
Medicaid and State Health Care Reform: Process, Programs, and Policy Options

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Health care reform is a continuously evolving process. The States and the Federal Government have struggled with policy issues to combat escalating Medicaid expenditures while ensuring access and quality of care to an ever-expanding population. In the absence of national health care reform, States are increasingly relying on Federal waivers to develop innovative approaches to address a myriad of issues associated with the present health care delivery system. This article provides a summary of State health care reform efforts that have been initiated under Federal waiver authority.

INTRODUCTION

States have long been proponents of changes to the current health care system. As major purchasers of health care and partners in the Federal/State Medicaid program, States are at the forefront of health care policy issues. Current public debate focuses on the ability to pay for rapidly increasing health care costs and how to provide universal insurance coverage, as well as access to high-quality, affordable care. Faced with congressional mandates to expand Medicaid services and escalating Medicaid costs amid diminishing resources, States have been seeking remedies for their health care financing problems for some time.

With health care reform stalled at the Federal level, States are relying increasingly on the flexibility provided under section 1115 of the Social Security Act to restructure their existing programs by implementing both incremental and comprehensive reform initiatives. Section 1115 waivers provide States with flexibility from meeting certain statutory requirements of the Medicaid program. Congress has provided DHHS with this discretionary waiver authority as a mechanism to test new and innovative approaches to the Medicaid program. While certainly not the answer for all States, section 1115 waivers do represent a valuable option for those States seeking to experiment with new methods of health care delivery and financing.

A major issue at the Federal level during the recent health care reform debate was whether health care reform should consist of one national system or whether States should bear primary responsibility for reform efforts. Irrespective of the merits of these arguments, there is a general consensus that there is much to be learned from individual State reform endeavors. This was recognized by President Clinton who, shortly after taking office, committed to the Nation's governors that the Administration would work with the States in the testing of new ideas and programs within existing health and welfare demonstration waiver authorities.

In August 1993, policy principles reflecting these commitments were enunciated, and ultimately published in the *Federal Register* (1994).

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The Administration's commitments include the following:

- Streamlining the process for considering waivers pursuant to section 1115 of the Social Security Act, and establishing procedures by which Federal agencies can work constructively with the States to develop research and demonstrations in areas consistent with DHHS policy goals.
- DHHS's consideration of proposals that test alternatives that deviate from that policy direction.
- Waivers would be approved for a duration sufficient to provide an adequate test of new policy approaches (large-scale statewide reform programs will typically require waivers for a 5-year period, given their magnitude and complexity).

Furthermore, DHHS is committed, if appropriate, to working with State governments to seek permanent statutory change reflecting successful aspects of waiver programs.

This article will provide a description of different waiver authorities available to the States. A profile of section 1115 waivers is provided, including a description of the waiver review, implementation, and evaluation processes, and current State health care reform initiatives utilizing section 1115 waiver authority. A discussion of policy implications and legal issues pertaining to the use of section 1115 waivers is also provided.

WAIVER AUTHORITIES

Two different types of waivers are available to the States to increase their flexibility in providing high-quality, efficient health care services through the Medicaid program. Both section 1915 "program" waivers and section 1115 "research and demonstration" waivers are designed to exempt States from certain

statutory requirements as set forth in the Social Security Act. These waivers, which are delegated to HCFA by the Secretary of DHHS, allow States to pursue program options not available through the State plan amendment process.

Section 1915 Program Waivers

There are two types of section 1915 program waivers. Section 1915(b) waivers, often referred to as "Freedom of Choice" waivers, allow States to pursue greater use of managed-care delivery models for Medicaid recipients. Section 1915(b) waivers enable States to mandate participation in a managed-care program and restrict the providers from whom recipients receive Medicaid-covered services. These waivers are granted for 2-year time periods, but can be continued indefinitely through renewal.

Section 1915(b) waivers are used extensively by the States. As of June 30, 1994, approximately 7.3 million Medicaid recipients have been enrolled in managed-care plans, either on a mandatory basis or voluntarily (Health Care Financing Administration, 1994). The majority of this population has been enrolled as a result of 1915(b) waiver authority.

Unlike section 1115 waiver authority, section 1915(b) waivers are restricted to section 1902 provisions of the Social Security Act; therefore, these waivers are limited in scope and flexibility. These waivers do not allow States to:

- Cover traditionally non-Medicaid populations.
- Modify the Medicaid benefit package.
- Restrict access to family planning providers.
- Restrict services provided by federally qualified health centers (FQHCs).
- Pay for FQHC services at less than 100 percent of reasonable costs.

- Cover services provided by health maintenance organizations (HMOs) which do not comply with the requirements of section 1903(m).

Section 1915(b) waivers do not, however, have the stringent evaluation requirements that accompany section 1115 waiver programs.

