



~~2000~~ Reconciliation 1997 File

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

THE DIRECTOR

June 23, 1997

The Honorable Trent Lott  
Majority Leader  
United States Senate  
Washington, DC 20510

Dear Mr. Leader:

As the Senate begins consideration of S. 947, the spending-related portion of this year's budget reconciliation legislation, I am writing to transmit the Administration's views. We will transmit separately the Administration's views on the tax reconciliation bill.

While many provisions of the bill are consistent with the Bipartisan Budget Agreement, in some key areas others are not. We understand there are ongoing efforts to resolve as many issues as possible through a bipartisan Leadership amendment. Such an amendment would advance the bipartisan process which began last month with the Budget Agreement. The Administration intends to continue working closely with the Leadership on remedial amendments.

Key areas where the bill is inconsistent with the Budget Agreement include the failure to: "restore SSI [Supplemental Security Income] and Medicaid eligibility for all disabled legal immigrants who are or become disabled and who entered the U.S. prior to August 23, 1996"; assist low-income Medicare beneficiaries in paying premiums; provide Medicaid benefits for certain disabled children and the full 70 percent Federal match for Medicaid in the District of Columbia; properly implement the Medicare home health reallocation; provide for State SSI administrative fees; and achieve the agreed-upon levels of savings from spectrum auctions and related provisions.

In addition, we have significant concerns about a number of issues which the Budget Agreement did not specifically address: the lack of quality standards and protections against balance billing in private fee-for-service plans in Medicare Choice and in Medical Savings Accounts (MSAs); the added burden of new copayments for certain Medicare Part B and Medicaid beneficiaries; the higher eligibility age for Medicare recipients and the income-relating of the Medicare deductible; the failure to include all of the Administration's prudent purchasing reforms; the lack of a Federal Disproportionate Share Hospital (DSH) targeting standard; the failure to put the proper parties in charge of administering the welfare-to-work program; the proposal to privatize eligibility determinations in Texas; and the lack of adequate maintenance-of-effort requirements for Food Stamps.

The Bipartisan Budget Agreement is good for America, its people, and its future, and we are fully committed to working with Congress to see all of its provisions enacted into law by the August recess.

## Items Contrary to the Bipartisan Budget Agreement

Continued SSI and Medicaid Benefits for Legal Immigrants -- While the Senate reported provision giving benefits to new applicants for a limited time is preferable to the House provision, it fails to provide sufficient assistance for the most vulnerable individuals. The Budget Agreement explicitly states: "Restore SSI and Medicaid eligibility for all disabled legal immigrants who are or become disabled and who enter the U.S. prior to August 23, 1996." As the President stated in a June 20, 1997 letter, he views this issue as of paramount importance. As the letter states: "To achieve our common goal of a signable bill that balances the budget, it is essential that the legislation that is presented to me include these provisions. I will be unable to sign legislation that does not." The reported bill fails to reflect the Agreement. As a result, in 2002 it would protect an estimated 55,000 fewer immigrants than the Budget Agreement calls for.

In addition, the President's strong preference is to cover both elderly and disabled immigrants. We will work with you to identify the necessary resources to do so.

Assistance for Low-Income Medicare Beneficiaries -- Recognizing that premiums represent a significant burden on low-income beneficiaries, the Budget Agreement allocated \$1.5 billion to ease the impact on this population of increasing Medicare premiums related to the home health reallocation. The reported bill does not include this provision.

Medicaid Benefits for Certain Disabled Children -- The Budget Agreement clearly includes the proposal to restore Medicaid for current disabled children losing SSI because of the new, more strict definition of childhood eligibility. The reported bill failed to include this proposal. We strongly urge the Senate to include this provision and retain Medicaid benefits for about 30,000 children who could lose their health care coverage in FY 1998.

DC Medicaid -- We are pleased that the reported bill includes a higher matching payment for the Medicaid program in the District of Columbia, but we are concerned that the increase is not sufficient. The matching rate proposed in the reported bill sunsets at the end of FY 2000 and is 10 percentage points lower than the matching rate of 70 percent in the FY 1998 President's budget. A 60 percent matching rate would still leave the District paying more to the Medicaid program than any other local government.

Home Health Reallocation -- The home health reallocation in the Budget Agreement is not properly reflected in the reported bill. During the negotiations, we discussed at great length the shift of home health expenditures to Part B, and all sides clearly understood that it would be immediate. The Committee's phase-in would cost two years of solvency on the Part A trust fund -- two years that we can ill afford to lose. We urge the Senate to incorporate the same provision included in the House Commerce Committee reported title.

State SSI Administrative Fees -- The reported bill fails to reflect the provision of the Budget Agreement which calls for increasing the administrative fees that the Federal Government charges States for administering their supplemental SSI payments -- the proceeds of which would be available, subject to appropriations, for Social Security Administration (SSA) administrative expenses.

Spectrum -- While the Senate reported provisions are a substantial improvement over counterpart House legislation, we continue to have serious concerns. The reported language would not achieve the full \$26.3 billion in savings and policies described in the Budget Agreement. In addition, the bill does not include two of the proposals included in the Budget Agreement -- auction of "vanity" toll free telephone numbers and the spectrum penalty fee. Additionally, the bill does not provide a firm date for terminating analog broadcasting, thus causing significant savings reductions.

