Cite this article as:
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The role of federal waivers in the health policy process
Health Affairs 11, no.4 (1992):72-94
doi: 10.1377/hlthaff.11.4.72

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Prologue: On 3 August 1992, after nearly a year of evaluation, Secretary of Health and Human Services Louis W. Sullivan denied Oregon the federal waiver it needed to proceed with its sweeping Medicaid reform plan. The denial was based on perceived violations of the Americans with Disabilities Act (ADA), which had gone into effect a month earlier. A number of policy analysts have questioned whether the ADA was truly a significant factor in the denial, or whether election-year politics played a role. Whatever the case, "if Oregon is any example, [the federal waiver process] has the potential to have a chilling effect" on state efforts to reform health care, said Lynn Read, director of the Prioritized Health Care System in Oregon's Department of Human Services. The ramifications of Oregon's Medicaid waiver denial illustrate the power that such waivers have on the health policy process. While the increased role of the states in the health care reform debate has focused new attention on the federal waiver process, there is little published research in this area. Here a group of researchers from Lewin-VHI in Fairfax, Virginia, present their findings from a major new evaluation of federal waivers, which was funded by The Henry J. Kaiser Family Foundation. Allen Dobson, a vice-president at Lewin-VHI, earned his doctorate in economics from Washington University. He was a principal with Consolidated Consulting Group and served in the federal government as director of the Office of Research, Health Care Financing Administration. Donald Moran, also a vice-president at Lewin-VHI, joined the research group in 1985 after his tenure at the Office of Management and Budget, where he was Executive Associate Director for Budget and Legislation. Gary Young, a senior associate at Lewin-VHI, earned a doctorate in business management and a law degree from the State University of New York at Buffalo.
Abstract: Federal waiver programs enable states to bypass the requirements of federal programs such as Medicare and Medicaid to experiment with different ways of financing, organizing, and delivering health care. In tracking waiver activity from 1980 to 1990, the authors found that federal involvement with waivers lost momentum during the latter part of the 1980s, while state involvement increased. Three key issues dominate the discussion of waivers: administrative control, the role of the states, and the ability to evaluate demonstration waivers. Examination of the chronology of waiver activity suggests the emergence of a new era, wherein federal control reemerges as a way to counter the increased fragmentation of health policies among states. If this is the case, four areas need to be addressed: (1) balance of political and research objectives; (2) administrative flexibility for states; (3) careful scrutiny of rules; and (4) increased accountability. These recommendations can guide the federal government, with the states as partners, in its attempt to regain momentum in the USC of waivers to expand the knowledge base.

In 1932 Franklin Delano Roosevelt wrote, “The country needs, and, unless I mistake its temper, the country demands, bold, persistent experimentation. It is common sense to take a method and try it. If it fails, admit it frankly and try another. But above all, try something.” These words capture the spirit driving the great majority of social welfare program initiatives undertaken in the United States in this century. Beginning with the social insurance system constructed under the Social Security Act in the 1930s) the federal government has exercised a substantial leadership role in social welfare program innovation, After successful implementation of major programs to ensure income support (Old Age and Survivor’s Insurance, Disability Insurance, Unemployment Insurance, and Aid to Families with Dependent Children), the federal government began experimenting in new directions with programs designed to supplement cash assistance. These programs were targeted to such key human needs as food, housing, and medical care. The adoption of the Medicare and Medicaid statutes (Titles XVIII and XIX of the Social Security Act) in 1965 represented a high-water point in federal leadership in the development of social welfare policy as it relates to health care. Since that time, however, the federal government has been less actively involved in program innovation, at least in the field of health care. Most legislative efforts in health care have been directed toward moderating cost growth in existing programs rather than toward devising new programmatic approaches to address unsolved health care problems. As a result, the locus of innovation appears to be shifting away from Washington. Today, most of the major new approaches to solving health care problems-ranging from systemwide cost control strategies to insurance financing schemes-are being considered at the state level. The increased role of states in health care innovation has focused much attention on the federal waiver process. Indeed, federal waivers, which permit policymakers to test alternatives to existing federal pro-
gram rules and requirements, are a visible, critical component of evolving health care reform. Several states have passed or proposed health care reform legislation in recent months that, if implemented, would likely require them to seek one or more waivers from the requirements of Medicare, Medicaid, and the Employee Retirement Income Security Act (ERISA) of 1974. Most recently, the federal government announced in August 1992 its decision to deny Oregon’s controversial request for a waiver, intended to extend Medicaid eligibility to all persons below the federal poverty level while at the same time redefining benefits through a prioritization process. The Oregon decision has stimulated much discussion and controversy regarding the efficiency and effectiveness of the current waiver process.

Despite this attention, the federal waiver process has been subject to relatively little systematic research. This paper discusses the results of a research study that Lewin-VHI is conducting for The Henry J. Kaiser Family Foundation, which is examining the federal waiver process as it applies to the U.S. health care system. The study has two objectives: (1) to determine what types of waiver projects have been funded over the past decade and how they have been used to shape legislative and administrative decision making; and (2) to examine the current waiver process, how it evolved, and where it might be headed.

As part of the study, we developed an automated database on waiver activity between 1980 and 1990. We also interviewed individuals who have had significant experience with the waiver process, to determine how waivers have been administered and used, how they have influenced the health policy process over time, and how they might be used in the future. We also used the interview data to verify and illuminate patterns observed in our database. This paper presents findings from our database analyses, investigation of secondary data sources, and interviews. We then highlight major problems associated with the waiver process, evaluate waiver activity, and offer a series of recommendations.

