent of the Medicaid and Medicare populations but accounts for approximately

Competitive bidding demonstrations tested whether competition could lower prices without adversely affecting quality or access.

24 percent of Medicare expenditures and 35 percent of Medicaid expenditures. A number of states have proposed projects that attempt to integrate care for frail elders in hopes of improving coordination and access to care. However, since both the federal government, in its role as Medicare administrator, and the states, as Medicaid administrators, must be involved, negotiations are difficult and have resulted in limited projects to date.

These projects are complex because of the need to use both Section 1115 authority and Medicare demonstration authority to make the two programs work together. A key point of contention has been budget neutrality. CMS has required that the calculations be made separately for Medicaid and Medicare, and savings from one program can not be used to offset spending in the other program. This policy has greatly limited states' ability to propose and receive approval for demonstrations for the dually eligible. In addition, one of the key tenets of the Medicare program is to ensure freedom of choice of providers, which has prevented states from using a mandatory managed care approach. Other issues include Medicare's and Medicaid's conflicting enrollment policies, appeal rights, and health plan qualifications; CMS has been reluctant to provide more flexibility to states in these areas for Medicare beneficiaries.

Nonetheless, two projects have been mandated by Congress and are operational and two states have implemented small demonstrations for frail elders. (Other projects are in the developmental stage.)

Program for All-Inclusive Care for the Elderly

The Program for All-Inclusive Care for the Elderly (PACE) is a capitated managed care benefit for the frail elderly age 55 and older who would otherwise require a nursing home level of care. Comprehensive medical and social services are delivered in adult day health centers, supplemented by in-home and referral services. PACE built on the successful On Lok Medicare demonstration that ran in San Francisco from 1983 to 1986. Congress first required the DHHS secretary to implement PACE demonstration projects in 1986. In 1997, the BBA made PACE a permanent benefit category under Medicare and allowed states the option to implement PACE as part of the Medicaid state plan, without the need for waivers. The numbers of PACE sites are limited under the law and the number of people served through a PACE project can be limited. Currently, there are approximately 6,000 enrollees in 25 PACE sites in 14 states.⁴¹

Social HMOs

Section 2355 of the Deficit Reduction Act of 1984 directed the secretary to undertake S/HMO demonstration projects. S/HMOs integrate health and social services with a coordinated case management system. They serve a cross section of the elderly population, including both functionally impaired and well elderly. In July 2003, there were 114, 895 enrollees at four S/HMO sites.⁴²

Providers are paid through a direct financial arrangement that pools funds from Medicare, Medicaid, and member premiums in a fixed annual pre-paid rate of 100 percent of the AAPCC of treating these patients in other settings (5.3 percent higher than the Medicare+Choice county payment rates). In March 2003, CMS released a *Federal Register* notice proposing that S/HMOs be phased in to become regular Medicare+Choice plans and paid at the standard rate, but with a “frailty adjuster” to increase payment rates to account for the more complex needs of S/HMO members. However, the Medicare Payment Advisory Commission (MedPAC) has recently released a report disagreeing with the CMS proposal and proposing that the conversion of S/HMOs into Medicare+Choice plans take place as scheduled at the end of 2003. MedPAC does not recommend use of a frailty adjuster at this time, but suggests that DHHS study payment adjustments for the frail population in the Medicare+Choice program.⁴³

Evercare Choice

Evercare Choice is another demonstration that provides services to dual eligibles. In operation since 1993, Evercare’s primary goal is to provide better case management for permanent nursing home residents. The program does not expand the Medicare benefit per se but brings physicians and geriatric nurse practitioners to the bedside at the nursing home. It is intended to improve the quality of care and health outcomes and to develop practice guidelines. As of September 2003, Evercare has enrolled 24,000 nursing home residents in 11 states.⁴⁴

The prescriptive nature of integrated service delivery systems has made them difficult to replicate on a large scale. For example, in PACE, only a subset of dual eligibles—those who require a nursing home level of care—can be served. In addition, the adult day care model used in PACE has proven to be a deterrent for individuals who strongly prefer home-based care. These limitations have led to states’ interest in other initiatives for dual eligibles. Two states, Minnesota and Wisconsin, have implemented dual eligible demonstration projects. Minnesota’s Senior Health Options, which was implemented in 1997, is unique in that the state (rather than the federal government) contracts with health plans to provide Medicare services. In 1998, Wisconsin established its Partnership Program to serve the frail elderly as well as individuals with physical disabilities; the program uses a model similar to PACE’s. Two additional projects—the Monroe County (New York) Continuing Care Network Demonstration (approved in 1999) and the Massachusetts Senior Care Options demonstration (approval anticipated by October 2003)—have not yet begun enrollment.

