



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

NOV - 1 1995

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L/C

MEMORANDUM FOR THE PRESIDENT

The President's Committee on Mental Retardation (PCMR) is currently operating under an Executive Order dated 1974. The existing Executive Order clearly should be revised to reflect correctly contemporary thinking in the field of mental retardation. I recommend that you consider and sign the enclosed revised Executive Order, which was developed and unanimously approved by the current membership of the Committee. As the designated Chair of the Committee, I strongly support the content of the revised Executive Order.

The current Committee consists of 21 citizen members appointed by the President and six ex officio members, including the Attorney General of the United States, the Secretary of Education, the Secretary of Labor, the Secretary of Health and Human Services, the Secretary of Housing and Urban Development, and the President and CEO of the Corporation for National and Community Service. The Secretary of Health and Human Services serves as the designated Chair of the Committee.

President Kennedy appointed a blue ribbon panel, the President's Panel on Mental Retardation, in 1961. The Panel was charged to assess national issues in the field of mental retardation and to submit a report with recommendations to the President in 1962. The Panel submitted a highly acclaimed report to the President as requested.

President Johnson founded the PCMR in 1966 under Executive Order 11280. The Committee was established to help fulfill the unmet needs of the Nation in regard to mental retardation.

President Nixon issued Executive Order 11776 for a revised PCMR in 1974, superseding the previous Executive Order and adding two national goals. The language in the Executive Order has not been updated since 1974 and the Committee is currently functioning under this Executive Order. The 1974 Executive Order should be revised in order to (1) Acknowledge changes in organizational titles of Federal Departments and agencies listed in the Executive Order, (2) recognize changes in national goals and Committee functions, (3) address changes in the membership of the Committee, and (4) document changes in references to statutes cited.

Prepared by [signature]

95/1060021

Under the revised Executive Order, I would no longer serve as the designated Chair for the Committee. I prefer to serve as one of the ex officio members, representing one among many Federal Departments and agencies serving and supporting people with mental retardation. I recommend that one of the 21 citizen members of the Committee be designated by you to serve as Chair of the PCMR. This will better reflect the breadth of the field of mental retardation and provide the Committee with a greater degree of independence. The Department of Health and Human Services would continue to provide administrative support to the Committee, but permit the Committee greater freedom to express its own views as to its goals and to the content of its reports.

The PCMR is an advisory committee whose members are appointed by the President of the United States. The Committee's primary role is to advise the President and the Secretary of Health and Human Services on matters relating to mental retardation.

The Committee addresses major issues of concern to the Nation, including the States and territories. From time to time, the Committee addresses international issues. The Committee holds quarterly meetings, convenes annual conferences and academies, prepares and disseminates papers and proceedings and submits an Annual Report to the President.

There are over 7,000,000 Americans with mental retardation. One out of ten families in the United States is affected by the presence of mental retardation. That includes some 26,000,000 family members.

The total number of Americans with disabilities is estimated at 49,000,000. Over 12 million persons have cognitive disabilities, which includes mental retardation, autism, specific learning disabilities and Alzheimer's disease.

I recommend that you sign the new Executive Order for the President's Committee on Mental Retardation.

You may wish to hold a signing ceremony at the White House, as was done by President Kennedy, President Johnson and President Nixon before you, inviting the membership and staff of the Committee and some highly recognized notables in the field of mental retardation. This would acknowledge your support for people with disabilities and their family members.



Donna K. Shalala

Enclosure

Executive Order Number

Date

**Continuing the President's Committee on Mental Retardation and Broadening its Membership and Responsibilities.**

The President's Committee on Mental Retardation, established by Executive Order No. 11280 on May 11, 1966, as superseded by Executive Order No. 11776 on March 28, 1974, has organized national planning, stimulated development of plans, policies and programs and advanced the concept of community participation in the field of mental retardation.

National goals have been established to:

- (1) promote full participation of people with mental retardation in their communities;
- (2) provide all necessary supports to people with mental retardation and their families for such participation;
- (3) reduce the occurrence and severity of mental retardation by one-half by the year 2010;
- (4) assure the full citizenship rights of all people with mental retardation, including those rights secured by such landmark statutes as the Americans with Disabilities Act of 1990, Pub. L. No. 101-336;
- (5) recognize the right of all people with mental retardation to self-determination and autonomy; to be treated in a non-discriminatory manner; and to exercise meaningful choice, with whatever supports are necessary to effectuate these rights;
- (6) recognize the right of all people with mental retardation to enjoy a quality of life that promotes independence, self-determination, and participation as productive members of society; and
- (7) promote the widest possible dissemination of information on models, programs, and services in the field of mental retardation.

The achievement of these goals will require the most effective possible use of public and private resources.

NOW, THEREFORE, by virtue of the authority vested in me as President of the United States, it is hereby ordered as follows:

Section 1. *Committee continued and responsibilities expanded.*

The President's Committee on Mental Retardation, hereinafter referred to as the Committee, with expanded membership and expanded responsibilities, is hereby continued in operation.

Section 2. *Composition of Committee.*

(a) The Committee shall be composed of the following members:

- 1) The Secretary of Health and Human Services.
- 2) The Secretary of Education.
- 3) The Attorney General.
- 4) The Secretary of Labor.
- 5) The Secretary of Housing and Urban Development.
- 6) The President and Chief Executive Officer of the Corporation for National and Community Service (formerly ACTION).
- 7) The Commissioner of Social Security.
- 8) The Chair of the Equal Employment Opportunity Commission.
- 9) The Chair of the National Council on Disability.
- 10) No more than twenty-one other members who shall be appointed to the Committee by the President. The citizen members shall include self-advocates with mental retardation and members of families with a child or adult with mental retardation, persons employed in either the public or the private sector and individuals who as a group represent a broad spectrum of perspectives, experience, and expertise on mental retardation.

(b) Except as the President may from time to time otherwise direct, appointees under this paragraph shall have three-year terms, except that an appointment made to fill a vacancy occurring before the expiration of a term shall be made for the balance of the unexpired term.

- (c) The President shall designate the Chair of the Committee from the twenty-one citizen members. The Chair shall advise and counsel the Committee and represent the Committee on appropriate occasions.

Section 3. *Functions of the Committee.*

- (a) The Committee shall provide such advice and assistance in the area of mental retardation as the President or Secretary of Health and Human Services may request, and particularly shall advise with respect to the following areas:
- 1) evaluating and monitoring the national effort to establish appropriate policies and supports for people with mental retardation;
  - 2) providing suggestions for improvement in the delivery of mental retardation services, including preventive services, the promulgation of effective and humane policies, and the provision of necessary supports;
  - 3) identifying the extent to which various Federal and State programs achieve the national goals in mental retardation described in the preamble and have a positive impact on the lives of people with mental retardation;
  - 4) facilitating liaison among Federal, State and local governments, foundations, non-profit organizations, other private organizations, and citizens concerning mental retardation;
  - 5) developing and disseminating such information as will tend to reduce the incidence and severity of mental retardation; and
  - 6) promoting the concept of community participation and development of community supports for citizens with mental retardation.
- b) The Committee shall make an Annual Report to the President concerning mental retardation. Such additional reports or recommendations may be made as the President may require or as the Committee may deem appropriate.

#### Section 4. *Cooperation by other agencies.*

To assist the Committee in providing advice to the President, Federal departments and agencies shall designate liaison officers to the Committee, as requested. Such officers shall, on request by the Committee, and to the extent permitted by law, provide it with information on department and agency programs that do or could contribute to achievement of the President's goals in the field of mental retardation.

#### Section 5. *Administrative arrangements.*

- (a) The Office of the Secretary of the Department of Health and Human Services shall, to the extent permitted by law, provide the Committee with necessary staff, administrative services, and facilities. The Secretary of Health and Human Services shall have the authority to enter into interagency agreements with other ex officio members of the Committee for the purpose of having their agencies participate in providing financial resources and staff, as authorized by law, to implement the stated goals and functions of the Committee under this Executive Order.
- (b) Each member of the Committee, except any member who then receives other compensation from the United States, may receive compensation for each day he or she is engaged in the work of the Committee, as authorized by law (5 U.S.C. 3109), and may also receive travel expenses, including per diem in lieu of subsistence, as authorized by law (5 U.S.C. 5703) for persons in the Government service employed intermittently. Committee members with disabilities may be compensated for attendant expenses, consistent with government procedures and practices.
- (c) The Secretary of Health and Human Services shall perform such other functions with respect to the Committee as may be required by the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2; 86 Stat. 770), as amended.

#### Section 6. *Construction.*

Nothing in this Order shall be construed as subjecting any Federal agency, or any function vested by law in, or assigned pursuant to law to, any Federal agency, to the authority of the Committee or as abrogating or restricting any such function in any manner.

Section 7. *Superseded Authority.*

Executive Order No. 11776 of March 28, 1974 is hereby superseded.

PRESIDENT

The White House



DEPARTMENT OF HEALTH & HUMAN SERVICES

ADMINISTRATION FOR CHILDREN AND FAMILIES  
Office of the Assistant Secretary, Suite 600  
370 L'Enfant Promenade, S.W.  
Washington, D.C. 20447

September 1, 1995

TO: The Secretary  
Through: DS WDBradshaw / Mr. B/20  
COS \_\_\_\_\_  
ES Wmley 10/20

FROM: Assistant Secretary  
for Children and Families

SUBJECT: Request to Transmit to the President for Signature a  
Revised Executive Order Authorizing a Continuation of  
the President's Committee on Mental Retardation -  
ACTION

Action Requested By: 09/06/95

ISSUE

Request to transmit to the President for signature a revised Executive Order authorizing a continuation of the President's Committee on Mental Retardation (PCMR). (TAB A)

DISCUSSION

The President's Committee on Mental Retardation (PCMR) was established by Executive Order 11280 on May 11, 1966, which Order was superseded by Executive Order 11776, on March 28, 1974, expanding its membership and functions, and continued at appropriate intervals by subsequent Executive Orders, the last being Executive Order 12869, dated September 30, 1993.

The PCMR provides advice to the President and the Secretary on a broad range of goals concerning the field of mental retardation. With twenty-one members representing several professions from both the public and private sectors, the PCMR meets quarterly and reports annually to the President on specific current issues in mental retardation.

Current priorities of the Committee are: Federal policy; Federal research and demonstration; State policy collaboration; minority and cultural diversity; and mission and public awareness. The Committee has sponsored several publications and convened a Presidential Forum addressing six areas of the President's Reform Agenda. Attendees of the forum consisted of experts in the field of mental retardation, self-advocates, and parents of children with mental retardation and other developmental disabilities.

Many of the goals and objectives contained in the 1974 Executive Order have been largely achieved or have become obsolete. (TAB B) The proposed revised Executive Order reflects contemporary goals, objectives and trends in improving the quality of life for persons with mental retardation and their families, and expands the membership of the Committee to include the Commissioner of Social Security, the Chair of the Equal Employment Opportunity Commission and the Chair of the National Council on Disability. Consistent with your recommendation to grant us more independence, the proposed revised Executive Order replaces you as Chair of the President's Committee on Mental Retardation with one of the twenty-one citizen members of the Committee.

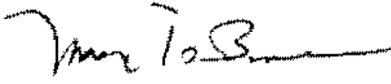
RECOMMENDATION

If you agree to the changes in the revised Executive Order, please sign the attached letter of transmittal. I understand that the contents of the Executive Order and the letter of transmittal reflect your position.

