



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

SEP - 9 REC'D

SEP 7 1994

MEMORANDUM FOR THE ACTING DIRECTOR AND CAROL RASCO

From: Nancy-Ann Min <sup>NAM</sup> and Kathi Way <sup>KW</sup>

Subject: The Potential Costs of State Health Reform Waivers - file

This memorandum discusses the potential impact State health reform waivers could have on Federal expenditures and on efforts to gain passage of Federal health reform legislation.

**Section 1115 Demonstration Authority.** Section 1115 gives the Secretary broad authority to grant waivers of most provisions in the Social Security Act, including the Medicaid statute, for any "experimental, pilot, or demonstration project." There is virtually no statutory limit on the size, scope, length, or cost of these waived projects. Under the Reagan and Bush Administrations, demonstration waivers were generally required to be research-oriented, to include a rigorous evaluation component, to be limited generally to four or five years, and to be budget neutral, i.e., costs may be no higher with the waiver than without the waiver.

Administration policy concerning State health reform waivers was formally reviewed last year as part of negotiations with the National Governors Association (NGA). These negotiations resulted in a written agreement conveying the Administration's desire to simplify and shorten the waiver review process and to remain flexible with respect to the requirements that demonstration waivers be research-oriented and budget neutral.

**Waiver Activity Update.** Five States -- Arizona, Oregon, Hawaii, Kentucky, and Rhode Island -- received approval for State health reform waivers before the agreement with the NGA was reached. Together with Tennessee, which was granted a Statewide Medicaid waiver at about the same time of the NGA agreement, these six States represent over 7% of national Medicaid spending.

Since the NGA agreement was reached, requests for Statewide health reform waivers have surged. HCFA is now reviewing eight (new) Statewide waiver proposals -- Florida, South Carolina, Ohio, Massachusetts, New Hampshire, Missouri, Minnesota and Delaware -- which together represent about 16% of national Medicaid expenditures, in addition to reviewing significant waiver amendments from Oregon and Arizona. Another nine States representing about 9% of national Medicaid expenditures have expressed serious interest in seeking State health reform waivers.

All told, States representing about 33% of national Medicaid spending have received, requested, or expressed serious interest in State health reform waivers.

**Waiver Benefits and Costs.** States often use §1115 waivers to secure Federal financial support for Statewide initiatives that expand health insurance to non-Medicaid low-income individuals. States may also introduce structural reforms through Medicaid waivers. States requesting §1115 demonstration waivers to support ambitious reform programs face two critical challenges related to the financing of their proposals:

- *funding the State share.* To free up State funds, States have sought to: 1) realize savings by enrolling Medicaid recipients in capitated managed care plans; 2) bill Medicaid for previously State-funded health services; and/or 3) use Medicaid disproportionate share hospital (DSH) funds to provide or subsidize health insurance for the uninsured; and
- *maximizing Federal financing.* States have also sought to obtain Federal matching funds for expenditures that have not traditionally been matched under Title XIX, including employer and employee contributions to health insurance premiums and local government contributions to public hospitals.

Federal expenditures in States with health reform waivers are heavily dependent upon State estimates of Medicaid costs without the waiver. Baseline expenditures are the State's waiver "budget." Budget neutrality may be difficult to demonstrate for States that are seeking to expand Medicaid eligibility or to extend subsidies to large numbers of uninsured individuals. States have an incentive to bolster their claim of budget neutrality by projecting very high baseline Medicaid expenditures.

**Demonstrating Budget Neutrality.** In reviewing waivers for budget neutrality, HCFA faces a very real challenge. Estimates of Medicaid expenditures at the State and Federal level can be highly inaccurate and are generally unstable. Medicaid expenditure growth varies widely across States in patterns that cannot easily be predicted. Methods of prediction also vary widely across States and have evolved steadily at the Federal level. Though precise analysis of budget neutrality is difficult, we note that several States appear to have artificially inflated estimates of baseline expenditures by: 1) using unrealistically high rates of growth; and/or 2) inflating expenditures in the base year.

*Unreasonable growth?* Annual growth in total Federal Medicaid expenditures, as estimated for the Mid-Session Review (MSR) of the FY 1995 Budget, averaged 10.7% between FY 1995 and 1999. State estimates of average annual growth in baseline Medicaid expenditures over roughly the same period, as reflected in §1115 waiver submissions, range from 9% to over 13%. State baseline estimates do not always

reflect the recent slowdown in Medicaid expenditure growth. States may estimate enrollment growth based on recent patterns that do not reflect the improving economy. States may also incorporate per-capita expenditures that assume the State will take limited action to control costs absent the waiver.

*Inflated base-year estimates.* State estimates of average growth in baseline Medicaid expenditures from the year before the waiver to the first, or “base year” of the waiver range from 18% to over 26%, compared to average Federal growth of around 10%. States wishing to enhance their waiver budget may include in their estimate of baseline expenditures costs associated with program expansions that have not yet been implemented, i.e., “hypothetical spending,” or unsustainable program spending, e.g., DSH payments financed with provider taxes that expire during the life of the demonstration.

**Administration Review of Budget Neutrality.** HCFA reviews State budget estimates for reasonableness and generally does not project State Medicaid expenditures independently. HCFA circulates the State’s waiver request, including components related to budget neutrality, to various sections of HHS and OMB to solicit comments, questions, and concerns. The waiver review process typically culminates in a series of formal and informal negotiations with the State.

This review process does not appear to be sufficient to ensure that State estimates of baseline Medicaid expenditures -- the State’s waiver budget -- are consistent with Federal estimates of the Medicaid baseline. In addition, the lack of a consistent methodology for calculating baseline expenditures in waiver States complicates and delays negotiations.

The lack of a clear nexus between State and Federal baseline estimates may undermine the Administration’s enforcement of the budget neutrality requirement.

HHS recently began an effort to formalize the review standards and procedures for budget neutrality. It is unclear whether HHS will seek Administration approval for these standards before granting additional waivers. HHS may seek approval for specific standards as they arise in the context of individual waivers.

**Potential Interactions with Federal Health Reform Initiatives.** The proliferation of State health reform initiatives may complicate the challenge of crafting Federal legislation guaranteeing universal coverage for all Americans. For example, certain elements of §1115 waivers may be inconsistent with the principles and goals of health reform, e.g., true community rating, quality assurance standards, data collection requirements, employer responsibilities, and consumer choice. In addition, some States may expect to achieve greater savings under State health reform initiatives than under Federal health reform legislation. States with healthy

tax-bases may prefer Medicaid-based State-level reforms that do not contain inter-State redistributions of wealth. It is difficult to say whether State waivers will -- on net -- adversely affect the financing for Federal health reforms. Nevertheless, as waivers may be pursued or retained at State option, one might expect that States will consider waivers as an alternative to reform largely, if not primarily, if it is to their financial advantage.

*The Mitchell Bill.* The Mitchell health reform bill appears to exempt Medicaid waivers in existence upon enactment from any conflicting provisions in the bill. If this exemption applies to §1115 demonstration waivers, then estimates of Medicaid savings and offsets, maintenance of effort payments, and Federal subsidy costs (at a minimum) would have to be amended. CBO did not take this waiver exemption provision into account in their August 9 pricing of the Mitchell bill.

**Recommendations.** Before granting additional requests for §1115 State health reform waivers, the Administration may want to take steps to better understand the potential effects of the waivers on Federal Medicaid expenditures and the policy objectives and financing mechanisms of Federal health reform. Specifically, the Administration may want to consider approaches such as:

- completing the process now underway at HHS to establish a formal set of review benchmarks or targets for budget neutrality -- and endorsing the result -- before approving additional waivers; and
- requesting independent HCFA actuary pricing of baseline expenditures in States requesting waivers in a manner consistent with Federal baseline estimates.

File: Medicaid  
Waiver  
Process

cc:  
CJR

Joel:

The attached represents the information provided to me by a friend of the Administration who received the papers from a hospital association asking the friend if final copies of the negotiations were ever produced on paper...we don't know, and I have not contacted HHS on this matter yet.

Other concerns raised by the friend:

HHS is operating the waiver process in a closed manner with no access to the proposals by outside groups when asked for the opportunity to comment.

Is the department utilizing the 1115 process to help states circumvent provisions they do not like rather than research? How much leeway is there in the legislation as to how states may use the waivers for purposes other than "research"?

Thank you...

March 3, 1994

MEMORANDUM

To: Carol

Fr: Sara

Re: Section 1115 waivers

Enclosed are several documents. The first is a table I prepared that compares the 5 waivers granted to date in accordance with a number of criteria. As you can see, there are striking similarities on issues that do not seem to relate directly to the gravamen of the waiver. A court could potentially interpret these similarities to be tantamount to using Section 1115 to circumvent provisions that states do not like rather than to conduct research. I find nothing in any of the waivers' evaluation designs (which are pretty weak to begin with) that even proposes to examine the effect of tightening eligibility standards, eliminating women and children, eliminating certain services, etc. This could be read to mean that the waivers are being granted to circumvent the law rather than as part of a coherent research effort. The uniformity of so many provisions also suggests a "boilerplate" approach to the waivers rather than careful use of the authority to do research.

The second set of materials includes both the Secretary's memo to Thorpe and Toby and internal decision memos that flat out discuss the NGA negotiations. They were given to me by someone from a hospital association about 2 weeks ago, who asked me if there were final versions of these things. I have no way of knowing, but if I have them, this means that they are clearly out and about. Even in draft form, they are damaging.