CURRENT INITIATIVES, FUTURE DIRECTIONS

Current initiatives in research, demonstration, and program waivers are driven by many of the same forces that have driven the use of waivers since the early 1980s. Health care costs continue to increase at rates

The prescriptive nature of integrated service delivery systems has made them difficult to replicate on a large scale.

considered to be unsustainable. A substantial portion of the population continues to lack health insurance, and quality of care continues to be a challenging issue. As the factors contributing to these problems have evolved over the years, research and demonstration projects and program waiver initiatives also have changed. For example, several current initiatives address the increasingly larger share of budgets devoted to the cost of pharmaceuticals and to serving elderly or disabled individuals, whose costs make up more than 70 percent of Medicaid expenditures.

Pharmacy Plus

In the absence of a Medicare prescription drug benefit, Pharmacy Plus Section 1115 research and demonstration projects are helping states to control the high cost of pharmaceuticals. DHHS issued guidance for the Pharmacy Plus Demonstration initiative in January 2001. Pharmacy Plus demonstrations extend coverage to certain low-income elderly and disabled individuals with incomes below 200 percent of the federal poverty level who do not qualify for Medicaid. Drug benefits may differ from those in the Medicaid state plan. These projects theorize that participants will stay healthier, which will reduce service utilization and allow them to spend down to Medicaid eligibility levels at a slower rate than they would have without the program. Four states had approved projects as of July 2003 and several more were pending.⁴⁵ The unique feature of these demonstrations is that they set a global spending cap on all Medicaid beneficiaries over age 65, including the newly eligible, putting states at financial risk for all Medicaid costs associated with this population. The current debate over the Medicare prescription drug benefit will undoubtedly have a significant impact on these demonstrations. Many analysts are predicting that states might discontinue them if a new benefit is enacted, even though the bills do include incentives to encourage states to maintain their programs.

Independence Plus

CMS is also promoting more choices for consumers through the Independence Plus initiative. Based on the cash and counseling model, this initiative continues opportunities for seniors and people with disabilities to direct their own services. CMS has developed standard application templates for both the Section 1915(b) and Section 1115 programs. Section 1115 is used when eligible beneficiaries and their families receive a cash allowance directly. Arkansas, Florida, and New Jersey have converted their cash and counseling demonstrations into Independence Plus demonstrations; New Hampshire and South Carolina received approval for Section 1915(b) programs in December 2002. Consumer advocates are clamoring for more of these types of community-based services as an alternative to institutions. The impetus for this movement was the *Olmstead* decision by the Supreme Court, which affirmed individuals' rights to live

in the least restrictive environment.⁴⁶ Concerns about the total costs of community-based programs to states' Medicaid programs, however, have led most states to continue their programs with capped enrollments.

Health Insurance Flexibility and Accountability

The Health Insurance Flexibility and Accountability demonstration initiative was announced by the secretary of DHHS in August 2001.⁴⁷ It provides states with an opportunity to expand health care coverage to more individuals and new flexibility to design their programs through the use of Section 1115 authority. HIFA continues many of the features from previous statewide health care reform and SCHIP demonstrations. Budget neutrality is calculated in much the same way, but HIFA allows states to use excess SCHIP allotment dollars to fund eligibility expansions. It does not restrict the use of SCHIP funds to parents and pregnant women, so single adults can also be covered. It also encourages the use of premium assistance to help families and individuals purchase private insurance through employers. HIFA set a precedent for expanding coverage to additional populations by permitting reduced benefits and increased cost sharing for populations that states were already covering under their Medicaid programs. This approach was previously permitted in a limited number of projects on a case-by-case basis. However, HIFA signaled the Bush administration's willingness to consider proposals to limit benefits and increase cost sharing on a wide scale. This approach has aroused much controversy around appropriate minimum federal standards. In light of the recent fiscal crisis in most states, some fear HIFA will lead to cost containment without regard for the health care needs of eligible individuals, many of whom have very low incomes. Proponents of HIFA point out that these projects provide health care coverage to many individuals who would otherwise be uninsured.