DECISION

I will sign and forward the attached letter of transmittal and the revised Executive Order to the President of the United States. (TAB C)

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date NOV 1 1995



Mary Jo Bane

3 Attachments:

- TAB A - Revised Executive Order Authorizing the President's Committee on Mental Retardation
- TAB B - Current Executive Order Authorizing the President's Committee on Mental Retardation
- TAB C - Letter of transmittal to the President and the Revised Executive Order



NOV - 1 1995

## NOTE TO LEE ANN INADOMI

Attached please find a note from Secretary Shalala requesting that the President sign a revised Executive Order authorizing the continuation of the President's Committee on Mental Retardation (PCMR). The PCMR first was established by executive order in 1966, and the last major revisions were made in 1974. Many of the goals and objectives contained in the 1974 Executive Order largely have been achieved or have become obsolete. The proposed revised Executive Order reflects contemporary goals, objectives and trends in improving the quality of life for persons with mental retardation and their families, and expands the membership of the Committee to include the Commissioner of Social Security, the Chair of the Equal Employment Opportunity Commission, and the Chair of the National Council on Disability. In order to grant the Committee more independence, the proposed revised Executive Order replaces the Secretary of Health and Human Services as Chair with one of the 21 citizen members of the Committee.

Please feel free to call me if I can be of further assistance.



Kevin Thurm

Attachments



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

OCT 20 1995

MIMORANDUM FOR THE PRESIDENT

For the last 19 years, November has been designated as National Adoption Month. It has been an opportunity to focus the Nation's attention on the thousands of children waiting for a family of their own, and make strides in breaking down barriers to adoption.

You and the First Lady have both made vocal commitments to increasing adoptions, and this Administration has taken a number of significant steps to meet this goal:

- ▶ Ensuring that states make full and effective use of the Adoption Assistance Program, which provides critical economic support to families who adopt special needs children, since they may have large medical and other expenses. (Under the Clinton Administration, the number of children for whom adoption subsidies are provided has increased by about 30 percent.)
- ▶ Making grants to public and private agencies to develop successful models for recruiting families, provision of post-legal adoption services, support for parent groups, and the development of training curricula.
- ▶ Conducting national and regional leadership conferences to build the capacity of public and private agencies to facilitate the adoption of minority and special needs children.
- ▶ Providing support for the National Adoption Exchange, the Adoption Clearinghouse, the National Resource Center for Special Needs Adoption, and the Interstate Compact on Adoption and Medical Assistance.
- ▶ Fully enforcing the Multiethnic Placement Act, whose non-discrimination and recruitment provisions should increase the number of children who are adopted.
- ▶ Voicing strong opposition about "welfare reform" proposals that would jeopardize these programs and eliminate the guarantee of federal funds to help support adoptions.

It is my recommendation that you continue these notable efforts and proclaim the month of November 1995 as National Adoption Month.

  
Donna E. Shalala

Prepared by ACS/Markowitz

9510240018

NATIONAL ADOPTION MONTH

November 1995

A Presidential Proclamation

For thousands of children in the United States, adoption is the key to a permanent, loving family. Adoption also enriches the lives of adults by enabling them to become parents. Families that have adopted a child know the tremendous affection and joy the child brings to them and to others, as well as the positive development it provides the child. Because strong, loving families are the cornerstones of stable and caring communities, adoption also strengthens our Nation.

Nearly 70,000 children in the Nation's foster care system have a goal of adoption -- they cannot return safely home and need another family to call their own. Many of these children are sisters and brothers, are older, are physically or emotionally challenged or are members of a minority group.

Regardless of their special need, all of these children long for the same kind of permanent and loving family that most of us have always taken for granted, yet too many of them have been waiting, or will wait for years to be adopted.

I am pleased to say that this Administration has taken key steps to encourage adoptions of special needs children and to support the families that choose to open their hearts and their homes.

We have championed programs that find and assist adopting families, and we are breaking down barriers in our homes, in our communities and in our child welfare system.

This month we celebrate the new beginnings and the rewards that adoptions bring. But we also recognize that there is much more work to be done. Communities across the country -- business and religious leaders, educators, media, health care providers, law enforcement officials, child welfare workers, voluntary organizations and child advocates -- must join together. We must renew our commitment to breaking down even more barriers, and to finding homes for all of the children who are waiting for a family of their own.

NOW, THEREFORE, I, BILL CLINTON, President of the United States of America, do hereby proclaim the month of November 1995 as National Adoption Month. I urge all Americans and every level of government to observe this month and to participate in efforts to find permanent homes for our children.

IN WITNESS WHEREOF, I have hereunto set my hand this \_\_\_\_\_ day of \_\_\_\_\_, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and twentieth.

Prepared by Wilfred Hamm (205-8671) 10/10/95



ADMINISTRATION FOR CHILDREN AND FAMILIES  
Office of the Assistant Secretary, Suite 600  
370 L'Enfant Promenade, S.W.  
Washington, D.C. 20447

October 10, 1995

TO: The Secretary  
Through: DS *10/10/95*  
COS *10/10*  
ES *10/10*

FROM: Assistant Secretary  
for Children and Families

SUBJECT: Request for the President to Proclaim November 1995 as  
National Adoption Month -- ACTION

ISSUE:

For the past 19 years, November has been designated as Adoption Month. A Presidential Proclamation declaring November 1995 as National Adoption Month would provide an opportunity to focus national attention on the 69,000 children who are still waiting for a permanent, loving family of their own, and to highlight Administration efforts to increase adoptions.

DISCUSSION:

The President and the First Lady have made a commitment to increasing adoptions for waiting children, especially for those with special needs -- those who are older, in sibling groups, mentally, emotionally or physically challenged, or from minority groups.

The Administration has taken a number of significant steps to meet this goal:

- ▶ ensuring that states make full and effective use of the Adoption Assistance Program, which provides critical economic support to families who adopt special needs children, since they may have large medical and other expenses. (Under the Clinton Administration, the number of

children for whom adoption subsidies are provided has increased by about 30%.)

- ▶ Making grants to public and private agencies to develop successful models for recruiting families, provision of post-legal adoption services, support for parent groups, and the development of training curricula.
- ▶ Conducting national and regional leadership conferences to build the capacity of public and private agencies to facilitate the adoption of minority and special needs children.
- ▶ Providing support for the National Adoption Exchange, the Adoption Clearinghouse, the National Resource Center for Special Needs Adoption, and the Interstate Compact on Adoption and Medical Assistance.
- ▶ Fully enforcing the Multiethnic Placement Act, whose non-discrimination and recruitment provisions should increase the number of children who are adopted.
- ▶ Voicing strong opposition about "welfare reform" proposals that would jeopardize these programs and eliminate the guarantee of federal funds to help support adoptions.

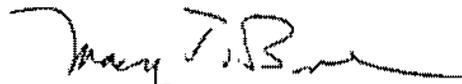
I am requesting that the President proclaim November to be National Adoption Month to draw further attention to the children awaiting permanent homes.

RECOMMENDATION:

I recommend that the attached proposed proclamation be immediately forwarded to the White House.

DECISION:

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date \_\_\_\_\_

  
Mary Jo Bane

Attachment



AUG 7 1995

MEMORANDUM FOR THE PRESIDENT

In response to Executive Order 12862, "Setting Customer Service Standards," and your follow-up memorandum "Improving Customer Service" on March 22, 1995, I am pleased to forward to you our 1995 Customer Service Plan for the Department of Health and Human Services (HHS).

Last year HHS responded to Executive Order 12862 by providing our initial Customer Service Plan which included the following information: an HHS Customer Service Model; customer service brochures setting standards of service for direct customers for the Health Care Financing Administration, the Indian Health Service and the Social Security Administration; a letter setting standards to guide our relations with our partners in the Administration on Aging's Aging Network of service providers; and a letter I sent to the Governors and our partners in State and local governments setting service standards for HHS responsiveness to their needs.

This year, we have updated our HHS Customer Service Plan by focussing our efforts on partner standards through the development of generic HHS Service Standards for Partnership with our 11,000 Grantees. We expect these standards to promote closer collaboration and more productive relationships with our grantee partners.

In regard to our direct customers, our efforts to improve services continue with the addition of four HHS program offices in the Public Health Service (PHS) who have introduced new customer service standards. They include: the National Cancer Institute's Information Associates Program, the National Library of Medicine, the Health Resources and Services Administration's Hansen's Disease Center and the PHS Clearinghouses and Information Centers.

Additionally, there are other action items required by the Executive Order which we have addressed in our plan and which highlight an impressive and exciting scope of activities that are underway to make HHS even more customer focused.

I want to thank you and Vice President Gore for the leadership you have provided to make the Federal Government more customer focused. We have come a long way in the past year, and while we have a long journey ahead, I am confident we are improving our services to our customers and partners every day. We will continue to report our progress to you and to our customers and partners as we move forward.

Donna E. Shalala

Attachment



AUG 7 1995

**TO ALL HHS GRANTEE PARTNERS**

I am delighted to announce the Department's partnership service standards which will promote even closer collaboration with you, our grantee partners. As the largest granting agency in the Federal Government, HHS awards 60,000 grants worth nearly \$140 billion annually to its 11,000 grantee partners.

As our partners in state, tribal, local government and in the academic, non-profit, and private sectors, you are the vital link in carrying out our mission. Our customers, the American people, are helped by the work that we do together through activities such as overseeing research on preventing and curing disease, providing health care and early childhood enrichment and increasing the economic and social well-being and productivity of families.

To accomplish this mission, it is important that we work together in a manner that provides the highest quality of service to the American people, assures fairness and equity, and protects the public investment in our programs. You, our partners, are critical to carrying out the HHS mission, and these new standards represent our pledge to work with you in a cooperative and effective manner.

We will be soliciting your views and recommendations to assure that these standards are meaningful and relevant to your needs and, on an ongoing basis, will measure results achieved against them and report these results to you periodically. Your cooperation and support in assisting us to implement and refine these standards will be greatly appreciated.

Together we can fulfill President Clinton's commitment to provide customer service that is the best in the business. The winners will be our customers.

Donna E. Shalala

**Department of  
Health and Human Services**



**Customer Service Plan**  
in response to  
**Executive Order 12862**

**August, 1995**



July 28, 1995

## MEMORANDUM

TO: The Secretary  
Through: DS *[Signature]* 8/4/95  
COS  
ES *[Signature]* 8/4

FROM: Carl Montoya, Chair *[Signature]*  
Allan Rivlin *[Signature]*  
HHS Customer Service Work Group  
Continuous Improvement Program

SUBJECT: HHS Customer Service Plan - The Department's Response to the President's Memorandum of March 22, 1995, "Improving Customer Service"  
Action Requested by: August 7, 1995

ISSUE

The President's memorandum of March 22, 1995 (see Tab A) directs agencies to treat the requirements of Executive Order 12862 of September 11, 1993, "Setting Customer Service Standards," as continuing requirements and requires each agency to publish and update its customer service plan. The memorandum also adds a new requirement that standards be developed for services that are delivered in partnership, for example, with state and local governments.

The National Performance Review (NPR) has established very tight time frames for the submission of agency customer service plans. The NPR requires that the final text of the HHS Customer Service Plan be signed out by agency Heads and submitted to the President by August 7. This is necessary to meet the September 1st publishing date and the September 15th release date of the agency plans. The HHS Customer Service Work Group, under the auspices of the Continuous Improvement Program (CIP), has been meeting on an almost weekly basis since April to meet these due dates.

FACTS

Last year HHS responded to Executive Order 12862 in a memorandum from you to the President which provided the following information: an HHS Customer Service Model; customer service brochures setting standards of service for direct customers for HCFA, IHS and SSA; a letter setting standards to guide our relations with our partners in AoA's Aging

Network of service providers; and a letter from you to the Governors and our partners in State and local governments setting service standards for HHS responsiveness to their needs.

New Standard for Service to our Partners

This year, in response to the Presidential Memorandum of March 22, we have updated our HHS Customer Service Plan (see Tab C) and focused our efforts on partner standards by developing generic HHS Service Standards for Partnership with our 11,000 Grantees. The HHS Customer Service Work Group, with spirited enthusiasm and many candid discussions, successfully reached consensus on eight generic standards to guide our collaboration with HHS grantee partners.