To the extent that there are actual memoranda of agreement between NGA and HCFA on a revised Section 1115 process they would suggest to a court an effort to systematically expand state flexibility, and change federal Medicaid rules state by state without any public comment. Add to this the refusal of HCFA to make the applications available and the comments by HCFA staff to outside groups that they have to "check with NGA" before going further, and the picture is not a pretty one.

I would urge that the agency develop a public process, akin to notice and comment on rules, for future waivers. In my opinion, a state's process does nothing to relieve the federal government of the obligation to make policy in an open fashion. To the extent that a waiver changes all Medicaid eligibility and benefit rules for entire populations in a state, the issuance of a waiver is tantamount to the promulgation of rules. The Administrative Procedures Act certainly

appears to be implicated.

I am even more concerned given the bad press that Tennessee is getting and the potential for litigation there and in other states.

**AN OVERVIEW OF SECTION 1115 MEDICAID WAIVERS APPROVED IN 1993**

STATE	Oregon	Hawaii	Rhode Island	Kentucky	Tennessee
<p><b>Name and General Description</b></p>	<p>Oregon Medicaid Demonstration (approved March, 1993).</p> <p>Extends Medicaid coverage to additional categories of low income persons and replaces a portion of the defined Medicaid benefit package with a system of fixed, annual per capita expenditures for care and services ranked in order of priority. Mandates enrollment in managed care.</p>	<p>Health Quest (approved July, 1993).</p> <p>Creates a public funding pool to purchase capitated managed care coverage on a mandatory basis for low and moderate income persons receiving Medicaid or state-funded medical assistance.</p>	<p>Rite Care (approved October, 1993).</p> <p>Creates mandatory system of prepaid managed care with increased cost sharing for certain Medicaid recipients (including certain recipients newly eligible under waiver).</p>	<p>Kentucky Medicaid Access and Cost Containment Demonstration Project (approved December, 1993).</p> <p>Expands existing existing KenPac non-risk mandatory managed care system to additional low income persons.</p>	<p>TennCare (approved November, 1993).</p> <p>Extends Medicaid coverage to additional number of uninsured persons with mandatory enrollment in managed care plans. Premiums, deductibles and coinsurance for enrollees with incomes &gt; 100% FPL.</p>

STATE	Oregon	Hawaii	Rhode Island	Kentucky	Tennessee
Key waivers requested	<p>Amount, duration and scope of benefits;</p> <p>Financial eligibility;</p> <p>Medically needy eligibility;</p> <p>Categorical eligibility;</p> <p>Retroactive eligibility;</p> <p>Eligibility determination rules;</p> <p>Freedom of choice;</p> <p>Capitation contract rules for case mix , upper payment limits;</p> <p>FQHC coverage and payment;</p> <p>Uniformity and statewideness;</p> <p>EPSDT treatment services.</p>	<p>Amount, duration and scope of benefits;</p> <p>Financial eligibility;</p> <p>Medically needy eligibility;</p> <p>Categorical eligibility;</p> <p>Retroactive eligibility;</p> <p>Eligibility determination rules;</p> <p>Freedom of choice;</p> <p>Capitation contract rules for case mix , upper payment limits;</p> <p>FQHC coverage and payment;</p> <p>Uniformity and statewideness;</p> <p>DSH payments;</p> <p>Cost sharing;</p> <p>HMO medical audits.</p>	<p>Amount, duration and scope of benefits;</p> <p>Financial eligibility;</p> <p>Medically needy eligibility;</p> <p>Categorical eligibility;</p> <p>Retroactive eligibility;</p> <p>Eligibility determination rules;</p> <p>Freedom of choice;</p> <p>Capitation contract rules for case mix , upper payment limits;</p> <p>FQHC coverage and payment;</p> <p>Uniformity and statewideness;</p> <p>Cost sharing;</p> <p>HMO medical audits;</p> <p>3rd party liability</p>	<p>Financial eligibility;</p> <p>Categorical eligibility;</p> <p>Freedom of choice;</p> <p>DSH payments;</p>	<p>Amount, duration and scope of benefits;</p> <p>Financial eligibility;</p> <p>Medically needy eligibility;</p> <p>Categorical eligibility;</p> <p>Retroactive eligibility;</p> <p>Eligibility determination rules;</p> <p>Freedom of choice;</p> <p>Capitation contract rules for case mix , upper payment limits;</p> <p>FQHC coverage and payment;</p> <p>Uniformity and statewideness ;</p> <p>DSH payments;</p> <p>Cost sharing</p> <p>HMO medical audits</p> <p>3rd party liability</p>

STATE	Oregon	Hawaii	Rhode Island	Kentucky	Tennessee
Changes in eligibility	<p>Adds coverage of non-elderly persons with incomes below 100 % of the FPL (133% standard for pregnant women and children &lt; 6);</p> <p>Eliminates coverage of medically needy pregnant women and children;</p> <p>Eliminates income disregard; gross income test used and all family income deemed available;</p> <p>Eliminates asset test;</p> <p>Eliminates retroactive eligibility.</p>	<p>Adds coverage of all persons with incomes below 300 % of FPL, subject to premium payments of 0% under FPL and 10% increments for each 25% above FPL;</p> <p>Eliminates income disregard for gross income test and counts income of all family members;</p> <p>Waives eligibility QA reviews;</p> <p>Presumptive eligibility upon completed application;</p> <p>Retroactive coverage waived.</p>	<p>Demonstration covers all state beneficiaries except children in foster care, persons in institutions, ABD persons, and QMBs;</p> <p>Adds premiums for pregnant women and children &lt; 6 with incomes between 185% and 250% of FPL;</p> <p>Post partum women with incomes &lt; 250% of FPL : 2 yr coverage for family planning and nutrition counselling;</p> <p>Presumptive eligibility upon completed application;</p> <p>Retroactive coverage waived;</p> <p>IMD residents remain eligible.</p>	<p>Adds adults with incomes under 100% FPL, including aged persons;</p> <p>Adds children with incomes under 200% FPL;</p> <p>All family income deemed available;</p> <p>Asset test waived.</p>	<p>Adds uninsurable persons of all incomes who can afford TennCare costs;</p> <p>Adds uninsured persons of all incomes, (up to a limit) who can afford cost sharing;</p> <p>Eliminates medically needy pregnant women and children;</p> <p>Eliminates asset test.</p> <p>Eliminates retroactive coverage;</p>

STATE	Oregon	Hawaii	Rhode Island	Kentucky	Tennessee
Changes in benefits and cost sharing	<p>EPSDT mandated treatment services eliminated;</p> <p>FQHC services eliminated;</p> <p>Prohibition in coverage restriction eliminated;</p> <p>Benefit coverage based on condition/treatment pairs, with prior approval of changes in coverage list by HCFA.</p>	<p>Cost sharing for physician and non-emergency services;</p> <p>FQHC services eliminated;</p> <p>Limits on outpatient and inpatient mental health coverage for persons not in mental illness managed care;</p> <p>Hospital and rehab limited to \$50,000 per year, with added catastrophic wrap-around.</p>	<p>Post-partum family planning for women with incomes &lt; 250% of FPL;</p> <p>FQHC services eliminated;</p> <p>Point-of-service cost sharing for women and children who are subject to premium requirements but who elect POS instead;</p> <p>Cost sharing for non-emergency use of ER.</p>	No changes	<p>Hearing aids for children under EPSDT appear to be eliminated;</p> <p>Mental health limited to 45 visits annually;</p> <p>Adds substance abuse treatment, subject to limits;</p> <p>Premiums, copayments and deductibles for persons with incomes &gt; 100% FPL; \$250 /\$500 individual/family deductible. OOP limits of \$1250 for persons with 100%-200% FPL.</p>

STATE	Oregon	Hawaii	Rhode Island	Kentucky	Tennessee
Changes in treatment of providers	<p>Elimination of FQHCs as mandatory provider, and of FQHC cost payment methodology;</p> <p>Cost-related payments to hospitals; DSH payments not waived;</p> <p>Mandatory use of managed care for services covered under demonstration ;</p> <p>No payment to out-of-plan providers.</p>	<p>Elimination of FQHCs as mandatory provider, and of FQHC cost payment methodology;</p> <p>Elimination of DSH payments;</p> <p>Mandatory use of managed care for services covered under demonstration ;</p> <p>No payment to out-of-plan providers.</p>	<p>Elimination of FQHCs as mandatory provider, and of FQHC cost payment methodology;</p> <p>Mandatory use of managed care for services covered under demonstration ;</p> <p>No payment to out-of-plan providers.</p>	<p>Providers must be part of KenPac system to qualify for payment</p> <p>DSH payments reduced.</p>	<p>Elimination of FQHCs as mandatory provider, and of FQHC cost payment methodology ;</p> <p>Elimination of DSH payments;</p> <p>Mandatory use of managed care for services covered under demonstration ;</p> <p>No payment to out-of-plan providers;</p> <p>Direct funding of state's publicly funded health system redirected into insurance funding pool.</p>

STATE	Oregon	Hawaii	Rhode Island	Kentucky	Tennessee
Changes in managed care	<p>Mandatory managed care enrollment;</p> <p>Use of fully, partially capitated and managed fee-for-service arrangements;</p> <p>All- Medicaid fully capitated plans permitted.</p>	<p>Mandatory managed care enrollment for all members of public pool (AFDC, GA and SHP clients);</p> <p>Use of fully capitated plans; mandatory fee-for-service in rural areas;</p> <p>All- Medicaid fully capitated plans permitted;</p> <p>6-month guaranteed enrollment; no guaranteed enrollment for dental or mental health managed care enrollees;</p> <p>Special managed care programs for seriously mentally ill persons.</p>	<p>Mandatory enrollment in managed care for all AFDC clients, pregnant women and children;</p> <p>Use of fully capitated managed care plans;</p> <p>All-Medicaid managed care plans permitted.</p>	<p>Mandatory enrollment in KenPac system, an established section 1915(b) mandatory Medicaid enrollment program;</p> <p>Future plans to develop risk based plans .</p>	<p>Mandatory managed care enrollment for all Medicaid enrollees except for persons receiving long term care benefits;</p> <p>Mandatory managed care for waiver enrollees;</p> <p>Premiums set on community rate basis; subsequent premiums paid at lowest priced premium.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator  
Washington, D.C. 20201

MAY 26 1983

Draft

TO: The Secretary  
Through: DS \_\_\_\_\_  
COB \_\_\_\_\_  
SS \_\_\_\_\_

FROM: Administrator  
Health Care Financing Administration

SUBJECT: The Medicaid Demonstration Authority - State  
Flexibility and Administrative Streamlining  
-- ACTION

ISSUE

This memorandum outlines our recommendations for using Medicaid demonstration waiver authority to promote prudent State innovations and for streamlining the waiver approval process.

