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Shaping Medicaid Waivers to Serve the Poor

The Advocacy Challenge of a Lifetime: Shaping Medicaid Waivers to Serve the Poor

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I. Introduction

In recent months, states have begun using the Social Security Act's section 1115 experimental waiver provision to expand Medicaid to additional uninsured groups and to mandate prepaid managed care for the poor. /1/ HCFA has already approved section 1115 waivers in several states, and additional requests are pending.

The National Health Law Program has prepared an extensive advocate's guide to the section 1115 process, Section 1115 Medicaid Waivers: An Advocate's Primer, which is available from the program's Washington, D.C., office. Following the outline of the guide, this article will acquaint the reader with the section 1115 process and the important advocacy and legal issues it involves.

Short of national or state-based comprehensive health care reform, section 1115 represents perhaps the greatest hope for available and affordable health services for the uninsured poor. A section 1115 waiver is allowing the State of Tennessee, for example, to provide health insurance to over 300,000 Tennesseans who were uninsured a year ago. /2/ Moreover, these waivers hold the promise of establishing a medical home for many Medicaid clients who now rely on hospital emergency rooms for their care. /3/

However, section 1115 waivers also have the potential to cause confusion and harm. Because risk-based managed care is a component of these waivers, current and future beneficiaries face a potential loss of provider choice and dangerous incentives for underservice if the provider plans are undercapitalized, inadequately staffed, and ineffectively monitored. /4/

Legal services attorneys face a twofold challenge: to represent our uninsured clients to assure that health care coverage is expanded carefully and as promised in the waiver /5/ while at the same time representing our Medicaid clients to avoid harmful cutbacks and inadequate, unmonitored managed care plans that are nothing more than mills for the poor.

Not surprisingly, advocates support some section 1115 waivers and oppose others. But in

all states where waivers are involved, advocates affirm the crucial need for clients' interests to be actively represented in program design and throughout implementation. Medicaid waivers' potential for good or ill is, in fact, so great that there are few other occasions in a legal services advocate's career when effective, skillful advocacy can make such an important difference in the lives of so many clients.

You need not have extensive experience with Medicaid or health advocacy to be a successful section 1115 advocate. Sufficient backup support exists within the legal services community to enable advocates to be effective. Commitment of resources is needed, however. Programs where waivers are being discussed or implemented should make whatever adjustments necessary to enable advocates to engage in shaping the waiver on behalf of clients, including coordinating work with other legal services offices in the state. Once this occurs, local advocates can position themselves to make the difficult judgment about whether to support or oppose a waiver and how to influence its design and implementation.

II. The Various Waivers

A. HHS's Waiver Authority

Absent a waiver, state Medicaid programs must meet the minimum requirements of the federal Medicaid law. These requirements are contained in the Medicaid Act, particularly section 1396a, which lists nearly 60 standards for state programs. These include mandates for a single state agency, /6/ fair hearings and due process, /7/ comparability of benefits among recipients, /8/ statewide operation, /9/ independent quality review of prepaid health plans, /10/ and early and periodic screening services for children. /11/

Two separate statutory provisions, sections 1915 and 1115 of the Social Security Act, authorize the Secretary of HHS to waive the otherwise mandatory provisions of the Medicaid Act. Notably, any provisions not expressly waived by the Secretary continue to apply. /12/

Section 1915 waivers are available for two specific purposes. First, they are used to limit recipients' free choice of provider, typically by establishing a system of primary care case management or risk-based managed care. /13/ Section 1915 also authorizes states to provide home- and community based services to the elderly, disabled children, and persons with AIDS, mental illness, or mental retardation/developmental disability. /14/ The statute and implementing regulations describe the documentation states must make to obtain a section 1915 waiver. States must show, among other things, that freedom-of-choice restrictions are consistent with access, quality, and the efficient and cost-effective provision of care and services, and that restrictions do not discriminate among classes of providers on grounds other than efficiency and effectiveness. /15/ In addition, participating providers must meet quality and utilization standards. /16/ The majority of states operate at least one section 1915 waiver. /17/

By contrast, section 1115 of the Social Security Act authorizes experimental, pilot, or

demonstration projects that, in the judgment of the Secretary, are likely to assist in promoting the objectives of the Medicaid statute. /18/ This experimental waiver authority was added to the Social Security Act in 1962 /19/ and extended to include Medicaid when that program was enacted in 1965. /20/

In the past, section 1115 Medicaid waivers have been used to test pilot, experimental innovations. /21/ According to HHS administrators, states could not merely copy what other states have done. /22/ Typically, these waivers included a formal research methodology involving, for example, control/study group assessments. The projects were of limited duration (usually three to five years) and were not renewable. /23/ For the most part, Medicaid section 1115 experimentation assessed various aspects of mandatory copayments and mandatory enrollment in Medicaid managed care.

B. The Current Section 1115 Waivers

HCFA has recently approved waivers from Arizona, Florida, Hawaii, Kentucky, Oregon, Rhode Island, and Tennessee. Waivers are pending from Delaware, Illinois, Massachusetts, Minnesota, Missouri, New Hampshire, Ohio, and South Carolina. California, Colorado, the District of Columbia, Nebraska, New Jersey, New York, Oklahoma, Washington, West Virginia, and Wisconsin are developing waiver proposals.

In contrast to traditional section 1115 waivers, all of the current section 1115 waivers are similar to one another in that they all seek to demonstrate the ability of the state to provide increased access to health services for a portion of the uninsured population. /24/ The current waivers require persons above some state-set percentage of poverty to meet cost-sharing obligations, usually based on a sliding income scale. In almost every case, the waiver requires beneficiaries to enroll in at-risk, prepaid managed care plans. Uniformly, the states seek unlimited waivers of specific Medicaid provisions. For example, rather than listing the specific services it would like to cut, a state may seek a broad waiver of the Medicaid mandatory service provision. Existing federal requirements regarding data gathering, reporting, and quality assurance that apply to managed care plans are replaced by often ill-defined, state-developed requirements. /25/ Medicaid medically needy programs and retroactive eligibility are typically eliminated. Disproportionate-share hospital funding is commonly used to fund some part of the program. The programs propose statewide changes and do not seriously contemplate a return to the previous system.

Each state's iteration of the formula does differ slightly. For example, Hawaii already guarantees coverage for most of its citizens, so its waiver is designed to fill the gaps in the existing program, specifically for persons with incomes at less than 300 percent of poverty who are not otherwise eligible for Medicaid as aged, blind, or disabled. /26/ As part of its waiver, Oregon obtained permission to ration covered services based upon annual funding. /27/ Notably, the state has mentioned the need to cut 20 percent from its Medicaid budget after only the first operational year of the waiver. /28/

Kentucky's waiver authorizes the expansion of privatized, managed care coverage to all

individuals with incomes below the federal poverty level, in part through increased provider taxes. /29/ The Kentucky Medicaid agency obtained the waiver somewhat secretively, and the state legislature later refused to authorize necessary appropriations for the expansion. /30/ Massachusetts's proposal includes a program to reimburse employers for insurance provided to low-income employees and direct, sliding-scale subsidies to employees whose gross household income is at or below 200 percent of poverty. /31/ Massachusetts's free care pool would be diverted to fund the subsidies. As an incentive for state residents to purchase insurance, unpaid medical bills incurred by uninsured state residents are designated as debts owed to the commonwealth, and the Medicaid agency will collect amounts due. /32/ Tennessee's plan to expand coverage is notable for its requirement that health care providers who participate in the Blue Cross/Blue Shield Provider Network for state employees must also participate in TennCare. /33/

III. Advocating Effectively for All Clients

Advocacy begins with the accumulation of information about the waiver and involves analysis and strategy regarding program structure, legal compliance, adequacy of regulatory and administrative provisions, adequacy of provider contracts and/or requests for proposal, and postimplementation monitoring. /34/ This section discusses how to obtain information, the review process, and issues for review. /35/

A. Obtaining and Providing Information

It is important to learn as much as possible about your state's waiver, as early as possible. Becoming "part of the loop" may require some homework, however, because the waiver process is not inherently friendly to affected consumers. Federal law does not generally require public notice that a section 1115 waiver of Medicaid Act provisions is being planned or submitted. /36/ There are, however, numerous times during the waiver process at which legal services clients may become formally involved. Obviously, the earlier the involvement, the better. Listed below are steps advocates can take to obtain information and monitor activities in their states:

(1) Develop contacts within your state Medicaid agency.

(2) Make contacts with the person in the HCFA Regional Office who has been assigned responsibility for your state's waiver. /37/

(3) Obtain a copy of the waiver and any other public documents that refer or relate to the waiver, including the state's model health plan/provider contracts and requests for proposals.

(4) Submit comments and/or attend public meetings about the waiver.

(5) Inject your clients into the review process by commenting to your state agency and

HHS on the waiver, in writing, at the earliest possible moment.

(6) Schedule meetings with the appropriate state agency personnel.

(7) Review state legislation to make sure that the administrative agency is acting within the law in seeking a waiver.

(8) Review the state Administrative Procedure Act (APA). The state should publish its program rules of general applicability consistent with the requirements of the state APA. If this is not occurring, both the state and HHS should be aware of your clients' concerns. Where regulations are proposed, comment on them.

(9) Obtain information about other states' section 1115 waivers. /38/

B. Benchmarks for Client-Based Review

A few benchmarks apply to client-based review during all phases of advocacy. First, it is important to take note of any positive aspects of waiver proposals, such as expanded eligibility, elimination of assets tests, and/or six-month continuous eligibility. In many cases, however, no matter how good the proposed program appears to be on paper, in reality the program will not work unless realistic cost sharing, adequate time for planning and implementation, and adequate resources devoted to quality assurance exist, and the state provides a meaningful role for consumers and consumer advocates.