### Legislative Authorities

All of the major health and social welfare programs operated under the Social Security Act—including Social Security, Aid to Families with Dependent Children (AFDC), Supplemental Security Income (SSI), Medicare, and Medicaid—are based on systems of federal rules governing program eligibility, benefits, and operations. Even those programs, such as SSI and Medicaid, that permit latitude to states in determining program rules nevertheless have uniform requirements that constrain states’ discretion with respect to program administration.
An important drawback of enforced national-level program uniformity is that it limits experimentation with potential reforms. To address this problem, the Social Security Act provides the secretary of health and human services (HHS) with the authority to waive program requirements on a limited basis to allow policymakers to explore new approaches to program administration. Several waiver authorities pertain specifically to the Medicare and Medicaid programs. These waivers fall into two basic categories: demonstration and programmatic. Demonstration waivers, which are time limited, permit policymakers to expand the knowledge base underlying a program through research and program experimentation. By contrast, programmatic waivers, which may be renewed indefinitely, give states flexibility over major program design variables within federal statutory and regulatory requirements.

**Demonstration waivers.** Demonstration waivers allow policymakers to experiment with Medicare and Medicaid program innovations on a pilot study basis. The goal is to encourage innovative ideas that might eventually be used nationwide. Demonstrations are intended to be time limited, research oriented, and subject to rigorous evaluation. Several demonstration waiver authorities are discussed below.

First, Section 1115 of the Social Security Act provides the basic statutory authority for Medicaid demonstration waivers. This section, which pertains specifically to experiments and demonstrations sponsored by state Medicaid agencies, provides authority to waive federal Medicaid requirements, including statewide applicability; amount, duration, and scope of services covered; eligibility definitions; and level-of-care certification. Section 1115 waivers were the waiver authority most frequently requested by state Medicaid agencies before the advent of programmatic waivers during the early 1980s.

Second, Section 402(a) of the 1967 Social Security Amendments, as amended by Section 222(b) of the 1972 Social Security Amendments, authorizes waivers related to research on Medicare and Medicaid provider reimbursement. This section, which provides authority to waive reasonable cost and reasonable charge requirements of Medicare and Medicaid, has been used to support various demonstration projects, including state rate setting for institutional providers as well as reimbursement for ambulatory surgery centers.

Third, Section 222(a) of the 1972 Social Security Amendments authorizes the HHS secretary to engage in experiments and demonstrations that test the virtues of paying Medicare and Medicaid providers prospectively. As is the case with Section 402(a) of the 1967 Social Security Amendments, Section 222(a) authorizes waivers from Medicare and Medicaid reimbursement requirements.
Fourth, Section 2355 of the 1984 Deficit Reduction Act authorizes waivers to undertake social health maintenance organization (SHMO) demonstration projects. SHMOs integrate health and social services under the direct financial arrangement of a provider at a fixed annual prepaid rate for Medicare of 100 percent of the adjusted average per capita cost of treating these patients in other settings.

**Programmatic waivers.** In the Omnibus Budget Reconciliation Act (OBRA) of 1981, Congress enacted several Medicaid waiver authorities that are fundamentally different from those described above. These programmatic or policy waivers were designed to address Medicaid restrictions that can impede states from developing new reimbursement practices, creating organized systems of care, and substituting noninstitutional services for institutional care. The waivers are called programmatic because they are concerned primarily with expanding states’ flexibility with respect to program administration rather than supporting demonstration projects. The two most frequently requested programmatic waivers are discussed below.

The first, Section 2175 of OBRA 1981, authorizes waivers to allow states to create alternative health care delivery and reimbursement systems. This section provides for what are commonly known as freedom-of-choice waivers because it permits states to establish systems in which Medicaid recipients must receive their care from certain providers. Under this waiver authority, states can implement case management and selective contracting arrangements that are designed to increase access to primary care services and control program costs. The second, Section 2176, established what are known as home and community-based services waivers, which allow states to provide a coordinated set of noninstitutional services to Medicaid recipients who require or are likely to require long-term care at the intermediate nursing care level or higher. The section is designed to encourage more appropriate and less costly alternatives to institutional care, when available. The home and community-based waiver program grew out of prior research and demonstration projects that tested the cost-effectiveness and quality of community-based services for Medicaid recipients who require long-term care.

**Employee Retirement Income Security Act (ERISA).** Many states are contemplating broad reforms that likely will affect private-sector employee benefits. These reform initiatives, however, may conflict with ERISA, a complex federal statute that regulates employee benefit plans. This statute, which is administered by the U.S. Department of Labor, preempts states from regulating and taxing employee benefit plans.

ERISA is a potential barrier to state-based reform initiatives because so many of these initiatives involve mandated health benefit packages as
well as premium or provider taxes to finance health care for the uninsured. Many U.S. companies are self-insured and thus are effectively insulated by ERISA from state regulation and taxation of their health plans. ERISA currently does not have waiver authority. Consequently, states must petition Congress to obtain an exemption from ERISA requirements. Hawaii is the only state with an ERISA exemption.  

Waiver administration. The administration of demonstration and programmatic waivers differs in many respects. The Health Care Financing Administration (HCFA) is responsible for administering Medicare and Medicaid demonstration waivers. Within HCFA, the Office of Research and Demonstrations (ORD) manages the demonstration waiver process day to day. HCFA has administered Medicare and Medicaid waivers since the agency was formed in 1977.