New Standard for Service to Direct Customers

In regard to our direct customers, our efforts to improve service continue with the addition of four HHS program offices who have introduced new customer service standards. They include: the National Cancer Institute's Information Associates Program, the National Library of Medicine, the Health Resources and Services Administration's Hansen's Disease Center and the PHS Clearinghouses and Information Centers.

Finally, there are other action items required by the Executive Order which we are addressing in this package and which highlight an impressive and exciting scope of activities that are underway to make HHS even more customer focused. These activities cover HHS accomplishments and progress in the following areas: providing partners with choices in both sources of service and means of delivery; making information, services, and complaint systems easily accessible; providing means to address complaints; measuring results of direct customer service standards; and benchmarking customer service standards and performance measures against the best in the business.

RECOMMENDATION

We recommend that you sign the memorandum to the President which transmits our HHS Customer Service Plan for 1995, as well as the letter introducing the partner standards to our grantees.

DECISION

Approved  Disapproved \_\_\_\_\_ Date \_\_\_\_\_

Attachments:

- Tab A: Executive Order 12862 and the President's Customer Service Memorandum of March 22, 1995 (These documents will not be included in the package that is being sent to the President.)
- Tab B: A transmittal memorandum from the Secretary to the President.
- Tab C: The HHS Customer Service Plan



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D. C. 20201

JUL 27 1995

MEMORANDUM FOR THE PRESIDENT

In July, 1993, at the request of Senators Kennedy and Graham and Representative Goss, I asked the Institute of Medicine (IOM) to review the events of the early 1980s, during which HIV was transmitted through blood products to more than half of the 16,000 hemophiliacs in the U.S. The IOM convened an expert panel, which released its report last week.

Consistent with the HHS request, the panel did not review the existing blood safety program or the current safety of the blood supply, but rather, studied the events and public health structure of the early 1980s. Recognizing the substantial scientific uncertainty of the time, the panel concluded that there was no wrongdoing by any agency or employee of this Department.

The panel found, however, that all of those involved, including government agencies and private organizations, had been overly cautious, that there had been a failure of Federal leadership, and that opportunities to protect hemophiliacs from the dangers of infected blood had been missed. Based upon the events of the 1980s, the panel developed 14 recommendations "that might have moderated some of the effects of the AIDS epidemic," and urged government and private organizations responsible for blood safety "to evaluate their current policies and procedures to see if they fully address the issues raised" by the recommendations.

Key recommendations include improving coordination through a "blood advisory council" of Federal agencies and private organizations; ensuring that advisory panels are balanced with both consumer and industry voices; and ensuring that the government has sources of information independent of industry. The IOM also recommended that the Federal Government "consider" a no-fault plan for compensating, in the future, those who are injured through the use of blood or blood products.

Many of the recommendations are already addressed by the current blood safety system. To evaluate all of the recommendations, and also to thoroughly review HHS' blood

Page 2 - The President

safety activities, I have appointed the leaders of the relevant public health agencies as a Task Force that will report to me by the end of August.

In my response to the report, I stated that the infection of hemophiliacs had been a national tragedy and announced the formation of the Task Force while embracing the goals of the IOM recommendations. I also reassured the public that the current blood supply, while not risk-free, is very safe. (Press release is attached.) The risk of HIV transmission through blood and blood products has been vastly diminished since the HIV blood test became available in 1985, and there have been no known cases of HIV transmission through anti-hemophilic products since 1987.



Donna E. Shalala

Attachment

# HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

EMBARGOED FOR RELEASE  
Thursday, 5 P.M. EDT, July 13, 1995

Contact: HHS Press Office  
(202) 690-6343

## STATEMENT OF HHS SECRETARY DONNA E. SHALALA RELEASE OF REPORT ON H.I.V. AND THE BLOOD SUPPLY

In the early- and mid-1980s, thousands of Americans who had hemophilia and others who received blood transfusions were infected with HIV. That was a national tragedy. Every instance of suffering from HIV/AIDS, and every AIDS-related death, diminishes us as a people.

For that reason, and in response to public concern, in 1993 I asked the Institute of Medicine (IOM) to undertake a comprehensive study of the events leading to HIV transmission to people with hemophilia during the 1980s.

The IOM study covers the period 1982-1986 and the decision-making process during that time. It does not treat the period since 1986, in which we have made a number of changes to improve the blood safety assurance process.

The IOM has done a valuable service by analyzing the events that occurred between 1982 and 1986 and suggesting how we can learn from them. While different individuals and organizations may have divergent views and recollections about events that occurred 9-13 years ago, there is no doubt that during a time of great scientific uncertainty, our country's public health system missed opportunities to intervene. We cannot change the past, but we must learn from the past so that history does not repeat itself.

We embrace the goals reflected in the IOM recommendations: the need for active top-level leadership; effective coordination across the Department's agencies; a system for responding quickly and decisively in the case of crises; the inclusion of multiple stakeholders in decisions; and accountability to the American people. In principle, we accept the IOM recommendations; in practice, I believe we have already implemented many of them. We must continue to do everything in our power to see that similar tragedies will not occur again.

To assess all of the recommendations in light of current practices, I have created a Task Force made up of seven senior public health officials, and asked them to report back to me as soon as possible.

- More -

Even though no system is risk-free, the blood supply in the United States is very safe. The blood test for HIV became available in 1985, and many more safeguards exist today than did between 1982 and 1986.

Our blood supply is a well-spring of life, a source of security, and vivid testimony to the civic spirit that unites us as one people. Our obligation as health leaders and citizens is to protect this national resource -- now and forever.

///



JUL 27 1995

TO: Carol Rasco  
Assistant to the President for  
Domestic Policy

FROM: Chief of Staff

SUBJECT: Memorandum for the President

Attached is a memorandum from Secretary Shalala to the President, which the President requested. The memorandum describes a recently released Institute of Medicine report on the infection of hemophiliacs by HIV during the 1980s, and HHS's response to the report.

Kevin Thurm

Attachment

cc: Kitty Higgins

90-5-9  
L/C



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

JUN 7 1995

MEMORANDUM FOR THE PRESIDENT

August marks the 20th Anniversary of the Office of Child Support Enforcement.

Since the Child Support Enforcement Program began in 1975, over \$62.5 billion have been collected from noncustodial parents. Over 4.5 million paternities and more than 11 million support obligations have been established, and over 24 million absent parents have been located.

You have made child support enforcement a cornerstone of your welfare reform proposals. You have issued an Executive Order making the Federal Government a model employer for other employers to emulate.

A National Child Support Awareness Month will focus attention on parental responsibility, and will provide States the opportunity to mount a public information campaign. It is my recommendation that you proclaim the month of August as the National Child Support Awareness Month.

Donna E. Shalala

Prepared by ACF/Ministry

9506120041

billion have been provided for children by their non-custodial parents.

We must keep the American Dream alive and well for all our children and their children after them. We must foster strong families and responsible parenting: we must tell parents who choose not to continue a relationship with each other that their children need, and have the right to, both parents' continuing love and financial support; and we must teach our young people not to risk bearing a child until they are willing and able to provide for that child's needs.

Children learn values from their parents. Parents who fulfill their financial obligations; who accept responsibility for the consequences of their actions; who, if necessary, overcome anger and resentments to nurture their children, teach those children values that have helped make America strong.

When a parent does not teach a child the values that allow a human society to flourish, then society must do it. For twenty years, the Federal/State/local Child Support Enforcement Program has been there for children, providing hope and support. "Children First" is Child Support's watchword. It will have truly fulfilled its mission when parents voluntarily put their children first.

I, WILLIAM JEFFERSON CLINTON, President of the United States of America, do hereby proclaim the month of August 1995 as National

Child Support Awareness Month. I call upon all Americans to observe this month with appropriate programs, ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this \_\_\_\_\_ day of \_\_\_\_\_, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and nineteenth.

Prepared by: David Siegel (401-9373) 3/29/95



DEPARTMENT OF HEALTH & HUMAN SERVICES

ADMINISTRATION FOR CHILDREN AND FAMILIE  
Office of the Assistant Secretary, Suite 600  
370 L'Enfant Promenade, S.W.  
Washington, D.C. 20447

April 4, 1995

TO: The Secretary  
Through: DS *W. B. Woodruff 6/2*  
COS *6/1/95*  
ES *6/2*

FROM: Assistant Secretary  
for Children and Families

SUBJECT: Request for the President to Proclaim August 1995 as  
National Child Support Awareness Month -- ACTION

ISSUE:

August 1995 is the 20th Anniversary of the Support Enforcement Program. A Presidential Proclamation declaring August as Child Support Awareness Month would provide a focus for the public to emphasize the importance to children, and to the taxpayer, of parental responsibility.

DISCUSSION:

The President has made child support a cornerstone of welfare reform. He has forcefully described the importance of child support enforcement on numerous occasions, including both State of the Union Addresses. On February 27, he signed an Executive Order making the Federal Government a model employer for other employers to emulate. The program is also one of the Government Performance and Results Act (GPRA) pilot projects.

Since the National Child Support Program began in 1975, over \$62.5 billion have been collected for children from non-custodial parents. Over 4.5 million paternities and more than 11 million support obligations have been established as well. Over 24 million parents have been located through this program.

I am requesting that the President proclaim August to be National Child Support Awareness Month to further draw attention to children who need the financial and emotional support of their parents.

95-0289





THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D. C. 20201

JUN 1 1995

MEMORANDUM FOR THE PRESIDENT

I am pleased to provide you with the report of the Department of Health and Human Services (HHS) on the in-depth review of our existing regulations, as requested in your memorandum of March 4, 1995.

HHS has been a significant contributor to, and supporter of, this Administration's efforts "to provide the American people a regulatory system that works for them and not against them."

Let me assure you that this Department remains committed to pursuing substantial reform of its regulatory system and rules to achieve the principles established in Executive Order 12866 and reaffirmed in your memorandum of March 4, 1995.

The attached report represents another step in HHS' efforts to institute real and lasting regulatory reform. These reforms are intended to reduce regulatory burden, and promote better communication, consensus building and a less adversarial environment.

This project was a significant undertaking for the Department and involved the review of more than 6900 pages in the Code of Federal Regulations. As a result of this review, HHS is proposing to eliminate more than 1,000 pages (approximately 15 percent) and reinvent another 2200 pages (approximately 32 percent).

The changes recommended in this report reflect our commitment to achieve the goals noted above, while maintaining the critical health and safety protections the American people expect and deserve. Other potential reform initiatives are being actively considered within the Department at this time and I look forward to additional regulatory improvements in the months to come.

Donna E. Shalala

Attachment

9506010054



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

FROM: Kevin Thurm

SUBJECT: Report to the President on Results of Line-By-Line Review of Regulations--ACTION

#### PURPOSE

To request your signature on the attached memorandum to the President transmitting the Department's report on the line-by-line review of our regulations.

#### BACKGROUND

As part of his March 4, 1995, memorandum, the President directed all Federal Departments and Agencies to conduct an in-depth review of all regulations currently in force with the goal of eliminating or revising those that are outdated or otherwise in need of reform. The memo specified that a report, containing a chart of the regulations to be eliminated or revised, be submitted to the President on June 1, 1995.

This project has been a major undertaking for the Department. Using guidance provided by the National Performance Review, OPDIVs and Agencies have conducted the requested reviews and identified those regulations they believe should be eliminated or otherwise revised. A draft of this report was submitted to the Office of Management and Budget earlier this month for review and comment.

#### CONCERNS

OMB provided several general comments on the draft reports submitted by all the Departments and had some specific suggestions for our submission, concerning the Food and Drug Administration (FDA) and the Health Care Financing Administration (HCFA).

In the area of general concerns, OMB indicated that target dates for proposed actions to eliminate/revise regulations were too late (1997 and beyond even for preliminary actions such as Advanced Notices of Proposed Rulemaking (ANPRMs), the reports contained few recommendations for legislative/statutory changes; and many target actions were rather tentative (i.e., many ANPRMs as opposed to final or at least proposed rules).