Currently, eight states have received approval for HIFA demonstrations and two more are under review.⁴⁸ HIFA has gained added significance because the administration's Medicaid reform proposal in the fiscal year 2004 budget includes several features of the HIFA initiative. However, the impact of HIFA demonstrations on the health care system and beneficiaries is unknown at this time. To date, there have been no systematic evaluations of HIFA, although some case studies are under way and a federal evaluation is planned for the future.

Disease Management: "Waive" of the Future?

In Medicare, disease management initiatives are a significant part of the current research and demonstration agenda. These activities are being touted as the means to better coordinate care for beneficiaries and contain costs, much as managed care was in the 1990s. The Medicare Coordinated Care Demonstration Project, authorized in 1997 by the BBA, tests enhanced quality of care and the effectiveness of paying on a fee-for-service basis for

HIFA has aroused much controversy around appropriate minimum federal standards.

case management and disease management services that supplement routine care and enhance quality of care for the chronically ill. Beneficiaries with chronic conditions such as asthma, diabetes, congestive heart failure and related cardiac conditions, chronic lung disease, and cancer receive comprehensive care planning, patient education, and ongoing monitoring between doctor visits. Some projects provide additional benefits. CMS selected 15 demonstration sites in January 2001, and implementation began on a rolling basis in April 2002; more than 12,000 Medicare beneficiaries now are enrolled.⁴⁹

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Congress mandated the Medicare Demonstration Project for Disease Management. It targets beneficiaries with chronic conditions of congestive heart failure, diabetes, or coronary heart disease and requires the participating disease management organizations to provide full prescription drug coverage and assume risk for the cost of coverage. These projects are primarily for beneficiaries in the Medicare fee-for-service program; three sites are participating.

The Capitated Disease Management project was announced in February 2003. This CMS initiative will test the feasibility and appeal of specialty Medicare+Choice-type plans targeted at beneficiaries with one or more chronic conditions. Such plans will be paid on a predetermined, risk-adjusted rate each month, providing the Medicare benefit along with the disease management services. On the horizon are two additional demonstration projects dealing with disease management—one for beneficiaries with end-stage renal disease and a larger scale population-based demonstration in the traditional FFS Medicare targeted at beneficiaries with specific chronic diseases with emphasis on outreach, education, and lifestyle modification.

Medicare + Choice: New Life?

Another area of interest is expanding the choices of providers for Medicare beneficiaries. Medicare+Choice was introduced as part of the BBA to increase the range of alternatives to fee-for-service Medicare; however, despite an initial rise, the numbers and types of health plans available to Medicare beneficiaries has, in fact, decreased.⁵⁰ As a result, CMS initiated the Medicare Preferred Provider Organization Demonstration, which began implementation during the January 2003 enrollment period. Thirty-three health plans in 23 states are participating. This demonstration tests direct contracting between Medicare and a variety of health plans, including PPOs and provider-sponsored organizations. Partial capitation and reinsurance are also being tested. Since its implementation in January, 54,000 Medicare beneficiaries have joined Medicare PPOs; however, 44,000 seniors are enrolled in one plan, Horizon Blue Cross/Blue Shield of New Jersey, that brought them into the option from an existing Medicare HMO.⁵¹ Despite a slow start, CMS believes, enrollment will pick up as seniors become more familiar with the PPO option.

The Capitated Disease Management project will test the feasibility and appeal of specialty M+C-type plans targeted at beneficiaries with one or more chronic conditions.

CONCLUSION

The broadened use of research and demonstration authority, particularly in Medicaid, during the Clinton and Bush administrations has caused much controversy. In March and April 2001, as well as in June 2003, Congress sent inquiries to CMS asking for detailed information about Medicaid Section 1115 demonstrations and expressing concerns about the approval process as well as quality, access, and the manner in which budget neutrality is calculated. As noted earlier, the GAO has criticized HIFA in particular for diverting SCHIP funds from children's coverage to adults. These types of controversies have surrounded research and demonstration projects and program waivers throughout their histories.