Each year HCFA develops a research agenda for demonstration projects. The agenda consists of projects proposed by HCFA staff as well as those mandated by Congress. The final agenda typically is a broad statement of the agency’s research priorities. New demonstration projects are then solicited through announcements in the Federal Register. Proposals for Medicaid demonstrations must be submitted through the state’s Medicaid program. By contrast, public- and private-sector organizations may submit proposals for Medicare demonstrations. Applications for demonstration waivers must include a cost estimate of the waiver project, a formal research or experimental methodology, and a plan for an independent evaluation of the project. In the waiver cost estimate, applicants must show that yearly program costs per recipient will be lower under the waiver project relative to what they would be without the waiver. A technical review panel, comprising individuals from the public and private sectors who have appropriate technical expertise, rates each proposal according to a standard set of criteria. The panel ratings, along with recommendations from the director of ORD, are submitted to the HCFA administrator for final approval. As noted below, the nature of the approval process has changed dramatically over the years and appears to be highly politicized (for example, the Oregon waiver may have been decided on the basis of election-year politics rather than scientific criteria).

HCFA is also responsible for administering home and community-based (2176) and freedom-of-choice (2175) waivers. Both waiver programs are situated within HCFA’s Medicaid Bureau. States applying for either programmatic waiver are not required to present a formal research design or evaluation protocol. A state waiver application is deemed granted unless the HHS secretary issues a denial or a request for additional information within ninety days of receiving the application.
Moreover, these waivers are renewable for unlimited consecutive terms. Programmatic waivers, however, are not granted to applicants automatically. States must comply with several statutory requirements. Most importantly, to acquire a 2175 waiver a state must show that its proposed program will be cost-effective and that the restrictions established by the waiver will not impair beneficiaries’ access to medically necessary services of adequate quality. By contrast, a state seeking a 2176 waiver must demonstrate that its project will be budget-neutral. That is, the projected costs to the Medicaid program under the waiver must not exceed what they would be if the waiver were not granted.\textsuperscript{15}

### Profile Of Demonstration Waiver Activity

**Data sources.** For this paper, we have drawn from two secondary data sources to develop a profile of Medicare and Medicaid waiver activity between 1980 and 1990: HCFA Status Reports and HCFA program files. We discuss these data sources and their limitations below.

We obtained data on demonstration waivers from HCFA Status Reports, which have been published annually (except 1982) since 1978. We abstracted information from these reports to create a database of demonstration waivers from 1980 to 1990. To determine the number of demonstration waivers initiated and ongoing in each fiscal year, we sorted the projects by their start date. To determine the completion time of a project, we relied on its scheduled end date or the last year in which the project appeared in a Status Report, whichever was later.

During the study period a substantial number of multisite demonstrations were conducted. We chose to count the projects within a multisite demonstration separately when they were conducted by different grantees. The rationale for our decision is that each project was independently managed and accountable for unique results.

As a data source, the Status Reports were limited in two important ways. First, reports issued before 1983 contain a narrative on demonstration activities but do not report information by project. This format limited our ability to abstract information in a systematic manner. This limitation may have compromised the reliability of our database with respect to the number and type of demonstrations occurring in the early 1980s. In 1983 HCFA changed the format of the Status Reports to provide project-by-project descriptions of demonstrations.

Second, we observed that demonstration waivers were not reported consistently between their start and end dates in the Status Reports. For example, a project scheduled to begin in 1985 and end in 1988 might be reported in the 1986 and 1988 Status Reports but not in the 1987 Status
Report. This reporting inconsistency was an important obstacle in our attempt to obtain accurate counts of demonstration waivers for each year of the study. We filled in missing values; however, based on our discussions with HCFA staff, none of the Status Reports are likely to be complete with respect to the number of initiated or ongoing demonstrations in a given year. Thus, our database potentially undercounts waiver activity. This, of course, is an important caveat for the study.

We obtained information for programmatic waivers from HCFA’s Medicaid Bureau. The information was in the form of hard-copy reports that list all awards of 2175 and 2176 programmatic waivers since these programs began in 1982. These reports enabled us to develop an accurate account of programmatic waiver activity during the study period.

**Results.** During the study period (1980-1990) we counted 172 demonstration waivers (Exhibit 1). The early 1980s represented the most active period for demonstration waivers: More than 50 percent of the total number of demonstrations during the study period were initiated between 1980 and 1982, when many of the multisite demonstrations were initiated. Thus, the high level of waiver activity in the early 1980s is to some degree an artifact of several large multisite demonstrations (Exhibit 2). Fewer than twenty-five demonstrations were initiated between 1983 and 1987. This reduction in new demonstrations had the most observable impact on the number of ongoing projects in 1987. After 1987 the number of ongoing projects remained relatively steady.

The decline in demonstration waiver activity during the 1980s is also revealed through changes in program spending devoted to demonstrations. For example, four of the all-payer demonstrations, in Maryland,
Massachusetts, New Jersey, and New York, represented $6.2 billion in 1980, or about 18 percent of total Medicare program expenditures. By comparison, HCFA estimates the service costs of demonstration waivers at $1.3 billion for fiscal year 1992 (0.5 percent of fiscal year 1992 Medicare expenditures).

The mean completion time for demonstration waivers between 1980 and 1990 was approximately 4.5 years. This does not include evaluation time, which can extend a year or two beyond the end of a waiver project. The range was between one and ten years; however, roughly 94 percent of the demonstrations were completed within seven years. Thus, demonstration waivers represent a lengthy process requiring considerable front-end planning and execution before results are typically available.