The other type of program waiver, section 1915(c) waivers, or "home and community-based waivers," permit States to offer a cost-effective alternative to institutionalization. Like section 1915(b) waivers, section 1915(c) waivers are limited in scope, and States that use this waiver authority must conform to specific guidelines.

Many States are proposing to incorporate changes in their programs that would not be permitted under section 1915 waiver authority; hence, States are increasingly seeking section 1115 waivers to advance their health care reform efforts.

Section 1115 Research and Demonstration Waivers

Section 1115 waivers differ significantly from section 1915 program waivers in several respects. First, they are broader in scope: Under section 1115, the Secretary of DHHS may waive certain statutory requirements which, in her judgment, are "likely to assist in promoting the objectives of the Medicaid statute." Section 1115 permits waiver of section 1902 provisions, and also authorizes Federal matching payments which would not otherwise be matchable under section 1903(m) provisions for services provided by managed-care entities not meeting specific statutory restrictions which must be met under section 1915(b) program waivers. For example, although Medicaid beneficiaries may be restricted to one provider, and "locked in" to using this provider for up to 6 months for federally

qualified HMOs, and up to 1 month for State-qualified HMOs, section 1115 waivers provide for up to a 12-month lock-in.

As part of many statewide health care reform initiatives, States are requesting section 1115 waivers to expand coverage to uninsured populations not statutorily entitled to Medicaid, modify the Medicaid benefit package, and restrict access to certain providers. Many States are seeking section 1115 waivers: to permit the imposition of premiums and copayments on newly eligible individuals; to be relieved of the requirement to reimburse FQHCs at 100 percent of reasonable costs; and to cover services provided by HMOs which do not comply with the requirements of section 1903(m). A risk contract must maintain an enrollment composition of no more than 75 percent Medicare or Medicaid enrollees.

In conjunction with the increased flexibility that section 1115 waivers offer, States must agree to bear additional burdens of a research and demonstration project. A critical requirement that HCFA has imposed on all States with section 1115 health care reform program waivers is the provision of complete person-level encounter data. States are expected to capture all service utilization data for all persons served by their waiver programs, including all hospital-based, physician, and other ambulatory services. The purpose of encounter data is twofold: It is used by the States and HCFA to monitor access and quality of services, and by independent evaluation contractors to assess the impact of the demonstration programs.

Despite the additional requirements that accompany section 1115 waivers, States are increasingly opting for the greater flexibility afforded under section 1115 waiver authority to develop innovative approaches to expanding health coverage and providing affordable, quality care to their most vulnerable populations.

BREAKING NEW GROUND

As of December 31, 1994, DHHS has approved section 1115 waivers to enable the following States to implement health care reform initiatives: Oregon, Hawaii, Tennessee, Rhode Island, Kentucky, and Florida. A discussion of each of these waiver programs follows.

Oregon

In 1991, Oregon presented the Bush Administration with the first section 1115 waiver proposal that featured managed care and expanded eligibility. Prior to that time, Arizona was the only State to introduce the extensive use of managed care through section 1115 waivers. Oregon resubmitted its proposal in 1992, and subsequently received waiver approval by the Clinton Administration in March 1993.

The Oregon Health Plan Demonstration is unique among the State health reform demonstrations in that the Medicaid benefit package was revised through a prioritization process (Oregon Health Services Commission, 1993). This prioritization process, which ranks a comprehensive set of physical and mental health services, is controversial because it has been labeled as "rationing." In order to evaluate which medical services were the most effective and appropriate, the Governor appointed an 11-member Health Services Commission which reviewed existing medical outcomes data, heard expert testimony of health care professionals, and held hearings and community meetings to develop a priority process to weigh the benefit each medical service provides for its cost and medical effectiveness. The current list includes categories based on the avoidance of death, cost, illness prevention, medical ineffectiveness, prevention of additional

complications, future costs, and self-limiting conditions. The list, to be updated every 2 years to reflect the latest medical outcomes research and changing social values, includes mental health and chemical dependency services.

The prioritization process for defining the Medicaid benefit package is one of three components of Oregon's section 1115 waiver program. The program also incorporates expanded eligibility and the utilization of managed-care delivery systems. It is estimated that the program will provide coverage to approximately 120,000 additional individuals with incomes up to 100 percent of the Federal poverty level (FPL). All acute-care services will be delivered through three managed-care models: (1) fully capitated health plans, (2) partial-service prepaid health plans (such as physician care organizations [PCOs]), and (3) primary-care case managers (PCCMs) (Oregon Health Services Commission, 1993).

Since it was the first State to use section 1115 waiver authority as the basis for comprehensive statewide health care reform, Oregon's review process was carefully scrutinized. Many predicted that if the Oregon proposal were approved, DHHS would soon receive similar proposals from other States seeking to revise their Medicaid benefit packages through priority lists. Although this prediction proved incorrect, following DHHS approval of the Oregon proposal, a number of applications from States seeking to use section 1115 as a cornerstone of statewide health reform efforts were submitted to DHHS (State of Oregon, 1991).