Second, states can and should be judged on past performance. Wherever states are proposing to expand managed care programs, advocates should attempt to gather as much information as possible on the successes and/or failures of existing Medicaid managed care programs in their state. Advocates should also collect monitoring reports that are required under federal and state law, /39/ any General Accounting Office, HCFA, HHS Office of Inspector General, or any other federal or state reports, and any anecdotal evidence.

Third, when providing input, divide the task into the following areas: (1) raising procedural and substantive legal issues in order to alert the state to potential litigation; (2) making demands regarding the process for providing consumer input; (3) raising areas of concern; and (4) providing or offering to provide concrete suggestions regarding specific areas of concern.

IV. Issues for Review

The following areas of concern should be explored in considering any section 1115 waiver and its impact on clients.

A. Accessibility

Often, states promote their waivers and expanded use of mandatory managed care as a means to improve access. Advocates need to evaluate clear indicators of improved access.

1. Maintaining Existing Patient-Provider Relationships

Does the waiver provide a meaningful mechanism to include providers who currently participate in the Medicaid program? Will the waiver enable recipients who currently have Medicaid providers with whom they are satisfied to continue seeing those providers?

2. Clear Access Standards

Any Medicaid waiver proposal should provide clear, uniform access standards. For example: /40/

- Emergency medical care shall be available on a 24-hour basis, seven days a week.
- Urgent medical and dental care shall be available within a time that meets community standards for the privately paying/insured population.
- Average waiting times for primary care, including preventive care, initial assessments, and Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) screens, shall not exceed 30 days, except for pregnant women who should wait no longer than 14 days.
- Average waiting times for specialist and dental care shall not exceed 45 days.
- Primary services sites shall be within 10 miles from each beneficiary; specialty service sites and pharmacies shall be within 15 miles or 30 minutes of travel time; however, exceptions will be made for plans that demonstrate that broader standards are reasonable under the circumstances.
- Each plan shall provide all services (including enrollment materials, membership services, health education, and medical services) in a language other than English where at least 5 percent of the population of the plan's service area, or more than 1,000 persons, prefer receiving services in that language.

At the same time, recipients who would prefer seeing a provider whose location falls outside the travel and distance standards, or, conversely, who meets the travel and distance standards but cannot meet the recipients' linguistic needs, should be able to maintain that choice.

3. Case Management/Continuity of Care

In order to ensure that the gatekeeper, a primary care provider who has the power to limit access to follow-up services, truly expands access to coordinated care, it is important to institute clear definitions and expectations of case management. Under federal Medicaid law, case management is an optional service, /41/ defined as "services which will assist individuals . . . in gaining access to needed medical, social, educational, and other services." /42/ Under EPSDT, case management is mandatory for children. /43/ Advocates should ensure that case management is part of any waiver system.

4. Adequate Provider Participation

As states attempt rapid implementation of managed care waivers, advocates should beware of inadequate numbers of new providers willing to participate. Standards regarding the ratio of physicians to enrollees are necessary to ensure that enrolled recipients actually have timely access to needed care.

5. Services

To the extent that there is not a waiver, all the services otherwise required under federal Medicaid law, or available under the state's Medicaid plan, should be available to recipients, regardless of enrollment in the managed care plan. This means that whatever Medicaid services have not been waived still must be available according to the same medical necessity standard, unless there is a specific waiver on statewideness or comparability for this particular purpose. Otherwise, managed care plans should be prohibited from using their own standards. /44/

6. Affordability of Cost Sharing

Most of the proposed waiver programs have sought some copayments for services, as well as premiums and deductibles from newly eligible individuals with higher incomes. Cost-sharing arrangements need to be scrutinized carefully to determine whether they are truly affordable. If they are not affordable, currently uninsured persons will not enroll in the program, thereby resulting in a mandatory prepaid managed care program for current recipients without meaningful expansion. Studies reviewing cost-sharing arrangements have found a detrimental impact on the use of needed medical care because individuals have no way of determining whether they should immediately pursue care or wait. /45/

B. Quality Assurance

1. Data Collection

It is essential that states collect and be able to assess uniform data. /46/ In addition, the data collected should provide meaningful information about the accessibility and quality of care. For example:

- The percentage of enrolled children under the age of 21 who received their initial health assessment within 60 days of enrollment.
- The percentage of total enrollees who have received their initial health assessments.
- The average waiting time for an appointment with a primary care provider.
- The average waiting time for an appointment with a plan specialist provider.
- The percentage of disenrollments (recipients and providers) from the plan within the previous 12 months and the reasons for disenrollment.
- The average telephone waiting times, including the length of time on hold and number of calls answered with busy signals.
- The percentage of enrolled pregnant women who began their prenatal care in the first trimester (pregnancy was diagnosed after enrollment).
- The percentage of plan enrollees under age two with up-to-date immunization.

Information should be collected by county, race, and gender.

2. Quality Goals

Clear goals by which quality can be measured are necessary. For example, there might be a goal of 80 percent of all enrollees being up-to-date with immunizations and preventive care, or no more than 10 percent exceeding the minimum waiting, travel, and distance standards. Such goals should be used to institute corrective action plans. Corrective action plans should be required automatically for plans failing to meet clear thresholds and should be enforceable by both the state monitoring agency and beneficiaries.

3. Monitoring and Enforcement

If inadequate resources are devoted at the state level to monitoring and enforcement, the requirements related to access and quality will be meaningless. However, it is often difficult to determine an adequate amount of resources and commitment. As well as asking these questions themselves, advocates may consider requesting legislators to call hearings and seek information on this issue.

4. Ombudsprogram

Advocates are becoming increasingly aware of the potential benefits of ombudsprograms, independent of the state as well as of the plans, to monitor access and quality of care. Such programs might provide a variety of services, including direct assistance to recipients, legal advocacy, access to and review of financial and medical audits, and client education, such as plan report cards and guidance on how to use plans effectively. Some advocates have proposed funding such programs through capitation, for example, $1 per enrollee per month.

5. Choice

While the ordinary right of freedom of choice might be waived in order to mandate enrollment, choice still is an important tool in enabling recipients to protect themselves by "voting with their feet." Advocates should consider the benefits of limiting mandatory enrollment unless there are at least three plans from which to make a choice. In addition, it is important to ensure choice of plans by enabling recipients to disenroll from any plan for any reason, at least within an open enrollment period every six months or one year, and to ensure choice of providers within plans, such as the right to change providers at any time.

6. Mainstreaming

While states may waive the 75/25 requirement, under which at least 25 percent of the enrollees must be non-Medicaid and non-Medicare recipients, /47/ advocates should consider whether it is important to insist on access to mainstream managed care plans, that is, plans that see non-Medicaid recipients. For example, in Tennessee, all participating managed care plans also must be available to state employees. /48/ Often, mainstream managed care plans are regulated by an agency other than the state Medicaid agency, which helps offset the obvious conflict of interest that the state Medicaid agency has in holding down its own costs.

7. Consumer Role in Oversight

To ensure that these systems are accountable to consumers, it may be essential to include consumers or their advocates on governing boards and/or advisory boards, where there is a formalized relationship between consumer interests and the interests of the plans.

C. Financial Risks

Capitation implies many important questions regarding the nature of financial risks on individual providers and provider groups. It is important to determine whether, in your individual state, there has been a history of bankruptcy or undercapitalization associated

with Medicaid-participating managed care plans. While it is often difficult to master these areas as advocates for consumers, advocates need to ask questions about (1) the adequacy of capitation rates; (2) whether there are special arrangements or considerations made for chronically or acutely ill or disabled individuals; (3) the availability of reinsurance; (4) solvency requirements; and (5) the regulation of particular risk arrangements within particular plans. These questions (and standards) need to be applied to the plan and to all the providers with whom the plan subcontracts.

D. Grievance Procedures/Due Process

States often encourage recipients to use plan grievance procedures. While federal law requires managed care plans to provide grievance procedures, the regulations are quite vague and open-ended. /49/ Whether or not this provision is waived, grievance procedures can be an essential tool in addressing recipients' interests in access to timely, quality care. The grievance procedure should, at a minimum, include (1) clear information to enrollees on the availability of such a procedure; (2) a requirement that all written or oral grievances be recorded in writing, along with information regarding the timing and result of the resolution, and that such information be available for state review; (3) a timely resolution of all grievances, with special time limits for resolving issues related to emergency and urgent care needs; and (4) a requirement that named individual employees are assigned responsibility within each plan for ensuring that grievances are resolved. The system should also provide for in- and out-of-plan second opinions when an at-risk provider denies a medical service.

Despite the availability of a grievance procedure, recipients still are entitled to fair hearings to contest denials, reductions, or terminations in services. /50/ The right to a fair hearing cannot be conditioned on exhausting a plan grievance procedure. /51/ Thus, notification of this right and the right to aid pending a fair hearing should accompany all denials, reductions, and terminations in services. /52/

E. Special Populations

Advocates need to consider whether managed care plans can meet adequately the needs of special populations. Such groups include (1) the mentally ill, for whom case management needs to be handled by specialists in their needs; (2) chronically ill and disabled recipients; (3) foster care children; and (4) homeless and migrant individuals.

F. Narrowing the Waivers

It is important to consider whether the waiver is as limited as it needs to be to accomplish the purposes of the program. Even if the state needs a waiver of a particular requirement, the waiver requested should be tied expressly to the limited purposes it is to serve.

V. Legal Issues

This section of the article summarizes a range of legal claims that may arise during the review and implementation process.