With regard to the DHHS submission, OMB noted that neither HCFA nor FDA appeared to be proposing any additional substantive eliminations or revisions of their respective regulations, beyond those items already approved or publicized as part of the President's ongoing reform initiatives. Both HCFA and FDA were criticized for not proposing many significant legislative changes and OMB also commented on the lack of any proposals for welfare reform.

DISCUSSION

Following discussions with OMB on its review of the draft report, we asked each reporting OPDIV/Agency to take another look at their original submissions and make revisions to the extent possible to assure that target dates for proposed eliminations or revisions are as early as realistically practicable; to determine if there are and include any additional regulations that could or should be eliminated or revised; and to evaluate whether any of the actions listed as ANPRMs should be changed to at least proposed rules.

In response to the general OMB concerns, HCFA has revised a majority of its target dates to accomplish the actions proposed by September of 1996 and FDA has moved up some of its dates, as well as indicating timeframes for both proposed and final rules for actions they intend to take. HCFA has indicated that the major reforms of its rules were proposed as part of the Vice President's REGO II Regulations Workgroup, and there are no other significant candidates for elimination or revision at this time. HCFA made some late attempts to propose one or two legislative changes. However, there was not enough time for them to be properly reviewed and vetted, so there was general agreement not to include them in this report.

FDA has reconsidered its original intent to publish an ANPRM to cover all of its food standards regulations, seeking comment on eliminating or revising them. FDA now intends to directly propose elimination of about a dozen standards (involving oysters and fruit nectar) and publish an ANPRM by October of this year seeking comment on all the remaining food standards, including the one for green beans, on how and whether they should be revised or eliminated. [FDA is of the opinion that the green bean standard is in need of revision, rather than total elimination.]

While the attached report does not incorporate all of the changes recommended by OMB, particularly with respect to suggestions for additional regulations for elimination or revision, I believe it responsibly responds to the President's March 4 directive, and reflects a serious commitment by the Department to reform the way we do business to reduce regulatory burdens, without compromising the public health.

RECOMMENDATION

I recommend you sign the cover memorandum and forward the attached report to the President.

DECISION

Concur \_\_\_\_\_ Non-Concur \_\_\_\_\_ Date \_\_\_\_\_

Attachment:

Cover memo with Report to the President



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

MEMORANDUM FOR THE PRESIDENT

I am pleased to provide you with the report of the Department of Health and Human Services (HHS) on the in-depth review of our existing regulations, as requested in your memorandum of March 4, 1995.

HHS has been a significant contributor to, and supporter of, this Administration's efforts "to provide the American people a regulatory system that works for them and not against them."

Let me assure you that this Department remains committed to pursuing substantial reform of its regulatory system and rules to achieve the principles established in Executive Order 12866 and reaffirmed in your memorandum of March 4, 1995.

The attached report represents another step in HHS' efforts to institute real and lasting regulatory reform. These reforms are intended to reduce regulatory burden, and promote better communication, consensus building and a less adversarial environment.

This project was a significant undertaking for the Department and involved the review of more than 6900 pages in the Code of Federal Regulations. As a result of this review, HHS is proposing to eliminate more than 1,000 pages (approximately 15 percent) and reinvent another 2200 pages (approximately 32 percent).

The changes recommended in this report reflect our commitment to achieve the goals noted above, while maintaining the critical health and safety protections the American people expect and deserve. Other potential reform initiatives are being actively considered within the Department at this time and I look forward to additional regulatory improvements in the months to come.

Donna E. Shalala

Attachment

**REPORT OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES  
ON  
PAGE-BY-PAGE REVIEW OF REGULATIONS**

**JUNE 1, 1995**

# HHS Report on Review of Regulations

## HIGHLIGHTS

### INTRODUCTION

The Department of Health and Human Services began its comprehensive review of existing regulations with implementation of the President's Executive Order 12866 of September 30, 1993, on Regulatory Planning and Review. The goal of this review was to reduce regulatory burden while effectively meeting the health and human services responsibilities of the Department. To assist us in identifying priorities for our review of existing regulations, we solicited recommendations from the public on our plans for review in a January 20, 1994 Federal Register notice. More recently, on May 8, 1995, we again requested public comment on the Unified Agenda of this Departments' regulations, seeking suggestions for furthering regulatory reform efforts.

Our review accelerated with the establishment of regulatory reinvention task forces targeted at specific industries under the leadership of the Vice President. Working closely with the Domestic Policy Council, the Office of Management and Budget, and the National Economic Council, HHS played a lead role on two of these groups -- one on drugs and devices and one on the health care industry.

In response to the President's March 4, 1995, directive, HHS expanded its review to conduct an in-depth review of all regulations currently in force with the goal of eliminating or revising those that are outdated or otherwise in need of reform. This report conveys the results of this latest review.

This project has been a major undertaking for the Department. In accordance with the President's memorandum, and using guidance provided by the National Performance Review, we directed the relevant Operating Divisions/Agencies to conduct the requested reviews and identify those regulations they believe should be eliminated or otherwise revised.

In preparing this report we reviewed more than 6900 pages in the Code of Federal Regulations. As a result of this review, DHHS is proposing to eliminate more than 1,000 pages (approximately 15 percent) and reinvent another 2200 pages (approximately 32%).

Arranged by Operating Division/Agency, following are narrative highlights identifying the methods used for the review, the magnitude of the changes being proposed, selected examples of recommended changes, and the improvements expected as a result of these changes:

## HHS Report on Review of Regulations

### FOOD AND DRUG ADMINISTRATION

#### Actions Already Taken

Prior to the line-by-line review, FDA had already begun a number of actions during the Clinton Administration to review and streamline its regulations development process. These actions were aimed at both reducing the number and complexity of regulations as well as the burden placed upon regulated industry. They include:

- o A January 1993 examination of FDA's rulemaking process which resulted in new procedures for planning and tracking regulations, and the revocation of 100 outstanding proposed regulations.
- o Pursuant to the President's Executive Order on regulations review, FDA sought public comment in January 1994 on its individual program areas, to seek public advice aimed at identifying regulations that are outdated, burdensome, inefficient, or otherwise unsuitable or unnecessary. This resulted in a comprehensive retrospective review of the agency blood regulations.
- o In March 1995 the President announced a series of regulatory reforms aimed at reducing burden from FDA regulations on the drug and device industries. Most of those reforms will be accomplished through changes in FDA's current regulations, and one set of regulations, totalling 700 pages, will be eliminated entirely. It is estimated that those reforms will save the drug and device industries about \$500 million per year. Another set of reforms for the food and veterinary medicine industries is also being prepared.

#### Method of Review

Under the direct supervision of FDA's Deputy Commissioner for Policy, the agency convened groups of front-line regulators who were expert in each subject matter, to carry out an intensive, line-by-line review of the agency regulations. Their reviews were augmented by advice from the agency's attorneys, senior management officials, and program officials from all levels of the agency. In addition, the agency conducted a series of partnership meetings around the country to solicit advice from the food, drug, and medical device industries who make the products FDA regulates.

HHS Report on Review of Regulations

Magnitude of Recommended Changes

FDA's regulations are divided into two broad categories--rules guiding the marketing and production of the products regulated and marketing status of specific products. The former impose actual regulatory requirements, the latter merely contain lists of products approved or classified by FDA (e.g., animal drugs, food and color additives, medical device classifications, and over-the-counter drug monographs). With those divisions in mind, the agency's line-by-line review had the following results:

Total Pages in the Code of Federal Regulations (CFR)	- 3808
Minus Product Approval Lists/Classifications	- <u>1953</u>
Regulations (not approvals/classifications)	- 1855
Pages proposed for deletion	- 206
Pages proposed for reinvention	- 1170
Remaining pages unchanged	- 479

Thus, FDA proposes to delete or reinvent 74% of its rules that actually have a regulatory impact, including deleting entirely 11% of its rules guiding the marketing and production of regulated products. Further, if FDA were to cease publishing the product approvals in the CFR, the agency's portion of the Code could be reduced from 3808 pages to 1649, a reduction of 57% (i.e., the current nine volumes of FDA's CFR would be reduced to three volumes). This idea is currently under discussion at the agency.

Selected Examples of Changes and Expected Improvements

Listed below are some of the regulations scheduled for deletion or revisions and how those changes will be beneficial:

Product Licenses and Establishment Licenses for Biological Products - The agency is reinventing its procedures for applying for and receiving product and establishment licenses to make the process less burdensome and more user friendly to manufacturers. At the present time, the agency is planning to implement these innovations administratively by the issuance of a sequence of guidance documents, which will begin leaving the agency by the end of June. If it is later determined that regulations are necessary, notice and comment rulemaking will follow.

- HHS Report on Review of Regulations

Seafood Inspection -- Numerous pages of regulations detail the operation of a seafood inspection program that is being superseded by a new performance standard approach and can be eliminated.

Food Standards -- FDA has 270 pages of regulations establishing "recipes" for various foods, such as flour, fruit juices, canned fruits and vegetables, and other food staples. The agency will be proposing to eliminate 12 of these standards and is preparing to issue an Advance Notice of Proposed Rulemaking this summer seeking public comment on which of these remaining standards should be eliminated or shortened.

Milk Importation -- This regulation, resulting from an obsolete statute dating back dozens of years, poses unnecessary requirements. The statute and the regulation are being proposed for elimination.

Methadone Clinic Inspection -- Twenty-two pages of FDA regulations implement FDA's inspection program for methadone treatment clinics. In conjunction with the Interagency Narcotic Treatment Policy Review Board, FDA will redesign those regulations from the current Federal inspection regime to an accreditation program in which non-governmental bodies will carry out those inspections in the future.

New Animal Drug Approval -- The regulations overseeing the development and marketing approval of new drugs for pets and food-producing animals will be substantially reformed to make them more flexible and understandable for the producers of such drugs.

Radiation Emitting Electronic Products -- Many requirements governing recordkeeping and reporting of adverse experiences with radiation emitting products (such as televisions and microwave ovens) will be streamlined and made more useable by producers of those machines.

Cardiac Pacemaker Registry -- FDA will propose legislation to rescind regulations requiring pacemaker manufacturers to submit information to a registry of all pacemakers sold. The need for these regulations has been superseded by more recent legislation that accomplishes the same goal.

Intraocular Lenses -- 22 pages of regulations cover the investigational use of intraocular lenses. Those regulations have been made unnecessary by changes in the law and technology, and are no longer needed.

- HHS Report on Review of Regulations

Licensing Requirements for Biologics -- Due to technological advances in recent years, regulations overseeing the licensing of biologics (such as vaccines and drugs made from biotechnology) can be greatly streamlined and made more flexible for manufacturers of those drugs.

FDA's review of its regulations has resulted in a recommendation that over 1300 pages of the CFR be deleted or reinvented. Indeed, if one excludes the pages that essentially list product approvals or classification, such as new animal drugs approved for marketing, only 479 pages, or less than 15% of FDA's portion of the CFR will remain unchanged.

The impact of these deletions and reinventions is difficult to assess quantitatively. But many of the changes will reduce burden upon the regulated industry, make the remaining regulatory requirements more flexible or understandable for manufacturers trying to comply with them, and for other interested persons.

HEALTH CARE FINANCING ADMINISTRATION

Method of Review

HCFA's approach to the overall review was to have each Bureau/Office responsible for regulations review the specific CFR provisions under their purview. Components quickly met the challenge and performed a triage analysis of regulations before formulating an overall plan to meet the President's goals. In some cases recommendations reflect actions based on collaborative efforts, including public consultation with industry groups, beneficiary organizations, and State associations and agencies.