The overarching question, however, seems to be, what is the appropriate role of research and demonstration projects? Changes to programs accomplished through these mechanisms can have a huge impact on beneficiaries, providers, and the health care system as a whole. To the extent that demonstrations change the program without legislative backing, analysts have speculated, DHHS may be overstepping its bounds. On the other hand, many features of public programs that are widely accepted today were controversial when they were first tested through research and demonstration projects. Legislative change can be slow to occur, particularly when states are having immediate budget crises and Medicare Part B costs are rising at alarming rates. However, in each budget crisis, innovative responses from states and the federal government have helped to contain costs and have permitted the program to evolve. Especially in Medicaid, the evolutionary use of program waivers and demonstrations to provide greater and greater flexibility to states has changed the nature of the program. In Medicare, research and demonstration projects have significantly altered payment and delivery mechanisms over the years. Projects are driven sometimes by administration policies, as seen in earlier years of the Medicare program as well as in the current flurry of new initiatives; sometimes by statutory mandates; and often in response to rapidly escalating costs. Some have suggested that Medicare could benefit from additional demonstration or waiver authority more similar to Medicaid—to waive specific sections of title XVIII—in order to move the program forward.⁵² The controversies are not likely to be resolved any time in the near future. In the meantime, the experience gained from research and demonstration projects and program waiver initiatives will continue to help inform the debate about how best to address the challenges of uninsurance, cost containment, and quality of care facing the nation's health care system.

Appendix

The Early History of Section 1115 Demonstrations

Since the creation of the Medicaid program, the federal government has used Section 1115 demonstration authority to allow states to modify components of their programs. Congress hoped that innovative projects would provide a scientific basis for improving the program through greater knowledge of more cost-effective health care delivery strategies. An early study looked at demonstration projects initiated during the 15-year period between 1970 and 1984 and highlighted findings from various initiatives.⁵³ This study documented that project activity accelerated during the 1970s and peaked in 1981. Over that period, 213 demonstration projects were initiated, most between 1976 and 1981. Activity in the areas of long-term care, hospital care, and alternative payment and delivery systems during these years contributed significantly to changes in the Medicaid program.

Long-Term Care

Between 1974 and 1981, almost three times as many demonstration projects were conducted in the area of long-term care as in other areas. At that time, as today, the rapid increase in cost growth of long-term care was a serious concern. Long-term care service expenditures had increased about 26 percent annually from 1975 through 1982, due primarily to an increase in the size of the aging population and greater acceptance of nursing home care as an alternative to family caregivers. The Medicaid program was based on a medical model with an institutional orientation. Services tend to be provided by professional staff in institutional settings such as nursing homes. Demonstrations during this period began to test alternatives to nursing home care, such as adult day care and community care, and explored approaches such as case management, a single point of entry to obtain services, and prospective payments for services. They hypothesized that the amount of nursing home care could be reduced through the increased use of paraprofessionals and the coordination of an appropriate mix of health and social services. The demonstrations began a paradigm shift toward addressing the person as a whole by attempting to address the combination of social, psychological, and basic needs of daily living (such as housing).

These demonstrations greatly increased knowledge about assessment instruments that are used to determine the need for nursing home placement. They found that most instruments of the day did not adequately identify those at high risk for placement and that client selection was a critical factor in reducing the amount of nursing home care. The lack of appropriate assessment instruments for determining the need for nursing facility level of care, coupled with pressure to provide services to those not otherwise eligible for placement in a nursing home, contributed to a

finding that these demonstrations did not substantially reduce admissions and were cost-effective only if linked to strong control over the nursing home admission process. The most consistent findings were that beneficiaries did not suffer ill effects from residence in the community (there were no significant effects on functioning or mortality) and were more satisfied with their care in the community setting. However, the findings from the demonstrations eventually provided the impetus for the enactment of Section 1915(c), the home and community-based waiver program, in 1981.