We also have the following additional concerns with the reported spectrum language: the lack of authority for the Federal Communications Commission (FCC) to use economic mechanisms, other than auctions, where appropriate (i.e., user fees to create incentives for efficient spectrum management); a very expansive definition of public safety that would create loopholes permitting too many entities to be exempted from auctions; language that would protect spectrum for use by the National Aeronautics and Space Administration and the National Oceanic and Atmospheric Administration, which is contrary to the Administration's policy on managing spectrum across the government through a process managed by the National Telecommunications and Information Administration; and the lack of authority for the FCC to revoke and reauction licenses when an entity declares bankruptcy, which is essential to preserving licenses awarded in previous auctions.

### Additional Concerns

Although the Budget Agreement did not specifically address the following items, the Administration has significant concerns about them. The Administration urges the Senate to address these concerns during Floor action.

#### *Medicare*

Private Fee for Service in Medicare Choice. While the Administration supports the introduction of new plan options for Medicare beneficiaries, we believe that any new options must be accompanied by appropriate beneficiary protections. We believe that inclusion of private fee-for-service plans in Medicare Choice without balance billing or quality assurance protections is bad policy. Beneficiaries should not be exposed to billing in excess of current law protections. Also, we are concerned that this option will attract primarily healthy and wealthy beneficiaries and leave sicker and poorer beneficiaries in the more expensive, traditional Medicare program.

Medical Savings Accounts. We believe that any demonstration of this concept should be limited in order to minimize potential damage and costs to the Medicare program. We commend the Finance Committee for limiting the demonstration to 100,000 participants, but still believe that a geographically limited demonstration would be much preferable. We are also pleased that the cost-sharing and deductibles for MSAs that have been reported are similar to the provisions that were enacted under the Health Insurance Portability and Accountability Act (HIPAA). We also strongly believe that the current law limits on balance billing should be applied to this demonstration to protect beneficiaries from being subjected to any additional charges providers choose to assess. We believe this demonstration should be limited geographically for a trial period which would enable us to design the demonstration to answer key policy questions.

Home Health Copayments. We note that the bill would impose a Part B home health copayment of \$5 per visit, capped at an amount equal to the annual hospital deductible. Medicare beneficiaries who use home health services tend to be in poorer health than other Medicare beneficiaries. Two-thirds are women, and one-third live alone. Forty-three percent have incomes under \$10,000 per year. We are concerned that a copayment could limit beneficiary access to the benefit. Imposing a home health copay is not necessary to balance the budget, and any further consideration of this policy should be part of a bipartisan process to address the long-term financing challenges facing Medicare.

Medicare Eligibility Age. Raising the eligibility age for Medicare is not necessary to balance the budget, and any further consideration of this policy should be part of a bipartisan process to address the long-term financing challenges facing Medicare. Moreover, this proposal does not contain provisions to address the fact that early retirees between the ages of 65-67 may not be able to obtain affordable insurance in the private market.

Prudent Purchasing. We applaud the bill's inclusion of our inherent reasonableness and competitive bidding proposals. However, we urge the Senate to take advantage of all the prudent purchasing proposals. The Medicare program is governed by a strict set of provider payment rules that have the effect of limiting the ability of the Federal government to secure the most competitive terms available to other payers in the marketplace. We have advanced a set of proposals to allow Medicare, the nation's largest health insurer, to also take advantage of lower rates providers offer to other payers.

Income-related Deductible. The reported bill includes a proposal to income-relate the Medicare Part B deductible. While the Administration is not opposed to income relating Medicare in principle, we have a number of concerns about this proposal. First, as the President mentioned yesterday, we believe this provision is outside the confines of the underlying budget agreement. Second, we are concerned that the proposal has design flaws. It would be extremely difficult to administer. Moreover, it may not achieve its intended purpose of reducing unnecessary utilization of services because the vast majority of beneficiaries have supplemental "Medigap" policies that pay for Part B deductible costs. While we do have serious concerns about this proposal, we remain interested in discussing it, or proposals like it, in the broader context of reforms to address the long-term financing and structural challenges facing the program.

Medicare Commission. The reported bill would establish a Medicare commission. Establishing a bipartisan process that is mutually agreeable is essential to successfully address the challenges facing Medicare. We look forward to working with you on the development of the best possible bipartisan process to address the long-term financing challenges facing Medicare while simultaneously ensuring the sound restructuring of the program to provide high-quality care for our nation's senior citizens.

Medicare Choice Payments. We would prefer to limit the growth in Medicare Choice payments to Fee-for-Service Medicare, rather than having two separate growth targets. To do so may lead to an erosion of the value of the Medicare choice benefit package and expose beneficiaries to increased premiums.

### *Medicaid*

Disproportionate Share Hospital Savings. We have concerns about the details of the allocation of the disproportionate share hospital (DSH) payment reductions among States. The bill may have unintended distributional effects among States. We recommend that the Congress revisit the FY 1998 President's budget proposal, which achieves savings by taking an equal percentage reduction off of states' total DSH spending, up to an "upper limit." Although the reported bill includes a provision to require States to develop DSH targeting plans, we are concerned that the bill does not include a federal DSH targeting standard. Without federal standards, providers with high-volume Medicaid and low-income utilization may not be sufficiently protected from reductions in the DSH program.