Hawaii

Hawaii is unique among the States for its nearly universal coverage of its population. Hawaii is the only State to obtain an

exemption from the Employee Retirement Income Security Act of 1974 (ERISA) and have a mandatory health insurance program that requires employers to provide a package of benefits to employees who work at least 20 hours a week. ERISA preempts State efforts to regulate self-insured plans which provide health coverage. The employer mandate is permissible in Hawaii because it was the only State to pass a mandatory program (the Hawaii Prepaid Health Care Act) prior to ERISA. Congress granted Hawaii the ERISA exemption in January 1983, enabling the State to require employers to offer health care coverage to their employees. Hawaii's section 1115 waiver program, approved in July 1993, is designed to provide coverage to its uninsured and underinsured populations that do not have access to employer-based health coverage.

Hawaii's section 1115 waiver program, referred to as Hawaii QUEST (Quality care, ensuring Universal access, encouraging Efficient utilization, Stabilizing costs, and Transforming the way health care is provided to public clients), is a statewide initiative which creates a public purchasing pool that arranges for health care through capitated managed-care plans. Under the program, the Medicaid eligibility income limits are extended to 300 percent of the FPL. The Hawaii QUEST program will test several health care reform strategies, including: (1) the expanded use of capitated managed-care plans to provide more efficient service utilization and contain expenditures; (2) the mainstreaming of public program recipients into a health care system operating under an ERISA exemption; and (3) the privatization of public health care programs (State of Hawaii, 1993).

Tennessee

Section 1115 waivers to enable Tennessee to implement its statewide TennCare program were approved in

November 1993. The TennCare program, which became operational in January 1994, provides health care benefits to currently eligible Medicaid beneficiaries, and expands coverage to uninsured State residents and those who are unable to obtain health care insurance due to existing medical conditions. Enrollment is capped at 1,400,000. If this enrollment cap is met, individuals in mandatory Medicaid coverage groups will continue to be enrolled, while enrollment for the uninsured and uninsurable will be limited. All TennCare participants are being served in managed-care plans that are either HMOs or preferred provider organizations (PPOs).

All adults and children with incomes above 100 percent of the FPL are required to share in the cost of their care, with the exception of those in mandatory Medicaid eligibility groups. Cost sharing is in the form of premiums, deductibles, and copayments (State of Tennessee, 1993).

Rhode Island

Section 1115 waivers for the Rhode Island Rite Care program were approved in November 1993. Rite Care is a statewide initiative that seeks to increase access to primary and preventive health care services for all Aid to Families with Dependent Children (AFDC) beneficiaries and certain low-income women and children. Approximately 65,000 AFDC beneficiaries and approximately 10,000 pregnant women and children 6 years of age and under, with family incomes up to 250 percent of the FPL, will be enrolled in the program. Individuals who are eligible for the program will be required to enroll in prepaid health plans under contract with the State to provide comprehensive health care services to participants for a fixed cost per enrollee

per month. Each health plan will offer medical and basic mental health benefits.

Pregnant women enrolled in the Rite Care program who lose eligibility 60 days postpartum will be offered the opportunity to enroll in an extended family planning program for a 2-year period. Enrollment of eligible participants into managed-care plans began on August 1, 1994 (State of Rhode Island and Providence Plantations, 1993).

Kentucky

Section 1115 waivers for the Kentucky Medicaid Access and Cost Containment program were approved in December 1993. This program would provide access to health care coverage in a managed-care environment with an emphasis on primary and preventive care services. Individuals with incomes up to 100 percent of the FPL, including single adults and couples without children, as well as children up to 18 years of age, with family incomes up to 100 percent of the FPL, will be eligible for the program.

All eligible individuals will be enrolled in the State's primary-care case management program, Kentucky Patient Access Care (KenPAC), which operates under a section 1915(b) waiver, or enrolled through alternative managed-care plans. Future managed-care options may include HMOs, a combination of KenPAC and PPOs, and specialized case management (State of Kentucky, 1993).

In June 1994, a special legislative session passed a budget bill that included language which prohibits the operation of programs that expand Medicaid services or eligibility if they were not implemented by January 1, 1994. Therefore, at this time, the Kentucky Medicaid Access and Cost Containment program demonstration program has not been implemented.