BACKGROUND

In a meeting with the National Governors' Association (NGA) in early February, President Clinton promised States increased flexibility through streamlined Medicaid waiver approvals. As a follow-up to this meeting, you directed us to consult with the NGA and develop options for responding to its concerns and proposals.

This memorandum discusses the NGA concerns regarding the Medicaid demonstration waiver authority under Section 1115 of the Social Security Act. We will address NGA proposals on Medicaid program waiver authorities and additional Medicaid policy issues in a separate memorandum.

In December 1992, NGA presented four recommendations on Section 1115 waivers:

- (1) approvals of demonstration waivers should be expedited;
- (2) no frivolous terms and conditions should be imposed;
- (3) approval should be assumed if the project is budget neutral and does not adversely affect quality or access; and
- (4) "administrative extensions" should be allowed for successful projects.

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After these original proposals were presented, HCFA held a number of discussions with NGA and State representatives. These discussions have been extremely fruitful in clarifying States' interests in greater Medicaid program flexibility and in broader State health reform initiatives. We also have a better understanding of the nature of their concerns about administration of the Section 1115 demonstration waiver program. Our summary of these discussions is attached at Tab A.

In general, our discussions revealed that, to some extent, the States' concerns can be addressed through a better understanding of the waiver program, more Federal assistance to the States in developing acceptable proposals, and streamlining our administrative processes. We have outlined a number of administrative actions that can be taken immediately to improve the efficiency of the waiver process and our assistance to States.

However, the more significant NGA policy issue relates to how broadly the Section 1115 authority should be interpreted to allow expanded State flexibility. We believe this issue requires your decision.

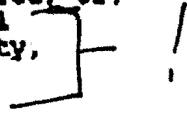
**ISSUE 1: REVISION OF SECTION 1115 WAIVER POLICY**

**DISCUSSION**

Section 1115 of the Act allows you to waive most (but not all) of the Medicaid statutory requirements, for ". . . any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of. . . title XIX. . . ."

This authority is extremely broad, but it is intended and has been used for innovative, time-limited projects which are designed to support an evaluation that surfaces "lessons learned" of larger policy value. This premise is reflected in the existing Section 1115 waiver policy, which was established in response to a 1984 Departmental review of HCFA's waiver practices (Tab B).

The NGA discussions clearly revealed that States want more flexibility to implement alternative Medicaid program approaches, as well as Statewide health reform initiatives, that either (1) would be automatically approved, if budget neutrality and access to quality care are assured, or, preferably, (2) would not be subject to Federal demonstration requirements for budget neutrality, evaluations, or time-limited projects.



We could considerably expand state flexibility by significantly relaxing existing Federal standards for section 1115 waivers. Additional statutory authority would be needed, however, to fully satisfy States' health reform interests in waivers affecting Medicare and ERISA.

There are two significant risks in expanding application of the section 1115 waiver authority:

- o Proliferation of State program variations reflecting different principles could make it difficult to preserve the infrastructure necessary for national health reform.
- o Congress and advocacy groups might challenge increased demonstration flexibility as undermining basic Medicaid statutory provisions. Congress or the courts might act to redefine, limit or remove our waiver authority.

RECOMMENDED POLICY

We can be responsive to States' needs for more ready access to the section 1115 waiver authority, through more flexible standards for waiver approval, while preserving the purpose of the section 1115 authority for time-limited, evaluable demonstration projects.

We can also provide demonstration-related incentives to encourage State proposals that support the Administration's policy goals.

Changes in Standards

We recommend the following to allow greater flexibility in defining Federal standards for waiver approval:

- (1) Demonstration project design and evaluation standards would be tailored to the policy value of the project.

We would attempt to reach up-front agreement with the State about our mutual interests in what is to be learned from the initiative and the consequent design of the project and its evaluation.

We would be more receptive to cross-State comparisons or case studies or, as appropriate, allow States to conduct their own evaluations. Randomization and in-State control groups would only be required when feasible and justified by the policy value of the project. Statewide health reform demonstrations appear to preclude randomized control groups. Data reporting requirements to support evaluations will need to include encounter data from managed care arrangements.

*but not  
baseline  
expectations/  
projections for  
evaluations, for  
comparison*

(2) Budget neutrality standards would be more flexibly applied.

- Budget neutrality standards would be imposed over the life of the project (rather than annually), with interim target(s) that, if not met, would trigger corrective action, including expenditure recoupments. This approach has been used in the welfare reform demonstrations.
- Multi-site budget neutrality measures could allow greater flexibility among individual State projects in a common demonstration initiative.
- We could also allow some expenditures beyond budget neutrality (e.g., +5 percent) for individual projects, to acknowledge that the Federal government should also assume some risk in policy-relevant experiments.
- We could also consider defining an annual aggregate dollar amount that would be allowed for all State demonstration costs above budget-neutral project expenditures.

In considering more flexible budget neutrality standards and a streamlined budget review process, we will need to discuss this with OMB and reach consensus.

(3) Selectively rely on State assurances of operational viability and access to quality care for waiver approvals.

The Federal standards in these areas would not change. However, we can be more flexible by selectively relying on State assurances rather than requiring extensive supporting evidence. Documentation requirements would depend on the policy significance and risk of the project.

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Demonstration Incentives for States

In applying our redefined standards, we would propose to offer incentives to states to propose demonstrations consistent with the Administration's policy priorities. To encourage State proposals that support our interests in

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demonstrating particular policy or program innovations, we would:

- communicate Administration priorities to all States;
- commit to a greater degree of flexibility (e.g., through more generous budget parameters) and faster approval for responsive proposals; and
- provide priority technical assistance for project development and operations, including Federal resources to minimize the cost and burden of the evaluation and project management.

We could also work with NGA to identify innovations of mutual interest to the States and the Administration.

**ISSUE 2: ADMINISTRATIVE ACTIONS TO EXPEDITE AND IMPROVE PROCESS**

Our discussions with NGA also revealed that States' concerns about section 1115 waivers are partly attributable to misunderstandings of the purpose and operation of the waiver program, and to frustrations with the complexity and timeliness of the waiver approval process.

We agreed that those concerns can be significantly alleviated with immediate administrative actions to: (1) streamline the waiver process, (2) limit OMB CONCURRENCES, and (3) provide more active support for States, in understanding the requirements and in submitting approvable proposals.

We propose or have implemented the following administrative actions:

**(1) Streamlining the Waiver Approval Process**

Specific streamlining actions we have already implemented are presented at Tab C. Essentially, we are: establishing a separate process for waiver-only proposals (i.e., those proposals where Federal grant funds are not requested); making a one-step approval of both the project design and the waivers, reducing the number of steps in the formal waiver clearance, while increasing the level of informal consultation with OS and OMB staff; and preparing for Congressional and press notices while decisions are being made. ?

**(2) Limiting OMB Concurrences**

We are also proposing to seek OMB's up-front concurrences only for the more significant proposals.

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This will need to be included in discussions with OMB on revised budget neutrality standards.

(3) Providing Active Support to States

More proactive Federal communications and assistance to States will increase the likelihood that States will submit acceptable proposals that can be rapidly reviewed.

Actions we are taking now to improve communications, simplify applications forms and guidelines, and provide more "hands on" technical assistance, are also presented at Tab C.

It is important to note that reducing the time and intensity of the Federal review process and the burden on States (in preparing acceptable proposals), depends greatly on the rigor of the standards that are imposed.

The timeliness of waiver approvals will still depend on how well each State proposal addresses the revised standards, the complexity and sensitivity of the proposal, and how well the review and clearance timeframes are adhered to by all involved in the process.

We would appreciate further suggestions you may have for additional actions.

NEXT STEPS

I believe the proposals outlined here will substantially further the Administration's commitment to supporting State innovations through greater flexibility and timeliness in waiver approvals. If you approve our recommended approach to revising the standards and administrative actions, the following steps would need to occur to effectuate it:

- o advising the President;
- o confirming OMB's cooperation in more flexible budget neutrality standards and revised review process;
- o communicating the new policies, and your expectations for adherence to a timely clearance process, throughout the Department; and
- o communicating our new section 1115 waiver policies and priorities to all States.

We are prepared to discuss specific activities necessary to implement those actions upon your agreement with this approach.

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RECOMMENDATIONS

I recommend that you approve our proposal for redefining the demonstration waiver approval standards and providing demonstration-related incentives to support the Administration's policy goals. I also recommend you support our initiatives for a more streamlined, collaborative process and more proactive support to States.