Medicaid Cost Sharing. The bill would allow States to require limited cost sharing for optional benefits. We are concerned that this proposal may compromise beneficiary access to quality care. Low-income Medicaid beneficiaries may forgo needed services if they cannot afford the copayments. We urge the Senate to revisit the FY 1998 President's budget proposal, which would allow nominal copayments only for HMO enrollees. This proposal would grant States some flexibility and would allow HMOs to treat Medicaid enrollees in a manner similar to non-Medicaid enrollees, without compromising access to care.

Criminal Penalties for Asset Divestiture. The reported bill would amend Section 217 of the HIPAA of 1996 to provide sanctions against those who assist people in disposing of assets in order to qualify for Medicaid. We would prefer to repeal Section 217 because we believe that the Medicaid laws in effect before the enactment of the Health Insurance and Portability and Accountability Act are sufficient to protect the Medicaid program against inappropriate asset divestiture.

Return to Work. We are pleased that the reported bill includes a provision allowing States to permit workers with disabilities to buy into Medicaid. We recommend the President's Budget proposal which would not limit eligibility for this program to people whose earnings are below 250 percent of poverty. We believe that this limit in the reported bill would not allow States sufficient flexibility to remove disincentives to work for people with disabilities.

Medicaid Payments to Puerto Rico and the Territories. We are pleased that the reported bill includes adjustments for the Medicaid programs in Puerto Rico and the territories, but we would prefer the language included in the FY 1998 President's Budget.

### *Children's Health*

We are encouraged that the Senate reported bill includes notable improvements over the provisions reported by the House Commerce Committee. Specifically, we commend the decision not to allow use of the \$16 billion investment in areas other than insurance coverage. In addition, we are pleased to note the improved definition of benefits relative to the House Commerce Committee provisions.

While the Senate-reported bill represents a positive step forward, we are particularly concerned about the benefits definition and the lack of low income protections. It is our hope that the intent of this legislation was to ensure that children receive a benefit package that is at least commensurate with the standard Blue Cross/Blue Shield FEHBP-benefit. However, the actual statutory language is much more limiting and would permit much less significant coverage. In addition, while the HHS Secretary would have discretion to define whether or not the benefit package meets the statutory requirement, she would not have the ability to ensure that low income children do not have to shoulder unrealistically high cost sharing that could lead to reduced access to needed health care. We also want to ensure that this investment is properly targeted to cover children who do not currently have health insurance. Finally, as the Administration has stated many times, we do not support limiting access to medically necessary benefits, including abortion services. We look forward to working with the Congress to resolve these important issues.

### *Welfare to Work*

Local Program Administration -- The challenge of welfare reform -- moving welfare recipients into permanent, unsubsidized employment -- will be greatest in our Nation's large urban centers, especially those with the highest number of adults in poverty. Mayors and other local elected officials, working with private industry councils, have been entrusted by Congress with the responsibility for administration of other Federal job training funds. The Administration strongly believes that a substantial amount of all Welfare to Work funds should be managed by these entities, which have the experience to address most effectively the challenge of moving long-term welfare recipients into lasting unsubsidized employment that reduces or eliminates dependency.

The committee reported bill, however, would provide for local administration of formula grant funds only through the Temporary Assistance for Needy Families (TANF) agency. The bill's competitive grant structure would not ensure that an appropriate portion of funds outside rural areas will be administered by cities with high concentrations of adults in poverty. The Administration is concerned that the reported bill provides that the competitive grant portion would be only 25 percent of the total funds available, still further limiting resources for cities

with the greatest need. The Administration urges the Senate to follow the approach taken by the House Ways & Means Committee which would increase the share of competitively awarded funds to 50 percent and set aside a substantial portion of these funds for cities with the highest poverty populations.

Performance Bonus. The Administration is pleased that the Finance Committee included a performance bonus concept. We are concerned, however, that the performance fund simply augments the existing TANF performance fund without establishing any new expectations on grantees for additional performance using these welfare-to-work funds, or rewards for placing the hardest-to-serve in lasting, unsubsidized jobs that promote self-sufficiency. In addition, the Administration agrees with the House that the way to administer welfare-to-work grant funds so as to have the greatest likelihood of success is through the Department of Labor, the mayors, and the private industry council system.

Federal Administering Agency. The reported bill would place the program under the authority of the Secretary of Health and Human Services. While consistency with Federal TANF strategies is essential, Welfare to Work program activities should be closely aligned with the workforce development system overseen by the Secretary of Labor. The Administration therefore believes that the Secretary of Labor should administer this program in consultation with the Secretaries of HHS and HUD (as in the House bill).

Non-displacement. We understand the Senate adopted non-displacement provisions during committee action. However, we strongly urge the Senate to adopt, at a minimum, the provisions included in the House Education and the Workforce Committee-reported bill, which apply both to activities under the new Welfare-to-Work grants and TANF.