Florida

The Florida Health Security Program (FHS) was approved in September 1994. FHS will be a voluntary, employer-based, discounted premium program designed to provide access to private health insurance for working-uninsured Floridians. FHS is different from other demonstrations in that the population covered under the expansion is served by a separate program rather than by Medicaid. FHS is expected to provide health insurance to an estimated 1.1 million uninsured Florida residents at or below 250 percent of the FPL. It will utilize a managed competition delivery model. Health plans will be offered by Accountable Health Partnerships (AHPs) which are State-licensed managed-care or indemnity plans. The health plans will be administered by existing community health purchasing alliances (CHPAs). CHPAs are State-chartered, non-profit health benefits purchasing organizations that operate in specific territories. CHPAs will obtain prices and quality information from AHPs, and will assist individuals eligible for FHS to compare available AHPs on the basis of price and quality. The benefit package that is to be provided to FHS participants is less comprehensive than the State's traditional Medicaid benefit package; transportation, dental, and chronic mental health services are not covered under the FHS program. The FHS program will become operational 90 days after the passage of the enabling State legislation (State of Florida, 1994).

Several other State section 1115 waiver proposals are currently pending, and a number of States are expected to submit proposals in the near future.

COMMON CHARACTERISTICS OF WAIVER PROGRAMS

All of the section 1115 waiver programs that have been awarded to date have two common features: Medicaid expansions and the use of managed-care delivery systems.

Medicaid Expansions

One element common to each of the comprehensive, statewide section 1115 proposals is the expansion of eligibility to low-income uninsured individuals not currently eligible for the Medicaid program. Most statewide programs include expanding eligibility to individuals at a higher percentage of the FPL than currently used, and eliminate categorical eligibility requirements (i.e., linkage to the AFDC and Supplemental Security Income [SSI] programs) and asset tests from the eligibility determination process. For example, Oregon has expanded eligibility up to 100 percent of the FPL for current Medicaid eligibles and the uninsured, while Hawaii has expanded eligibility to 300 percent of the FPL. Rhode Island's RItE Care program has expanded coverage for pregnant women and children under 6 years of age, with family incomes up to 250 percent of the FPL.

Access and Managed Care

Associated with each section 1115 waiver program is the expectation that greater access to services will be achieved. States expect to significantly increase access to care by mandating enrollment in managed-care entities. All of the States currently using, or seeking to use, section 1115 waivers as a mechanism for reform of the Medicaid system are proposing to utilize some form of managed care. These managed-care delivery systems include fully capitated, full-risk HMOs, partially

capitated providers, and primary-care management and gatekeeper mechanisms.

The appeal of managed care is the anticipated potential of managed-care organizations to contain or reduce health care costs without compromising quality of care, resulting in a more effective and efficient health care delivery system (Hadley and Langwell, 1991). States anticipate the expanded utilization of managed care to promote continuity of care and result in more preventive and primary care being obtained. The enhanced access to preventive and primary care services is expected to improve the health of program beneficiaries, particularly those most vulnerable, including pregnant women and children.

Table 1 shows a side-by-side presentation of approved State health reform demonstration characteristics.

SECTION 1115 REVIEW PROCESS

In recognition of the potential that individual State initiatives can offer, DHHS is committed to streamlining the section 1115 waiver process, and has implemented procedures to minimize the administrative burden on the States and reduce the processing time for waiver requests.

Prior to submission of the waiver proposal, a State is required to notify the public of its intent to restructure its Medicaid program via section 1115 waiver authority. The following section discusses the public notice requirement and describes each phase of the section 1115 waiver review process.

Public Notice

On September 27, 1994, in an effort to facilitate public understanding of the process by which section 1115 waivers are reviewed and developed, DHHS issued a statement in the *Federal Register* (1994) to inform the