Hospital Care

Another area of deep concern during the 1970s and early 1980s was the fiscal crisis that was occurring in Medicaid hospital spending. Expenditures in this area grew on average 16.7 percent annually over the period from 1970 to 1980. During the 1970s, HCFA granted Section 222(a) or 402(a) waivers to nine states or substate areas, to include Medicaid in operational prospective payment system programs. Also incorporating Medicare in many cases, these projects were the precursors to the Medicare prospective payment system demonstrations discussed earlier in this paper. The Medicaid statute at the time provided for a retrospective reimbursement based on cost. Under this system, reimbursement is maximized when more services are provided and hospital stays are longer. As might be expected this led to rapidly escalating costs. Demonstrations in New Jersey, New York, and Massachusetts, among others, took advantage of demonstration waivers to address the fiscal crisis in Medicaid hospital spending. The projects experimented with providing payments to hospitals on a prospective per diem or per case basis. The demonstrations added greatly to the body of knowledge about cost inflation for per diem and per case payments, as well as inappropriate utilization and uncompensated care.

Alternative Payment and Delivery Systems

Medicaid, as originally enacted, was a program that paid providers solely on a retrospective fee-for-service basis. The federal government soon recognized the incentives this payment methodology creates to maximize reimbursement. DHHS decided to promote demonstrations to develop HMOs that would accept Medicaid beneficiaries in order to research cost, utilization, and quality under a capitated payment system. During the early 1970s, however, only 12 states developed agreements with the HMOs and most involved only one health plan. California was the exception and contracted with multiple plans, but unethical marketing, poor access and quality, and inappropriate reimbursement resulted in the development of stringent regulation for HMOs participating in the Medicaid program. None of these early projects were successful. They were met by legal barriers to establishing risk-based provider organizations, low enrollment, and insurer and state government reluctance to participate.

In 1978, rising costs led the federal government to consider again the wider use of HMOs. Voluntary enrollment in qualified managed care plans was available to Medicaid beneficiaries at the time, but few HMOs were accepting Medicaid enrollees and few beneficiaries were choosing to enroll. By 1980, there were plans in only 17 states with about 1 percent of beneficiaries enrolled. HCFA then developed a major demonstration designed to allow plans to compete, under the belief that competition would lead to lower capitation rates and good quality. Projects were conducted in New Jersey, Oregon, Massachusetts, and California, with states taking more control as the designers of the alternative delivery systems. Once again, the projects met with only limited success.

In 1982, HCFA funded seven demonstration projects in six states to test innovative health care financing and delivery approaches including a variety of capitated or partially capitated arrangements; for the first time, some projects included mandatory enrollment.⁵⁴ However, these demonstrations tended to be small and, as a whole, again met with limited success. Nonetheless, some experience was gained in setting capitation rates, recruiting providers, and enrolling consumers. It was also in this year that Arizona's entire Medicaid program, which uses a managed care model, was approved under Section 1115 demonstration authority. After a rocky start in 1982, the Arizona Medicaid program has operated continuously as a demonstration to this day.

ENDNOTES

1. Andy Schneider, Risa Elias, Rachel Garfield, David Rousseau, and Victoria Wachino, *The Medicaid Resource Book* (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, July 2002), 59-61.
2. Statewide health care reform demonstrations, as discussed later in this paper, are initially approved for a five-year period and renewed for subsequent three-year periods. CMS has not required additional evaluations for the renewal periods.
3. Aid to Families with Dependent Children was the welfare program that provided cash payments to low-income women with dependent children. It was replaced by the Temporary Assistance for Needy Families (TANF) block grant program in 1996.
4. Intermediate care facilities for persons with mental retardation are defined as public or private facilities whose primary purpose is to provide health or rehabilitative services to individuals with mental retardation or related conditions (such as cerebral palsy). States have the option to cover services provided in these facilities. See Schneider et al., *Medicaid Resource*, 169.
5. The reasonable cost and reasonable charge requirements under Medicare are generally defined as "the reasonable cost of any services shall be the cost actually incurred, excluding any part of the incurred cost found to be unnecessary in the efficient delivery of needed health services." See section 1861(v) of the Social Security Act. (Section 222 also applies to the Medicaid program and was used in early research and demonstration projects on hospital rate setting.)
6. The Health Care Financing Administration (HCFA) is the former name of the Centers for Medicare and Medicaid Services (CMS) in the U.S. Department of Health and Human Services. This paper refers to CMS as HCFA when discussing historical information or activities that occurred under the agency's former name.