Distribution of Funds by Year. It does not appear that the bill's allocation of \$3 billion in budget authority over fiscal years 1998-2000 would, when combined with the program structure, result in an outlay pattern consistent with an estimate of zero outlays in FY 2002, as provided in the budget agreement. The Department of Labor is available to work with staff to craft provisions that satisfy this agreement.

We are pleased that the reported bill includes provisions that would address priorities, including: the provision of formula grant funds to States based on poverty, unemployment, and adult welfare recipients; a sub-state allocation of the formula grant to ensure targeting on areas of greatest need; appropriate flexibility for grantees to use the funds for a broad array of activities that offer promise of resulting in permanent placement in unsubsidized jobs; funds awarded on a competitive basis; a substantial set-aside for evaluation; and a performance fund to reward States that are successful in placing long-term welfare recipients. We look forward to working with the Congress during conference to refine these provisions.

### *Minimum Wage and Workfare*

The reported bill appropriately refrains from modifying current law with respect to the application of the minimum wage and other worker protections for working welfare recipients under TANF. The Administration believes strongly that everyone who can work must work, and everyone who works should earn at least the minimum wage and receive the protections of existing employment laws -- whether or not they are coming off welfare.

### *Privatization of Health and Welfare Programs*

The reported bill would allow the eligibility and enrollment determination functions of Federal and State health and human services benefits programs in the State of Texas -- including Medicaid, WIC, and Food Stamps -- to be privatized. The Administration believes that changes to current law would not be in the best interest of program beneficiaries and strongly opposes this provision. While certain program functions, such as computer systems, can currently be contracted out to private entities, the certification of eligibility for benefits and related operations (such as obtaining and verifying information about income and other eligibility factors) should remain public functions.

### *Food Stamps*

While we support much of the Committee's approach to implementing the Agreement we are concerned that the proposal would create an estimated 100,000 fewer work opportunities over five years than proposed by the Administration's bill, which includes a specific target of 70,000 new slots each year. We are pleased that the Senate adopted a performance-based structure to reward States that provide employment and training (E&T) opportunities for individuals facing the 3-month food stamp time limit. This is highly preferable to the less accountable provisions in the House bill. The Senate's proposal should also be strengthened by conditioning receipt of the new 100 percent Federal E&T funds provided in the agreement upon a State maintaining 100 percent of their 1996 E&T spending. CBO estimates that the Senate's proposed 75 percent maintenance-of-effort requirement would result in States decreasing their E&T spending by \$89 million over 5 years. We urge the Senate to adopt provisions similar to the House maintenance-of-effort provisions.

### *Student Loans*

We are pleased that the reported bill includes \$1.763 billion in outlay savings, including \$1 billion in Federal reserves recalled from guaranty agencies, \$160 million from eliminating a fee paid to institutions in the Direct Loan program, and \$603 million in reduced Federal student loan administrative costs. All these savings are being achieved without increasing costs or reducing benefits to students and their families.

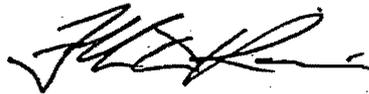
However, the Administration opposes a new provision, unrelated to the Budget Agreement, requiring administrative cost allowances (ACAs) to guaranty agencies in the Federal Family Education Loan (FFEL) Program at a rate of .85% of new loan volume, to be paid

from mandatory funding authorized under Section 458 of the Higher Education Act of 1965 (HEA) in FY 1998-2002. This provision would represent a new federal entitlement. It would also limit inappropriately the funds available to the Secretary to manage the FFEL Program effectively. Any allowance to these agencies should bear some relationship to the costs these agencies incur and not be based on an arbitrary formula. This is an issue for the upcoming HEA Reauthorization.

The Bipartisan Budget Agreement reflects compromise on many important and controversial issues, and challenges the leaders on both sides of the aisle to achieve consensus under difficult circumstances. It is critical that we do so on a bipartisan basis.

I look forward to working with you to implement this historic agreement.

Sincerely,

A handwritten signature in black ink, appearing to read 'Franklin D. Raines', written in a cursive style.

Franklin D. Raines  
Director

IDENTICAL LETTER SENT TO HONORABLE THOMAS A. DASCHLE,  
HONORABLE PETE V. DOMENICI, HONORABLE FRANK LAUTENBERG

## Addendum: Additional Comments

### *Housing*

We are concerned that the bill's provisions regarding FHA multifamily housing restructuring would not transform this housing in the most effective and efficient fashion. By ruling out the possibility of providing portable tenant-based assistance, the bill would limit the ability of tenants to seek out the best available housing and prevent projects from developing a more diverse mix of income levels. By establishing a preference for delegating restructuring tasks to housing finance agencies, the bill places an unnecessary constraint on HUD's ability to design the most effective partnerships. Finally, by failing to address tax issues explicitly, the bill does not resolve impediments that could discourage owners from participating in a restructuring process.

The administration is also concerned about Section 2203 of the Senate reconciliation bill which repeals federal preferences for the Section 8 tenant-based and project-based programs. The Administration has supported these repeals only if they are combined with income targeting that would replace the federal preferences. That targeting would ensure: 1) that the tenant-based program continues to serve predominantly extremely low income families with incomes below 30 percent of the area median income and 2) that all developments in the project-based program are accessible to a reasonable number of extremely low income families.