A. Nondelegated Administrative Actions

A number of state Medicaid agencies have developed and submitted section 1115 waiver proposals to HCFA and even agreed to conditions placed on the new programs, all without any clear state legislative authorization. Where state agency personnel are either understaffed or unqualified to develop a waiver, advocates may consider a challenge based upon nondelegated administrative actions.

Generally, an administrative agency may exercise only those powers that have been either expressly or implicitly delegated to it by legislation. /53/ Be aware, however, that the trend in both federal and state courts is to grant implied powers wherever justified by a "reasonable interpretation" of the statute. /54/

Even if a court found that the power had been implied, it could strike down actions taken under grants of power that the court determines are overly broad. According to several judicial pronouncements, the prohibited delegation of overly broad state power serves two purposes: (1) it assures that basic policy choices are made by duly authorized and politically responsible officials; and (2) it protects against the arbitrary exercise of unnecessary and uncontrolled discretionary power. /55/ Courts have been particularly attentive to situations in which statutory standards or procedures for review are completely absent. For example, a federal court struck down as unconstitutional a North Carolina provision that permitted automatic sterilization of mentally retarded girls and women based solely on petitions filed by next of kin or legal guardians. /56/ According to the court, the provision authorized an "arbitrary and capricious delegation of unbridled power." /57/

B. Obtaining Public Information

All states and the federal government require that individuals have access to public information. /58/ Advocates having difficulty obtaining requested documents might consider bringing legal action to order production. One exception to producing documents is the "deliberative process" or "executive" privilege. It is important that consumer advocates not accept a claim of executive privilege without first considering the parameters of the privilege.

The claim of a deliberative process privilege arises from the federal Freedom of Information Act (FOIA) and, at the state level, from state public records acts, most of which are modeled on the FOIA. /59/ The FOIA exemption attaches to "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." /60/ Given the statute’s presumption for disclosure, the exemption is to be construed narrowly. /61/

To qualify for withholding under executive privilege, the information must be both

"predecisional and deliberative." /62/ Courts have considered whether the document (1) makes recommendations or sets forth the reasons for an agency decision already made; /63/ (2) is from a subordinate to a superior official; /64/ (3) is essential to the decisionmaking or a peripheral item that merely supports a position with cumulative materials; /65/ (4) reflects the frank, personal opinions of a writer rather than the policy of the agency; /66/ or (5) is an unfinished draft which, if disclosed, could mislead the public as to the agency policy. /67/

Clearly, the waiver itself, once submitted by the state to HHS, should not be protected. If there are documents that do appear to be privileged, it is well established that purely factual material that is severable from opinion is not protected and must be disclosed. /68/

C. Medical Care Advisory Committee

States are required to establish a medical care advisory committee (MCAC) to participate in policy development and program administration. /69/ Challenges might be raised in a state that fails to consult with its MCAC in formulating and implementing a waiver request.

D. The Social Security Statute

The Secretary of HHS may approve a state waiver that violates the requirements of Social Security Act section 1115. Adversely affected low-income clients may seek to challenge that approval under the APA. /70/ Notably, all of the reported section 1115 cases have allowed for APA review. /71/

While the Secretary of HHS is given great latitude, that discretion is not unfettered. /72/ Rather, section 1115 provides clear, relevant factors upon which the Secretary's approval of a Medicaid waiver must be based. The law provides:

In the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of subchapter . . . XIX or this chapter . . . the Secretary may waive compliance with any of the requirements of section . . . 1396a of this title . . . to the extent and for the period he finds necessary to enable such state or states to carry out such project. /73/

Thus, the statute allows waivers only for (1) the period and extent necessary to implement experimental, pilot, or demonstration projects that are (2) likely to assist in promoting the objectives of the Medicaid program. /74/ Waiver provisions that violate these principles should be amended or stricken from the proposal.

1. The Need for Experimental, Demonstration Waivers

The waiver must be limited to an experimental, pilot, or demonstration project of limited scope and duration. /75/ Legislative history, while limited, has consistently confirmed

that Congress meant what it said. At the time of its enactment, Congress described section 1115 as a way to "test out new ideas and ways of dealing with the problems of public welfare recipients." /76/ It stated that demonstration projects "usually cannot be statewide in operation" and "are expected to be selectively approved by the Department." /77/

2. The Objectives of the Medicaid Act

Section 1115 also requires the waiver to be consistent with and, in fact, promote "the objectives of the Medicaid Act." /78/ This provision assures that the Secretary will not be given the discretion to ignore congressional dictates in granting waivers. /79/ Otherwise, "administrative prerogative will quickly become legislative in nature." /80/

The question, then, arises, What are the objectives of the Medicaid Act? Courts have answered this question by looking to the statute, statements from legislative history, federal regulations, and other courts. /81/ Specifically, one of the broad purposes of the Medicaid Act has been identified as "provid[ing] medical assistance to those whose income and resources are inadequate to meet the costs." /82/ Congress has additionally noted the important Medicaid objective of ensuring comparability of services and eligibility standards /83/ and of ensuring "high-quality care." /84/ Courts have set forth consistent interpretations of the aim of Medicaid; for instance, in Atkins v. Rivera the Supreme Court stated that the purpose of the Act is to cover "medical assistance to persons whose income and resources are insufficient to meet the costs of necessary care and services." /85/ Taken together, these sources establish the Secretary’s power to approve waivers that promote the provision of uniformly prompt, high-quality medical assistance to those whose income and resources are inadequate to meet the cost of necessary care and services. /86/ Additional guideposts for determining whether a waiver provision is consistent with the objectives of the Act include whether the provision comports with congressional intent, the common law of Medicaid, sections 1915(b) and 1936a of the Social Security Act, and constitutional protections.

a. Congressional Intent

Congress may have expressed its clear intent regarding waiver of certain provisions in the Medicaid Act itself. These specific statements of congressional intent should control over the more general section 1115.

For example, Congress has specifically described how it expects the Secretary to exercise her authority to waive the copayment and cost sharing protections of the Act. /87/ The Act authorizes only "nominal" cost sharing, a requirement not waivable "except for demonstrations under tightly limited circumstances." /88/

Specifically, no cost sharing may be imposed "under any waiver authority of the Secretary," unless the waiver is for a "demonstration project which the Secretary finds

after public notice and opportunity for comment"

(1) will test a unique and previously untested use of copayments;

(2) is limited to a period of not more than two years;

(3) will provide benefits to recipients of medical assistance that can reasonably be expected to be equivalent to the risks to the recipients;

(4) is based on a reasonable hypothesis that the demonstration is designed to test in a methodologically sound manner, including the use of control groups of similar recipients of medical assistance in the area; and

(5) is voluntary, or makes provision for assumption of liability for preventable damage to the health of recipients resulting from involuntary participation. /89/

Congress has also specifically limited the Secretary's authority to allow "household deeming" in the case of certain pregnant women and children. Under Medicaid law, states may not deem income other than from parent to child and spouse to spouse. /90/ While this rule is waivable under section 1115, a specific statutory exception is found for certain pregnant women and children -- mainly the poverty-level populations. /91/

The Medicaid Act provision states that the Secretary "shall require" any state providing assistance under a section 1115 waiver to provide medical assistance to pregnant women and children "in the same manner as the state would be required to provide such assistance" were it not operating under a waiver. /92/ This means that deeming for poverty-level pregnant women and children is limited to parent to child and spousal deeming. Deeming among other household members is, thus, prohibited. Moreover, as noted in legislative history, section 1115 states must adhere to the following additional eligibility mandates in the same manner as other states:

- coordinating Medicaid eligibility with the Women, Infant and Children (WIC) supplemental food program;

- initiating eligibility determinations at "outstationed" locations frequented by pregnant women and children (minimally federally qualified health centers and disproportionate share hospitals); /93/ and

- ensuring adequate payment rates for pediatric and obstetrical services.

Notably, in the current round of waiver activity, the Secretary has permitted household deeming and ignored the other requirements that apply to eligibility determinations.

b. "Common Law" of Medicaid

The purposes of the Medicaid Act can also be inferred from aspects of the Medicaid program that have been tailored so consistently and specifically that they have become part of the "common law of the Social Security Act and part of its essential purposes." /94/ Administrative waiver of a Medicaid Act provision that conflicts with that legislative objective should not be allowed.

Over the past ten years, for example, a "major theme" of Medicaid legislation has been expansion of eligibility and services for pregnant women and children. /95/ Beginning with the Deficit Reduction Act of 1984, /96/ Congress has enacted significant expansions in child eligibility and services at a near annual pace. /97/ Most notably, in 1967 and again in 1989 and 1993, Congress amended the Medicaid Act to codify specific EPSDT requirements for poor children under age 21. /98/ All of these requirements evidence Congress's clear intent that an essential purpose of Medicaid is to assure that every poor child in this country receives a minimum floor of preventive services and treatment benefits as set forth in the EPSDT statute. It is unreasonable for the Secretary to disregard this "common law" of the Medicaid Act and allow states to waive EPSDT services for children and pregnancy-related services for women as part of health care reform waivers. /99/

c. Section 1915(b) of the Social Security Act

Section 1915(b) of the Social Security Act /100/ delineates the Secretary's authority to grant waivers that incorporate managed care concepts. Thus, for instance, recipients may not be deprived of access to quality health care. /101/ Consumer protections must be included. /102/ Program review must occur every two years. /103/ Mandatory participation in a program can occur only if there is adequate provider participation. /104/ Section 1915(b) does not view Medicaid managed care, which has a long history within the Medicaid program, as an experiment.