Table 1
Approved State Health Reform Demonstrations

Characteristic	Oregon	Hawaii	Kentucky	Rhode Island	Tennessee	Florida
Project Name	Oregon Health Plan (OHP)	Hawaii Quest (QUEST)	KenPAC	Rite Care	TennCare	Florida Health Security (FHS)
Project Implementations	Awarded March 19, 1993. Implemented February 1, 1994. Amended waiver approved September 2, 1994.	Awarded July 16, 1993. Implemented August 1, 1994.	Awarded December 1993. Implementation pending.	Awarded November 4, 1993. Implemented August 1, 1994.	Awarded November 18, 1993. Implemented January 1, 1994.	Awarded September 15, 1994. Implementation pending.
Project Goals	Provide access to care to the uninsured through Medicaid expansions in a managed-care delivery system.	Provide "seamless" access to the uninsured through Medicaid expansion in a managed-care delivery system.	Provide access to care to the uninsured through Medicaid expansions in a managed-care delivery system.	Provide access to care to uninsured women and children through Medicaid expansion in a managed-care delivery system.	Provide access to care to the uninsured through Medicaid expansions in a managed-care delivery system.	Provide access to care to the uninsured through a managed competition model for FHS participants.
Populations	Medicaid beneficiaries and the uninsured up to 100 percent Federal poverty level (FPL) with current supplemental security income eligibles to be included after January 1, 1995.	Medicaid beneficiaries and the uninsured up to 300 percent FPL. Excluded are aged, blind, disabled, and adults covered by employer-mandated insurance.	Medicaid beneficiaries and the uninsured up to 100 percent FPL.	All current Aid to Families with Dependent Children (AFDC) eligibles and all pregnant women and children up to 250 percent FPL.	Medicaid beneficiaries, the uninsured, and those who are uninsurable. Excluded are those who have access to employer or government-sponsored health insurance.	Legal full-time residents of Florida up to 250 percent FPL who have been uninsured for a period of 12 months prior to enrolling in FHS.
Population Enrollment	Expansion group of 120,000 to be included with 210,000 current eligibles.	Expansion population of 25,000 to be included with 90,000 current and 1902(r) eligibles.	Estimated enrollment of 112,000 by the end of the second year, covering 26 percent of the uninsured.	Expansion group to include an additional 10,000 to the current AFDC eligibles of 65,000.	Expansion population of 361,789 to be included with 758,192 current eligibles. Enrollment cap of 1.4 million.	Enrollment cap of 1.1 million individuals.
Benefit Package	Same as Medicaid. Benefits defined by a prioritization of health care services.	Same as Medicaid.	Same as Medicaid.	Same as Medicaid. Enhanced family planning benefits available.	Enhanced Medicaid benefit package.	FHS participants will receive a modified benefit package that is less comprehensive than currently offered under Medicaid.

See footnotes at end of table.

Table 1—Continued
Approved State Health Reform Demonstrations

Characteristic	Oregon	Hawaii	Kentucky	Rhode Island	Tennessee	Florida
Eligibility Criteria						
Revised Income Deeming Rules	Yes	Yes	Yes	Yes	No	Yes
Asset Test	No	No	No	No	No	No
Three-Month Retroactive Eligibility	No	No	Yes	No	No	No
Medically Needy	Medically Needy for AFDC-related groups eliminated.	Medically Needy for AFDC-related groups eliminated.	No impact.	Medically Needy spend down excluded, but new income deeming methodology for Rite Care does apply.	Medically Needy included with eligibility assured for an entire year.	Medically Needy eliminated with current eligibles to be grandfathered into Medicaid.
Special Populations						
SSI Included	Yes	No	No	No	Yes	No
Mental Health	Mental health and substance abuse services effective February 1, 1995.	Managed care for acute mental health and for seriously mentally ill adults only.	No	Mental health services available out of plan for adults classified as chronically or seriously mentally ill, and children who are seriously emotionally disturbed.	Services for persons with chronic mental illness, will be included effective April 1, 1995.	Some coverage for both inpatient and outpatient mental health services. No coverage for residential and intensive non-residential services.
Long-Term Care	No	No	No	No	No	Skilled nursing care available. Lifetime maximum of 100 days, and 80/20 coinsurance.

See footnotes at end of table.

Table 1—Continued
Approved State Health Reform Demonstrations

Characteristic	Oregon	Hawaii	Kentucky	Rhode Island	Tennessee	Florida
Delivery System	Health maintenance organizations (HMOs) and partially capitated health plans; primary-care case management (PCCM); separate dental capitation plan.	HMOs	PCCM with HMOs and preferred provider organizations (PPOs) to be developed in the future.	HMOs	HMOs and PPOs.	HMOs and indemnity insurers.
Savings Initiatives¹						
Managed-Care Efficiencies	Yes	Yes	Yes	Yes	Yes	Yes
Disproportionate Share Redistribution	No	Yes	Yes	No	Yes	Yes
Cost Sharing	No	Premiums and cost sharing required for those with incomes above 133 percent FPL. Exceptions are pregnant women and infants up to 185 percent FPL who are exempt from both premiums and copayments, and children under age 19 who are exempt from copayments only.	No	Copayments or premium contributions for those with incomes between 185 percent and 250 percent FPL.	Premium payments, deductibles, and copayments for all individuals with income above 100 percent FPL with adjustment made according to income levels. Exempt are Medicaid-eligible groups.	Coinsurance, and deductibles for FHS participants with individual premium payments adjusted according to individual income.
Other	Prioritized benefit package.	None	Lower inflation rate.	Lower inflation rate.	None	Medicaid program reforms and reimbursement caps for managed care and outpatient hospital costs.

¹For funding expansion populations.

NOTES: Kentucky held a special legislative session in June 1994 which passed a budget bill including language which prohibits operation of any waiver program expanding Medicaid services or eligibility at this time. Therefore, the State cannot implement this Kentucky Medical Access and Cost Containment demonstration project.