### *Unemployment Insurance Integrity*

The reported bill fails to support the provision of the Budget Agreement that achieves \$763 million in mandatory savings over five years through an increase in discretionary spending for Unemployment Insurance program integrity activities of \$89 million in 1998 and \$467 million over five years. We urge the Senate to include in the bill provisions to authorize and guarantee the discretionary activities and the resulting savings. The Administration separately transmitted draft legislative language on June 6th to implement this provision of the Budget Agreement.

### *Vocational Education and TANF*

The Administration is concerned with the reported bill's provision on vocational education in TANF. The agreement did not address making changes in the TANF work requirements regarding vocational education and educational services for teen parents.

### *Smith-Hughes*

The reported bill does not include a provision that would repeal the Smith-Hughes Act of 1917, although the bill finds the agreed-upon \$29 million savings from other sources. In light of the \$1.2 billion annual appropriations under the Carl D. Perkins Vocational and Applied Technology Education Act, there is no justification for mandatory spending of \$7 million per

year under the Smith-Hughes Act. We urge the Senate to adopt the provision included in the House Education and Workforce Committee reported title, which is consistent with the Budget Agreement.

### *Refugee and Asylee Eligibility*

The Agreement would extend the exemption period from five to seven years for refugees, asylees, and those who are not deported because they would likely face persecution back home. The Administration supports the reported language, which implements this policy and also extends the exemption to Cuban and Haitian entrants.

### *Other Immigrant Provisions*

We urge the adoption of a provision that would provide the same exemption period for Amerasian immigrants as provided to refugees. Amerasian immigrants share many of the problems and barriers confronted by refugees and have the same level of need as refugees. The Administration is pleased that the Committee bill exempts permanent resident aliens who are members of an Indian tribe from SSI program restrictions. We urge the Senate to extend this exemption to include the five year ban on eligibility for those who enter the country after August 22, 1996. Neither of these provisions will change the spending estimates associated with the Committee bill.

**HEALTH CARE: BUDGET STRATEGY**

**MEDICARE**

<b>Issues in Disagreement</b>	<b>Mark-Up Status</b>	<b>Policy Options and Process</b>	<b>Final Policy Goal</b>
<b>Medical Savings Accounts (MSAs)</b>	House Republicans will include program-wide MSA option, similar to what was included in the BBA. Rules governing MSA are currently unclear -- as is CBO scoring. House Dems will likely try to strike/alter provision.	Since Senate Finance may not have MSAs, taking an immediate position on a demo may be premature. NEC/DPC policy process reviewing acceptable demonstration options. Options will be available for Principal's sign-off as early as June 6th. In the interim, POTUS should raise major concerns with Members.	Eliminate the provision altogether or, if necessary to finalize an agreement on Medicare, develop an acceptable demo.
<b>Medical Malpractice</b>	Republicans will include a BBA-like provision in House mark-up. It will likely cap punitive and non-economic damages at \$250,000.	No policy development options underway or likely necessary, since Senate will not include in their version and will strongly oppose in conference.	Eliminate provision through a strategy designed to ensure that conferees recede to Senate.
<b>Academic Health Center "Carve-Out"</b>	The House Mark will not include our proposal to "carve out" the portion of managed care payments being credited to plans for their costs of contracting out with teaching and DSH facilities.	Not many policy options other than to either keep or eliminate the "carve-out." The Senate Mark will likely retain the President's provision. (High priority for Moynihan.) POTUS may want to stress as priority with Members.	Work to get conferees to recede to likely Senate provision.
<b>Home Health Reallocation</b>	House and Senate Republicans (with exception of Commerce Committee) will change our policy to phase in not only the premium increase, but also the actual transfer of home health expenditures. Change will reduce the life of the Trust Fund by about 2 years and undermine our policy rationale for the transfer.	Should continue to argue for our original policy and clear (through OMB and normal NEC/DPC process) strong position for HHS to take during Mark-Ups. NOTE: It certainly could be argued that Republican position is explicitly inconsistent with balanced budget agreement addendum.	Strongly push the Republicans to accept our current policy. If unsuccessful, use this as leverage for other issues. (The Republican approach will still probably extend the life of the trust fund until at least 2007).

Issues in Disagreement	Mark-Up Status	Policy Options and Process	Final Policy Goal
<b>Prudent Purchasing Reforms</b>	Republicans (and probably a number of Democrats) will likely reject the President's proposals to enhance Administration's ability to utilize market-oriented purchasing techniques (e.g., competitive bidding).	These provisions are a high priority to OMB, HHS, and have Administration-wide support. They illustrate our commitment to business-oriented mechanisms to purchase medical devices, lab services, etc. HHS should be empowered to continue to advocate for them, even though it will be very difficult to get Congress to respond. The meeting with the Members might be a good opportunity for the POTUS to push this initiative.	Although will be difficult to achieve, attempt to integrate all or most of the Administration's prudent purchasing provisions in the final bill. In so doing, secure "elite" validation that the Administration is committed to true structural reforms.
<b>Medicare Commission</b>	Republicans or Democrats may include language in the Mark or in subsequent amendments for the establishment of a bipartisan Commission to address long-term Medicare financing challenges.	NEC process that had been discussing these issues is being reconvened by Gene to consider options for both Medicare and Social Security, as well as how best to respond to Hill pressures.	Get out in front of the issue so that the President -- not the Congress -- has greater influence over the structure of any Commission. Ensure nothing gets passed on this issue that we cannot fully support. Preferably work out an agreement on the handling of this issue outside of the budget agreement.