7. Allan Dobson, Donald Moran, and Gary Young, "The Role of Federal Waivers in the Health Policy Process," *Health Affairs*, 11, no. 4 (Winter 1992); accessed August 15, 2003, at <http://www.healthaffairs.org/readeragent.php?ID=/usr/local/apache/sites/healthaffairs.org/htdocs/Library/v11n4/s5.pdf>.
8. Dobson, Moran, and Young, "Role of Federal Waivers."
9. Sara Rosenbaum, Julie Darnell, Patricia Seliger Keenan, and Lois Simon, "Section 1115 Medicaid Waivers: Charting a Path for Medicaid Managed Care Reform," in *Access to Health Care: Promises and Prospects for Low-Income Americans* (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, 1999); accessed August 15, 2003, at <http://www.kff.org/content/1999/2137>.
10. Section 2107(e)(2)(A) of the Balanced Budget Act states that Section 1115 applies to the State Children's Health Insurance Program (Title XXI) in the same manner as it does to Medicaid (Title XIX). The seven SCHIP waivers are in Arizona, California, Colorado, Illinois, Maryland, New Jersey, and New Mexico. See Centers for Medicare and Medicaid Services, "State Children's Health Insurance Program (SCHIP) Approved Section 1115 Demonstration Projects," July 25, 2003, U.S. Department of Health and Human Services; accessed August 15, 2003 at <http://www.cms.hhs.gov/schip/1115waiv.pdf>.
11. The participation requirements for Medicaid managed care organizations—found at Section 1903(m) of the Social Security Act—require, in general, that organizations must (a) make services available to all eligible individuals residing within the service area and (b) make adequate provision against the risk of insolvency. (The BBA of 1997 altered these participation requirements, virtually eliminating the need for states to use demonstration authority for this purpose.)
12. Disproportionate share hospital payments are made by states' Medicaid programs to hospitals that are documented as serving a "disproportionate share" of low-income or uninsured patients. The federal matching funds that states can use to make these payments are capped as specified by the Medicaid statute.
13. For example, Tennessee's original Section 1115 demonstration, TennCare, had an aggregate cap; however it was changed to a per member per month cap in the most recent revisions to the program. Indiana's Pharmacy Plus waiver also uses an aggregate cap on all long-term care spending to finance its program.
14. U.S. General Accounting Office, *Medicaid Section 1115 Waivers: Flexible Approach to Approving Demonstrations Could Increase Federal Costs*, GAO/HEHS-96-44, Washington, D.C., November 1995; accessed August 15, 2003 at <http://www.gao.gov/archive/1996/he96044.pdf>.
15. States participating in SCHIP receive an annual allotment based on the Current Population Survey annual estimates of the number of uninsured children in each state. Each annual allotment remains available to the states for three fiscal years. For more information, see Judith D. Moore, "SCHIP in the Formative Years: An Update," National Health Policy Forum Issue Brief No. 759, Washington, D.C., September 2001, 4–5; available at http://www.nhpf.org/pdfs_ib/IB759_SCHIPUpdate_9-21-00.pdf.
16. States that have spent all of their annual SCHIP allotments can receive additional funds that are "redistributed" from states were not able to spend their full allotments.
17. U.S. General Accounting Office, *Medicaid and SCHIP: Recent Approvals of Demonstration Waiver Projects Raise Concerns*, GAO-02-817, Washington, D.C., July 2002; accessed August 15, 2003 at <http://www.gao.gov/new.items/d02817.pdf>.
18. U.S. General Accounting Office, *Major Management Challenges and Program Risks: Department of Health and Human Services*, GAO-03-101, Washington, D.C., January 2003; accessed August 15, 2003 at <http://www.gao.gov/pas/2003/d03101.pdf>. On June 16, 2003, the House Energy and Commerce Committee issued a letter to all governors announcing an investigation as a result of this report.
19. The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 created a new TANF block grant, which provided states with flexibility and funding to design welfare

reform strategies; and added to the Medicaid statute a new Section 1931, which permits states to liberalize eligibility requirements for low-income families as they move from welfare to work.