Magnitude of Recommended Changes

As a result of HCFA's review of approximately 1,611 pages of CFR regulations text (with approximately 1,539 pages reflecting actual regulatory text and the remainder reflecting tables of contents, statutory authority cites, and other information), we will: eliminate 397 pages (26%), and reinvent 525 pages (34%). The remaining 617 pages (40%) are unchanged. Viewed in terms of the CFR parts affected, of HCFA's 46 CFR parts we will eliminate 5 parts, reinvent 8 parts, and leave 6 parts unchanged. The remaining 27 parts will include a combination of these actions (i.e., reinvention, elimination, and no change). This represents a total reform effort to the CFR of 922 pages, or 60% of HCFA's regulations.

## HHS Report on Review of Regulations

### Selected Examples of Changes and Expected Improvements

Examples of burden reduction and other reinvented regulations that embrace the President's regulatory philosophy which have been published since E.O. 12866 went into effect or are soon to be published, and other administrative program enhancement initiatives include:

- Medicare regulations were revised to require a hospital to obtain, from each attending physician, only upon being granted admitting privileges, a signed acknowledgement that the physician understood the penalty for misrepresenting the information relating to principal and secondary diagnoses and major procedures performed on patients. This acknowledgement was previously required on an annual basis.
- Although eliminating the annual acknowledgement that hospitals had to obtain from attending physicians helped to eliminate an unnecessary "hassle" factor, physicians still must sign an "attestation statement" for each Medicare discharge from a hospital before the claim can be submitted. We are proposing to eliminate this requirement for the physician attestation entirely. The hospitals will be held solely responsible for accuracy of the diagnoses and procedures. Elimination of the physician attestation form will save almost 200,000 hours of physicians' time and hospitals will have improved cash flow and reduced labor costs.
- HCFA and the Centers for Disease Control and Prevention, which share responsibility for the CLIA program, have taken actions to continually reduce burden and improve the entire CLIA system. We have already reduced burden on laboratories in the following ways:
  - A flexible survey system that employs data analysis to target good performers and allows for self-attestation and off-site review has already been initiated for certain laboratories.
  - Information requirements have been reduced and we have eliminated unnecessary paperwork.
  - Final rules were issued in April 1995 that provide more flexibility in meeting education and training requirements for laboratory personnel.
  - The inspection process was revised and streamlined.

## HHS Report on Review of Regulations

We are now taking a number of additional steps to:

- Waive the biannual inspection of laboratories performing tests with certain accurate and precise technologies, and substitute a limited sample inspection of those testing systems. This will create incentives for manufacturers to develop more reliable testing equipment by stimulating demand for accurate and precise technological testing systems, and it will reduce paperwork and costs in small laboratories.
- Clarify and expand the waiver criteria and streamline the process so that more tests can be waived from CLIA requirements.
- Use information and education as a substitute for sanctions. We will use proficiency testing results for education and as an outcome indicator of laboratory quality. Sanctions will be imposed only in cases of immediate jeopardy or when the laboratory has refused to correct the problem or has had repeated failures on proficiency testing.
- Proposed regulations are under development for hospitals, home health agencies, and end stage renal disease facilities, that would eliminate unnecessary process requirements and instead develop outcome-based performance standards; collect and analyze patient care data needed for continuous quality improvement and performance evaluation; increase consistency of requirements across providers; and, ask the customer to provide input on what the outcome measures should be and to evaluate the services they received.
- Medicare and Medicaid inspections of health care facilities for all providers (except HHAs and nursing homes) are done using a flexible survey cycle. Providers with poor compliance histories and/or current consumer complaints are surveyed more frequently than providers with good performance records. A legislative proposal to extend the flexible survey cycles to HHAs is pending in the FY 96 budget package. We are not proposing flexible survey cycles for nursing homes due to the vulnerability of the nursing home population and historical problems with the quality of nursing home care.
- Revisions have been made to both the requirements nursing homes must meet to participate in Medicare and Medicaid and the rules for monitoring and enforcing these requirements.

## HHS Report on Review of Regulations

The improved participation rules focus on resident quality of care and quality of life using outcome-based performance measures where possible, rather than burdensome process standards.

- A final rule with comment period simplified the process of obtaining Medicaid home and community-based services waivers by eliminating the requirement that States document their actual or projected institutional bed capacity to serve beneficiaries in the absence of a waiver. HCFA also simplified the waiver cost neutrality formula. These changes enabled States to offer a wider variety of home and community-based services as cost-effective alternatives to more expensive institutional care. The changes will assist states in preserving the independence and quality of life for thousands of frail elders and persons with disabilities. These revisions reflected, in part, negotiations with the National Governors' Association and States.
- A final Medicaid eligibility regulation withdrew all Federal policy that would define a standard filing unit. States believe that this kind of flexibility will ease their burden from having to make major eligibility systems changes.
- In the Medicaid program, progress in making the survey and certification process more responsive to beneficiaries' needs enables us to drop the prescriptiveness contained in the Utilization Control regulations as they pertain to hospitals, nursing facilities, and intermediate care facilities for the mentally retarded. We are also eliminating associated utilization control penalty regulations.
- HCFA will reinvent the Medicaid program drug rebate dispute resolution process to make it more effective. We convened representatives of State Medicaid agencies, drug manufacturers, and pharmacies, and reached consensus on the steps which should be incorporated into a regulation to make the dispute resolution process more effective.
- The Medicaid Eligibility Quality Control process will be made less burdensome and more productive for States by relaxing prescriptiveness and freeing up State resources for greater concentration in continuous quality improvement in their Medicaid programs.
- We are re-engineering the Medicaid State Plan process in consultation with State programs. Under the new process, State Medicaid agencies will be able to amend most of their

## HHS Report on Review of Regulations

State Plans without sending the amendments to HCFA for approval. State Plan Amendments that will still have to be submitted to Regional Offices for approval are those that pose the greatest risk to Medicaid beneficiaries or expose the Federal government to high financial risk.

HCFA's regulatory reform efforts are resulting in significant improvements. With the strong encouragement and support of the Clinton Administration, HCFA has dramatically changed the culture within the Agency on developing new rules and reinventing existing rules. This culture change recognizes the needs of all affected parties. We are deeply committed to open consultation because we know that this is the best way to ensure our customers' concerns are expressed and fully considered. By doing so, we are able to issue workable rules that best meet the needs of all affected interests. The President's initiatives have created the right climate for a balanced approach that allows for the elimination of unnecessary burden on providers, while ensuring the best possible medical care to the American people.

### ADMINISTRATION FOR CHILDREN AND FAMILIES

#### Method of Review

ACF began its review of regulations in late 1993 following issuance of E.O. 12866. On January 20, 1994, the Department issued in the Federal Register a public call for comment on its plans for periodic review of regulations to minimize burden and improve effectiveness. ACF regulations were covered by this announcement, though public feedback was minimal.

More recently, ACF expanded these efforts in response to the President's March directive and have completed a review of all ACF-relevant parts of the Code of Federal Regulations. In the welfare arena, ACF took a cautious approach because of pending legislative deliberations which could have a major impact on related regulations. ACF identified some regulatory changes, but generally limited action to areas where interim reform would be consistent with the President's legislative plan.

ACF approached this latest review using a two-pronged approach. First, we identified those regulations which are truly obsolete. These represent regulations which have been overtaken by events such as statutory change but which have nevertheless remained in the Code of Federal Regulations. As provided below, a significant amount of regulatory language will be eliminated from this phase of our review.

## HHS Report on Review of Regulations

The second part of our strategy involved the review of our remaining regulations to identify those which could be reduced or streamlined to meet the objectives of regulatory reform. We challenged each of our program and staff offices to quickly examine their remaining regulations and to identify those specific rules which may hinder, rather than enhance program performance. Some of our program offices used this opportunity to solicit input into regulatory reform from their external partners and utilized the resulting feedback in determining appropriate action. These discussions involved an analysis of existing regulations and the development of a strategy for reinventing those regulations in a manner that was consistent with the President's Regulatory Reform initiative.

In addition, given our early adoption of the President's regulatory reinvention philosophy, we consistently work with focus groups, which include the public, regulated agencies and front-line regulators on new regulatory efforts before they are written. This early input has resulted in a major improvement in the quality and responsiveness of ACF regulations. This approach is reflected in the vast majority of regulations annotated on the chart (Tab C) as "reinvent."

### Magnitude of Recommended Changes

ACF is responsible for approximately 827 pages of material in the 1994 Code of Federal Regulations. As a result of our systematic review, 311 of these pages or 38% of the total will be deleted; 299.5 pages or 36% of the total will remain unchanged and 26% of the total will be reinvented. In terms of CFR Parts, this equates to 20 CFR Parts reinvented or (31%); 23 CFR Parts unchanged (36%); 17 CFR Parts deleted (27%); and, the remaining 4 CFR Parts, some combination of these actions (6%).

### Selected Examples of Changes and Expected Improvements

Since the President's 1993 Executive Order, ACF has dramatically revised its regulatory approach. Examples of recently published, or soon to be published, rules which embrace the regulatory philosophy of the directive, include:

- o A Child Support final rule published in December 1994 which significantly streamlined program audit requirements by eliminating process requirements in favor of a performance-driven assessment of services. This rule was developed based on input from States, the National Governors' Association and the American Public Welfare Association.

## HHS Report on Review of Regulations

- c. A Child Care final rule which is designed to eliminate and reduce barriers faced by States attempting to provide coordinated systems of child care services for low-income families. It was developed based on input received from several focus groups and meetings with major stakeholders.
- c. Computer System rules designed to reduce reporting and recordkeeping burdens on States (associated with the existing Advanced Planning Document process). These were developed based on an ongoing partnership started with the States approximately 18 months ago.
- o. An AFDC proposed rule which creates an administrative waiver process to give States greater flexibility in administering the program. It is consistent with an American Public Welfare Association committee recommendation to achieve consistency between AFDC and Food Stamp programs and suggestions obtained in meetings with State partners.
- o. A Refugee Resettlement final rule which eliminates certain requirements, providing greater flexibility to the States, and which was developed based on broad consultation with States, voluntary agencies, refugee organizations, and local governments.
- o. Family Preservation and Family Support rules which provide a consultative and coordinated approach to service planning and utilize a 5-year plan which consolidates all requirements of the two service programs under Part IV-B of the Social Security Act, based on broad consultation with members of 30 focus groups.
- o. Child welfare monitoring proposed regulations which will provide a performance orientation to service monitoring, with technical assistance provided in areas in which performance does not meet expectations and which is being developed utilizing focus groups.

Regulatory reform efforts have produced positive improvements in our rulemaking business. All new and reinvented rulemaking efforts are approached with a direct view to responding to the needs of our State and local partners and the public at large by employing a process that is open and reaches out to all involved parties. In tandem with this approach, we are actively seeking to reduce burden and focus on outcomes rather than process.

Direct improvements have resulted. For example, under our child care rule referenced above, we have removed regulatory barriers and helped States create seamless systems of child care services

## HHS Report on Review of Regulations

for low-income families. Our revised child support audit process responds to State concerns and Congressional interest and will allow us to move toward a result-oriented focus on State performance. Our review of advanced planning document requirements for State automation efforts will provide an emphasis on increasing leadership, technical assistance and program integrity while significantly streamlining the paperwork currently associated with this process.

While most of these achievements can't be quantified they are no less important to meeting the President's regulatory reform agenda. The cultural change which has resulted will continue to generate future regulatory improvement.

### PUBLIC HEALTH SERVICE (other than FDA)

#### Method of Review

Each of the Public Health Service (PHS) components with regulations under its jurisdiction performed a review. The Food and Drug Administration's results are covered separately.

The PHS agencies represented here are responsible for a relatively small number of regulations, many of which are vital to the protection of the nation's health and safety. A great deal of regulatory reform activity has been underway at PHS and additional activity was sparked by the President's initiative. PHS has now identified a significant number of unnecessary regulations as well as regulations which need to be reinvented.