SOURCE: Health Care Financing Administration, Office of Demonstrations and Evaluations, 1994.

public of the process the Department would normally use in reviewing proposals, the principles which would normally guide the review, and the types of procedures the States would be expected to employ in involving the public in the development of proposed waiver projects. The *Federal Register* (1994) statement also indicated that DHHS will publish a monthly notice listing all new and pending section 1115 proposals.

The State may notify the public of the demonstration proposal and acquire public input through the following means: public hearings; developing the proposal through a commission that holds open meetings; providing for formal notice in accordance with State notice and comment requirements; announcing the intent to submit a proposal in a newspaper of general circulation; or, any other process which affords interested parties the opportunity to learn about and comment on the State's proposal. Public notice requirements would also be met if the program is developed through legislative enactment prior to submission of the proposal.

Conceptual Development

Several HCFA components (principally the Medicaid Bureau, Office of Managed Care, Office of Research and Demonstrations, and regional offices) are integrally involved in the waiver process, and the States are encouraged to discuss potential demonstration project concepts with HCFA early in the process. These components work as a team throughout the waiver process, enabling various areas of expertise to participate in the conceptual development. During this stage, HCFA can provide guidance to the States on the process and requirements for submitting demonstration proposals, input on the general policy relevance of the proposed project, and insights based on other States' experiences.

HCFA can also assist in identifying section 1115 waivers that would be required.

HCFA often meets with State representatives prior to the submission of a proposal. These meetings provide an opportunity to discuss general guidelines that support the goals of the 1115 waiver process. If appropriate, HCFA will provide recommendations for modifying the waiver concept to satisfy those goals. Additionally, HCFA may alert the State to problematic aspects of its proposed program that might violate HCFA principles, for example, the utilization of block grants or enhanced Federal matching rates. HCFA's desire is to work cooperatively with the State in the development of its program design.

Proposal Review and Decision

A statewide section 1115 proposal, once submitted to HCFA, is disseminated to all appropriate Federal components within DHHS and the Office of Management and Budget for concurrent review. For example, specific DHHS components examine the proposal in terms of policy relevance and the State's capacity to implement, monitor, and conduct the demonstration. Potential adverse impacts on demonstration participants are also taken into consideration. Within a month or so of receipt of the proposal, HCFA notifies the State in writing of potential issue areas and begins a dialogue with the State to develop alternatives. Detailed questions are forwarded to the State for clarification approximately 60 days from proposal submittal. Throughout this process, Federal staff and State representatives continue discussing any remaining issues. Upon receipt of the States's response, a technical panel is convened which makes a recommendation to approve, approve with conditions, or disapprove the proposal. The panel's recommendation is considered part of the Department's decision to approve or

disapprove a proposal. Every attempt is made to make a decision within 120 days after the submission of a proposal; however, significant issues may require a longer review period.

Post-Award and Preimplementation

If section 1115 waivers are ultimately approved, an award letter, which includes Special Terms and Conditions, is sent to the State. The Special Terms and Conditions are generally extensive, and specify all requirements that must be met prior to implementation of the demonstration, as well as those the State must adhere to during the operational phase of the demonstration. The terms and conditions also include ongoing requirements for program eligibility and benefits, Federal financial participation, cost control and fiscal administration, quality assurance and data collection procedures, and reporting requirements.

HCFA validates State assurances that preimplementation Special Terms and Conditions are met and assesses the State's operational readiness for project implementation. HCFA works closely with the State after approval to ensure a timely and smooth transition to the implementation of the new program.

Post-Implementation and Evaluation

The State implements and manages the operations of the project in accordance with the Special Terms and Conditions that accompany the award letter. HCFA provides operational assistance, oversight, and enforcement; reviews modifications to the terms and conditions; monitors compliance with the terms and conditions; oversees the evaluation of the project; and assesses cost neutrality. HCFA extensively evaluates all section 1115 waiver demonstration projects, usually through an independent contractor which examines a wide range of issues.

STATE HEALTH REFORM DEMONSTRATION EVALUATIONS

All section 1115 health care reform demonstrations will be evaluated by a competitively selected contractor. Two evaluation contracts were awarded in September 1994. A \$3.2 million award was made to Health Economics Research, Inc. (HER) and its subcontractors (Research Triangle Institute and Indiana University) for the evaluation of the Oregon Medicaid Reform Demonstration. A second contract, for \$5.6 million, was awarded to Mathematica Policy Research, Inc. (MPR) and its subcontractors, The Urban Institute and Systemetrics. This contract is examining the impact of the State Medicaid reform demonstrations in Hawaii, Rhode Island, and Tennessee. These contractors will also evaluate the next two States to implement section 1115 waiver approval. The evaluation of the Oregon Health Reform program was awarded as a separate contract because the demonstration includes the employer component and a priority list, unique demonstration features that require an evaluation design with a somewhat different focus from that of the other States. Additional evaluation contracts will be awarded for other groups of States as additional demonstration projects are approved.