By contrast, section 1115 requires that, in order to waive Medicaid provisions, the state must propose an experimental project. The earlier-passed section 1115 is a general waiver provision, applicable to many Social Security Act benefit programs. It contains none of the specificity of 1915(b).

Most of the waivers now being developed by the states have elements that fall under the rubric of section 1915(b); these elements should be evaluated under the more specific provisions of section 1915(b). And, since Congress has addressed the subject of managed care systems directly and extensively, section 1115 proposals that cannot comply with section 1915(b) cannot "assist in promoting the objectives" of Medicaid, as required by section 1115, and should not be approved. /105/

d. Section 1936a of the Social Security Act

To be waived, a provision must be contained in section 1396a of the Social Security Act.

Thus, where Congress has placed the requirement outside of section 1396a, that requirement must stand even under a waiver system. Examples of important protections found outside of section 1396a include protections for observance of religious beliefs, /106/ provisions regarding Indian Health Service facilities, /107/ protections against liens and recovery, /108/ and requirements for nursing facilities. /109/

e. Constitutional Protections

Medicaid provisions may involve constitutionally protected interests, which are not waivable by the Secretary. Thus, section 1115 waivers that include managed care should clearly delineate grievance and fair hearing procedures that are consistent with constitutional due process protections. /110/ Notably, advocates have scored recent successes in curbing the Secretary's authority to approve section 1115 welfare reform waivers that do not adhere to constitutional minimums. /111/

f. The Need for a Particularized Record

Waiver proposals are hundreds of pages long. This volume does not, however, automatically guarantee that the state has made an adequate showing to support the waiver or that the waiver has an adequate research design. States should explain and justify a true research design for their proposals so that the flawed managed care systems of the past will not be replicated. /112/

A recent Ninth Circuit decision, Beno v. Shalala, includes helpful instruction regarding the requisite nature of the Secretary's section 1115 review. /113/ According to Beno, the Secretary should assess what information the project is likely to yield and whether the experiment reaches an unreasonably large population or continues for an unreasonably long period of time. /114/ The Secretary should determine whether the research will cause danger to participants' physical, mental, and emotional well-being. /115/ She needs to decide whether the design of the project is methodologically defensible and to review the feasibility of alternative designs. /116/ In its ruling, the court took special notice of the positions and advice from plaintiffs' experts and amici. /117/

Advocates reviewing section 1115 proposals should, if possible, use expert testimony to assess the research design and methodology of the waiver and make this testimony part of the written record. Written comments on the waiver, including reasonable alternative suggestions, are essential.

E. Human Experimentation

Medicaid recipients and newly eligible populations covered by a section 1115 waiver are, under the terms of the statute, participants in "experimental" programs. "It goes without saying that experiments upon the most basic living conditions of human beings who are to a very large extent totally dependent upon governmental programs for their very

existence [are] a most serious matter." /118/

Since 1974, HHS's annual appropriations act has provided for the protection of human subjects in any federally funded experiment, and this protection is now codified:

None of the funds appropriated [to the Department] shall be used to pay for any research program . . . which is of an experimental nature, or any other activity involving human participants, which is determined by the Secretary or a court of competent jurisdiction to present a danger to the physical, mental, or emotional well-being of a participant or subject of such program, project or course, without the written, informed consent of each participant or subject. /119/

And, although HHS exempted section 1115 demonstration projects from Institutional Review Board review in 1983, /120/ it has acknowledged that the exemption does not excuse the agency from conducting the review for danger that is required by the appropriations act:

In order to make clear that we will continue to fulfill that [appropriations act] obligation, . . . the Department will include in its review of such proposed research activity consideration of the effects on participants. To the extent that the proposed activity is determined to pose a danger to the participants, informed consent in writing will be required. /121/

Thus, meaningful human subject protection should be enforced in Medicaid waivers -- through both the appropriations act and section 1115. /122/

F. Rulemaking

All states and the federal government have APAs that require public notice and comment procedures for "rule" changes.

1. Federal APA

Under the federal APA, federal agencies must proceed by notice and comment when promulgating rule changes. /123/ Where rulemaking is required, implementation of invalid "rules" can be enjoined until the appropriate procedures are followed.

Case law has focused on whether the changes establish "binding norms" over the agency; no rules are required for directives, under which agencies remain free to apply or not to apply particular standards in individualized situations. /124/ At the same time, the case law also suggests that rulemaking is required when the result of exercising discretion is to institute a "binding norm" that conclusively determines rights in the future. /125/ It can be argued, therefore, that, even though HHS has discretion over the contents of the states' individual waivers, the waivers, once adopted, will create "binding norms" that affect recipients' rights. Thus, while proposed waivers might not require rulemaking, finalized

waivers should.

2. State APA

State administrative procedure acts typically define "rules" very broadly to encompass any policies or procedures of "general applicability." /126/ Again, failure to promulgate rules properly can result in an injunction of the rule's implementation.

G. Competitive Bidding

In most states, competitive bidding requirements apply to the equipment, materials, supplies, and services used by administrative agencies. /127/ Unless there is a specific statutory exception, /128/ the state agency's purchases must adhere to the bidding process set forth in the state statute.

Competitive bidding requirements can have numerous applications to the section 1115 waiver process. For example, if the state is using a consulting firm to develop and prepare the waiver (most do), the public competitive bidding process should apply to the selection of that consulting firm.

H. Title VI of the Civil Rights Act

Section 1115 experimental waivers are explicitly made subject to the requirements of Title VI of the Civil Rights Act of 1964. /129/ Title VI prohibits programs and activities receiving federal financial assistance from discriminating on the basis of race, color, or national origin. /130/ Thus, the state waiver program

> may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program [with] respect [to] individuals of a particular race, color, or national origin. /131/

In states where people of color are disproportionately represented among the Medicaid/waiver-expansion populations, Title VI is implicated if the state allows providers to discriminate against, place quotas on, limit services to, provide different benefits to, provide benefits in a different manner to, or define service areas to exclude minority enrollees. /132/ Programs operating on a less than statewide basis or being phased in over time may also raise Title VI concerns.

I. Americans with Disabilities Act and Rehabilitation Act

Another civil rights consideration is whether a section 1115 waiver would lead a state's Medicaid program to discriminate on the basis of disability or handicap. Title II of the

Americans with Disabilities Act provides that

no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity. /133/

Suppose, for example, that a Medicaid-waivered community residential services program provides services to mildly disabled people but refuses to provide services to more severely disabled people. /134/ Or suppose that a state fundamentally restructures its Medicaid program by creating a priority list of medical services, with the services needed to "restore function" systematically favored over the "maintenance" services typically needed by people with disabilities. /135/ Both rationing systems may be challenged under the Americans with Disabilities Act and section 504 of the Rehabilitation Act, 29 U.S.C. Sec. 794.

Unfortunately, Title II of the Americans with Disabilities Act does not provide direct claims against HHS because the "public entities" governed by that title do not include federal agencies. However, states and their agencies are "public entities" that may be sued under Title II if their Medicaid programs discriminate against the disabled. Relief against the state may obviate the need for relief against HHS.

In addition, regulations implementing the Rehabilitation Act /136/ and the Americans with Disabilities Act /137/ require state agencies to conduct a "self-evaluation" of their policies and practices; 45 C.F.R. Sec. 85.11 requires HHS to conduct a similar "self-evaluation." HHS could require that states, as a condition of waiver approval, assess the effects of proposed waivers as part of the states' Medicaid program evaluations. Meanwhile, a practice of failing to consider waiver proposals' effect on persons with disabilities might well merit change as a result of HHS's own self-evaluation.

J. Contract Actions

When considering a contract action, it is necessary to determine (1) whether Medicaid recipients will be able to enforce the section 1115 waiver as a "contract" and (2) whether Medicaid recipients will be able to enforce terms contained within the contracts between state Medicaid agencies and managed care plans in order to implement provisions contained within the waivers.

The definition of a "contract" is very broad. According to the Second Restatement of Contracts, "[a] contract is a promise, or a set of promises, for breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty." /138/ Because the Secretary has the legal power to enforce representations made in the waiver application or provisions contained within the "Special Terms and Conditions of Approval," the waivers themselves meet the above definition of a "contract." In addition, even though the waivers can be modified, they are still "contracts" that can be enforced. /139/

Medicaid recipients, however, can sue only to enforce either the waiver agreements or the contracts between state Medicaid agencies and managed care plans if they are found to be "intended" third-party beneficiaries of the contracts. Most states approach this question consistent with the Restatement of Contracts, which states that third parties can enforce provisions "if recognition of a right to performance . . . is appropriate to effectuate the intention of the parties" and "the circumstances indicate that the promisee intends to give the beneficiary the benefit of the promised performance." /140/ Most courts additionally require that the benefit be "direct" rather than incidental. /141/ Notably, in the case of contracts involving government parties, courts look to both the contract itself and the statutory authorization to determine whether there was an intent to benefit the alleged third-party. /142/ Given these standards, Medicaid recipients should be recognized as third-party beneficiaries of the waiver contracts.

Third-party beneficiaries have the same rights of enforcement as the contracting parties. /143/ However, third parties are prohibited from enjoining revisions or modifications to the contract in most circumstances. /144/ In the case of a government contract, the courts will look both to the rights of enforcement explicitly contemplated by the contract and to the rights of enforcement conferred by statutes. /145/ This means, for example, that, if the statute contains an administrative exhaustion requirement limiting relief, the third-party beneficiaries are equally bound by that exhaustion requirement.