#### Magnitude of Recommended Changes

1. Total NUMBER of CFR PARTS PHS has -- 43
2. NUMBER of CFR PARTS to be ELIMINATED -- 4
3. PERCENTAGE of CFR PARTS to be ELIMINATED as % of total CFR PARTS PHS has -- 10%
4. NUMBER of CFR PARTS to be REINVENTED -- 13
5. PERCENT of CFR PARTS to be REINVENTED as % of total CFR PARTS PHS has -- 30%
6. Total NUMBER of CFR PAGES PHS has - 611
7. NUMBER of PAGES to be ELIMINATED -- 123
8. PERCENT of PAGES to be ELIMINATED as % of total CFR PAGES PHS has -- 20%
9. NUMBER of CFR PAGES to be REINVENTED -- 308
10. PERCENT of CFR PAGES to be REINVENTED as % of total CFR PAGES PHS has -- 50%

## HHS Report on Review of Regulations

### Selected Examples of Changes and Expected Improvements

As the Vice President recently announced, PHS plans to combine 107 grant programs into six performance partnerships and eleven consolidated grants. This will significantly change the way PHS relates to the States and other grantees by greatly increasing flexibility and reducing reporting burdens. At the same time, the grantees will continue to be accountable to the taxpayer, through measures that focus upon performance rather than upon process. Of the 385 pages of regulations not already being eliminated or reinvented, 201 pages, over half, will be reinvented as a result of the consolidations, and a large reduction is likely. Many regulations being removed are obsolete or unnecessary in light of current program structure:

In addition to eliminating obsolete regulations, and in addition to consolidating grant programs, PHS has initiated several important regulatory and non-regulatory reinvention activities. For example:

#### Transferring Responsibilities From Federal Government to Tribes

An interagency negotiated rulemaking is currently underway pursuant to the Indian Self-Determination Contract Reform Act, with Indian tribes, the Department of Interior, and the Indian Health Service (IHS) participating. The results of this rulemaking will govern the transfer of administrative responsibility for Indians' health care and other service delivery programs from the federal government to the tribes. This significant de-centralization will result in the reinvention of 23 pages of the CFR currently under the jurisdiction of the IHS.

#### Simplifying Grant Application, Review and Reporting Requirements

\* Rather than reviewing State applications for the mental health block grant in Washington, the Substance Abuse and Mental Health Services Administration (SAMHSA) now conducts the reviews regionally, and allows the state mental health officers to participate. This eliminates the need for a great deal of time-consuming back-and-forth with far-away state officials, and has allowed SAMHSA to make grants as much as six months earlier in the year. SAMHSA is assessing the use of this process in connection with its other block grant program relating to substance abuse prevention and treatment.

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\* The Centers for Disease Control and Prevention (CDC) has developed a computerized application for the Preventive Health and Health Services Block Grant, so that states need simply fill in information on a series of computer screens. Once completed, the information is transmitted to CDC via server. In addition, CDC's contractor supplies as much of the requested data as is available from national databases, so that the State is asked to provide only that information which is not available from other sources, typically less than one-third of the data requested.

\* For the Maternal and Child Health Block Grant, the Health Resources and Services Administration (HRSA) previously required States to submit an annual, detailed plan and annual data report. HRSA has now adopted a streamlined application and annual report that greatly minimizes the burden of federal reporting on state and local governments. States now submit a detailed application every five years, rather than annually. During the intervening years, States report only on significant changes to goals and objectives. These revisions resulted from intensive consultations with stakeholders.

\* The National Institutes of Health (NIH) has developed uniform regulations for several classes of grants, so that the regulations will not need to be amended, as happened in the past, each time a new grant program is established and so that requirements will be consistent and more easily understandable for applicants. In addition, certain reporting requirements have been eliminated for research project grants, minority biomedical research support program grants, and NIH center grants.

### Updating Requirements for Respirators

CDC's National Institute for Occupational Safety and Health tests and certifies respirators to make sure they protect against the transmittal of disease. CDC's proposed new rule allows for performance-based specifications for respirators and for the replacement of outdated, design-specific requirements. CDC has worked closely with the Department of Labor, the regulated industry, and representatives of respirator purchasers and users in developing this proposed rule.

### Facilitating Industry/Government Research Partnerships

PHS has lifted the requirement that a "reasonable pricing clause" appear in all cooperative research and development

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agreements and exclusive licenses. After meetings with representatives of industry, consumer groups, and government scientists, PHS determined that the pricing clause had driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public. Eliminating this burden upon collaboration will foster public/private research partnerships and the swift transfer of technology from laboratory to marketplace.

### OFFICE OF THE INSPECTOR GENERAL

#### Method of Review

In an effort to eliminate or revise outdated regulations or those regulations in need of reform, the Office of Inspector General (OIG) and Office of the General Counsel has conducted a thorough page-by-page review of OIG regulatory authorities set forth in 42 CFR Chapter V.

In addition, through proposed regulations published on April 2, 1990 (55 FR 12205) and February 28, 1994 (59 FR 9452), the OIG solicited public comment and input on a major rewrite of both our program exclusion and Peer Review Organization (PRO) sanction authorities contained in 42 CFR parts 1001 and 1004, respectively.

#### Magnitude of Recommended Changes

Overall, we anticipate neither a significant reduction or increase in the number of pages setting forth the revised OIG regulations. The OIG has 60 pages in the CFR. Approximately 2 percent of the pages will be eliminated and 17 percent will be reinvented.

Rather than placing added burdens or requirements on the health care provider community, the development of both the additional "safe harbor" regulations and those clarifying aspects of the original safe harbors to 42 CFR 1001.952 will serve to provide additional interpretive guidance for compliance by health care providers with the Medicare and Medicaid anti-kickback statute. In addition, as part of our revisions to the PRO sanctions process, we will be adding regulations (amendments to 42 CFR part 1004) providing relief to health care providers by allowing a practitioner in specified rural areas to request a preliminary hearing prior to a PRO recommended exclusion action.

- HHS Report on Review of Regulations

As a result of this review, 4 of the 8 parts (50 percent) comprising Chapter V of the OIG regulations will remain unchanged. Significant sections of parts 1001 and 1004, as well as one section addressing the hearing and appeals process in part 1005, are being reinvented as part of this process (37.5 percent). Part 1003 will see the elimination of certain CMP authorities as discussed above (12.5 percent).

Selected Examples of Changes and Expected Improvements

The development of additional "safe harbor" regulations, and the clarification of the existing safe harbor provisions for codification in 42 CFR 1001.952 ~~serve as positive~~ examples of regulatory reform by the OIG. The intent of the safe harbor provisions is to clearly specify those payment practices that will not be subject to criminal and administrative prosecution under the anti-kickback statute. The regulations are designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. In doing so, the regulations impose no requirements on any party, but rather allow health care providers and others to voluntarily seek compliance with these provisions so that they have assurance that their business practices will not be subject to any enforcement action under the statute.

An additional example of positive regulatory reform can be found in the revisions to 42 CFR part 1004 in which the OIG is setting forth an alternative notification process that will allow sanctioned practitioners the option of informing their patients directly of a sanction action against them. If they choose this option, sanctioned practitioners would be exempt from the existing regulatory requirements for public notice of the sanction action.

ADMINISTRATION ON AGING

Method of Review

The Administration on Aging (AoA) began its regulatory review in 1993 in preparation for new regulations to implement the 1992 amendments to the Older Americans Act (OAA).

In line with the President's regulatory reform effort, we have focused our efforts on identifying those regulations which are obsolete, as well as those which could be reduced or streamlined. The process of regular dialogue with our partners (States, area

## HHS Report on Review of Regulations

agencies and tribal organizations), has provided AoA an opportunity to be more responsive to the needs of its 'customers' in the development of its regulations.

### Magnitude of Recommended Changes

AoA is responsible for approximately 23 pages of material in the 1994 Code of Federal Regulations. As a result of our systematic review, approximately 30 percent of the total pages will be deleted because of elimination or reinvention.

### Selected Examples of Changes and Expected Improvements

- Subpart B, § 1321.7 (Mission of the State agency) and Subpart C, § 1321.53 (Mission of the area Agency) currently contain very prescriptive language concerning the responsibilities of State and Area Agencies on Aging. We propose to revise the language of these subparts to include only a general objective statement and eliminate the prescriptive language.
- Subpart C § 1321.55 (Organization and staffing of the area agency) details requirements which restrict the capacity of area agencies on aging to build a comprehensive and coordinated service system at the local level. We propose to eliminate these requirements.

The impact of the regulatory reform effort will result in significant changes in the regulations to implement the OAA. Inherent in the OAA is the concept of a federal/state/local partnership. Recent efforts have built upon this concept and expanded the opportunities for our state and local partners to have input into the process of regulations development. The objective of our efforts has been the reduction of burden on our partners and a focus on outcome rather than process.

### SUMMARY

The Department of Health and Human Services has been a significant contributor to, and supporter of, this Administration's efforts "to provide the American people a regulatory system that works for them and not against them."

HHS remains committed to pursuing substantial reform of its regulatory system and rules to achieve the principles established in Executive Order 12866 and the President's memorandum of March

## HHS Report on Review of Regulations

4, 1995. This report represents another step in HHS' efforts to institute real and lasting regulatory reform. These reforms are intended to reduce regulatory burden, and promote better communication, consensus building and a less adversarial environment. The changes recommended in this report reflect our commitment to achieve these goals while maintaining the critical public health protections the American people expect and deserve. Additional reform initiatives are under consideration within the Department at this time and will be reviewed for possible future implementation.

Attached at Tabs A-F are the tables of the line-by-line reviews for FDA, HCFA, ACF, PHS (other than FDA), OIG, and AoA.

### Attachments:

- Tab A - FDA Tables
- Tab B - HCFA Tables
- Tab C - ACF Tables
- Tab D - PHS (other than FDA) Tables
- Tab E - OIG Tables
- Tab F - AoA Tables



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JAN 19 1995

**MEMORANDUM FOR THE PRESIDENT**

**SUBJECT: Block Granting Income Security Programs**

As many of us expected, the Republican welfare strategy has shifted yet again. Their initial bill from last year included training, time limits, and work requirements, and was similar in important respects to our own. The bill included in the Contract with America is mostly a plan that penalizes poor families and children by highly restrictive (some would say vindictive) eligibility rules and arbitrary cut-offs with no additional supports to help people get off and stay off welfare. Now they are moving toward a third strategy, converting many domestic programs, many of them entitlements, into discretionary block grants and leaving welfare reform to the states in a grand bargain with the governors.

We believe this may be a defining issue for your Presidency. The proposal you submitted last year has as its goal a nationwide transformation of the welfare system into one that emphasizes work and responsibility while protecting needy children and supporting parents who play by the rules. By contrast block grants largely abandon the hope of bold national change toward a welfare system more in keeping with the nation's values. Moreover, block grants would represent a profound and largely irreversible change in the policies designed to support low income families. In the end, we fear real welfare reform would not be achieved, and that both states and low income families could be far more vulnerable as a result of such a plan.

**The Emerging Republican Proposal**

Although their proposal is continually evolving, it appears that Republicans in Congress and selected Republican governors are currently discussing an alternative that creates three block grants, for cash assistance, food assistance and child care, and leaves open the possibility of six more block grants. The two block grant proposals that involve the most dramatic change from current policy involve cash assistance and food stamps. The proposal appears to have the following elements:

- ① fixed federal funding with annual spending caps for the programs included in the block grants (not a "swap" of both fiscal and programmatic responsibility);
- ② a shift from entitlement to discretionary status within the federal budget, with the implication that the annual spending caps come under the overall discretionary spending caps imposed by the budget, and thus compete with all

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other discretionary spending;

an allocation of these fixed federal funds to the states by formula, probably a formula based on state spending on the programs in a base year, perhaps with some adjustments over time;

dramatically increased flexibility for the states in administering these programs, including the freedom to eliminate any state matching funding for the programs and to define the groups eligible for help.