Each evaluation is a 5-year effort that will provide four annual reports and a final report. Each report from the evaluation of the five State health reform demonstrations will contain a chapter on observations and analyses specific to each of the five demonstrations, as well as, a chapter with activities and findings related to cross-demonstration analyses. The first annual report for each evaluation is due December 31, 1995; the final report for each evaluation is due September 30, 1999. Primary issues to be examined include the following: organization of the demonstration programs; the impact of the demonstrations

on use and cost of services; and the impact of the demonstrations in terms of access to care and the quality of care received.

Evaluation Design

Both the Oregon and the five-State evaluations include a series of site visits to assess the implementation processes and to collect information to assist the evaluators in understanding the organizational structure of the demonstrations and the role that diverse organizational components play in the demonstration. Both evaluations will include, as part of their site visits, interviews with a number of individuals, including State officials, providers, advocacy group leaders, and employers. In all States, the evaluators will examine the impact of the new organizational structures and payment reforms on health care organizations and providers. Of particular interest is the impact of the demonstrations on provider participation and the financial viability of providers who traditionally serve large segments of the Medicaid population in each of the States (e.g., FQHCs, rural health clinics, and public hospitals).

Each of the evaluations also has unique features. For example, MPR's design for the five-State evaluation provides for a separate set of interviews to be conducted in urban and rural areas to illuminate differences between these markets in terms of implementation and organization. MPR will also conduct a series of focus groups in each State for low-income clients, disabled clients, and physicians. HER's site visit team will include a medical ethicist who will participate in the case study interviews and examine the ethical implications of the prioritization list for physicians and hospitals.

Quality of Care and Satisfaction

Both evaluations will study the impact of the demonstration programs on the overall health status and routine preventive health practices of participants, satisfaction with the care they receive, and their access to health care services. Particular emphasis will be placed on assessing the demonstrations' impacts on the health status of participants with chronic conditions and potentially vulnerable populations. The effects of the demonstration programs will be examined through surveys, claims/encounter data, hospital discharge/readmission data, and mortality/morbidity data from birth and death certificates.

Additional emphasis is being placed on the examination of quality in the Oregon evaluation because of the potential impact of the prioritization of benefits and the discontinuation of funding for certain services.

Use and Cost of Services

While States are extending Medicaid coverage to new populations, they are relying on the concurrent expansion of managed-care delivery systems to control costs. The evaluation of these demonstrations will examine the extent to which the expanded use of managed care is able to reduce emergency room, specialist, and hospital inpatient services. The evaluations will also explore the extent to which newly covered individuals exhibit pent-up demand for services immediately following enrollment. A variety of statistical methods will be employed to control for the effects of enrollee selection bias.

Determining the impact of the demonstrations on both public and private expenditures is an important and complex part of the evaluations. Overall changes in Medicaid costs for the States and the Federal

Government will be examined, as well as the impact of the demonstrations on individuals' out-of-pocket costs, employer health insurance costs, and provider bad debt.

As HCFA has worked with States to develop section 1115 waiver proposals, a number of issues have emerged, including financial and legal concerns.

FUNDING AND BUDGETARY CONSIDERATIONS

Budget Neutrality

DHHS has specified fiscal policies which require meeting conditions for waiver approval. One of these conditions is that all section 1115 demonstration projects be budget neutral. Budget neutrality exists if Federal title XIX expenditures are no greater under a section 1115 demonstration program than they otherwise would be in the absence of the demonstration. The requirement of budget neutrality has had a tremendous impact on a number of State reform proposals. The challenge to States wishing to test new ways of expanding publicly subsidized health insurance through section 1115 waivers is to demonstrate that planned program savings offset the cost of the expanded coverage. Because budget neutrality determines how much Federal money will be available to a State to fund its waived Medicaid program, this aspect of the 1115 process has been an important one in negotiations between HCFA and the States.

The method for ensuring budget neutrality under statewide reform demonstrations is to place a limit on the amount of the Federal financial participation (FFP) that a State can claim during the demonstration period. This limit is based on a projection of the amount of FFP that the State would have drawn in the absence of a demonstration. The limit may be applied to the State's

entire Medicaid program or only to those parts of the program affected by the demonstration, depending on the scope of the demonstration, among other factors.

If the projections upon which budget neutrality is based are too high, the result is a windfall for the State (and a corresponding outflow of funds from the Federal Treasury); if they are too low, serious fiscal problems for the State or cutbacks in services may result. To protect both the States and HCFA from the effect of forecast inaccuracies due to changes in economic conditions, some State expenditure limits vary, depending on the actual demonstration period economic and program variables. For example, expenditure limits calculated using the "per capita" method will vary with actual Medicaid enrollments, since only those individuals who would have been eligible without the demonstration are counted. This shields the State from the impact of Medicaid enrollment increases that are beyond the State's control and unrelated to the demonstration. The "aggregate method," by contrast, makes no allowance for variation in enrollment during the demonstration period.