In the case of Medicaid waivers, the Secretary has broad powers to withdraw her authority and thus to prevent states that fail to comply with the terms of the waiver from implementing their programs. /146/ Moreover, the Secretary obviously has the authority to enforce the terms and conditions she has placed on the waiver. /147/ This means that the power of Medicaid beneficiaries should be just as broad.

VI. Conclusion

Section 1115 experimental waivers clearly involve a mixed bag of complex issues. Most notably, they offer the promise of coverage for currently uninsured groups of adults and older children. However, this new coverage may come at the expense of services and choice for currently covered populations. Legal services must aggressively protect clients' rights during development and implementation of a section 1115 proposal. The National Health Law Program's Advocate's Primer contains a thorough discussion of the issues introduced by this article and should help advocates with the task now at hand.

Footnotes

/1/ See 42 U.S.C. Sec. 1315. For background on Medicaid managed care, see, e.g., Michele Melden & Lorna Hennington, Quality Assurance in Medicaid Managed Care, 26 Clearinghouse Rev. 1450 (Mar. 1993); Michael Parks, An Advocate's Guide to Medicaid Case Management Systems (1988) (Clearinghouse No. 44,300).

/2/ Telephone conversation with Gordon Bonnyman, Legal Services of Middle Tennessee

(July 27, 1994).

/3/ See, e.g., The Medicaid Access Study Group, Access of Medicaid Recipients to Outpatient Care, 330 N. Eng. J. Med. 1426 (1994) (urban recipients have limited access to outpatient care apart from hospital emergency rooms).

/4/ See, e.g., Deborah Freund & Eugene Lewit, Managed Care for Children and Pregnant Women: Promises and Pitfalls, 3 The Future of Children 92 (1993); Joan L. Buchanan et al., HMOs for Medicaid: The Road to Financial Independence Is Often Poorly Paved, 17 J. of Health Pol., Pol'y & L. 71 (1992); Goldfarb et al., Impact of a Mandatory Medicaid Case Management Program on Prenatal Care and Birth Outcomes, 29 Med. Care 64 (1991); Office of Inspector General, Quality Assurance in Medicaid HMOs (Draft Report), reprinted in Medicare & Medicaid Guide (CCH) Para. 40,082 (Mar. 1992); U.S. General Accounting Office, HealthPass: An Evaluation of a Managed Care Program for Certain Philadelphia Recipients (May 1993) (GAO/HRD-93-67); U.S. General Accounting Office, Medicaid: Oversight of Health Maintenance Organizations in the Chicago Area (Aug. 1990) (GAO/HRD-90-81); U.S. General Accounting Office, Managed Care: Oregon Program Appears Successful But Expansions Should Be Implemented Cautiously (Sept. 16, 1991) (GAO/HRD-91-48).

/5/ E.g., states should not be allowed to obtain a section 1115 expansion waiver and then implement it piecemeal, cutting services and locking current recipients into risk-based managed care and only at some unknown, future date expanding coverage to the uninsured.

/6/ 42 U.S.C. Sec. 1396a(a)(5).

/7/ Id. Sec. 1396a(a)(3).

/8/ Id. Sec. 1396a(a)(10).

/9/ Id. Sec. 1396a(a)(30)(C).

/10/ Id.

/11/ Id. Sec. 1396a(a)(43)(B).

/12/ See, e.g., McMillan v. McCrimon, 807 F. Supp. 475 (C.D. Ill. 1992) (Clearinghouse No. 48,234) (timely processing requirements enforced in home- and community based waiver system); Christy v. Ibarra, 826 P.2d 361 (Colo. Ct. App. 1991) (same with respect to statewideness requirements); Skandalis v. Rowe, 811 F. Supp. 782 (D. Conn. 1993) (statutory limits regarding groups eligible for coverage apply to all waivers), rev'd on other grounds, 14 F.3d 173 (2d Cir. 1994) (appellate court disagreed with lower court's interpretation of the statutory limits).

/13/ Section 1915(b) of the Social Security Act; 42 U.S.C. Sec. 1396n(b). See also 42

U.S.C. Sec. 1396b(m) (provision governing HMOs that enroll recipients).

/14/ Section 1915(c) -- (d) of the Social Security Act, 42 U.S.C. Sec. 1396n(b) -- (e).

/15/ 42 U.S.C. Sec. 1396b(n); 42 C.F.R. Sec. 431.55.

/16/ 42 U.S.C. Sec. 1396b(n); 42 C.F.R. Sec. 431.55.

/17/ Telephone conversation with Christopher Eisenberg, HHS Office of Managed Care (July 27, 1994) (41 states and the District of Columbia hold 1915(b) waivers).

/18/ 42 U.S.C. Sec. 1315. In contrast to section 1915, there are no implementation regulations detailing section 1115 Medicaid waivers.

/19/ Pub. L. No. 87-543, Sec. 122 (adding 42 U.S.C. Sec. 1315).

/20/ Social Security Amendments of 1965, Pub. L. No. 80-97 (amending 42 U.S.C. Sec. 1315(a)(1)).

/21/ Section 1915(b) of the Social Security Act; 42 U.S.C. Sec. 1396n(b). See also 42 U.S.C. Sec. 1396b(m) (provision governing HMOs that enroll recipients).

/22/ Memorandum from David Ellwood, Bruce Vladeck, & Laurence Love, HHS, to the Secretary of HHS 2 (June 22, 1993) (available from the National Health Law Program (NHeLP)).

/23/ Id. A notable exception is the Arizona Health Care Cost Containment System, which has been authorized by the Secretary and then Congress since 1982.

/24/ For a general discussion of these requirements, see Melden & Hennington, supra note 1.

/25/ Id.

/26/ Hawaii Dep't of Human Servs., Hawaii Health Quest: Executive Summary iii (1993).

/27/ Oregon Dep't of Human Resources, Oregon Reform Demonstrations (approved Mar. 19, 1993).

/28/ Michael Bierman, Planning for Medicaid Under the Oregon Health Plan for the 1995 -- 97 Biennium (Apr. 8, 1994) (available from NHeLP).

/29/ Kentucky Dep't of Health & Human Servs., Kentucky Medicaid Access and Cost Containment Demonstration Project (Dec. 1993).

/30/ Kentucky H.B. No. 2 (Special Sess. 1994). Another notable part of the section 1115 waiver, expansion of managed care to the aged, blind, and disabled, was authorized by Kentucky H.B. No. 250 (Special Sess. 1994). The administrative agency will apparently resubmit this proposal as a section 1915(b) waiver request. Conversation with Rick Seckel, Office of Kentucky Legal Services Programs (June 1994).

/31/ Massachusetts Division of Medical Assistance, MassHealth: A Request to the Federal Health Care Financing Administration for a Research and Development Waiver Under Section 1115 of the Social Security Act (Apr. 12, 1994).

/32/ Id.

/33/ The White House has apparently asked the Department of Justice for a legal opinion as to the legality of the Blue Cross/TennCare link. See American College of Physicians news release (May 26, 1994), reprinted in Medicare & Medicaid Guide (CCH) Para. 42,438. In a letter to President Clinton, the American College of Physicians criticized TennCare as ill-conceived, ill-timed, and a dangerous precedent. They consider the financing unrealistic and the program planning inadequate. They argue that Tennessee has failed to demonstrate that it has met the conditions placed on the waiver by HHS. Id.

/34/ Parks, supra note 1. Parks's manual presents a comprehensive advocacy model in the section 1915(b) context; much of Parks's sage advice is relevant here as well.

/35/ Legal services programs must conduct administrative and legislative advocacy pursuant to 45 C.F.R. part 1612.

/36/ Compare 42 U.S.C. Sec. 1315(b)(3)(A) (requiring states to provide public notice and comment when seeking certain welfare reform waivers) with 42 U.S.C. Sec. 1396o(f) (notice of copayment waivers). But see the accompanying sidebar discussing HCFA's recent Federal Register notice.

/37/ For the addresses and telephone numbers of the HCFA regional offices, see the accompanying sidebar.

/38/ Id.

/39/ Under federal law, states are required to conduct annual medical audits. 42 C.F.R. Sec. 434.53.

/40/ These were suggestions made by Rosemary Bishop, Legal Aid Society of San Diego, Draft Regulations (July 1994)

/41/ 42 U.S.C. Sec. 1396d(a)(19).

/42/ Id. Sec. 1396n(g)(2).

/43/ Id. Sec. 1396d(r)(5).

/44/ E.g., the authors have heard of managed care plans unlawfully using a stricter standard for determining whether physical therapy or home nursing is appropriate than that used in the state's Medicaid program.

/45/ See, e.g., Office of Technology Assessment, Benefit Design in Health Care Reform: Background Paper -- Patient Cost-Sharing 4 -- 8 (Sept. 1993) (U.S. Government Printing Office OTA-BP-H-112); Kathleen Lohr et al., Use of Medical Care in the Rand Health Insurance Experiment: Diagnosis and Service-Specific Analyses in a Randomized Controlled Trial (Dec. 1986) (Rand Corp. R-3469-HHS); Robert Valdez, The Effects of Cost Sharing on the Health Status of Children (Mar. 1986) (Rand Corp. R-3270-HHS).

/46/ See Melden & Hennington, supra note 1.

/47/ 42 U.S.C. Sec. 1396b(m)(2)(A)(ii).

/48/ See supra note 33 and accompanying text.

/49/ 42 C.F.R. Sec. 434.32.

/50/ See generally Mathews v. Eldridge, 424 U.S. 319 (1975); Goldberg v. Kelly, 397 U.S. 254 (1970); J.K. v. Dillenberg, 836 F. Supp. 694 (D. Ariz. 1993) (Clearinghouse No. 49,988).