It's hard to overestimate how radical a change this would be. Since the establishment of the AFDC program in 1935 and the food stamps program in 1965, every needy family or individual who meets the requirements for the programs has been entitled to get help. The federal government has automatically adjusted its funding of these programs as the economy moved up and down and has matched state contributions to ensure that this commitment to support for the needy is a genuinely shared responsibility. And while the 1988 Family Support Act placed new requirements and responsibilities on individual recipients, it retained the central idea of an entitlement for individuals and states. A block grant proposal gives each state a fixed pool of money and leaves the states with virtually complete autonomy to decide who gets support and when, along with the complete fiscal burden for any spending above the grant.

### **The Appeal of Block Grants**

There are obvious advantages to changing the nature of the programs in this fundamental way, which make the block grant proposal attractive both to Republican members of Congress and to at least some governors. Block grants give enormous flexibility to the states and largely get the Federal government out of the business of determining welfare policy. States are eager for dramatically more flexibility to respond to their individual needs, circumstances and budget constraints. There are powerful and legitimate arguments that the Federal government has been too prescriptive and that the wide array of programs and rules has created needless bureaucracy and sometimes counterproductive impacts.

A second clear appeal of converting welfare into discretionary block grants is that it shrinks the federal government and controls federal costs. The proposal eliminates several entitlements and subjects the programs to the increasingly tight appropriations process; it can generate clear and immediate savings through direct budget cuts without the need to design practical programs that can be shown to actually get people off of welfare. In many ways, this proposal gets its proponents off the hook on welfare reform -- they neither have to embrace a plan similar to ours (giving you considerable credit), nor do they have to adopt the divisive and draconian plans that the most conservative members of their party are proposing.

Block grants could hold some appeal for our administration as well. In some respects they appear superior to the draconian cuts the Republicans have on the table now. And they seem consistent with your strong commitment to state flexibility. But such a plan holds considerable dangers.

## The Dangers of Block Grants

Block grants imply that we have no real national goals or vision for our social welfare system. But a national system has a critical role to play in reinforcing, protecting and supporting families struggling to achieve independence and in supporting and protecting states. As discussed below, block grants fail to protect vulnerable children, will not result in real welfare reform, and will not protect the states from economic changes. And eliminating the entitlement status of SSI, Medicaid, and food stamps along with AFDC will put millions of elderly, disabled, and working poor Americans at risk.

## Ending Welfare As We Know It

The current welfare system reinforces many of the wrong values and desperately needs to be transformed to emphasize work and responsibility. The federal government is certainly culpable in the current mess. But the states are equally responsible. Simply passing the buck to the states is not welfare reform.

- o *States could do considerable reform now, but efforts in most have been modest.* The states have had the flexibility through state options and waivers to fundamentally change their systems for years. Few have done much to really transform welfare. Every state could require work and training of nearly every recipient without any waiver at all. Yet only 17% of the caseload participates in the JOBS program each month.
- o *In the past, reform has been led by a few states which demonstrated a new and better vision, but large scale reform only came when the federal government insisted on real performance.* Your own leadership on the Family Support Act, for example, can be credited with starting state-level welfare reform. In areas from paternity establishment, to reduced error rates, to welfare to work programs, the history of reform is that the bulk of the states got serious only after the federal government insisted on improvements.
- o *Because many states face very tight budgets, there may be little room to invest in moving people off welfare.* If a block grant combines JOBS, AFDC and other resources, there is real danger that many states will opt for continuing benefit payments rather than spending new state money to pay for training and support services. It is often cheaper in the very short run just to write checks than to invest in training and job placement. The experience with the Family Support Act is quite revealing. Even with a very large federal match, many states did not draw down their entire allocation of JOBS money. They almost universally gave the reason that their budget situation did not allow it. With a block grant, every new dollar for welfare to work programs will have to come entirely from state funds.

The reasons states have been slow to change are many, but part of the problem involves resources and resolve. Fundamentally transforming welfare is difficult, unpredictable, initially costly, highly controversial, and potentially risky for the families involved (and the politicians). No wonder many in Congress would prefer to wash their hands of the whole problem. However, there are many valid reasons for a national framework for reform.

- o *Issues with a large interstate component require some federal role.* Some 35% of child support enforcement cases involve interstate claims. Only a national clearinghouse and tracking system can really do anything about such claims. Similarly a system of welfare where one state imposes time limits and another offers training while a third pays cash aid indefinitely plainly invites the needy to move between jurisdictions as benefits expire or requirements become serious.
- o *Without a federal vision and framework, it is hard to achieve any accountability.* Waste and fraud are nearly impossible to track in a few-strings-attached block grant where each state has its own wildly different program.
- o *Loss of a federal stake could lead to reduced commitment to training, child support and other activities.* Currently when the federal government spends money for child support enforcement or job training, it shares in any reductions in AFDC payments that are achieved because the program is a state and federal partnership. Unless the block grant will be reduced when child support collections rise or caseloads are reduced by training, there will be little direct fiscal benefit to the federal government from investing in child support or training. Thus the impetus for federal support for these activities could shrink.

#### Protecting States from Recession, Inflation, and Demographic Change

One of the least understood and most important benefits of the current federal role is the considerable protection it offers states during times of recession, inflation, and demographic change.

- o *Federal entitlement payments for Food Stamps and AFDC are automatic stabilizers.* When the economy dips in a state, federal dollars automatically move in early in ways that help maintain the economy and protect citizens. It is not uncommon for caseloads to rise 20 or even 40 percent in a year or two as a recession hits. The federal government pays an average of 80% of the benefits of AFDC plus food stamps. A block grant has no such stabilizing effect. The state will be faced with an even deeper recession since new federal dollars will not be flowing in. This will occur at the same time the state faces losses in tax revenues, and the need to pay the full cost of support for all the newly needy recipients. States may be forced to cut back on support at a time when private resources, both those of families and those of private charities, are significantly diminished. Inflation also cuts the real value of benefits over time, a process which would be exacerbated with a set block grant.
- o *Entitlement payments automatically adjust for demographic shifts.* Demographic changes caused by migration and immigration can radically change the population base of a state over time. States like Florida and California have seen massive changes in population.

Obviously what states do with policy can and does have effects on caseloads. But many of the forces that drive need are beyond the control of the states. A block grant could leave them quite vulnerable. Just how quick and serious the effects of recessions, demographics,

and inflation can be are shown in the accompanying table which illustrates what would have happened if a block grant had been set in 1987. Texas and Florida would have lost 46 percent and 61 percent of their federal dollars in FY93. Indeed, every state would have been worse off except for two: Wisconsin and Michigan. And those two states would have suffered if the block grant had instead been in place in the previous five years when the Midwest suffered from recession.

### Protecting the Vulnerable

Franklin Delano Roosevelt, a harsh critic of "the dole," once said, "Human kindness has never weakened the stamina or softened the fiber of a free people. A nation does not have to be cruel in order to be tough." The Catholic Bishops start with ensuring the basic dignity of the individual. Ronald Reagan talked of a safety net. For more than 60 years there has been a clear national commitment to a core foundation of protection. The elderly and disabled are assured some minimum level of economic support through SSI and Medicaid. Food stamps ensure that no Americans, regardless of their state of residence, need go hungry. AFDC calls for every state to provide some financial protection for needy children. Our health plan was based on the notion that everyone should have the security of basic health coverage.

Moving toward block grants seems likely to have the following consequences:

- o *Increased variability across states.* There is currently a huge variation in AFDC benefit levels across states, ranging from \$120 per month for a family of three in Mississippi to nearly \$700 per month in Connecticut. But food stamps helps to equalize the disparity in the amount families get, and federal rules ensure that every family who meets the requirements actually gets help, in the form of a food stamp benefit set nationally and a cash benefit set by the state. Complete flexibility to the states would almost certainly mean that some states would lower their already meager state contributions to benefit levels, and some states would completely eliminate eligibility for some groups of people. For example, many states have eliminated their cash General Assistance programs; under the proposal they could presumably eliminate food aid for single individuals, childless couples or other groups as well. Some states might well keep benefits low and restrict eligibility, in part to encourage poor families to move out. This is particularly a danger with block grants where states absorb 100% of the additional cost of additional beneficiaries.
- o *Declines over time.* State funded programs rarely keep pace with inflation and often get cut in recessions. A federal block grant subject to annual appropriations will be an easy target for further cuts at the federal level. By contrast programs like SSI and food stamps not only adjust for inflation, they automatically grow to meet increased needs in recessions. A related problem is that the lack of a federal match may induce states to reduce their contributions over time. In the relatively poorer states, each state dollar leverages four federal dollars. Without that match, one would expect state contributions to fall, perhaps quite significantly.
- o *Waiting lists or reduced benefits when funds run out.* One of the biggest dangers of capped block grants is that funds will run out at some point toward

the end of the year, forcing states to reduce benefits across the board, to place arbitrary time limits on benefit receipt, or to refuse to accept new applications. These actions would not only place hardships on the needy families affected, but could lead to families being treated very differently depending on the time of year they applied.

- o *Special hardships for the working and transitional poor.* The working poor and near poor are the last hired and first fired, and the most likely to need to apply for benefits in economic hard times. These are precisely the times when spending caps are likely to prove constraining. If states followed a policy of refusing to accept new applications once their allocation was spent, these newly poor would be the hardest hit.

Lossing the national uniformity of the food stamp nutrition protections would be particularly devastating. Food stamps really are the ultimate safety net. They ensure that serious hunger is not a feature of the American landscape. Allowing that to erode could have serious long term consequences for children and their futures.

#### **Alternative Approaches**

The obvious next question is whether the problems noted above could be solved within some sort of block grant and/or capped entitlement program, or whether the advantages of state flexibility and controlled spending could be achieved within the structure of an uncapped entitlement to individuals. There is considerable confusion over the moving parts in any move toward block grants. We think it helpful to distinguish between three types of programs:

*Discretionary block grants to states--*The most extreme alternative, and the one being urged by House Republicans, is to convert the various individual entitlements to discretionary block grants to states. Block grants would be determined annually as part of the appropriation process.

This sort of approach would be the most dangerous and the hardest to improve. It would make block grants subject to separate authorizing and an annual appropriations process under increasingly tight caps. And it would be difficult to adjust the grants to economic and demographic changes over time. Although language can be inserted in the authorizing legislation that grants would be adjusted in some fashion, money must be appropriated anew each year. The cap is set well before the funds are actually paid since the budget cycle precedes the fiscal year. It seems extremely difficult to imagine any sort of state funding formula which rapidly adjusts payments based on economic conditions under a discretionary block grant. Since an overall level must be set in appropriations, then any adjustable formula implies that each state's allocation will depend on what is happening in every other state. Without some sort of very complicated reserve/loan fund, we simply do not see how an adjustable discretionary block grant would work.

*Capped block grant entitlement to states with economic and other adjustments--*A number of capped entitlements to states exist. And they can take many forms. Most

recently the Family Support and Preservation programs created capped state entitlements. Our welfare reform bill included a capped entitlement for JOBS funds, and capped the emergency assistance program. With a capped state entitlement, funds are allocated according to some formula, and states may be required to match funds to receive federal dollars. The overall cap typically limits the maximum federal expenditure, with limits for each state often set by formula within that cap. In principle, entitlement spending caps could adjust semi-automatically for economic and demographic changes. (We proposed such a cap for the JOBS and WORK programs in the Work and Responsibility Act.) Other programs have triggers such as extended UI coverage.

Putting block grant funding on the entitlement side helps solve two problems. It eliminates the need for an annual appropriation and one can more easily adjust for changing economic and demographic conditions. Congress would set out some sort of formula for future funding, perhaps with adjustable caps, and unless Congress acts affirmatively to change the caps or formula, the money will automatically flow to states. Still, it is worth noting that capped entitlements have not fared particularly well in the budget process; for example, the level of funding for the Social Service Block Grant is at the same level today as it was when it was first established in 1977--nearly a 60% cut when adjusted for inflation. Moreover, the new concern about entitlements is likely to lead to as much scrutiny for those programs as for discretionary programs. This change, therefore, would do rather little to solve the underlying problems.