20. For a fuller discussion of the *Federal Register* notice, see Jennifer M. Ryan, "1115 Ways to Waive Medicaid and SCHIP Rules," National Health Policy Forum Issue Brief No. 777, Washington, D.C., June 2002; available at http://www.nhpf.org/pdfs_ib/IB777_1115Waivers_6-13-02.pdf.

21. Federally qualified health centers (FQHCs) are community health centers and migrant health centers funded under Section 330 of the Public Health Service Act. States are required to include services provided by FQHCs in the Medicaid benefit package and to pay for those services on a cost-based reimbursement basis. Under some demonstrations, states were permitted to alter this payment method so that FQHCs were paid negotiated rates as providers within a managed care network. Waivers for this purpose became less common after the Balanced Budget Act of 1997 required FQHCs participating in Medicaid managed care to continue to receive cost-based reimbursement.

22. Substate demonstrations in Los Angeles County, California, and Alabama were approved during the same period. For more information, see Centers for Medicare and Medicaid Services, "1115 Waiver Research and Demonstration Projects," at <http://cms.hhs.gov/medicaid/1115/>.

23. Ryan, "1115 Ways," 3.

24. Washington, D.C., has not yet implemented its HIV/AIDS demonstration.

25. The Missouri and Wisconsin demonstrations also included expansions of Medicaid coverage, funded at the regular federal matching rate, to parents of children enrolled in SCHIP.

26. Four of these projects—Arizona, Colorado, New Jersey, and New Mexico—are now considered Health Insurance Flexibility and Accountability (HIFA) waivers.

27. Maren D. Anderston and Peter D. Fox, "Lessons Learned from Medicaid Managed Care Approaches," *Health Affairs*, 6, no. 1 (Spring 1987); accessed August 15, 2003 at <http://www.healthaffairs.org/readeragent.php?ID=/usr/local/apache/sites/healthaffairs.org/htdocs/Library/v6n1/s8.pdf>.

28. For more information on Section 1915(b) waivers, see Centers for Medicare and Medicaid Services, "1915(b) FREEDOM OF CHOICE WAIVERS," U.S. Department of Health and Human Services; available at <http://www.cms.hhs.gov/medicaid/1915b/default.asp>.

29. Primary care case management systems usually involve the state's providing a capitated payment for medical case management (sometimes including preventive care) for each enrollee, with other services continuing to be paid on a fee-for-service basis.

30. Mike Fiore, Centers for Medicare and Medicaid Services, conversation with author, March 20, 2003.

31. The waivers could be replaced by state plan amendments. State plan amendments are submitted to CMS for approval when the state wants to add a new component or revise an existing component in its Medicaid program. State plan amendments must be reviewed and approved (or disapproved) by CMS within 90 days.

32. Steven Lutzky, Lisa Maria B. Alecxih, Jennifer Duffy, and Christina Neill, "Review of the Medicaid 1915(c) Home and Community-Based Services Waiver Program: Literature and Program Data," U.S. Department of Health and Human Services, Washington, D.C., June 15, 2000; accessed August 15, 2003 at http://www.lewin.com/Lewin_Publications/Medicaid_and_SCHIP/Publication-4.htm.

33. For more information about Section 1915(c) waivers, see Centers for Medicare and Medicaid Services, "Home and Community-Based Services Waiver Program," U.S. Department of Health and Human Services; available at <http://www.cms.hhs.gov/medicaid/1915c/proginfo.asp>.