The number of congressionally mandated demonstrations as a percentage of total demonstrations fluctuated during the study period (Exhibit 3). In 1990, however, all new demonstration waivers were congressionally mandated. Although this is not shown in Exhibit 3, 1990 was the beginning of a trend: Congressionally mandated demonstrations have represented the great majority of the total demonstrations initiated each year since 1990.

Programmatic waivers have made up an increasingly larger percentage of the total number of waivers awarded each year since the mid-1980s (Exhibit 4). An important component of this trend is the growing interest among states in implementing long-term care initiatives using 2176 home and community-based waivers. The availability of 2176 waivers obviates a state’s need to conduct a formal long-term care demonstration. Programmatic waivers (for example, home and community-based) are used more often than demonstrations to address long-term care issues (Exhibit 5). Service expenditures for the 2176 programmatic waivers in fiscal year 1990 amounted to roughly $1.2 billion.

Exhibit 6 presents the distribution of demonstration waivers by research area for the study period. We assigned demonstrations to one of six research categories: hospital payment, physician payment, long-term care, alternative payment systems, coverage and access/quality/program
Exhibit 3
Number Of Congressionally Mandated And Nonmandated Demonstration Waivers Initiated, Fiscal Years 1980-1990

Source: Lewin-ICF analysis of Health Care Financing Administration reports.

*The congressionally mandated demonstrations correspond to the year the demonstration began, not the year the mandate was issued.

refinements, and other. We adhered to HCFA’s classification system in developing these categories, which encompass many different research topics. For example, long-term care demonstrations tested new ideas related to prospective payment, home health, community-based care, deinstitutionalization of the chronically mentally ill, hospice care, swing beds, and skilled nursing facilities (SNFs). The category of “coverage”

Exhibit 4
Number Of Programmatic And Demonstration Waivers Initiated, Fiscal Years 1980-1990

Source: Lewin-ICF analysis of Health Care Financing Administration reports.
refers to demonstrations designed to test the value of providing a new type of service for either Medicare or Medicaid beneficiaries.

Long-term care comprised the largest percentage of demonstration waivers during the study period. Two well-known demonstrations are the On Lok Community Care Organization for Dependent Adults and the National Long-Term Care Channeling Demonstration Program. Demonstration waivers testing alternative delivery or financing systems comprised the second-largest research category. These demonstrations include the Santa Barbara Health Initiative, which tested the utility of using a primary care network, and Health Care Plus: The Lutheran
Medical Center Program for Prepaid Managed Health Care.

The third-largest category of waivers was “other studies,” which addressed topics ranging from preventive health care to Medicaid program refinements. One such demonstration currently operating is the New York Welfare Reform: Child Assistance Program, a congressionally mandated demonstration designed to explore ways to assist AFDC recipients in securing work and making other life improvements. The demonstration has a waiver from certain Medicaid requirements.

The fourth-largest research category consisted of demonstrations linked to “coverage” issues. This includes the urban health clinics demonstration that targeted the medically indigent in California and Tennessee. This congressionally mandated demonstration aimed to test the relative advantages and disadvantages of reimbursing physician-directed clinics that employ physician assistants and nurse practitioners.

Physician payment was the fifth-largest research category. Although HCFA solicited physician payment demonstrations several times during the early to mid-1980s, the response rate was consistently low. Hospital payment contained the fewest number of demonstration waiver projects during the study period. However, several highly influential demonstration waivers have been concerned with hospital payment issues. Notable examples include the Prospective Reimbursement System Based on Patient Case-Mix for New Jersey Hospitals and the Incentive Prospective Payment Systems for Hospitals through Fiscal Intermediaries (Massachusetts) demonstrations, which were instrumental in the implementation of Medicare’s prospective payment system (PPS).

Interview responses. We provided those we interviewed with a list of the demonstration waivers in our database and asked them to comment on some of the ways in which the waiver projects were instrumental in health policy development. Below we integrate the most frequent responses of our interviewees with other findings on how waivers have benefited the health policy process.

First, waivers leverage the use of scarce research dollars. Because waiver projects have been mounted upon existing program service structures, the incremental costs of program experimentation have been relatively low. Second, waivers have helped to determine which program and financing concepts are feasible and cost-effective. In this sense, waivers have functioned as pilot tests of ideas and innovations before they were implemented nationally. Third, waivers have helped to provide a realistic measure of benefits that could be expected from an operational program. The benefits have been in the form of lower program costs, improved health status of enrollees, or overall improvement in service delivery (one example is the Arizona Health Care Cost
Containment System, or AHCCCS). Fourth, waiver solicitations have provided the federal government with a relatively inexpensive way to gauge how the states and providers perceive the financial risk and technical feasibility of proposed program innovations. The federal government has at times solicited demonstration proposals without attracting any responses. This typically indicated that the proposed concept was flawed because of its associated financial risk or technical feasibility. Finally, waivers have provided states with increased flexibility to pursue policy options that fit their unique circumstances. Without programmatic waivers (aside from program amendments) states would have to petition Congress for new legislation each time they wanted to test a new idea representing a departure from existing program rules.

### Issues Affecting The Waiver Process

Much controversy surrounds the federal waiver process. Three issues have been at the center of the controversy: administrative control over waivers, the role of states in the waiver process, and the evaluability of demonstration projects.

**Administrative control.** The major administrative controversy has revolved around the extent to which waiver proposals with significant policy and cost implications should remain within the discretionary authority of the secretary of HHS, or be subject to interagency review and presidential control. Such controversies play out daily in the working relationship between HCFA and the Office of Management and Budget (OMB) within the Executive Office of the President.