/51/ Grievance procedures are typically not an adequate substitute for the fair hearing rights required as a result of Goldberg, 397 U.S. 254, and incorporated into the Medicaid regulations at 42 C.F.R. Sec. 431.205.

/52/ See 42 C.F.R. Secs. 431.210, .230.

/53/ Norman J. Singer, Statutes & Statutory Construction Sec. 65.02 at 311 (5th ed.1992). According to Judge J. Skelly Wright, "[T]he delegation doctrine retains an important potential as a check on the exercise of unbounded, standardless discretion by administrative agencies." Beyond Discretionary Justice, 81 Yale L.J. 575, 583 (1972).

/54/ Id. See Tennessee Medical Ass'n v. Manning, No. 93-3839-I (Tenn. Chancery Ct. Aug. 8, l994) (provision of Tennessee's section 1115 TennCare waiver did not provide for an unconstitutional delegation of legislative authority).

/55/ See, e.g., Wm. Penn Parking Garage, Inc. v. City of Pittsburgh, 346 A.2d 269 (Penn. 1975).

/56/ North Carolina Ass'n for Retarded Children v. North Carolina, 420 F. Supp. 451 (M.D.N.C. 1976) (Clearinghouse No. 19,912).

/57/ Id.

/58/ See, e.g., 5 U.S.C. Sec. 552 (Freedom of Information Act).

/59/ Id. Sec. 552(b)(5) (Exemption 5).

/60/ Id.

/61/ See, e.g., National Labor Relations Bd. v. Robbins Tire & Rubber Co., 437 U.S. 214, 242 (1978). See also S. Rep. No. 813, 89th Cong., 1st Sess. 9 (1965) (exemption to be construed as "narrowly as consistent with efficient Government operation").

/62/ Petroleum Information Corp. v. U.S. Dep't of Interior, 976 F.2d 1429, 1433 (D.C. Cir. 1992) (citing National Labor Relations Bd. v. Sears, Roebuck & Co., 421 U.S. 132, 150 -- 53 (1975)). See also Schell v. HHS, 843 F.2d 933 (6th Cir. l988).

/63/ See, e.g., Renegotiating Bd. v. Grumman Aircraft Eng. Corp., 421 U.S. 168, 184 (1975).

/64/ Schell, 843 F.2d 933, 942.

/65/ Id.

/66/ See, e.g., Providence Journal Co. v. U.S. Dep't of the Army, 981 F.2d 552, 559 (1st Cir. 1992) (citing National Wildlife Fed'n v. United States Forest Serv., 861 F.2d 1114, 1118 -- 19 (9th Cir. 1988)).

/67/ Archer v. Cirrincione, 722 F. Supp. 1118, 1122 (S.D.N.Y. 1989).

/68/ 5 U.S.C. Sec. 552(b).

/69/ 42 U.S.C. Secs. 1396a(a)(4), (22)(D); 42 C.F.R. Sec. 431.12.

/70/ 5 U.S.C. Secs. 701 et seq.

/71/ See Beno v. Shalala, 30 F.3d 1057 (9th Cir. 1994), reh'g & reh'g en banc denied (9th Cir. Aug. 24, 1994), rev'g 853 F. Supp. 1195 (E.D. Cal. 1993) (Clearinghouse No. 48,727) ("federal plaintiff must show only that a favorable decision is likely to redress his injury, not that a favorable decision will inevitably redress his injury"); California Welfare Rights Org. v. Richardson, 348 F. Supp. 491 (N.D. Cal. 1972) (Clearinghouse No. 7371); Aguayo v. Richardson, 352 F. Supp. 462 (S.D.N.Y. 1972), aff'd in part, modified in part, 473 F.2d 1090 (2d Cir. 1973), stay denied, 410 U.S. 921 (1973), cert. denied sub nom. Aguayo v. Weinberger, 414 U.S. 1146 (1974); Crane v. Mathews, 417 F. Supp. 532 (N.D. Ga. 1976) (Clearinghouse No. 17,440). California Welfare Rights Org. and Crane involved Medicaid waivers; Beno and Aguayo involved AFDC waivers. In June 1994, the National Association of Community Health Centers filed suit in federal

district court in the District of Columbia challenging HHS's authority under section 1115. National Ass'n of Community Health Centers v. Shalala, No. 1:94CVO1238 (D.D.C. filed June 6, 1994) (Clearinghouse No. 50,038). The Secretary claims that her actions under section 1115 are nonreviewable. NHeLP has filed an amicus curiae brief in the case (see the accompanying sidebar). There are two additional reported Medicaid cases that discuss section 1115 waivers: Phoenix Baptist Hosp. & Medical Center v. United States, 728 F. Supp. 1423 (D. Ariz. 1989) (district court dismissed suit against U.S. under Federal Tort Claims Act for failure to monitor performance of contractors who went bankrupt following grant of section 1115 waiver), aff'd, 937 F.2d 452 (9th Cir. 1991) (expressly did not consider applicability of section 1115 to whether there was a breach of duty cognizable under the Federal Tort Claims Act); and Georgia Hosp. Ass'n v. Department of Medical Assistance, 528 F. Supp. 1348 (N.D. Ga. 1982) (challenge to waiver of provisions concerning rate of hospital reimbursement).

/72/ See, e.g., Sara Rosenbaum, Mothers and Children Last: The Oregon Medicaid Experiment, 18 Am. J. L. & Med. 97 (1992); Mark S. Coven, Altering State Welfare Programs Through the Administrative Waiver Process -- Or the End-Run Around Congress, 17 N. Eng. L. Rev. 1175 (1982).

/73/ 42 U.S.C. Sec. 1315(a).

/74/ See Coven, supra note 72.

/75/ 42 U.S.C. Sec. 1315(a). The Secretary's authority to grant health care reform waivers through section 1115 is being challenged in National Ass'n of Community Health Centers v. Shalala, No. 1:94CVO1238.

/76/ S. Rep. No. 1589, 87th Cong, 2d Sess. 19 -- 20 (1962).

/77/ Id.

/78/ 42 U.S.C. Sec. 1315(a).

/79/ Coven, supra note 72.

/80/ Id. at 1192.

/81/ E.g., Beno, 30 F.3d at 1070 (stating that the purpose of AFDC is to support needy children); California Welfare Rights Org., 348 F. Supp. at 496.

/82/ California Welfare Rights Org., 348 F. Supp. at 496.

/83/ See S. Rep. No. 404, 89th Cong., 2d Sess 943 (1965), reprinted in 1965 U.S.C.C.A.N. 2018.

/84/ 26 Cong. Rec. 17885 (1980) (colloquy between Sen. David Pryor and Sen. David

Boren).

/85/ Atkins v. Rivera, 477 U.S. 154, 156 (1986). See also Harris v. McRae, 448 U.S. 297, 309 (1980), reh'g denied, 448 U.S. 917 (1980) ("purpose . . . was to provide federal financial assistance for all legitimate State expenditures under an approved Medicaid plan").

/86/ Notably, in National Ass'n of Community Health Centers v. Shalala, No. 1:94CV01238, the plaintiff is arguing that the Medicaid Act prevents section 1115 waivers that reach poor single adults or childless couples who do not currently qualify for Medicaid.

/87/ The general copayment rules are set forth at 42 U.S.C. Secs. 1396a(e)(14) and 1396o.

/88/ H.R. Rep. No. 97-760, 97th Cong., 2d Sess. 435 (1982), reprinted in 1982 U.S.C.C.A.N. 1215.

/89/ 42 U.S.C. Sec. 1396o(f).

/90/ Id. Sec. 1396a(a)(17)(D); H.R. Rep. No. 100-391, 100th Cong. 1st Sess. (Oct. 26, 1987) (report of the Committee on the Budget to Accompany H.R. 3545), reprinted in Medicare & Medicaid Guide (CCH) Extra Edition No. 539 at 446 -- 48 (defining and describing limits of Medicaid deeming); HCFA, State Medicaid Manual Sec. 3311 ("do not deem income other than from parent to child and spouse to spouse"). "Deeming" is the process of counting the income of one family member as automatically available to another family member.

/91/ 42 U.S.C. Sec. 1396a(l)(4)(A). Specifically, the following persons are affected: pregnant women and infants under age one with incomes at or below 133 percent of the federal poverty level, children under age six with incomes at or below 133 percent of the poverty level, and children under age nineteen with incomes at or below 100 percent of the poverty level (phased in). Id.

/92/ Id.; 42 U.S.C. Sec. 1396a(l)(3); H.R. Rep. No. 101-247, 101st Cong. 1st Sess. 395 (1989), reprinted in 1989 U.S.C.C.A.N. 2121 (House Budget Committee report discussing Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, Sec. 6401); H.R. Rep. No. 101-881, 101st Cong. 2d Sess. 103 (1990), reprinted in 1990 U.S.C.C.A.N. 2115 (discussing Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, Sec. 4601).

/93/ Outstationing regulations were published at 59 Fed. Reg. 48805 (Sept. 23, l994).

/94/ Quiding v. Hegstrom, No. 81-251 PA, slip op. at 4 (D. Or. Nov. 10, 1981) (permanent injunction) (citations omitted). In Quiding, the court found a common law that "the sins of a parent cannot be visited upon the child," id. at 5 -- 6, and, thus, stated

that the Secretary had no power to waive an AFDC provision, 42 U.S.C. Sec. 602(a)(19), which provides that the needs of children will continue to be included in the AFDC grant, even if the parent recipient or applicant fails to cooperate with the work incentive program.

/95/ Congressional Research Serv., Medicaid Source Book: Background Data and Analysis 4 (Jan. 1993).