34. U.S. General Accounting Office, *Long-Term Care: Federal Oversight of Growing Medicaid Home and Community-Based Waivers Should Be Strengthened*, GAO-03-576, Washington, D.C., June 2003; accessed August 15, 2003 at <http://www.gao.gov/new.items/d03576.pdf>.
35. Dobson, Moran, and Young, "Role of Federal Waivers."
36. Joseph R. Antos, "Waivers, Research and Health System Reform," *Health Affairs*, 12, no. 1 (Spring 1993), accessed August 15, 2003 at <http://www.healthaffairs.org/readeragent.php?ID=/usr/local/apache/sites/healthaffairs.org/htdocs/Library/v12n1/s17.pdf>.
37. The term *skilled nursing facility* is defined under the Medicare statute in Section 1819(a) as "An institution (or a distinct part of an institution) which is primarily engaged in providing to residents (a) skilled nursing care and related services... or, (b) rehabilitation services for the rehabilitation of injured, disabled or sick persons."
38. Antos, "Waivers."
39. Antos, "Waivers."
40. Medicare Payment Advisory Commission, "Variation and Innovation in Medicare," report to the Congress, Washington, D.C., June 2003, 131-146; accessed August 15, 2003 at http://www.medpac.gov/publications/congressional_reports/June03_Entire_Report.pdf.
41. For more information on PACE, see Centers for Medicare and Medicaid Services, "Nationwide PACE Activity," U.S. Department of Health and Human Services, at <http://cms.hhs.gov/pace/pace-map.asp>.
42. The four S/HMO sites are located in Portland, Oregon; Long Beach, California; Brooklyn, New York; and Las Vegas, Nevada.
43. Medicare Payment Advisory Commission, "Social Health Maintenance Organization (S/HMO): Recommendations for the Future of the Demonstration," report to the Congress, Washington, D.C., August 2003; accessed August 15, 2003 at http://medpac.gov/publications/congressional_reports/Aug03_SHMO%20Report.pdf.
44. Evercare, "Evercare Choice"; accessed September 15, 2003, at <http://www.evercareonline.com/products/choice.html>.
45. The four states with Pharmacy Plus demonstrations are Florida, Illinois, South Carolina, and Wisconsin. Maryland has also implemented a similar pharmacy program which was approved as an amendment to its existing Section 1115 demonstration and, therefore, is not technically considered a Pharmacy Plus waiver.
46. Randy Desonia, "Is Community Care a Civil Right? The Unfolding Saga of the Olmstead Decision" NHPF Background Paper, Washington, D.C., March 12, 2003; available at http://www.nhpf.org/pdfs_bp/BP_Olmstead_3-03.pdf.
47. For more information on HIFA, see Cindy Mann, "The New Medicaid and CHIP Waiver Initiatives," Kaiser Commission on Medicaid and the Uninsured, Washington, D.C., February 2002, available at <http://www.kff.org/content/2002/4028/>; Cindy Shirk, "HIFA: Finding the Flexibility," National Governors Association, Washington, D.C., October 2001, available at <http://www.nga.org/cda/files/102401HIFA.pdf>; and Ryan, "1115 Ways," 4-9.
48. The states with approved HIFA waivers are Arizona, California (not implemented), Colorado, Illinois, Maine, New Jersey, New Mexico (not implemented) and Oregon. The states with pending HIFA waivers are Arkansas and Michigan.
49. Linda Magno, CMS Medicare Demonstration Program Group, conversation with author, September 11, 2003. There are more than 6,000 enrollees in intervention and 6,000 more in control groups. For more information on disease management, see Lisa Sprague, "Disease Management to Population-Based Health: Steps in the Right Direction?" Issue Brief No. 791, National Health Policy Forum, Washington, D.C., May 16, 2003.
50. For more information on Medicare + Choice plan participation, see Centers for Medicare and Medicaid Services, "Managed Care and Medicare+Choice Reports, Files, and Data," U.S. Department of Health and Human Services, at <http://cms.hhs.gov/healthplans/reportfilesdata/>.

51. Atlantic Information Services, *News and Strategies for Managed Medicare and Medicaid*, "Medicare PPO Demo Enrollment Starts Slow, But CMS Foresees Pickup by Year's End," March 18, 2003.

52. Study Panel on Medicare and Chronic Care in the 21st Century, "Building a Better Chronic Care System," National Academy of Social Insurance, January 2003; accessed August 15, 2003 at http://www.nasi.org/publications2763/publications_show.htm?doc_id=146189.

53. Jerry Cromwell, Sylvia Hurdle, Janice Singer, and Margaret Macadam, "Impact of Demonstration Projects on Medicaid and General Health Care Policy," Health Policy Research Consortium, Washington, D.C., October 7, 1987.

54. The six states were California, Florida, Minnesota, Missouri, New Jersey, and New York.