Controversies between OMB and HCFA over waivers date back to the formation of HCFA in 1977. The controversy arose initially over what was then HCFA’s nearly unlimited control over the waiver process and how the agency exercised this control. A case in point was HCFA’s decision (at the direction of the secretary of HHS) to authorize a demonstration waiver involving a few hospitals in New York City. The demonstration was ostensibly an attempt to rescue several financially distressed hospitals in the district of an influential member of Congress.

An additional source of controversy concerned the relationship between waivers and the Medicare budget. Approximately 20 percent of the Medicare program budget was operating under waiver authority during the late 1970s and early 1980s. This effectively removed a large portion of the program from congressional legislative control and placed it under HCFA. OMB and, to a certain extent, Congress were clearly uncomfortable with the de facto transfer in program responsibility.

OMB made several attempts during the 1970s to limit HCFA’s con-
control of waivers through budgetary oversight. Although not successful at first, OMB eventually gained substantial control over the waiver process. Since the early 1980s HCFA has had to obtain OMB approval for any demonstration waiver that exceeds $1 million in gross costs or involves more than 300 participants. OMB has also insisted that demonstration waivers be budget-neutral in that program service costs are no greater with the waiver than they would have been otherwise.

OMB’s ability to intervene in the waiver process was heightened during the 1980s by the Reagan administration’s practice of using the budget process as the major channel for policy control. The arrangement whereby HHS agreed to submit significant waivers to OMB for clearance was negotiated between OMB Director David Stockman and HHS Secretary Richard Schweiker during the fiscal year 1983 budget process. Thereafter, OMB was able to use this clearance process to (1) prevent a series of demonstrations during the mid-1980s (for example, demonstrations that would have linked Medicare to the provisions of long-term care services) on the grounds that demonstration activity threatened the Medicare trust funds; (2) defer or prevent outright numerous waivers on the grounds that the waiver process should make more extensive use of random assignment and otherwise improve the scientific rigor of demonstration design and evaluation; and (3) use the budgetary imperatives of the times to forestall testing of program alternatives that appeared likely, in OMB’s judgment, to motivate significant program expansions. In a period of significant retrenchment in the Medicare and Medicaid programs, it was relatively easy to advance this argument without considering the research merit of the proposed demonstration.

During the 1980s OMB officials clearly used their authority to restrain the level of waiver activity. While the actual number of waiver projects that OMB rejected (or otherwise prevented from taking place through extensive reviews) is not known, the agency’s entrance into the process coincides with the sharp decline in the number of demonstration waivers initiated around 1983 (see Exhibit 1). The full implications of this decline are not well understood, but several of our respondents during the study noted the dearth of research currently “in the pipeline.”

Ronald Reagan’s ascent to the White House in 1981 set the stage for another struggle for control over the waiver process, this one between the executive branch and Congress. During the early 1980s, HCFA, as part of the executive branch, developed research agendas that Congress perceived as narrowly focused on the priorities of the White House and OMB. Many of these priorities were inconsistent with congressional interests. This inconsistency in research priorities provided an impetus for Congress to become actively involved in the waiver process. Con-
gress exerted control over the waiver process by legislatively mandating HCFA to conduct specific demonstration projects (for example, social HMOs). Although Congress had issued mandates to HCFA during the 1970s, the number of congressional mandates during the 1980s increased substantially.\(^{16}\)

Congress has also intervened in the waiver process by legislating the continuation of waiver projects after they were scheduled to end (for example, the On Lok Community Care demonstration); using the waiver process to serve its own needs in determining potential costs of extensions in benefits coverage (for example, therapeutic shoes for diabetics); using its authority to prevent demonstrations (such as competitive bidding for laboratory services) from taking place; and using demonstrations to delay broader legislative activity by initiating pilot studies.

HCFA’s performance in conducting mandated studies has not always satisfied Congress. In the late 1980s Congress asked the U.S. Government Accounting Office (GAO) to examine HCFA’s performance vis-à-vis mandated studies. The GAO issued a report in 1988 that noted problems with the relevancy, technical adequacy, and timeliness of HCFA studies performed in response to congressional mandates.\(^{19}\) The GAO also criticized HCFA for planning mandated studies without first developing a strategic plan.\(^{20}\) The GAO, however, also noted several significant constraints that HCFA faced in performing mandated studies. These constraints consisted of declining financial resources, staff shortages, and an increase in congressionally mandated studies. These “contextual factors,” according to the GAO, had a clear, negative effect on HCFA’s ability to respond to congressional mandates.

**The role of states in waiver activity.** The role of states in waiver activity has been a highly controversial issue. Waivers provide states with one of the few opportunities they have to control major program design variables, such as eligibility rules, benefit designs, and administrative structures. Yet the waiver process itself is governed by myriad rules and regulations that many state policymakers perceive as unduly burdensome. Policymakers, for example, complain about the amount of time and resources that are needed to prepare waiver applications, particularly cost estimates. Thus, the rules that define the waiver process are also potential barriers to states seeking to reform their health care systems. Growing dissatisfaction with these barriers is behind recent proposals to expand state accessibility to waivers to implement health care reform initiatives.\(^{21}\) Whether the waiver process is so onerous that it deters states from investigating potentially valuable programmatic reforms is an important consideration. This concern is particularly relevant to future waiver requests such as Oregon’s that would support
extensive health care reform.

**Evaluation of demonstration waivers.** The evaluability of demonstration waivers has been a long-standing issue. HCFA requires an evaluation of all demonstration projects, but by their very nature demonstrations are difficult to assess. Most demonstration waivers do not permit classic experimental designs in which subjects are randomly assigned to treatment and control groups. In fact, most demonstration waivers are conducted in geographic areas that are decidedly atypical, thus limiting the generalizability of results.