A more important advantage is that it would be much easier to create some sort of formula that adjusts for changing economic and demographic conditions. A state's grant would change over time as conditions and the formula dictated. Still there are three significant problems with operationalizing this notion. First, a formula would be very hard to devise, and would inevitably create winners and losers. An illustration of the problems can be seen in the nutrition block grant formula in the Contract with America: Texas loses over \$1 billion per year; California gains over \$600 million. Over time, the formula will inevitably help some states and disadvantage others.

The second problem involves the speed of grant adjustment. A practical adjustment mechanism would almost certainly adjust caps after the fact rather than simultaneously with economic and demographic changes. This could put almost as much of a strain on states as fixed caps, since states must balance their budgets on an annual basis.

The final concern is unpredictability. When we examine state by state variations in cash and food assistance spending over the last five years, it seems that some of the variation can be explained by unemployment rates and population growth, but much cannot. Clearly other economic, demographic or social changes were going on, in addition to policy changes. The obvious way to respond to changes in demand that cannot be predicted and subjected to formula ahead of time is to cap the per person benefit, but allow total funding to vary with the number of eligible people. This kind of flexible cap would be almost indistinguishable from the present system.

Most importantly an adjustable capped entitlement to states still offers limited protection for the vulnerable. States would still be free to provide as much or as little help as they choose under whatever conditions they determine. And it suffers from the accountability issues described earlier.

*Uncapped entitlement to individuals with greater state flexibility*—As under the current system, anyone who meets the eligibility requirements established by the state or federal governments would continue to automatically get benefits. However, an uncapped entitlement does not mean that restrictions cannot or should not be placed on eligibility. Individuals can be required to work, for example, under an entitlement. But there are many opportunities for increased state flexibility within the current funding mechanisms. The fact that it is uncapped and an individual entitlement is what provides the automatic stabilizer protection to states since more individuals become eligible as economic conditions worsen or populations grow.

States could certainly have more flexibility than they now have in setting AFDC eligibility rules, providing incentives for work and family responsibility, counting income and assets and designing work and training programs. Indeed, we proposed increased flexibility in a number of areas in the Work and Responsibility Act which could dramatically reduce the need for waivers. One could increase flexibility in other areas to provide the states with the administrative and programmatic flexibility they are asking for. This strategy offers the most protection for vulnerable populations and the states, but states may not get all the flexibility they desire. Since the programs are uncapped, either benefit rules would have to be set at the federal level (as is the case of food stamps which is 100% federal), or a state match would have to be maintained. Moreover, the need for accountability and some basic standards to ensure the money is going where it is intended is much greater in an uncapped than in a capped program.

Ultimately the arguments over entitlement versus discretionary funding, capped versus uncapped spending, individual versus state grants, boil down to difficult tradeoffs between fiscal prudence, state flexibility, and protections for the vulnerable. The further one goes toward block grants the more difficult it will be to protect recipients and states and to generate real welfare reform. Still, in some areas, such as the JOBS and WORK programs, we already embrace adjustable capped programs. In others, such as food stamps, moving to block grants would represent a profound change in national protections to both individuals and states. For the benefits portion of AFDC, the arguments for continuing the individual entitlement status are nearly as strong—we must have real protections for children and the states they live in, but we should create more flexibility.

States are only beginning to realize just how vulnerable a block grant system could leave them. One important goal over the next few weeks is to educate them about the consequences of moving toward block grants.

### **Articulating Our Vision**

The debate over welfare reform is becoming naive at best and quite ugly at its worst. Stereotypes and simplistic solutions abound in the sound bites. In no time in recent memory

has there been a greater need for Presidential leadership on this issue. We believe it is critical that you articulate a clear vision based on our shared values as a nation. In the State of the Union address, we hope that you sharply criticize the failed welfare system and articulate a positive vision for the future, as you have done so eloquently on other occasions.

We urge you to caution the nation against two natural but ultimately unacceptable reactions to the failures of welfare. The first mistaken direction is to become harsh or vindictive--the attitude that we need to simply cut people off without offering any alternatives, whether or not they have had a chance to get education or training they may need to get a job, whether or not they are physically able to work, whether or not there are jobs available. This sort of strategy divides rather than strengthens us as a nation.

The second is to simply wash our hands of welfare nationally and leave everything in the hands of the states. No one can speak with more credibility than you about the need to sweep away unnecessary federal regulation and the importance of greater flexibility for states, so that they can meet the unique challenges facing their citizens. But there is a larger national purpose which must not be lost. We as a nation must find a way to move people from dependence to independence, to guarantee aid to the disabled, to ensure that children do not go hungry, and to help states and localities in time of economic distress. We must change the basic values of welfare everywhere, in part because we are a large and mobile nation. We must accept the challenge posed by the struggles of those at the bottom, not simply walk away. There must be some national framework, with plenty of state flexibility within it.

Then you must be clear what we are for. We have proposed reform based on the most basic of American values: work and responsibility. You articulated that vision with power and clarity in Kansas City in a way that reaches across the political spectrum and continues to resonate with all sides of the political spectrum. Yet surprisingly few Americans know anything about our plan. All the polls show strong support for education and training with time limits and a requirement to work, coupled with strict child support enforcement, and a strategy to reduce teen pregnancy. Even very specific probing shows far more support for our approach than any other. The Republicans are vulnerable on the apparent vindictiveness of their plans, on their failure to include serious child support enforcement, and on the ultimate dangers to states and working families that come from abandoning any national framework. But until you make clear what we believe in and stand for, Republicans will control the debate, and we may get a bad plan that the public does not understand. The public needs to understand that ours is a plan which really is a hand-up not a hand-out, a plan which is tough *and* fair.

It might even be helpful to articulate a few questions that ought to be asked in evaluating any reform plan:

- o Is it really going to help turn welfare recipients in to taxpayers?
- o Does it first and foremost hold parents responsible--both parents--for the support and nurturing of their children?

- o Does it really tackle the problems of teen pregnancy and out-of-wedlock childbearing -- and help young parents become good role models for their children?

And centrally,

- o Does it reinforce the values of work, responsibility, family, and opportunity?

The debate is just beginning. We think this issue can and should be a "win" for all Americans. Bold change may really be possible for the first time in decades. Still, working in welfare makes anyone more modest--we don't have all the answers. Fortunately many choices we make in welfare reform are reversible. If time limits, work or training programs fail to meet the nation's goals, they can be changed. But fundamentally altering the state-federal partnership--by eliminating entitlement status, by block granting programs, by putting rigid caps on--these are changes which are unlikely to be reversed for a generation. If these ideas are adopted and they fail, it will be states, working poor families and children who suffer.



Donna E. Shalala

Hypothetical Impact in FY 1993 if an AFDC Block Grant Provision Similar to the Block Grant Option in the Personal Responsibility Act Had Been Adopted in FY 1988 Using FY 1987 Funding Levels

(amounts in millions)

State	FY 1993: Actual Federal Payments	Block Grant: 103% of FY 87 Level	Difference	Percentage Change
Alabama	\$79	\$57	(\$22)	-28%
Alaska	\$60	\$29	(\$31)	-51%
Arizona	\$200	\$65	(\$135)	-67%
Arkansas	\$50	\$42	(\$8)	-16%
California	\$3,205	\$2,157	(\$1,048)	-33%
Colorado	\$102	\$70	(\$32)	-31%
Connecticut	\$207	\$124	(\$83)	-40%
Delaware	\$23	\$15	(\$8)	-35%
Dist. of Columbia	\$67	\$52	(\$15)	-22%
Florida	\$517	\$202	(\$315)	-61%
Georgia	\$297	\$189	(\$109)	-37%
Guam	\$8	\$3	(\$5)	-63%
Hawaii	\$76	\$38	(\$38)	-50%
Idaho	\$24	\$18	(\$7)	-28%
Illinois	\$487	\$487	\$0	0%
Indiana	\$158	\$111	(\$47)	-30%
Iowa	\$111	\$110	(\$1)	-1%
Kansas	\$84	\$56	(\$28)	-33%
Kentucky	\$166	\$110	(\$56)	-34%
Louisiana	\$141	\$129	(\$12)	-8%
Maine	\$75	\$62	(\$14)	-18%
Maryland	\$190	\$147	(\$44)	-23%
Massachusetts	\$408	\$303	(\$106)	-26%
Michigan	\$751	\$777	\$26	3%
Minnesota	\$239	\$198	(\$41)	-17%
Mississippi	\$75	\$69	(\$6)	-8%
Missouri	\$189	\$146	(\$43)	-23%
Montana	\$37	\$30	(\$7)	-19%

NOTES:

The table estimates, for FY 1993, the hypothetical impact of a mandatory AFDC block grant provision similar to the block grant option in the Personal Responsibility Act, assuming implementation of the provision in FY 1988. The level of the block grant for each State is set at 103 percent of FY 1987 Federal payments for AFDC benefits and administration, unadjusted for inflation.

The Family Support Act was not in effect during FY 1987. To avoid overstating the impact of a block grant, Federal payments for AFDC work activities (WIN/JOBS) and AFDC-related child care are not included in either column.

Hypothetical Impact in FY 1993 if an AFDC Block Grant Provision Similar to the Block Grant Option in the Personal Responsibility Act Had Been Adopted in FY 1988 Using FY 1987 Funding Levels

(amounts in millions)

State	FY 1993: Actual Federal Payments	Block Grant: 103% of FY 87 Level	Difference	Percentage Change
Nebraska	\$46	\$41	(\$5)	-11%
Nevada	\$28	\$10	(\$17)	-63%
New Hampshire	\$31	\$12	(\$19)	-61%
New Jersey	\$341	\$298	(\$43)	-13%
New Mexico	\$94	\$45	(\$49)	-52%
New York	\$1,684	\$1,268	(\$416)	-25%
North Carolina	\$263	\$154	(\$109)	-41%
North Dakota	\$22	\$14	(\$8)	-38%
Ohio	\$626	\$522	(\$105)	-17%
Oklahoma	\$140	\$84	(\$55)	-40%
Oregon	\$146	\$92	(\$53)	-37%
Pennsylvania	\$561	\$506	(\$56)	-10%
Puerto Rico	\$65	\$59	(\$6)	-10%
Rhode Island	\$75	\$50	(\$25)	-33%
South Carolina	\$92	\$86	(\$6)	-6%
South Dakota	\$19	\$17	(\$3)	-14%
Tennessee	\$166	\$95	(\$71)	-43%
Texas	\$385	\$207	(\$178)	-46%
Utah	\$67	\$51	(\$15)	-23%
Vermont	\$42	\$31	(\$11)	-26%
Virgin Islands	\$3	\$2	(\$1)	-26%
Virginia	\$138	\$117	(\$20)	-15%
Washington	\$365	\$239	(\$126)	-35%
West Virginia	\$97	\$87	(\$10)	-10%
Wisconsin	\$289	\$348	\$58	20%
Wyoming	\$19	\$11	(\$8)	-43%
<b>U.S. TOTAL</b>	<b>\$13,834</b>	<b>\$10,243</b>	<b>(\$3,591)</b>	<b>-26%</b>

NOTES:

The table estimates, for FY 1993, the hypothetical impact of a mandatory AFDC block grant provision similar to the block grant option in the Personal Responsibility Act, assuming implementation of the provision in FY 1988. The level of the block grant for each State is set at 103 percent of FY 1987 Federal payments for AFDC benefits and administration, unadjusted for inflation.

The Family Support Act was not in effect during FY 1987. To avoid overstating the impact of a block grant, Federal payments for AFDC work activities (WIN/JOBS) and AFDC-related child care are not included in either column.