**HEALTH CARE: BUDGET STRATEGY**

**MEDICAID**

<b>Issues in Disagreement</b>	<b>Mark-Up Status</b>	<b>Policy Options</b>	<b>Final Policy Goal</b>
<p><b>Disproportionate Share Hospital (DSH) Payment Reductions</b></p>	<p>\$15 billion in scorable DSH savings (roughly the amount we assumed) will require \$20 billion in dedicated cuts b/c of CBO 25% leakage assumption. Committees -- responding to heavy lobbying from the Governors and hospitals -- are reducing DSH cut to about \$9 billion by downsizing (non-kid) investments (see below) and increasing savings from flexibility provisions. Reportedly, allocation of remaining savings hits high DSH states quite hard.</p>	<p>NEC/DPC process reviewing all possible ways to reduce DSH cut without reducing any investments. This means we are focusing on additional flexibility options that CBO would score. Beyond the flexibility options we already assumed, our only other real option is to save \$5 billion by allowing states to use Medicaid rates (rather than Medicare rates) for dual eligibles. Problems include (1) Negative impacts on providers (and possibly beneficiaries) AND (2) A \$4.4 billion offset from Medicare.</p>	<p>Point out that the states won a big victory with the elimination of the per capita cap and push for all or most of the \$15-16 billion in DSH savings assumed in the budget agreement. Link these savings to need for better DSH targeting (outlined below) and the need to protect investments (also outlined below.)</p>
<p><b>DSH Targeting</b></p>	<p>Our rationale for relatively significant DSH savings was linked directly to our ability to better target the state spending of these dollars on those institutions that really did disproportionately serve the uninsured. Last night, we learned that the House Commerce Mark may have a modest targeting provision. (This is news, since we thought they would have none as a result of opposition from the Governors.)</p>	<p>HHS, OMB, DPC and NEC will review House targeting language as soon as available to determine adequacy. (Their provisions will likely be insufficient to respond to the concerns raised by the public hospitals, the children's hospitals, and the unions). We are in the process of developing alternatives. More likely, though, we will build off whatever the Hill starts with -- this is a major provider/union/state issue that is extremely complicated and formula driven.</p>	<p>To achieve the best possible agreement on targeting, most likely by pursuing a conference strategy. Final policy will likely not emerge until the very end.</p>

Issues in Disagreement	Mark-Up Status	Policy Options and Process	Final Policy Goal
<p><b>Medicaid investments</b></p>	<p>In order to reduce the size of the DSH cut, the House Republicans are reportedly planning on dropping <b>\$2.7 billion</b> in Medicaid investments for:</p> <ul style="list-style-type: none"> <li>-- D.C.(\$900 million),</li> <li>-- Puerto Rico (\$300 million), and</li> <li>-- Low income Medicare beneficiary protections (\$1.5 billion)</li> </ul> <p>that were called for in the budget agreement.</p> <p>So far, the Republicans have not reduced the dollars allocated for children's health (or other "below the line investments") to take care of their DSH problem. The House Republicans are planning to show the Governors budget tables that illustrate that with a new block granted children's program (with virtually no strings attached) they will have the same or more resources than they would have had with their DSH payments.</p>	<p>If the weekend reports are true, the House Republican Medicaid budget would be in clear violation of the budget agreement. Until the NEC/DPC process can meet to review the implications of these provisions (not until later this week), we of course would maintain our budget agreement position. The question is what, if anything, should the President say in his meeting with the Members on this subject?</p> <p>It is worth noting that both the Democratic and Republican staff on the Commerce Committee are asking us to consider using Medicare savings to offset the \$1.5 billion low income beneficiary protections cost. (This illustrates how difficult everyone is finding it to get savings from DSH.) If the Republicans include an MSA in their Mark-Up, one idea might be to use the savings from the elimination of the MSA to pay for this investment.</p>	<p>Protect most if not all the investments we won in the balanced budget agreement discussions.</p>