In addition, a long time lag exists between the initiation and evaluation of demonstrations. Demonstrations typically take between three and five years to complete; an evaluation study can take another year or more. Congress has more than once moved ahead with legislative policy without waiting for final results. The Medicare hospice legislation is one such example. Indeed, the difficulty in evaluating demonstrations in a reliable and timely manner has raised important questions regarding their utility—specifically, what can be learned from demonstrations and whether the information they produce is worth their costs.

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**Waiver Activity: Past, Present, And Future**

Our review and analysis of the data suggest that two well-defined eras characterize federal waiver activity to date. The first era witnessed the introduction and expansion of demonstration waivers during the 1970s. These waivers were initiated by the federal government and were largely focused on identifying potential solutions to the spiraling costs of Medicare and Medicaid. Many of the demonstration waivers authorized during this era have left an unmistakable imprint by providing the groundwork for future changes in federal health policy. Based on our research, it is objectively clear that the number of research-oriented demonstration waivers was consciously curtailed in the 1980s; as a result, policymakers who are now wrestling with difficult health policy questions may lack practical research on which to base their decisions. However, it is also important to note that the link between prior research and future policy issues is complex and that there may be other practical constraints on the ability of demonstration waivers to consistently enlighten issues of interest to policymakers.

Ideally, it would be desirable for federal research sponsors, such as HCFA, to anticipate policy problems and to develop and implement demonstrations involving alternative programmatic approaches to inform policy choices as issues crystallize. There is, in fact, some evidence, such as the research leading to the development and testing of the
diagnosis-related group (DRG) hospital payment methodology, that HCFA can be successfully anticipatory in developing programmatic alternatives. In reality, however, HCFA faces at least two important constraints in being visionary. First, HCFA has solicited some demonstrations testing important concepts, such as at-risk physician reimbursement, but has found no demonstration sponsors willing to undertake novel departures from the status quo. While HCFA has been able to fill in some of the blanks in its research agenda through research grants and cooperative agreements, rather than demonstrations, the lack of operational experience with alternative program models hampers our understanding of how such program changes would work in the real world.

Second, and perhaps more significant, the subject matter of interest in the health policy debate has shifted from a concentration on public insurance programs to a broader debate about the overall structure of the health care system. The debate about Medicare and Medicaid in the 1960s and 1970s was viewed as a precursor to a debate about far more comprehensive government-sponsored health insurance. By the late 1980s, however, the presumption that comprehensive reform necessitated a single government system was far less universal in the health policy community. Many current issues, including strategies that involve regulatory schemes focused on the operation of private insurance markets, have less direct relevance to research conducted solely within the walls of the Medicare and Medicaid programs.

In our view, this shift has been anticipated, in a subtle way, by the end of the era of HCFA-driven research and the beginning of successive new eras of leadership in demonstration activities. The second era began when Congress authorized programmatic waivers in 1981. With this development, waivers became more than a means to test potential reforms to existing program features; they became a vehicle for expanding states’ discretion over substantive health policy. In this sense programmatic waivers represented a fundamental change to the function of waivers. This second era of waiver activity saw a marked decline in the federal role in program experimentation.

State activity. We may now be witnessing the early signs of a third era. Several states have enacted or proposed major health care reform legislation during the past year that will likely require Medicaid, ERISA, and possibly Medicare waivers. For example, Florida has passed legislation that requires the state to study universal eligibility for a basic health care benefit package, reform of the small-group insurance market, and incentives for physicians to practice in underserved areas. Similarly, Vermont has enacted legislation that calls for analysis of single- and multiple-payer reform options. Vermont’s reform initiative could even-
tually provide for universal coverage while limiting state health spend-
ing.\textsuperscript{27} Minnesota intends to finance a state-operated health insurance program that will provide subsidies to the uninsured on a sliding scale.\textsuperscript{28}

The eventual use of waivers to support these types of state initiatives would represent a departure from previous applications of the waiver process in at least three respects. First, these state initiatives are not targeted specifically to the improvement of either Medicare or Medicaid. The initiatives are much broader, seeking to address the two major ills of today’s health care system: rising health care costs and the growing size of the uninsured population. Second, these initiatives, if implemented, likely would appear as a unique blend of demonstration and programmatic waivers. The broad scope of these initiatives would require that they be implemented under demonstration waiver authorities. Further, they would involve the testing of new concepts that may provide a foundation for future federal-level health care reform. But these state efforts also would resemble programmatic waivers because they are intended to establish permanent changes to a state’s health care system. Third, the initiatives are occurring without the guidance of the federal government. Consequently, there is an absence of centralized planning to the process. The likely result will be a patchwork of reform efforts scattered across the states that exhibit substantial variation regarding the way in which health care is financed, delivered, and organized. At best, this diversity of activity will represent a natural laboratory for the testing of new ideas. At worst, it will mean that individuals in different sections of the country have different levels of access to different types of health care. These differences in horizontal equity may lead to border crossing, whereby individuals and businesses move into or out of a state because of the relative generosity of its health care system.

Federal gridlock on health care reform is widely assumed to be the impetus for the growing state activity. While this is true in part, an equally important factor is that the federal government has expanded Medicaid over the past decade, giving the states increased financial responsibilities without commensurate funding. Given the states’ financial straits, they see waivers as a mechanism for doing more with less.