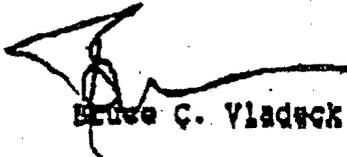
DECISIONS

Issue 1: Revision of Section 1115 Waiver Standards

Approve \_\_\_\_\_ Disapprove \_\_\_\_\_ Date \_\_\_\_\_

Issue 2: Administrative Actions to Expedite and Improve Process

Approve \_\_\_\_\_ Disapprove \_\_\_\_\_ Date \_\_\_\_\_

  
Bruce C. Vladeck

Attachments:

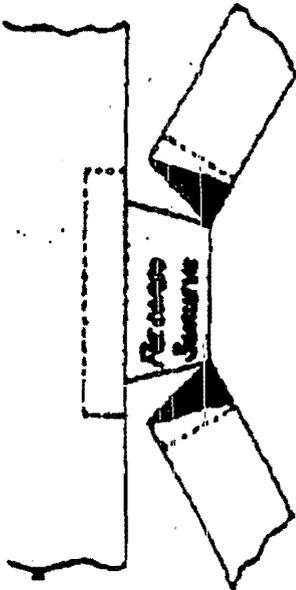
- Tab A - Summary of NGA Discussions
- Tab B - Demonstration Standards
- Tab C - Administrative Actions

**HOW TO USE  
THESE SEPARATORS**

Use one page for each  
separation.

Select appropriate tab,  
add further identification  
if desired, and cover it  
with scotch tape.

Cut off and discard all  
tabs except the one  
covered by tape.



**TABBED SEPARATOR SHEET**  
Form 88A-687 (5-59)

## STATE FLEXIBILITY

## Summary of NGA/HCPA Discussions on the Medicaid Demonstration Authority

(Section 1115 of the Social Security Act)

Recent discussions among HCPA, NGA and State representatives have been extremely fruitful in clarifying the nature of States' interests for greater flexibility to shape and manage their Medicaid programs, and to pursue broader statewide health reform initiatives.

Reflecting these discussions, NGA is developing a restatement of States' concerns, to elaborate on recommendations presented in the December 11, 1992 NGA document (Recommendations 4 -7, attached).

To summarize the essence of these discussions, this paper presents: agreements and suggested actions on issues that can be readily addressed; and significant issues that need to be considered by NGA and/or DHHS/HCPA leadership.

Overall, our discussions revealed that there are three areas of concern that merit attention:

- o Education and Communications - To some extent, States' concerns can be addressed through a better understanding of the federal expectations, standards and processes for Medicaid demonstration projects.
- o Administrative Streamlining - Administrative simplifications and flexibilities that can be made within the Section 1115 approval process, would alleviate additional concerns. Nonetheless -
- o Increased Flexibility - Revision of the basic parameters for the Sec. 1115 authority, and/or additional statutory authority, would be necessary to fully satisfy States' interests in expanded flexibility.

In general, agreements reached in the HCPA/NGA discussions necessarily relate to improved education/communications and administrative streamlining. Issues and questions that remain in these areas, and more significant policy issues related to opportunities for broader State flexibility, will be surfaced to HCPA/DHHS leadership.

Education and Communications

## Agreements and Suggested Actions

- Clear statements of the standards and processes for Section

1115 projects need to be framed and widely communicated to States, particularly regarding the purpose and limitations of the Section 1115 authority. When the policy parameters have been redefined, HCFA should immediately distribute clarifying information to all States, and incorporate the new "message" in speeches and meetings with State officials.

- States need a better understanding of the demonstration proposal application requirements. HCFA should simplify and reissue the existing "How To" guide for all States, with a clear description of the avenues for submitting proposals and the consequent Federal review and decision-making processes.

- States need technical assistance in preparing acceptable proposals and early feedback on issues likely to be of concern to the federal government. HCFA should encourage States to submit preliminary concept papers (with guidelines for doing so), and should respond quickly with policy-relevant reactions and offer assistance in framing formal proposals. NGA and the State representatives should advise HCFA on the nature of additional types of federally-sponsored assistance and/or information that would be most useful.

- A continuing dialogue among HCFA, NGA and State Medicaid Directors on demonstration policies, processes and interests, would be useful. NGA and the State representatives should advise HCFA on how they think this could best be accomplished.

*No one else?  
Beneficiary reps?  
Providers?*

**Issues and Questions**

- Policy decisions on the parameters for the Sec. 1115 authority will be necessary in order to better communicate those federal expectations to States (discussed below).
- The extent to which HCFA can be responsive to States' needs for technical assistance, particularly in helping individual States, will depend on the level of demand (which is rapidly increasing) and the availability of federal resources.

Administrative Streamlining

**Agreements and Suggested Actions**

- The structured review and approval process is perceived to be unduly lengthy. HCFA should identify and implement simplified, more efficient policies and processes for more timely reviews, clearances and decision-making.
- The paperwork necessary to submit an acceptable proposal is

unduly burdensome. HCFA should simplify the formats and forms required.

- True demonstration projects should be structured so something can be learned, but this need not invariably require a randomized design nor an in-State control group. The intensity and scope of the evaluation should "fit" the policy value of the project, and HCFA and the State should agree up front on mutual interests in what is to be learned and, therefore, how the project and its evaluation can best be structured.
- Budget neutrality requirements have been unduly rigorous, contributing to burden on States in providing documentation necessary for project approval, and delays in the federal clearance process. If budget neutrality remains a requirement, some flexibility should be considered: e.g., imposing budget neutrality over the life of the project, allowing some limited margin for excess expenditures, and/or broader definition of savings or benefits than just measurable federal program costs. HCFA should surface options for consideration by DHHS and CMS.
- States and the Administration have a mutual interest in not only surfacing "lessons learned" from demonstrations, but also in converting successful experiments into policy reforms for nationwide replicability. We should work together to explore, with congressional leadership and staff, ways to prompt more timely legislative action for State plan options reflecting successful demonstration experiences.

Issues and Questions

- Process efficiencies and some degree of increased flexibility can be achieved apart from the larger policy questions. However, the extent to which federal standards and processes for demonstrations can be significantly relaxed and streamlined depends greatly on policy decisions defining the purpose and parameters for the Section 1115 authority.

*Will this be treated as its own policy issue?*

- Whether imposing set time frames for Federal review and decision making (which, if not met, would trigger "automatic" approval) are appropriate to innovative demonstration proposals, and/or would be helpful or not in timeliness of the Federal response, remains an issue.

*Where else does this happen? (not in CHC-land to be sure) why not assume if not acted on in a certain time frame, thus triggering an appeal & this is all we asked for in CHC policy issues?*

Increased Flexibility

It is clear that States want flexibility to shape and manage their Medicaid programs, and to pursue Statewide health reform initiatives, without the constraints inherent in the Section 1115

authority (i.e., for time-limited, evaluable demonstration projects.) Section 1113 also does not provide the scope of waiver authority needed to fully implement some state health reform initiatives (e.g., for waiving ERISA or some Medicare provisions.)

There is agreement that the larger issue of state flexibility vs. federally-prescribed requirements or models, needs to be addressed at the highest levels within the Administration and HCA.

In surfacing our mutual need for policy guidance on that issue, it was agreed that the salient question is, essentially, how far the Administration is willing to "push the sec. 1113 envelope" by relaxing federal expectations that this authority will only be used for time-limited experiments subject to some relevant federal standards, or whether states should pursue legislation for an additional waiver authority.

States would like flexibility to implement alternative Medicaid program approaches, as well as statewide health reform initiatives, that either: would be automatically approved if budget neutrality and access to quality care were assured, or, preferably, was not subject to federal expectations for budget neutrality, evaluations, or time-limited approvals.

*but not clearly documented demonstration*

HCPA will surface this issue and related questions to the Administrator-designate and the Secretary, toward clarifying basic policies necessary to implement many of the above-mentioned agreements and actions.

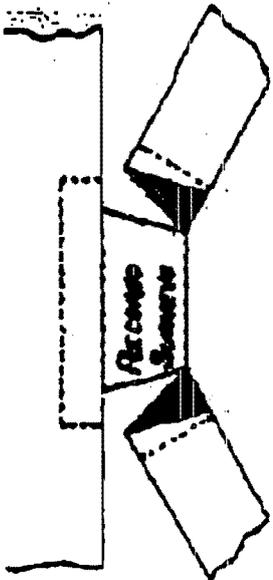


**HOW TO USE  
THESE SEPARATORS**

Use one page for each  
separation.

Select appropriate tab,  
add further identification  
if desired, and cover it  
with Scotch tape.

Cut off and discard all  
else except the one  
covered by tape.



**FABED SEPARATOR SHEET**  
Form SSA-627 (3-60)

## Standards for Medicaid Demonstrations

Demonstration proposals are, by definition and design, innovative and unique. The authorizing statute merely requires that a demonstration "in the judgment of the Secretary, is likely to assist in promoting the objectives" of one of the titles of the Social Security Act. An approval decision reflects a judgment that the overall value of the project merits testing and that the strengths of a particular proposal outweigh its weaknesses.

There are longstanding standards that have been consistently articulated and applied in reviewing demonstration proposals:

1. Research and Evaluation Design - The applicant must define hypotheses that are measurable. A research design must be provided which will permit the outcomes of the demonstration to be assessed, and data to support the evaluation must be available.
2. Policy Relevance - The proposal explains how the project is an innovative approach to significant issues relevant to programs administered by HCFA and the Department. Information or experience from the project would inform national policy interests, and/or could be replicated by other States.
3. Budget - The proposed budget should be the minimum required to achieve the project's objectives. Potential costs/savings are estimated, with an appropriate methodology and supporting data. A monitoring system to provide current information on actual project costs is defined.
4. Operational Capability - The proposal provides evidence that the project can be implemented and has a high likelihood of success. A workplan is provided that shows sufficient, qualified personnel are devoted to the project, with a reasonable timetable and appropriate milestones for operational development.
5. Evidence of Local Commitment - Evidence is provided that key elements of the local community, including affected special-interest groups, will support the demonstration and/or cooperate during the operations phase. Any required enabling legislation has been enacted. Where appropriate, evidence of sufficient provider cooperation to support demonstration service delivery, and of sufficient voluntary participation by persons to be served, should be provided.
6. Impact on Persons Served - The applicant must describe the impact on persons served by Federal programs, including procedures to assure that access to high quality health care will be provided and monitored, and that individuals' privacy and rights will be protected.