**HEALTH CARE: BUDGET STRATEGY**

**CHILDREN'S HEALTH**

<b>Issues in Disagreement</b>	<b>Mark-Up Status</b>	<b>Policy Options and Process</b>	<b>Final Policy Goal</b>
<p><b>Tax Deductions as Use for Some of the \$16 Billion Investment for Children</b></p>	<p>Despite the fact that CBO and other outside, independent validators have concluded that tax incentives are clearly not the most efficient policy option to insure children, the House Ways and Means Committee (Mr. Thomas) and the Finance Subcommittee on Health Chairman (Senator Gramm) seem intent on allocating between \$3-6 billion on tax deductions (including MSAs, under the Gramm approach) aimed at providing insurance for children.</p>	<p>The Thomas/Gramm approach is inconsistent with the budget agreement unless we explicitly alter our current NEC/DPC-cleared position against it. Our first priority is to ensure that we push the Committees back to the Medicaid and/or Capped-Mandatory approach that was outlined in the budget agreement. Tuesday's meeting would be a good time for the POTUS to say that tax approaches should be taken from the tax cut allotment (if used at all), rather than from the \$16 billion set-aside for kids.</p>	<p>Limit investment to either/or Medicaid or a new capped mandatory program, unless the funding for the tax incentive alternatives does not come from the \$16 billion children's health investment (and the alternatives are policy defensible).</p>
<p><b>Allocation of Investment and Optimal Children's Health Policy</b></p>	<p>Because Mark-Up is not until next week, we do not know exactly how the Committees of jurisdiction will allocate their dollars between Medicaid and a new grant program. It seems clear that Finance Committee will spend much more on Medicaid than on grants, and the Commerce Committee will do just the opposite.</p> <p>It also looks likely that the Finance Committee will place much greater accountability on the Governors to assure that dollars are used to pay for uninsured children (and not current state liabilities) and that they are spent on a "meaningful" benefit.</p>	<p>The NEC/DPC process is developing policy options for consideration by the Principals. We believe a policy that expands Medicaid to a certain, relatively low percentage of poverty, supplemented by a new capped grant program for children in higher incomes, seems to represent the most advisable policy.</p> <p>The NEC/DPC Deputy's policy team is reviewing options on targeting, state accountability, protection against state or employer substitution, benefits, etc. that could be ready for the Principals early next week.</p>	<p>To pass legislation that most efficiently and successfully provides a "meaningful" insurance benefit to the largest number of uninsured children.</p>

## HEALTH CARE CONCERNS

### CONTRARY TO THE BUDGET AGREEMENT

#### Medicare

- **Includes phase-in of home health reallocation.** The budget agreement did not include a provision to phase in the home health reallocation, which is included in both the House and Senate Committees' marks. It did include a provision to phase in the premium associated with this reallocation. By phasing in the reallocation itself, 2 years of Trust Fund solvency are unnecessarily lost.

#### Medicaid

- **Does not include Medicaid investments.** The budget agreement explicitly listed three investments: higher match for DC, inflation adjustment for Puerto Rico and the territories, and \$1.5 billion in premium assistance for low-income Medicare beneficiaries. The Commerce mark only included a portion of the premium assistance and, at that, the policy is unworkable. The draft Senate Finance Committee mark appears to have no provisions for the territories or premium assistance at all.

### OTHER MAJOR OBJECTIONABLE ITEMS

#### Medicare

- **MSA provision.** The Administration has concerns about the size (500,000) and scale of the demonstration. We believe that it should (1) have balance billing protections; (2) be limited geographically; and (3) be on a trial basis.
- **Home health copay (\$5 per visit).** The Budget Agreement limited the beneficiary contributions to the extension of the Part B premium and the premium increase associated with the home health reallocation. The Senate Finance Committee mark adds this provision, which we believe is at least inconsistent with the spirit of the budget agreement.
- **Private plan options.** The Senate Finance Committee mark includes a private plan option which clearly appears to allow for balance billing. We have consistently opposed any provision permitting physicians to bill above Medicare approved rates.
- **Raising Medicare eligibility age.** The Senate Finance Committee mark conforms the Medicare eligibility age with the Social Security eligibility age. We do not support this provision in the context of the balanced budget agreement. It was never discussed and it raises many issues that have not been thoroughly considered. For example, without policies to assure access to private insurance, many older Americans may become uninsured while waiting to enroll in Medicare.

#### Medicaid

- **No DSH targeting.** We support DSH reductions only if we are assured that the money remaining in the DSH program is targeted toward needy hospitals. There is no such provision in the Senate or House marks.

## **Children's Health**

- **Does not ensure funds are used for meaningful coverage.** Both the House and Senate marks do not require that the \$16 billion in funds be used for children's health coverage. They allow a direct service option that has no benefits package. The lack of accountability in the grant allows states to use the funds for services other than children's health coverage. For example, a state may use its grant as its share of Medicaid or to offset the reduction in DSH. [Relative to what has been offered, we prefer Rockefeller approach (Medicaid expansion)]