While much enthusiasm exists over the states’ future role in health care reform, a few caveats are in order. The continued momentum of state-based reform initiatives depends largely on whether states are successful in securing Medicare, Medicaid, and ERISA waivers for their programs. The federal government’s denial of Oregon’s Medicaid waiver request likely will have a chilling effect upon states’ waiver requests.

The need for ERISA waivers raises additional complications. Given that ERISA blocks both the direct regulation of employee benefits and
the financing of state reforms through the taxing of employee benefits plans and (perhaps) provider revenues, state reform activities may require rethinking. One possibility is for states to focus on incremental reform related to the small-group insurance market and to Medicaid expansions. Another possibility is for states to implement extensive single-payer systems financed through payroll taxes that completely bypass employer-based financing of health care as we currently understand it. Neither of these extremes would promote experimentation with employer-based health care financing. As we noted earlier, ERISA does not currently have waiver authority. While two proposals for such an authority have recently been introduced into Congress, they have met with severe opposition from employer groups and unions.29

Reemergence of federal control. Should the momentum for state-initiated reform continue, however, we may see yet a fourth era for federal waivers-the reemergence of the federal government in health care reform. Indeed, legislators and health policy experts have commented that state efforts alone will not suffice for a national solution. States lack the financial resources to address systematically all of the issues related to health care reform.

This fourth era would place the federal government in a unique position to identify which state-initiated reform models are most effective and determine under what circumstances they might be successfully exported to other states. For instance, the American Hospital Association, the Catholic Health Association, the Jackson Hole group, and the National Leadership Coalition for Health Care Reform have all suggested that systemwide health care reform be based upon extensive delivery reform. Many of the concepts advanced by these groups are complex and largely untested. Demonstrations of delivery reform would be necessary before a final nationwide reform plan could be set in place. A fourth era of this nature may in fact represent the most important opportunity this nation has ever had to identify and implement effective comprehensive reforms to our health care system.

Policy Recommendations

Balance political and research objectives. To reactivate waiver activity at the federal level that could support future health care reform initiatives, four aspects of the waiver process need immediate attention. First, the administration of the waiver process needs to more effectively balance political and research objectives. The decline in demonstration waiver activity over the past decade is related in part to political intervention, reflecting a lack of consensus on how waivers should be used. A
careful, strategic plan is needed, linking the data and information needs of the policy process for the remainder of this decade and into the next. This strategic plan should be developed in a public forum and include components that (1) outline program experimentation and infrastructure needs for the next several decades; (2) plan for the evaluation and conceptual integration of findings from state reform activities; (3) monitor the development of federal grant solicitations; (4) ensure that all proposals recommended for funding link a series of research hypotheses to key policy questions of interest and contain an evaluation designed to provide answers to research questions posed; and (5) provide for a system of accountability indicating proposals received, proposals funded, project budgets, and ultimately project findings. 30

Comprehensive health policy mechanisms will be required to develop a strategic plan related to the range of activities embodied in health care reform. Ultimately Congress and the president will need to debate the issues before deciding which components of health care reform are tested and how state program experimentation is folded into the overall equation. Legislation likely will be required to guide the process of developing the research agenda. This legislation could call for several government agencies to coordinate efforts to develop the research agenda. No one agency is currently in a position to provide this level of comprehensive policy guidance. The actual oversight of the research, however, should be left to the individual agencies, because they have the requisite technical expertise.

The final selection of funded projects will ultimately be the responsibility of the administration. Political appointees need flexibility to test their ideas. However, their selection of projects should balance federal and state budget constraints against the immediate policy needs of the current administration, the knowledge requirements to support policy decisions of future administrations, and the continued development of a health care services delivery infrastructure in terms of data collection, administrative structure, and various financing and reimbursement methodologies.

Give states administrative flexibility. States need to be given more administrative flexibility if they are to serve effectively as national laboratories for testing a wide variety of reform concepts. As noted, states are demanding a greater role in the waiver process, especially in regard to Medicaid, which involves so many of their dollars. State flexibility, however, should not preclude careful demonstration research and public reporting of findings on state experimentation. Flexibility cannot come at the expense of accountability.

A process for acquiring ERISA waivers is also needed; otherwise,
states will not be able to implement reforms of insurance systems based on employer-based financing. As noted, however, ERISA waivers will not come easily, since employers and unions are strongly opposed to any relaxation of ERISA rules. This is particularly true of national organizations that do not want state-by-state rule making to overturn hard-fought nationwide employee benefits agreements.

State concerns over financial and political risk also need consideration. Current federal financial requirements place the states at great risk if demonstrations increase expenditures. Risk-sharing arrangements might be considered that allow states to share both losses and gains as new programs are demonstrated. Political risks for the states are inherent in the uncertainty of the waiver process in terms of timing and currently-given Oregon’s situation—the likelihood of approval.

**Scrutinize rules carefully.** The rules that govern the waiver process need careful scrutiny. In particular, budget-neutrality is far from an objective standard. Both the states and OMB have learned how to use budget-neutrality assumptions to support their respective positions. In addition, budget-neutrality creates a bias against proposed projects with a combination of high start-up costs and delayed savings. Such proposals cannot survive the budget-neutrality test, although they might have much potential to reduce program expenditures in the long run. Preventive health services are one such example. A broader view of budget-neutrality that encompasses the life of a project (as opposed to annual accounting) might be considered. Another possibility is to have waiver projects, taken as a group, be budget-neutral. This would enable some projects that increase net service costs to be balanced by projects that save program dollars.