/96/ Deficit Reduction Act of 1984, Pub. L. No. 98-369, 98th Cong., 2d sess. (1984).

/97/ Congressional Research Serv., supra note 95, at. 35 -- 36.

/98/ Social Security Act Amendments of 1967, Pub. L. No. 90-248, Sec. 302(a) (adding 42 U.S.C. Sec. 1396d(a)(4)(B)); Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, Sec. 6403 (codified at 42 U.S.C. Secs. 1396d(a)(4)(B), 1396d(r), and 1396a(a)(43)); Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, Sec. 13631 (amending 42 U.S.C. Secs. 1396d(r) and 1396a(a)(43)).

/99/ See Rosenbaum, supra note 72

/100/ 42 U.S.C. Sec. 1396n(b).

/101/ 1981 U.S.C.C.A.N. 742 -- 43.

/102/ 42 U.S.C. Secs. 1396n(b) & 1396b(m).

/103/ Id. Sec. 1396n(b) & (h).

/104/ H.R. Rep. No. 3982, 97th Cong., 1st Sess, at 308 -- 9.

/105/ The amicus curiae brief prepared by NHeLP and Mental Health Legal Advisors Committee in National Ass'n of Community Health Centers fully argues this point. See the accompanying sidebar.

/106/ 42 U.S.C. Sec. 1396f.

/107/ Id. Sec. 1396j.

/108/ Id. Sec. 1396p(a) -- (b).

/109/ Id. Sec. 1396r.

/110/ Id. Sec. 1396a(a)(3); 42 C.F.R. Sec. 431.205 (specifically incorporating Goldberg, 397 U.S. 254).

/111/ Green v. Anderson, 811 F. Supp. 516 (E.D. Cal. 1993), aff'd, No. 93-15306 (9th

Cir. 1994), cert granted, 63 U.S.L.W. 3093 (Oct. 7, 1994) (No. 94-197) (Clearinghouse No. 48,733) (section 1115 AFDC welfare reform waiver provisions enjoined for violating constitutionally protected right to travel); Kronquist v. Whitburn, No. 89-C-1376 (E.D. Wis. July 23, 1992) (Clearinghouse No. 45,344) (section 1115 AFDC learnfare project notices to clients violated constitutional due process).

/112/ Reviews of all the Medicaid managed care programs, to date, consistently have concluded that Medicaid managed care systems have failed to improve access to cost-effective and necessary preventive care, such as prenatal care and immunizations. See, e.g., Freund & Lewit, supra note 4, at 93 -- 95. The amicus curiae brief prepared by NHeLP and Mental Health Legal Advisors Committee in National Ass'n of Community Health Centers fully argues this point.

/113/ Beno, 30 F.3d 1057.

/114/ Id. at 1069 -- 72.

/115/ Id.

/116/ Id..

/117/ Id. at 1072.

/118/ California Welfare Rights Org., 348 F. Supp. 491, 497. See also 44 Fed. Reg. 23192 (Apr. 18, 1979) (publication of the "Belmont Report," three ethical principles of human research established by a Presidential Commission).

/119/ Pub. L. No. 102-394, Sec. 211, 106 Stat. 1792, 1812 (1992) (codified at 42 U.S.C. Sec. 3515(b)).

/120/ 45 C.F.R. Sec. 46.101(b)(5)(i); 48 Fed. Reg. 9266 (1983) (Exemption of Certain Research and Demonstration Projects from Regulations for Protection of Human Research Subjects). But see 48 Fed. Reg. at 9268 ("[T]here will be a well-defined responsibility of federal program officials to take into consideration potential risks to the health and safety of participants in research activity before making decisions whether or not to approve particular projects.").

/121/ See 45 C.F.R. Sec. 46.101(d); 53 Fed. Reg. 45667 (1988); 48 Fed. Reg. 9266 -- 67 (Mar. 3, 1983).

/122/ The Secretary could waive the regulations altogether but would first have to publish notice of this decision. 45 C.F.R. Sec. 46.211.

/123/ 5 U.S.C. Sec. 553(b).

/124/ See Mada-Luna v. Fitzpatrick, 813 F.2d 1006 (9th Cir. 1987); Jean v. Nelson, 711

F.2d 1455, 1481 (11th Cir. 1983), rev'd in part as moot, 727 F.2d 957 (11th Cir. 1984), aff'd, 472 U.S. 846 (1985).

/125/ See Mada-Luna, 813 F.2d at 1013.

/126/ See, e.g., California's definition of "regulation," which requires rulemaking: "every rule, regulation, order, or standard of general application or the amendment, supplement or revision of any such rule, regulation, order or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure[.]" Cal. Gov't Code Sec. 11342(b).

/127/ See, e.g., Mass. Gen. L. ch. 7, Sec. 22A; Mo. Rev. Stat. Sec. 376.968; Ohio Rev. Code Sec. 125.7; R.I. Gen. Laws Sec. 37-2-54; S.C. Code Ann. Sec. 11-35-1590.

/128/ Some states exempt professional services from the competitive bidding process. In these instances, these contracts must be awarded on some other basis, such as "competence and integrity," Tenn. Code Ann. Sec. 12-4-106, or upon review and approval from the governor, R.I. Gen. Laws 37-2-54(1)(f).

/129/ 45 C.F.R. Part 80 (Appendix A, No. 124).

/130/ 42 U.S.C. Secs. 2000d et seq. For a more thorough discussion of Title VI, see Stan Dorn, Michael Dowell, & Jane Perkins, Anti-Discrimination Provisions and Health Care Access: New Slants on Old Approaches, 20 Clearinghouse Rev. 439 (Summer 1986).

/131/ 45 C.F.R. Sec. 80.3(b)(2).

/132/ See 42 C.F.R. Sec. 80.3(a). See generally In re A-4793, Docket No. 02-92-3111 (HHS Office for Civil Rights filed June 26, 1992) (Clearinghouse No. 48,283) (pending Office for Civil Rights complaint that section 1115 AFDC welfare reform waiver in New Jersey violates Title VI because it targets and has a disproportionate effect on minorities).

/133/ 42 U.S.C. Sec. 12132.

/134/ For an example of rationing on the basis of severity, see Martin v. Voinovich, 840 F. Supp. 1175 (S.D. Ohio 1993) (plaintiffs denied community-based Medicaid care due to severe disabilities state claim under the Americans with Disabilities Act and the Rehabilitation Act; section 1115 waiver not involved).

/135/ For an example of rationing through priority lists, see HHS Papers Explaining Rejection of Oregon Medicaid Waiver, Aug. 3, 1992, reprinted in Medicare & Medicaid Guide (CCH) Para. 40,406A (rejecting Oregon's original section 1115 waiver on Americans with Disabilities Act grounds because telephone survey may have biased priority list); see also Documentation on Secretary's Approval of Oregon Medicaid Waiver Request, Mar. 19, 1993, reprinted in Medicare & Medicaid Guide (CCH) Para. 41,313. In the March l993 document, HHS conditioned approval of Oregon's revised

priority list on alterations to address Americans with Disabilities Act concerns. Oregon's list had to be changed because it included "restore function/maintenance" distinctions between treatments. Id.

/136/ 45 C.F.R. Sec. 84.6(c).

/137/ 28 C.F.R. Sec. 35.105.

/138/ Restatement of the Law of Contracts Sec. 1 (2d ed. 1981).

/139/ See id. Sec. 311 (third-party beneficiaries can enforce contracts unless the parties have discharged or modified their duties by subsequent agreements; even so, such discharges or modifications will not apply if the beneficiary materially changes his or her position in justifiable reliance or if the beneficiary brings a lawsuit before the discharge or modification).

/140/ Id. Sec. 302. This analysis has been accepted by most courts. See, e.g., Ward v. Ernst & Young, 435 S.E.2d 628, 634 (Va. 1993) (citing Thacker v. Hubard & Appleby, 94 S.E. 929, 931 (Va. 1918)) ("in contracts not under seal, it has been held for two centuries or more, that anyone for whose benefit the contract was made may sue upon it").

/141/ See, e.g., Corrugated Paper Products Inc. v. Longview Fibre Co., 868 F.2d 908, 912 (7th Cir. 1989) (fact that seller knew that buyer would resell materials conferred no direct benefit on future purchaser of resold materials):
[T]here is an important difference between knowledge that a certain outcome will occur, and an intent to bring about that result. In order to establish third party beneficiary status, a plaintiff must show more than that the contracting parties acted against a backdrop of knowledge that the plaintiff would derive benefit from the agreement. The plaintiff must show that the benefit to plaintiff was a consequence which the parties affirmatively sought, in other words, the benefit to plaintiff must have been, to some extent, a motivating factor in the parties' decision to enter into the contract.
See also Witkin, Summary of California Law Secs. 653 -- 57 (9th ed.) (third party carries the burden of proving that the contracting parties' intended purpose in executing their agreement was to confer a direct benefit on the third party); Broadway Maintenance Corp. v. Rutgers, 90 N.J. 253 (N.J. 1982).

/142/ See, e.g., Martinez v. Sonoma Co., Inc., 113 Cal. Rptr. 585 (Cal. 1974) (Clearinghouse No. 7609); Shell v. Schmidt, 126 Cal. App. 2d 279 (Cal. 1954), cert denied, 348 U.S. 916 (1955). See also Restatement of the Law of Contracts Sec. 313 (2d ed. 1981) (government contracts enforceable by third parties as long as the action is consistent with the policy of law authorizing the contract and prescribing the remedies).

/143/ Corbin, Contracts Sec. 810 (1951) ("remedies available to a beneficiary are exactly the same as would be available to him if he were a contractual promisee of the performance in question"). But see Tennessee Medical Ass'n, No. 93-3839-I (plaintiff

medical association and doctors not parties to capitation rate contract between the state and managed care plans and plaintiffs had no right to challenge state's discretionary authority to contract with plans).