Another method for allowing ex post variation in the expenditure limit is to tie the limit to a medical price index. This method shields both parties from changes in the future rate of medical cost inflation. Regardless of the method employed, however, the objective is to find a way to ensure budget neutrality that neither unfairly burdens the State nor risks an unwarranted increase in Federal spending obligations.

LEGAL CONSIDERATIONS

In working with the States to develop section 1115 waiver programs, several legal concerns have been raised which HCFA has attempted to address.

Waiver Authority Challenges

Currently, one pending court case has challenged the Secretary's waiver authority under section 1115. The national association representing FQHCs has sued the Secretary, challenging her approval of specific demonstration projects, and seeking to prohibit her from approving additional demonstration projects that impact FQHCs (*The National Association of Community Health Centers v. Shalala*, pending, Case No. 1:94CV0128 [HHG][D.D.C.]). The FQHCs are most concerned with the effect these demonstrations will have on their future role in Medicaid. FQHC services are mandatory under current Medicaid law, and payments for FQHC services are required to be at 100 percent of their reasonable costs. Section 1115 has been used to waive these requirements under the State demonstration programs to make the provision of FQHC services optional for the State and enable participation of FQHCs as part of a managed-care network paid by capitated rates.

Related Federal Statute Restrictions

State efforts to implement comprehensive reforms to their Medicaid programs through section 1115 waiver programs have been impacted by the effects of other Federal statutes that regulate health care financing and delivery. Three statutes which have presented the greatest impediments for States are: the Anti-Kickback provision of the Fraud and Abuse Act (section 1128B of the Social Security Act); the Medicare Act (Title XVIII of the Social Security Act); and ERISA.

The Anti-Kickback provision of the Fraud and Abuse Act prohibits remuneration for the referral of individuals for services covered by Medicare, or a State health care program, including Medicaid. This prohibition directly affects a State's ability to incorporate the use of outside

agents, such as insurance agents or marketing representatives, into its section 1115 waiver program.

Medicare laws also restrict the scope of a State's demonstration program with respect to treatment of dual eligibles, i.e., persons eligible for both Medicare and Medicaid. Medicare waiver authority is distinct from, and more limited than, the Secretary's Medicaid waiver authority under section 1115. Medicare waivers have not been granted for projects intending to: restrict Medicare beneficiaries' provider choice and right to disenroll from a health plan on a monthly basis; reduce Medicare benefits; or increase beneficiary cost sharing. However, the Medicaid program may place restrictions on dual eligible (Medicaid/Medicare) beneficiaries as a condition of Medicaid payment of coinsurance and deductibles.

As explained in the discussion of Hawaii's health reform program, ERISA contains a Federal framework to govern self-insured health and pension plans. As such, ERISA largely preempts State control over these self-insured plans; thus, it is impossible for a State to comprehensively regulate health coverage provided in the State. There is no statutory waiver mechanism within ERISA to enable States to control self-insured health plans; rather, a State must seek congressional action to waive the preemption provision and enable the State to exercise control over these plans. Hawaii is the only State to obtain a legislative exemption from ERISA's provisions.

POLICY IMPLICATIONS AND LESSONS LEARNED

The scope and substance of section 1115 waivers are of significant policy relevance in the movement towards health care reform. The model of reform could well resemble any

of the presently implemented demonstration projects, which include provision of services based on publicly developed priority lists, such as that used by Oregon, to health insurance purchasing alliances for small businesses and the self-insured, as in the Florida plan, to the provision of subsidies for buying into the private sector health care market, as used by Hawaii in its demonstration. These reform demonstrations attempt to address issues of health care cost, access, and quality. Despite the initial setback of national reform efforts, both the Federal and State governments share a responsibility to continue to create innovative methods to address these important issues.

Although detailed results from these demonstration programs will not be available for several years, there are a number of tentative lessons to be derived from the initial implementation of the programs. The first lesson, and probably the most obvious, is that the implementation of statewide reform initiatives is complex and difficult, and acceleration of program implementation may become problematic. Second, a shift from primarily fee-for-service delivery systems to managed-care models requires paying careful attention to the establishment of adequate organizational and administrative structures, as well as beneficiary outreach and education. Efforts to transition traditional fee-for-service populations and low-income individuals into managed care has, however, encouraged creative thinking about delivery systems and how those systems will best respond to the needs of these populations. If the appropriate expertise is not available within the State, outside contractors may be procured for particular functions.

States have a critical role to play in determining the future course of health care policy. With or without substantial health care reform at the Federal level, the future health care system will, no doubt, be shaped by individual State initiatives.

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