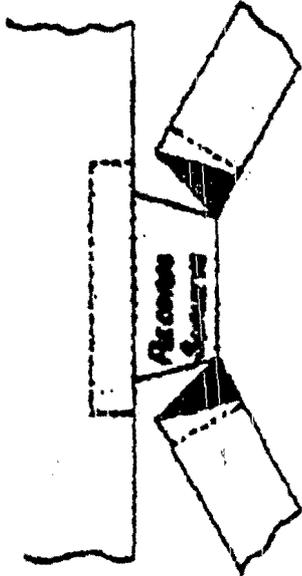
In applying these standards, proposals that have net program costs, or that reduce benefits, are subjected to closer scrutiny for overall value and policy-relevance, unless mandated by Congress.

**HOW TO USE  
THESE SEPARATORS**

Use one page for each  
separation.

Select appropriate lab.  
and further identification  
if desired, and cover it  
with each tape.

Cut off and discard all  
tabs except the one  
covered by tape.



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**USED SEPARATOR SHEET**  
FORM 82A-907 15-92

Tab C

**ADMINISTRATIVE ACTIONS****Streamlining the Waiver Approval Process**

Even without significant changes to the waiver standards, the approval process can be made more efficient, by:

- Establishing a separate streamlined process for reviewing waiver-only proposals, that is not encumbered by the requirements of the Federal Grants process.
- Consolidating the steps involved in formal waiver approval clearances.

Within the Department, recently implemented reporting procedures will keep ASPE, ASMB, ASL and Intergovernmental Affairs informed of all pending proposals, for early, informal collaboration. ASPE and ASMB will continue to review and transmit waiver cost estimates requiring OMB review.

Since 1984, all waivers involving more than \$1 million or 100 beneficiaries, or that are "policy significant" (regardless of the scale of operations) have required OMB's concurrence. Because requests for more information or project changes at this last stage in the clearance process are particularly troublesome, OMB needs to be involved early in the proposal review process. Limiting the type of projects subject to OMB's concurrence to those with a higher budget and participant impact (e.g., \$10 million and 1,000 participants) would reduce time and burden in approving most single-state, special purpose proposals.

- Preparing for press and congressional notifications during the decision process (rather than after approval). While efforts would be wasted if the project were not approved, immediate announcements could be made for those that are.

**Providing Active Support to States**

Specific actions we intend to take include:

- o A clear statement of our revised standards and process for section 1115 waivers, distributed to all Governors and State Medicaid Directors;

Page 3

Tab C

- o A more user-friendly "How To" package, with simplified forms, guidelines and examples for submitting proposals;
- o Invite States to submit short, "plain English" concept papers (with simple guidelines), to prompt feedback and assistance before they prepare a formal proposal;
- o ORD staff and contract resources to provide "hands on" technical assistance to individual States, in structuring projects, preparing proposals and evaluation designs, and data collection systems.

Our ability to respond to individual State requests for special assistance will, of course, depend on the level of demand (which is rapidly increasing) and available resources (which are not).

- o A continuing dialogue among NCPA, NGA and State representatives, on demonstration policies, processes and interests, possibly through establishment of a standing Technical Advisory Group.

712



HCFR/CEO : #9302231331

THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, DC 20201

FEB 23 1993

RECEIVED  
FEB 23 PM 2:12

TO: William Teby, Jr.  
Acting Administrator  
Health Care Financing Administration

Kenneth Thorpe  
Office of Planning and Evaluation

SUBJECT: Implementation of the President's Directives

As you know, the President recently directed this Department to undertake several Medicaid initiatives. The purpose of this memorandum is to outline the President's directives and specify a course of action for their timely implementation.

1. Revise the Medicaid regulations governing provider taxes and disproportionate share promptly following the new negotiations with the National Governors Association that were ordered by the President. I am pleased that the process of negotiating with the NGA has already begun. So that I can give direction to the negotiations, a briefing should be scheduled on the issues before the next meeting with the NGA. Please work together to develop an options paper addressing the pros and cons of various alternatives as well as their potential budget impact. This paper should be provided to me through the Executive Secretariat.

In the interim, actions which HCFA must take in this area of the Medicaid program must be consistent with current regulations.

2. Conduct a thorough review of the Medicaid waiver process, and act promptly to streamline the waiver process. HCFA should prepare a paper providing a broad range of options for streamlining the Medicaid waiver process. These options should address legislative and regulatory issues as well as possible administrative streamlining. The review should include consultation with the National Governors Association and should incorporate an analysis of each of the NGA recommendations related to Medicaid waivers. Please provide the options paper to the Executive Secretariat by March 15 so that we can meet the President's request to develop a list of streamlining recommendations by April 1.

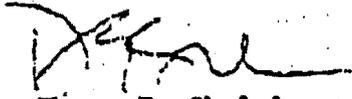
The options paper should also provide alternative approaches to implementing the President's directive that HCFA develop standardized initiatives for program waivers that can be approved automatically so that states can take advantage of other states' successes with far greater ease.

HCFA should take immediate action to revise the process for review of Medicaid program waivers ("freedom-of-choice" and home and community-based services waivers) so that HCFA will request additional information or clarification only once. Any further

requests for information must be related to, or be derived from the information submitted in response to the first request. In the options paper on waivers, HCFA should evaluate the applicability of this rule to all other waivers.

1. Evaluate the remaining NGA recommendations. By April 1, HCFA should complete its evaluation of the remaining NGA recommendations (i.e., excluding waivers and the donations and taxes/disproportionate share rule discussed above) and forward recommendations to the Executive Secretariat for review.

I am confident that these actions will go far in forging a stronger partnership between the federal government and the states to meet the health care needs of our citizens.

  
Donna E. Shalala

HCFA/CEO #2802251311  
RE: ACTION  
CC: Toby; Hays  
AAC; AAM; AAO; PRC; OLP; OGC; MR  
Mans; Trout; Glabellhaus;  
Schmidt; McCabe



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

TO: The Secretary  
Through: DS \_\_\_\_\_  
COB \_\_\_\_\_  
ES \_\_\_\_\_

FROM: Assistant Secretary  
for Planning and Evaluation  
  
Administrator  
Health Care Financing Administration  
  
Acting Assistant Secretary  
Administration for Children and Families

JUN 22 1993

SUBJECT: Issues in Approval of States' Section 1115 Demonstration Proposals --  
DECISION

The Federal Government is planning substantial reforms in welfare and in health financing. But we do not yet have a set of reform principles that we can share with the states to guide their planning. At the same time, states are not waiting for us: they are designing their own reforms -- some modest in scope and fairly straightforward, and others sweeping (extending to comprehensive, statewide health reform), the issues and analysis are complex, and they are politically sensitive. In order to implement these reforms, states are asking HCFA and ACF to approve research and demonstration projects under the authority of §1115 of the Social Security Act (the Act) and to provide waivers of program requirements to permit them to test innovations.

The purpose of this memorandum is to raise four issues related to §1115 demonstrations on which we need your decisions. These will guide us in our interactions with the National Governors' Association and the states on this subject. They will also lead toward common understandings within the Administration which will avoid inconsistent signals or actions. (Separate memoranda on Hawaii's Medicaid proposal and on discussions with NGA regarding program waivers and other NGA concerns are being sent to you.)

BACKGROUND

Section 1115 of the Act allows you to waive most (but not all) of the Medicaid and AFDC statutory requirements for

"... any experimental, pilot or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of (the AFDC, child support and Medicaid titles of the Act)."

States want us to simplify and shorten our review procedures; to raise fewer questions, require less extensive information and supporting evidence from them; to permit "successful" demonstrations to be converted routinely to program practices at their conclusion; and not to impose detailed terms and conditions related to monitoring a project's operations and costs, and overseeing the related research and evaluation.

01102 01137

Page 2 - The Secretary

ISSUES AND DECISIONS

1. How Shall the Department Accommodate States' Concerns About the Waiver Process?

President Clinton met with the National Governors' Association (NGA) in February and, in response to their complaints about complexities and delays in the Department's Medicaid waiver review and approval process, promised the states increased flexibility.

HCFA has been meeting with the NGA and designing a streamlining of the review process. (ACF already has a streamlined process.) This includes:

- Providing active support to the states. Clarifying the review procedures and standards, and providing increased technical assistance in advance of formal waiver submittal.
- Speeding up the review and decision-making process through intensive OPDIV, OS and OMB staff collaboration immediately upon receipt of a proposal.

In fact, both have already begun. HCFA is holding early and broad discussion with interested states, inviting concept papers around which to focus Federal-state dialogue, and procuring a technical assistance contractor. Hewell's proposal is the pilot test of a faster calendar for review, a more consolidated question-and-answer clarification with the state, and simultaneous (rather than sequential) action by HCFA, OS staff offices and OMB. It will be important for us to institutionalize this process (in particular OMB's involvement) once the bugs are ironed out.