The decision-making process for reviewing waivers also needs to be expedited. The federal government spent nearly a year reviewing Oregon’s waiver request. Such a lengthy review period is clearly excessive. A predictable time period should be set in place. Another area of concern is the degree to which demonstration waivers should be time limited. At the point when most lessons are learned, the project should be moved out of the demonstration arena to a programmatic status to conserve scarce research dollars.

**Establish accountability.** A system of accountability needs to be set in place. The federal government needs to keep better track of its decisions and activities as they relate to waivers. No automated database now exists for tracking numbers of waiver projects, project expenditures, and project results. Moreover, the federal government does not maintain a publicly available data set on numbers of waiver proposals, decision outcomes, and grounds for decision.
The authors acknowledge the following interviewees for their assistance in preparing this document: Drew Altman, The Henry J. Kaiser Family Foundation; Stuart Altman, Heller School, Brandeis University; Brian Burwell, Systematics; John Cogan, Hoover Institute; Bill Cox, Catholic Health Association; Carolyne Davis, Ernst and Young; Cliff Gnus, independent businessman; Jim Kaple, Office of Applied Studies, Substance Abuse and Mental Health Services Administration (HHS); Steve Lieberman, Arizona Physicians IPA; John Luehrs, National Governors’ Association; Steve Long, RAND; Bryan Luce, Medical Technology Assessment and Policy (METAP) Research Center; and Andy Schneider, House Energy and Commerce Subcommittee on Health and the Environment.

NOTES

3. For example, state Medicaid plans must meet forty-seven requirements set forth in Section 1902(a) of the Medicaid statute. Three of the most significant requirements are the following: (1) 1902(a)(1) Statewideness: All aspects of the state plan shall apply to all political subdivisions of a state. (2) 1902(a)(10) Comparability: The services provided to any individual shall not be different in amount, duration, or scope from those provided to any other individual. (3) 1902(a)(23) Freedom of choice: Eligible individuals may obtain services from any institution, agency, community, pharmacy, or person qualified to perform the service provided.
4. Not all demonstration projects involve waivers. Demonstrations that can be performed without departing from program rules and requirements do not need a waiver. This paper reports on demonstrations that require waivers only.
7. This provision allows waivers of Medicaid requirements related to a beneficiary’s free choice of providers but only for one of the following purposes: (1) to implement a primary case management or specialty physician services arrangement that restricts the provider from or through whom a recipient can obtain medical care services (other than in emergency circumstances); (2) to allow a locality to act as a central broker in aiding recipients to select among competing health care plans; (3) to share with recipients, through provision of additional services, savings resulting from recipients’ use of more cost-effective medical care; and (4) to restrict recipients to receive services (except in emergencies) only from cost-effective providers and practitioners.
8. For more detail on the 2176 waiver program, see N.A. Miller, “Medicaid 2176 Home and Community-Based Care Waivers: The First Ten Years,” in this volume of Health Affairs.
10. ERISA may preclude states from imposing a tax on the revenues of health care providers. In United Wire and Machine Health Welfare Fund vs. Morristown Hospital (Civil Action no. 90-2639), the U.S. District Court, New Jersey, struck down a surcharge on patient billing, the proceeds of which were used to finance health services for the uninsured. The court concluded that the surcharge violated ERISA’s preemp-
tion clause because it “forces [employee] benefit plans to structure benefits in a particular manner and subjects the benefit plans to inconsistent regulations” (page 26).

11. Shortly before ERISA was enacted in 1974, Hawaii passed legislation requiring all employers to provide health insurance to their employees. Because Hawaii created its employer mandate before ERISA was enacted, Congress agreed to give the state an exemption from ERISA requirements.

12. HCFA rarely receives unsolicited proposals (outside the grant selection process). When it does, ORD sends a decision memo to the HCFA administrator with a recommendation for or against reviewing the proposal out of the agency's normal review cycle. The final decision is left to the discretion of the HCFA administrator.

13. For congressionally mandated projects, HCFA, not the grantee, is responsible for arranging the evaluation.

14. This so-called budget-neutrality test is not required by federal law or regulations with respect to demonstration waivers. As we discuss later, the test has been incorporated into the process largely at the insistence of OMB.


16. Based on conversations with HCFA staff.

17. Waivers have the potential to entail enormous sums of money because “gross” waiver costs include the costs of program service delivery. As noted above, this was particularly true of statewide all-payer demonstrations. If a waiver leads to increased service delivery, the resultant increase in net cost could also be dramatic.


19. Ibid.

20. The GAO study was not the first time HCFA was criticized for conducting demonstrations without an explicit strategic plan. The office of the HHS secretary also leveled a complaint against HCFA for failing in the early 1980s to develop strategic plans “that provide an adequate framework to guide effectively the long and short term actions of the research staff” (Internal HHS memorandum, undated).

21. The State Care Act, S. 3180.

22. The Carter administration has been credited with establishing a more formalized process for reviewing demonstration waiver proposals that included technical review panels comprising individuals with research credentials. See Greenberg et al., “A Historical Note on Medicare and Medicaid Waivers.”

23. Ibid.


25. By contrast, programmatic waivers are not about research; they are designed to expand states’ administrative flexibility over Medicaid. Although states are required to conduct an assessment of their programmatic waiver programs, these efforts have been much less of an issue compared to demonstration waivers.


27. Creating a Health Care Authority, H. 733 (Vermont).


29. The State Care Act, S. 3180; and the State Health Care Financing Act, S. 3223.

30. The issue of randomization needs careful review. While it is very unlikely that randomization is possible in the majority of demonstrations, it may be useful in a few.