/144/ See Restatement of the Law of Contracts Sec. 311 (2d ed. 1981) (unless specifically prohibited by the terms of the contract, contracting parties can discharge or modify their duties by subsequent agreements unless the third-party beneficiary, before notice of the change, materially changes his or her position in justifiable reliance or institutes a lawsuit).

/145/ See, e.g., Schell v. Schmidt, 126 Cal. App. 2d 279 (Cal. 1954) (authorizing remedy for veterans whose homes did not meet specifications contained within contracts between builders and VA, based on legislative authorization for VA to collect monetary compensation for breaches of contract).

/146/ 42 U.S.C. Sec. 1315(a)(1).

/147/ See 42 U.S.C. Sec. 1396c.

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NHeLP Files Amicus Brief in Challenge to Section 1115 Medicaid Waivers

The National Health Law Program and the Mental Health Legal Advisors Committee have filed an amicus brief on behalf of several disability organizations in National Association of Community Health Centers v. Shalala, No. 1:94CV01238 (D.D.C. filed Aug. 17, 1994) (Clearinghouse No. 50,038), challenging HHS's implementation of new policy principles for granting section 1115 waivers. Plaintiff National Association of Community Health Centers (NACHC) is a nonprofit association of community, migrant, and homeless health centers. NACHC alleges that HHS has discarded critical protections under the old standards and in effect is allowing a wholesale restructuring of the Medicaid statute without congressional approval. NACHC maintains that, without reasonable cost reimbursement, its member health centers will be unable to operate and will be forced to close their doors, and Medicaid patients will lose their freedom to choose a provider.

Amici, the Massachusetts Mental Health Legal Advisors Committee, Rhode Island Direct

Action for Rights and Equality, the Florida Advocacy Center for Persons with Disabilities, and the Florida Drop-In Center Association, assert that, although section 1115 waivers offer the promise of expanded Medicaid eligibility, they fear dangerous, hasty, and unmonitored service and quality cutbacks and rationing of benefits that may be detrimental to persons with disabilities and other groups. Amici contend that section 1115 waivers must promote the objectives of the Medicaid Act. They argue that several waivers recently granted by the Secretary are contrary to those purposes because the waivers permit illegal household deeming and ignore other requirements that apply to the eligibility determination process, allow states to waive EPSDT services for children and pregnancy-related services for women, or authorize managed care plans that do not meet the requirements of section 1915(b) of the Social Security Act. Amici maintain that any waiver must be subject to an established research design. Amici are concerned that the current waiver projects, which may not be justifiable as having a true research purpose, instead have relaxed other consumer protection requirements that would have applied to managed care systems under 42 U.S.C. Secs. 1396n(b) and 1396b(m).

HHS Issues Notice Regarding Section 1115 Waivers

In the September 27, 1994, Federal Register, HHS published a "notice" regarding demonstrations pursuant to section 1115(a) of the Social Security Act. The notice very generally informs persons of the principles and procedures HHS ordinarily will apply when reviewing section 1115 waivers and the kinds of procedures HHS expects states to use to involve the public. /1/

As an initial matter, HHS goes to great lengths to explain the information-only nature of the notice: "The principles and procedures described in this public notice . . . are not legally binding. . . . This notice does not create any right or benefit, substantive or procedural, enforceable at law or equity by any person or entity, against the United States, its agencies or instrumentalities, the States or any other person." /2/. Given such absolution, the legal status of the notice is questionable. It is possible that the notice is an attempt to weaken plaintiffs' claims in the pending lawsuit, National Association of Community Health Centers v. Shalala (see other sidebar with this article), which charges HHS with operating the section 1115 program without published rules.

For the most part, the notice contains broad, general statements of agency policies that are already known to interested persons (and discussed in NHeLP's Manual) as a result of previous section 1115 reviews. Of significance, however, the notice for the first time includes a process for including consumer input in state and federal consideration of the waiver proposal.

State Notice Procedure. HHS now expects states to include the public in the decisionmaking process "prior to the time a proposal is submitted" to HHS. /3/ The Federal Register notice contains two alternate public notice processes, and HHS expects states to follow one (or more, at state option) of them.

-- The state may choose to develop a public notice process and submit it to HHS any time before submitting its section 1115 proposal. HHS will notify the state within 15 days whether the process is adequate. Under this alternative, HHS will accept any process that includes public comment and hearings, uses an open-meetings advisory commission, provides for notice and comment pursuant to the state's Administrative Procedure Act (APA), provides for publication of a notice regarding the waiver and comment period in a newspaper of general circulation, or other similar processes that would afford an interested party the opportunity to learn about the contents of the proposal and comment on it. /4/

-- If the state does not follow the above process, it must notify HHS of the process that was used at the time it submits its proposal. If this process is found by HHS to have been inadequate, the state can cure the problem by posting notice in a newspaper of general circulation stating the elements of the proposal and how interested parties can review and comment on the proposal. /5/ In this instance, the comment period is only 30 days.

HHS's announcement, while general, is an important first step in recognizing the crucial need for affected persons to have advance notice about and to comment on the waiver. In addition to outlining substantive concerns, advocates should use their early communications with the state to encourage implementation of a comprehensive public notice and participation strategy as early in the section 1115 process as possible. The second option listed by HHS will surely fail to provide a meaningful consumer role.

Advocates should press for a public notice process that includes multiple elements of the first alternative, namely, public hearings, an open-meetings advisory commission (including a consumer advisory board), and state APA processes. In addition, advocates should push for public input as early as possible and regularly as the waiver evolves. Moreover, states should be encouraged to use public-notice strategies in addition to those mentioned in the notice, including distribution of the waiver to public libraries, maintaining a list of persons/organizations interested in waivers and notifying such persons/organizations when a proposal is being developed, notifying the provider community through professional newsletters and state Medicaid agency bulletins, holding multiple public hearings across the state, public-service announcements, publication in various newsprint sources, and maintaining a toll-free telephone service that can answer questions about the status of the waiver and the public input process. States should be made aware (if they are not already) of their obligations to make public notices and waiver materials available to persons with disabilities and to persons who do not speak English. Above all, advocates should be aware of the limitations of merely publishing notice in a newspaper of general circulation, including English-only printing, lack of circulation in rural areas, and failure to print a visible, readable notice.

Federal Notices. According to the Federal Register notice, HHS will publish a monthly notice in the Federal Register of all new and pending section 1115 proposals, indicating that HHS accepts comments on all waivers. In addition, HHS will maintain a list of organizations that have requested notice that a section 1115 proposal has been received and will notify such organizations upon receipt of the proposal. HHS will consider

comments for at least 30 days after it receives a proposal. Thus, advocates should file comments with HHS as soon as possible after the state submits the waiver to HHS.

General Considerations. HHS states that it is looking for projects that "preserve and enhance beneficiary access to quality services." /6/ HHS also states that it expects to approve a range of proposals but that it "may disapprove or limit proposals on policy grounds or because the proposal creates potential constitutional problems or violations of civil rights laws or equal protection requirements." /7/ Unfortunately, there is no additional guidance on what all this means. Later on, the notice does state that, when a demonstration is to be implemented in only part of the state, the state "will be required to" provide information on the likely demographic composition of the population inside and outside the program and, if necessary, address the impact of the project on particular subgroups of the population. /8/ Presumably, this concern with substate demonstrations is driven by civil rights/equal protections concerns.

Finally, as a general matter, the agency notes its interest in approving waivers to test the same or related policy innovations in multiple states. /9/ The question of whether the agency has authority to grant "cookie cutter" waivers is at issue in National Association of Community Health Centers v. Shalala.

Duration. HHS will extend approvals that will give the new policies a "fair test." For instance, "large-scale statewide reform programs will typically require waivers of five years."

And, while the agency may label these projects "experimental demonstration," HHS will work with states to seek permanent statutory changes, including extensions of the waivers. /10/

Evaluation. In Beno v. Shalala, 30 F.3d 1057 (9th Cir. 1994), the Ninth Circuit required HHS to take the research components of a section 1115 waiver experiment seriously. The Federal Register notice includes a discussion of evaluation, but it is unclear what, if any, meaningful agency evaluation is planned: "This Department is committed to a policy of meaningful evaluations using a broad range of appropriate evaluation strategies (including true experimental, quasi-experimental, and qualitative designs) and will be flexible and project-specific in the application of evaluation techniques. This policy will be most evident with health care waivers." /11/ . Advocates should continue to rely on the guidance provided by Beno when reviewing a state’s section 1115 proposal.

Cost Neutrality. HHS will assess cost neutrality over the life of the demonstration project.

Timeliness and Administrative Complexity. HHS clearly intends to minimize the administrative burden on states in obtaining section 1115 waivers and to expedite the time frames for approval. A "well-defined" schedule for waiver review will be established early on. /12/ As noted in the accompanying article, advocates should make immediate contact with their HCFA regional office to obtain the applicable schedule for review. Moreover, the notice evidences HHS’s intent to consult with states early in the

waiver process, thus reinforcing the importance of early consumer participation in the process.

Footnotes

/1/ 59 Fed. Reg. 49249-51 (Sept. 27, 1994).

/2/ Id. at 49249.

/3/ Id. at 49250.

/4/ Id.

/5/ Id.

/6/ Id. at 49249.

/7/ Id..

/8/ Id. at 49251.

/9/ Id.

/10/ Id. at 49249 -- 50.

/11/ Id. at 49250.

/12/ Id.