*add PHS*

Although the process improvements are likely to be appreciated, they are unlikely to completely satisfy the NGA and the states. They would prefer that our review standards be relaxed, and that proposals be automatically approved if they appear to meet the relaxed standards or if decisions are not made within a predetermined time period. Issues affecting our review standards are presented in 2-4 below. Predetermined time frames, that would trigger automatic approval if not met, would constrain your decision-making authority or would frustrate states' expectations if last-minute questions extended the decision-making period.

Decision

- a. Prepare a memorandum for the President outlining the extent and results of consultations with the NGA. Continue to implement the above improvements. (Recommended)

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Other \_\_\_\_\_

- b. In a separate memorandum, highlight for me areas of continuing disagreement with NGA, and brief me on alternative ways of proceeding. (Recommended)

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Other \_\_\_\_\_

*OK*

Page 3 -- The Secretary

2. Must a Demonstration Be A Real Experiment?

We interpret §1118 authority as allowing the Secretary to grant waivers for projects that are innovative, of significant policy interest, time-limited, and capable of evaluation for "lessons learned." In the past, we have required that states' §1118 demonstrations be designed to test program innovations which, if positive in effect, could be implemented as of would significantly inform, broad program policy. Hence, they could not merely copy what other states have done, could not be routine program modifications designed to avoid inconvenient statutory or regulatory requirements, and they were expected to have the potential to shape national policy directions. Replications have been allowed on a limited scale when testing a policy in additional states seemed likely to yield additional useful information.

HCFA is seeing demonstration proposals that represent minor variations on a theme or are different only on the margin from what other states have already done (e.g., direct purchase of childhood vaccines). Or, on a larger scale, in state health system reforms, some states want to bring into Medicaid coverage large numbers of low-income, uninsured (or state-insured) people; states claim that these are valuable tests of national health reform objectives for expanded access and seamless coverage, when a major goal is to also likely to be to shift to the Federal Government costs now paid by state and local government budgets.

States will also argue that they should be permitted to test any program change that has the potential for controlling that state's costs or improving the effectiveness of the program regardless of any wider policy significance. An example would be a demonstration so idiosyncratic that, regardless of its success, there is virtually no chance of its influencing national policy. The waiver authority could become a way of relaxing statutory or regulatory provisions considered onerous by the states (e.g., limits on managed care). There are three special risks in this course. One is that the waiver authority will be used to slow down nationwide reform. This is particularly true for welfare reform where, if many more waivers are approved, it will be strongly argued that we need to see the results of those demonstrations before we proceed with national reform. A second is fragmentation - that the current variation among the states could become further accentuated. The third is that the Congress will conclude that we are misusing the demonstration authority, and will act to diminish its scope or our flexibility.

Decision

a. Impose more rigorous standards for innovation and policy relevance; discourage and disapprove multi-state replications of concepts which have previously or are currently being tested.

Approved: \_\_\_\_\_ Disapproved: \_\_\_\_\_ Other: \_\_\_\_\_

b. Maintain current standards; allow a limited number of replications if justified in the proposal (e.g., different operational approach, different economic setting, etc.). (Recommended)

Approved: \_\_\_\_\_ Disapproved: \_\_\_\_\_ Other: \_\_\_\_\_

*through an RFP - propose a specific set of dem's*

Page 4 - The Secretary

- d. Prepare for my review options for significantly relaxing our expectations for innovative, policy-relevant demonstration projects.

Approved: \_\_\_\_\_ Disapproved: \_\_\_\_\_ Other: \_\_\_\_\_

3. What Standards Shall We Set for Evaluation of Demonstrations?

A key aspect of the 3115 demonstrations is that they are for the purpose of learning lessons we would not otherwise have learned. Evaluation is the tool by which we crystalize those lessons. We have traditionally required a considerable degree of rigor in their designs: hypotheses that can be tested quantitatively, a clear baseline against which to measure the proposed intervention, assurance of available data with which to document actual effects on persons served and on the programs, and a time-limited experimental period. We agree that some evaluation requirements may have been too burdensome in the past. In particular, we believe that Medicaid and AFDC demonstrations are sufficiently different in scope and content that methods appropriate to their evaluation (e.g., use of randomized control groups) often differ.

ACF and HCFA approach the conduct of evaluations somewhat differently: In ACF, the state is required to procure an independent evaluator that will perform an evaluation approved by ACF; in general, HCFA hires a contractor to carry out the Medicaid evaluation. In discussions with the states that precede approval of the demonstration, the government identifies data needed to support the evaluation and incorporates into the approval requirements for production of the data and for state cooperation with the contractor.

The states would prefer still less rigorous and less intrusive research requirements. However, if we begin to compromise our ability to measure and interpret the effects of the experimental changes, we need to keep in mind that the Congress is likely to become concerned about misuses of the demonstration authority and we may be misinformed about the effects of the intervention which was being tested.

Decisions:

- a. Redefine evaluation standards for both Medicaid and AFDC demonstrations including the requirement that both provide for randomized control groups unless alternative methods are strongly justified.

Approved: \_\_\_\_\_ Disapproved: \_\_\_\_\_ Other: \_\_\_\_\_

- b. Use standards that recognize differences between Medicaid and AFDC (e.g., randomized control groups usually for AFDC, other methods for Medicaid). Maintain standards of documentation of expected changes, collection of data, cooperation with the evaluation effort, and a time-limited demonstration period. (Recommended)

Approved: \_\_\_\_\_ Disapproved: \_\_\_\_\_ Other: \_\_\_\_\_

OK

Page 5 - The Secretary

- C. Further relax demonstration research and evaluation standards for both Medicaid and AFDC.

Approved: \_\_\_\_\_ Disapproved: \_\_\_\_\_ Other: \_\_\_\_\_

4. What Shall Be The Standards of Budget Neutrality for Demonstrations?

In general, there is no statutory or regulatory requirement that §1115 demonstrations must be budget neutral for the Federal Government: that is a standard adopted by OMB and applied by the Department to enable policy flexibility while limiting Federal cost exposure and to avoid wholesale shifting of state costs onto the Federal budget. It is, however, a standard that states have every incentive to circumvent, and one that can be especially difficult to measure and maintain in the absence of a control group.

- Both baseline and cut-year trend variables contain matters of judgment: inflation rates and their impacts, changes in states' economies and dependency/caseload effects, behavioral effects (providers, beneficiaries), utilization rates (e.g., in managed care), disproportionate share payments.
- Identifying and responding to states' creative challenges to budget neutrality is intrusive, requiring the kind of often-iterative and time-consuming detailed questions and responses that NGA is complaining about.
- Thorough analysis of state claims would consume scarce staff resources.

The principal problem is that there are multiple and incompatible goals related to budget neutrality. On one hand, entitlement costs are skyrocketing and there is talk of capping entitlements including Medicaid and AFDC. This argues against allowing states to shift their costs to the Federal Government. On the other hand, there are arguments against strict budget neutrality including

- Fiscal relief for the States: Health costs are consuming increasing proportions of state budgets due to rising numbers of uninsured, increasing uncompensated hospital care, and Federally-legislated Medicaid mandates.
- The Federal Government should share some of the risks and costs of research and experimentation: States and the Federal Government have a mutual interest in investing in innovations.
- Begin setting the stage for health reform: Bringing the poor uninsured into coverage, expanding managed care, and enhancing cost-saving preventive and primary care are priorities which should not wait even if they are somewhat more costly.

These goals cannot all be reconciled in a single policy, and any retreat from the principal of budget neutrality will be rapidly used by states interested in drawing in maximum Federal dollars. Even in adhering to strict budget neutrality, contentious issues may arise in interpreting whether a proposal can be considered budget neutral. For example, how

Page 8 -- The Secretary

how should the Department react to a proposal where a state contemplates a legally permissible, future program expansion and proposes to count the costs of that expansion in the baseline as though it were already in effect in order to make demonstration costs smaller by comparison? The risk is that these sorts of techniques will be noticed and seized upon by other states and their consultants as a precedent to be exploited (much like taxes and donations).

Both HCFA and ACF have been diligent in holding to a standard of budget neutrality. As an accommodation to the states, and with CMB's consent, HCFA has begun to measure budget neutrality over the entire life of the demonstration rather than on a year-by-year basis: this permits excess costs in the early years as a demonstration begins provided they are offset by savings later in the project's life. ACF also uses this approach. HCFA has given some thought to the possibility of allowing limited Federal cost increases above the neutrality level (e.g., 5%) on selected demonstrations, perhaps with an annual aggregate Federal cap on all Medicaid demonstrations.

As one of its negotiating provisions, NGA has argued that "[w]aivers should be assumed approved unless ... the waiver request is not budget neutral over the life of the waiver according to agreed upon government accounting standards." This implies that we should accept the states' assurances of neutrality and not "look behind" them.

Whether the Department proposes to hold to relatively strict standards of budget neutrality or take a more flexible approach, it would be desirable to seek a common understanding with the White House in order to avoid inconsistent approaches on this issue.

Decision

a. Retain the current standard of budget neutrality. (Recommended)

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Other \_\_\_\_\_

b. Prepare an analysis of more flexible alternatives to the current standard.

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Other \_\_\_\_\_

*but it sounds like ACF & HCFA use different standards now, i.e., one year vs. life of project neutrality!*

NEXT STEPS

We are prepared to meet with you to discuss the above issues and recommendations. When your decisions are made, we will also need to define approaches for assuring coordination with the White House and for communicating our positions to the NGA and the states.

David T. Ellwood

Bruce C. Vladeck

Laurence Love

The Administrator  
Washington, D.C. 20201

MAY 26 1993

TO: The Secretary  
Through: DS \_\_\_\_\_  
COS \_\_\_\_\_  
SS \_\_\_\_\_

FROM: Administrator  
Health Care Financing Administration

SUBJECT: The Medicaid Demonstration Authority - State  
Flexibility and Administrative Streamlining  
-- ACTION

**ISSUE**

This memorandum outlines our recommendations for using Medicaid demonstration waiver authority to promote prudent State innovations and for streamlining the waiver approval process.

**BACKGROUND**

In a meeting with the National Governors' Association (NGA) in early February, President Clinton promised States increased flexibility through streamlined Medicaid waiver approvals. As a follow-up to this meeting, you directed us to consult with the NGA and develop options for responding to its concerns and proposals.

This memorandum discusses the NGA concerns regarding the Medicaid demonstration waiver authority under Section 1115 of the Social Security Act. We will address NGA proposals on Medicaid program waiver authorities and additional Medicaid policy issues in a separate memorandum.

In December 1992, NGA presented four recommendations on Section 1115 waivers:

- (1) approvals of demonstration waivers should be expedited;
- (2) no frivolous terms and conditions should be imposed;
- (3) approval should be assumed if the project is budget neutral and does not adversely affect quality or access; and
- (4) "administrative extensions" should be allowed for successful projects.

After these original proposals were presented, HCFA held a number of discussions with NGA and State representatives. These discussions have been extremely fruitful in clarifying States' interests in greater Medicaid program flexibility and in broader State health reform initiatives. We also have a better understanding of the nature of their concerns about administration of the Section 1115 demonstration waiver program. Our summary of these discussions is attached at Tab A.

In general, our discussions revealed that, to some extent, the States' concerns can be addressed through a better understanding of the waiver program, more Federal assistance to the States in developing acceptable proposals, and streamlining our administrative processes. We have outlined a number of administrative actions that can be taken immediately to improve the efficiency of the waiver process and our assistance to States.

However, the more significant NGA policy issue relates to how broadly the Section 1115 authority should be interpreted to allow expanded State flexibility. We believe this issue requires your decision.

#### **ISSUE 1: REVISION OF SECTION 1115 WAIVER POLICY**

##### **DISCUSSION**

Section 1115 of the Act allows you to waive most (but not all) of the Medicaid statutory requirements, for ". . . any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of. . . title XIX. . . ."

This authority is extremely broad, but it is intended and has been used for innovative, time-limited projects which are designed to support an evaluation that surfaces "lessons learned" of larger policy value. This premise is reflected in the existing Section 1115 waiver policy, which was established in response to a 1984 Departmental review of HCFA's waiver practices (Tab B).

The NGA discussions clearly revealed that States want more flexibility to implement alternative Medicaid program approaches, as well as Statewide health reform initiatives, that either (1) would be automatically approved, if budget neutrality and access to quality care are assured, or, preferably, (2) would not be subject to Federal demonstration requirements for budget neutrality, evaluations, or time-limited projects.

We could considerably expand State flexibility by significantly relaxing existing Federal standards for section 1115 waivers. Additional statutory authority would be needed, however, to fully satisfy States' health reform interests in waivers affecting Medicare and ERISA.

There are two significant risks in expanding application of the section 1115 waiver authority:

- o Proliferation of State program variations reflecting different principles could make it difficult to preserve the infrastructure necessary for national health reform.
- o Congress and advocacy groups might challenge increased demonstration flexibility as undermining basic Medicaid statutory provisions. Congress or the courts might act to redefine, limit or remove our waiver authority.

#### RECOMMENDED POLICY

We can be responsive to States' needs for more ready access to the section 1115 waiver authority, through more flexible standards for waiver approval, while preserving the purpose of the section 1115 authority for time-limited, evaluable demonstration projects.

We can also provide demonstration-related incentives to encourage State proposals that support the Administration's policy goals.

#### Changes in Standards

We recommend the following to allow greater flexibility in defining Federal standards for waiver approval:

- (1) Demonstration project design and evaluation standards would be tailored to the policy value of the project.

We would attempt to reach up-front agreement with the State about our mutual interests in what is to be learned from the initiative and the consequent design of the project and its evaluation.

We would be more receptive to cross-State comparisons or case studies or, as appropriate, allow States to conduct their own evaluations. Randomization and in-State control groups would only be required when feasible and justified by the policy value of the project. Statewide health reform demonstrations appear to preclude randomized control groups. Data reporting requirements to support evaluations will need to include encounter data from managed care arrangements.

(2) Budget neutrality standards would be more flexibly applied.

- Budget neutrality standards would be imposed over the life of the project (rather than annually), with interim target(s) that, if not met, would trigger corrective action, including expenditure recoupments. This approach has been used in the welfare reform demonstrations.
- Multi-site budget neutrality measures could allow greater flexibility among individual State projects in a common demonstration initiative.
- We could also allow some expenditures beyond budget neutrality (e.g., +5 percent) for individual projects, to acknowledge that the Federal government should also assume some risk in policy-relevant experiments.
- We could also consider defining an annual aggregate dollar amount that would be allowed for all State demonstration costs above budget-neutral project expenditures.

In considering more flexible budget neutrality standards and a streamlined budget review process, we will need to discuss this with OMB and reach consensus.

(3) Selectively rely on State assurances of operational viability and access to quality care for waiver approvals.

The Federal standards in these areas would not change. However, we can be more flexible by selectively relying on State assurances rather than requiring extensive supporting evidence. Documentation requirements would depend on the policy significance and risk of the project.

Demonstration Incentives for States

In applying our redefined standards, we would propose to offer incentives to states to propose demonstrations consistent with the Administration's policy priorities. To encourage State proposals that support our interests in

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demonstrating particular policy or program innovations, we would:

- communicate Administration priorities to all States;
- commit to a greater degree of flexibility (e.g., through more generous budget parameters) and faster approval for responsive proposals; and
- provide priority technical assistance for project development and operations, including Federal resources to minimize the cost and burden of the evaluation and project management.

We could also work with NGA to identify innovations of mutual interest to the States and the Administration.

**ISSUE 2: ADMINISTRATIVE ACTIONS TO EXPEDITE AND IMPROVE PROCESSES**

Our discussions with NGA also revealed that States' concerns about section 1115 waivers are partly attributable to misunderstandings of the purpose and operation of the waiver program, and to frustrations with the complexity and timeliness of the waiver approval process.

We agreed that those concerns can be significantly alleviated with immediate administrative actions to: (1) streamline the waiver process, (2) limit OMB CONCURRENCES, and (3) provide more active support for States, in understanding the requirements and in submitting approvable proposals.

We propose or have implemented the following administrative actions:

(1) **streamlining the Waiver Approval Process**

Specific streamlining actions we have already implemented are presented at Tab C. Essentially, we are: establishing a separate process for waiver-only proposals (i.e., those proposals where Federal grant funds are not requested); making a one-step approval of both the project design and the waivers; reducing the number of steps in the formal waiver clearance, while increasing the level of informal consultation with OS and OMB staff; and preparing for Congressional and press notices while decisions are being made.

(2) **Limiting OMB Concurrences**

We are also proposing to seek OMB's up-front concurrences only for the more significant proposals.

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This will need to be included in discussions with OMB on revised budget neutrality standards.

**(3) Providing Active Support to States**

More proactive Federal communications and assistance to states will increase the likelihood that States will submit acceptable proposals that can be rapidly reviewed.

Actions we are taking now to improve communications, simplify applications forms and guidelines, and provide more "hands on" technical assistance, are also presented at Tab C.

It is important to note that reducing the time and intensity of the Federal review process and the burden on States (in preparing acceptable proposals), depends greatly on the rigor of the standards that are imposed.

The timeliness of waiver approvals will still depend on how well each State proposal addresses the revised standards, the complexity and sensitivity of the proposal, and how well the review and clearance timeframes are adhered to by all involved in the process.

We would appreciate further suggestions you may have for additional actions.

**NEXT STEPS**

I believe the proposals outlined here will substantially further the Administration's commitment to supporting State innovations through greater flexibility and timeliness in waiver approvals. If you approve our recommended approach to revising the standards and administrative actions, the following steps would need to occur to effectuate it:

- o advising the President;
- o confirming OMB's cooperation in more flexible budget neutrality standards and revised review process;
- o communicating the new policies, and your expectations for adherence to a timely clearance process, throughout the Department; and
- o communicating our new section 1115 waiver policies and priorities to all States.

We are prepared to discuss specific activities necessary to implement those actions upon your agreement with this approach.

**RECOMMENDATIONS**

I recommend that you approve our proposal for redefining the demonstration waiver approval standards and providing demonstration-related incentives to support the Administration's policy goals. I also recommend you support our initiatives for a more streamlined, collaborative process and more proactive support to States.

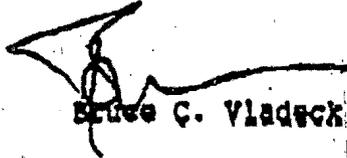
**DECISIONS**

Issue 1: Revision of Section 1115 Waiver Standards

Approve \_\_\_\_\_ Disapprove \_\_\_\_\_ Date \_\_\_\_\_

Issue 2: Administrative Actions to Expedite and Improve Process

Approve \_\_\_\_\_ Disapprove \_\_\_\_\_ Date \_\_\_\_\_



Bruce C. Vladeck

Attachments:  
Tab A - Summary of NGA Discussions  
Tab B - Demonstration Standards  
Tab C - Administrative Actions

## STATE FLEXIBILITY

## Summary of NGA/HCPA Discussions on the Medicaid Demonstration Authority

(Section 1115 of the Social Security Act)

Recent discussions among HCPA, NGA and State representatives have been extremely fruitful in clarifying the nature of States' interests for greater flexibility to shape and manage their Medicaid programs, and to pursue broader statewide health reform initiatives.

Reflecting these discussions, NGA is developing a restatement of States' concerns, to elaborate on recommendations presented in the December 11, 1992 NGA document (Recommendations 4 -7, attached).

To summarize the essence of these discussions, this paper presents: agreements and suggested actions on issues that can be readily addressed; and significant issues that need to be considered by NGA and/or DHHS/HCPA leadership.

Overall, our discussions revealed that there are three areas of concern that merit attention:

- o Education and Communications - To some extent, States' concerns can be addressed through a better understanding of the federal expectations, standards and processes for Medicaid demonstration projects.
- o Administrative Streamlining - Administrative simplifications and flexibilities that can be made within the Section 1115 approval process, would alleviate additional concerns. Nonetheless -
- o Increased Flexibility - Revision of the basic parameters for the Sec. 1115 authority, and/or additional statutory authority, would be necessary to fully satisfy States' interests in expanded flexibility.

In general, agreements reached in the HCPA/NGA discussions necessarily relate to improved education/communications and administrative streamlining. Issues and questions that remain in these areas, and more significant policy issues related to opportunities for broader State flexibility, will be surfaced to HCPA/DHHS leadership.

Education and Communications

## Agreements and Suggested Actions

- Clear statements of the standards and processes for Section

1113 projects need to be framed and widely communicated to States, particularly regarding the purpose and limitations of the Section 1113 authority. When the policy parameters have been redefined, HCFA should immediately distribute clarifying information to all States, and incorporate the new "message" in speeches and meetings with State officials.

- States need a better understanding of the demonstration proposal application requirements. HCFA should simplify and reissue the existing "How To" guide for all States, with a clear description of the avenues for submitting proposals and the consequent Federal review and decision-making processes.

- States need technical assistance in preparing acceptable proposals and early feedback on issues likely to be of concern to the federal government. HCFA should encourage States to submit preliminary concept papers (with guidelines for doing so), and should respond quickly with policy-relevant reactions and offer assistance in framing formal proposals. NGA and the State representatives should advise HCFA on the nature of additional types of federally-sponsored assistance and/or information that would be most useful.

- A continuing dialogue among HCFA, NGA and State Medicaid Directors on demonstration policies, processes and interests, would be useful. NGA and the State representatives should advise HCFA on how they think this could best be accomplished.

#### Issues and Questions

- Policy decisions on the parameters for the Sec. 1113 authority will be necessary in order to better communicate those federal expectations to States (discussed below).
- The extent to which HCFA can be responsive to States' needs for technical assistance, particularly in helping individual States, will depend on the level of demand (which is rapidly increasing) and the availability of federal resources.

#### Administrative Streamlining

#### Agreements and Suggested Actions

- The structured review and approval process is perceived to be unduly lengthy. HCFA should identify and implement simplified, more efficient policies and processes for more timely reviews, clearances and decision-making.
- The paperwork necessary to submit an acceptable proposal is

unduly burdensome. HCFA should simplify the formats and forms required.

- True demonstration projects should be structured so something can be learned, but this need not invariably require a randomized design nor an in-state control group. The intensity and scope of the evaluation should "fit" the policy value of the project, and HCFA and the State should agree up front on mutual interests in what is to be learned and, therefore, how the project and its evaluation can best be structured.
- Budget neutrality requirements have been unduly rigorous, contributing to burden on States in providing documentation necessary for project approval, and delays in the federal clearance process. If budget neutrality remains a requirement, some flexibility should be considered; e.g., imposing budget neutrality over the life of the project, allowing some limited margin for excess expenditures, and/or broader definition of savings or benefits than just measurable federal program costs. HCFA should surface options for consideration by DHHS and CMS.
- States and the Administration have a mutual interest in not only surfacing "lessons learned" from demonstrations, but also in converting successful experiments into policy reforms for nationwide replicability. We should work together to explore, with congressional leadership and staff, ways to prompt more timely legislative action for State plan options reflecting successful demonstration experiences.

#### Issues and Questions

- Process efficiencies and some degree of increased flexibility can be achieved apart from the larger policy questions. However, the extent to which federal standards and processes for demonstrations can be significantly relaxed and streamlined depends greatly on policy decisions defining the purpose and parameters for the Section 1115 authority.
- Whether imposing set time frames for Federal review and decision making (which, if not met, would trigger "automatic" approval) are appropriate to innovative demonstration proposals, and/or would be helpful or not in timeliness of the Federal response, remains an issue.

#### Increased Flexibility

It is clear that States want flexibility to shape and manage their Medicaid programs, and to pursue statewide health reform initiatives, without the constraints inherent in the Section 1115

authority (i.e., for time-limited, evaluable demonstration projects.) Section 1115 also does not provide the scope of waiver authority needed to fully implement some state health reform initiatives (e.g., for waiving ERISA or some Medicare provisions.)

There is agreement that the larger issue of state flexibility vs. federally-prescribed requirements or models, needs to be addressed at the highest levels within the Administration and HCA.

In surfacing our mutual need for policy guidance on that issue, it was agreed that the salient question is, essentially, how far the Administration is willing to "push the Sec. 1115 envelope" by relaxing federal expectations that this authority will only be used for time-limited experiments subject to some relevant federal standards, or whether states should pursue legislation for an additional waiver authority.

States would like flexibility to implement alternative Medicaid program approaches, as well as statewide health reform initiatives, that either: would be automatically approved if budget neutrality and access to quality care were assured; or, preferably, was not subject to federal expectations for budget neutrality, evaluations, or time-limited approvals.

HCPA will surface this issue and related questions to the Administrator-designate and the Secretary, toward clarifying basic policies necessary to implement many of the above-mentioned agreements and actions.

## Standards for Medicaid Demonstrations

Demonstration proposals are, by definition and design, innovative and unique. The authorizing statute merely requires that a demonstration "in the judgment of the Secretary, is likely to assist in promoting the objectives" of one of the titles of the Social Security Act. An approval decision reflects a judgment that the overall value of the project merits testing and that the strengths of a particular proposal outweigh its weaknesses.

There are longstanding standards that have been consistently articulated and applied in reviewing demonstration proposals:

1. Research and Evaluation Design - The applicant must define hypotheses that are measurable. A research design must be provided which will permit the outcomes of the demonstration to be assessed, and data to support the evaluation must be available.
2. Policy Relevance - The proposal explains how the project is an innovative approach to significant issues relevant to programs administered by HCFA and the Department. Information or experience from the project would inform national policy interests, and/or could be replicated by other States.
3. Budget - The proposed budget should be the minimum required to achieve the project's objectives. Potential costs/savings are estimated, with an appropriate methodology and supporting data. A monitoring system to provide current information on actual project costs is defined.
4. Operational Capability - The proposal provides evidence that the project can be implemented and has a high likelihood of success. A workplan is provided that shows sufficient, qualified personnel are devoted to the project, with a reasonable timetable and appropriate milestones for operational development.
5. Evidence of Local Commitment - Evidence is provided that key elements of the local community, including affected special-interest groups, will support the demonstration and/or cooperate during the operations phase. Any required enabling legislation has been enacted. Where appropriate, evidence of sufficient provider cooperation to support demonstration service delivery, and of sufficient voluntary participation by persons to be served, should be provided.
6. Impact on Persons Served - The applicant must describe the impact on persons served by Federal programs, including procedures to assure that access to high quality health care will be provided and monitored, and that individuals' privacy and rights will be protected.

In applying these standards, proposals that have not program costs, or that reduce benefits, are subjected to closer scrutiny for overall value and policy-relevance, unless mandated by Congress.

## ADMINISTRATIVE ACTIONS

Streamlining the Waiver Approval Process

Even without significant changes to the waiver standards, the approval process can be made more efficient, by:

- Establishing a separate streamlined process for reviewing waiver-only proposals, that is not encumbered by the requirements of the Federal grants process.
- Consolidating the steps involved in formal waiver approval clearances.

Within the Department, recently implemented reporting procedures will keep ASPB, ASMB, ASL and Intergovernmental Affairs informed of all pending proposals, for early, informal collaboration. ASPB and ASMB will continue to review and transmit waiver cost estimates requiring OMB review.

Since 1984, all waivers involving more than \$1 million or 100 beneficiaries, or that are "policy significant" (regardless of the scale of operations) have required OMB's concurrence. Because requests for more information or project changes at this last stage in the clearance process are particularly troublesome, OMB needs to be involved early in the proposal review process. Limiting the type of projects subject to OMB's concurrence to those with a higher budget and participant impact (e.g., \$10 million and 1,000 participants) would reduce time and burden in approving most single-State, special purpose proposals.

- Preparing for press and congressional notifications during the decision process (rather than after approval). While efforts would be wasted if the project were not approved, immediate announcements could be made for those that are.

Providing Active Support to States

Specific actions we intend to take include:

- o A clear statement of our revised standards and process for section 1115 waivers, distributed to all Governors and State Medicaid Directors;

- o A more user-friendly "How To" package, with simplified forms, guidelines and examples for submitting proposals;
  - o Invite States to submit short, "plain English" concept papers (with simple guidelines), to prompt feedback and assistance before they prepare a formal proposal;
  - o ORD staff and contract resources to provide "hands on" technical assistance to individual States, in structuring projects, preparing proposals and evaluation designs, and data collection systems.
- Our ability to respond to individual State requests for special assistance will, of course, depend on the level of demand (which is rapidly increasing) and available resources (which are not).
- o A continuing dialogue among NCPA, NQA and State representatives, on demonstration policies, processes and interests, possibly through establishment of a standing Technical Advisory group.
-