## HOUSE

## Items Contrary to the Bipartisan Budget Agreement

- **Immigrants** -- Ways and Means bill fails to cover legal immigrants who were in the U.S. when the welfare law was signed but who become disabled after that date and falls \$.7 billion short of the amount agreed to in the Budget Agreement.
- **Medicaid Investments** -- Commerce bill fails to include the Medicaid investments in the agreement (a higher Federal match for the D.C. Medicaid program and inflation adjustments for the Medicaid programs in Puerto Rico and the territories).
- **Assistance for Low-Income Medicare Beneficiaries** -- Commerce proposal for the Federal government to pay 100 percent of the "extra" amount of premium due to the home health reallocation is too administratively complex for the value of the benefit provided and spends only one-third of the \$1.5 billion investment included in the Budget Agreement.
- **Medicaid benefits for disabled children** -- Commerce fails to include the proposal in the Budget Agreement to restore Medicaid for approximately 30,000 disabled children who will lose SSI benefits under the new definition of childhood disability.
- **Home Health Reallocation** -- Ways and Means bill phases in the home health transfer from Part A to Part B, which takes two years away from the additional years of Part A Trust Fund solvency that would result from policies in the Agreement. (The Commerce Committee provision is consistent with the Agreement.)
- **Food Stamps** -- Agriculture Committee creates approximately 190,000 work slots, significantly less than the 350,000 in additional work slots for individuals facing the time limit in the Administration's proposal because it does not include any performance standards, as are included in the Administration and Senate proposals, and does not satisfactorily target the money to work slots for the targeted individuals.
- **Spectrum** -- The Commerce Committee-reported bill would save \$9.7 billion, or \$16.6 billion short of the level in the agreement. Major objectionable provisions include lack of reimbursement authority for Federal users forced to relocate and lack of hard cut-off date for analog broadcasting. In addition, the bill does not include two proposals agreed to in the agreement: (1) auction of vanity toll free telephone numbers; and (2) spectrum penalty fee. (Since the agreement, CBO has changed its scoring methodology to require specificity in the directed reallocation, which is causing reductions of several billion dollars in scoring.)
- **Welfare to work** -- Ways and Means proposal fulfills the terms of the Budget Agreement by targeting funds to urban areas through its split between formula (50 percent) and competitive (50 percent) grants; its formula grant sub-State allocation factors and method of administration; and its reservation of 65 percent of competitive grants for cities.

Education and Workforce proposal does not adequately fulfill the agreement because it reduces the competitive funding share from 50 percent to 5 percent. The Administration strongly prefers the Ways and Means proposal.

- **051/053** -- The House National Security Committee moves \$2.6 billion in 1998 budget authority intended to forward fund specific Department of Energy programs (subfunction 053) to Department of Defense military programs (subfunction 051) in HR 1119, the National Defense Authorization Act. The House Appropriations Committee shifts \$1.8 billion in BA to the Defense Subcommittee and \$.8 billion to the Military Construction Subcommittee. The Budget Agreement assumed that subfunction 053 would be funded at the President's request level, and that the additional spending in the agreement would go to Defense military activities.
- **Land Acquisition** -- The House Appropriations Interior Subcommittee has approved their FY 1998 bill without any of the \$700 million for priority land acquisition.
- **International Affairs funding** -- The House 602 (b) allocation appears to reduce international affairs funding by \$.5 billion below the FY 1998 level for function 150.

## HOUSE

### Other Major Objectionable Items

- **Minimum Wage and Workfare** -- Ways and Means and Education and the Workforce proposals deny the minimum wage to workfare participants by allowing States to either reduce hours of work requirements or count Medicaid/child care/housing/ etc. as income for calculating the minimum wage.
- **MEWAs** -- Education and the Workforce has adopted a proposal that would allow business members of multiple employer welfare associations (MEWAs) to form "association health plans," as provided for in H.R. 1515, the Expansion of Portability and Health Insurance Coverage Act of 1997. The Administration opposed a version of these provisions last year. The bill as drafted has inadequate consumer protections and has the potential to result in premium increases for small businesses and employees who may bear the burden of adverse selection.
- **Privatization** -- The Commerce bill allows all States to privatize Medicaid eligibility and enrollment determination functions. The Agriculture bill allows privatization of parallel Food Stamp functions. The Administration strongly opposes privatization of welfare eligibility determination and related functions.
- **Children's health (direct services)** -- The Commerce bill spends a portion of the children's health investment funds on direct services. The Administration is concerned that a State could spend all of its money on one benefit or to offset the effects of the DSH cuts on certain hospitals, and children would not necessarily get meaningful coverage. The Administration is also concerned that direct services may not be the most cost-effective way to expand coverage to children, as stated in the Budget Agreement.
- **Children's health (abortion)** -- Commerce bill extends the Hyde amendment to the \$16 billion children's health investment. The Administration opposes the Hyde Amendment.
- **Medicare Medical Savings Accounts** -- Commerce and Ways and Means Committee bills include an MSA demonstration that is too large, too expensive, and exposes beneficiaries to any additional charges providers choose to levy without limitation. The Administration strongly believes that the current law limits on balance billing should be applied to this demonstration and that it should be limited geographically for a trial period.
- **Medical Malpractice** -- Commerce and Ways and Means Committees have adopted the same medical malpractice provisions that the Administration opposed in the vetoed Balanced Budget bill and the House version of the Health Insurance Portability and Accountability Act (HIPAA).

- **Student loans** -- Education and the Workforce has adopted an objectionable provision regarding administrative cost allowances (ACAs) to guaranty agencies in the Federal Family Education Loan Program (FFELP). The provision would mandate ACAs to be paid at a rate of 0.85% of new loan volume from mandatory funding authorized under Section 458 of the Higher Education Act of 1965 (HEA), up to a cap of \$170 million in FY 1998 and 1999 and \$150 million in FY 2000-2002. This provision represents a new entitlement to these agencies not included in the Budget Agreement.
- **Welfare-to-Work Performance Fund** -- Ways and Means and Education and the Workforce proposals do not include a performance fund, which the Administration supports so that welfare to work funds generate greater levels of placement in unsubsidized jobs than States will achieve with TANF and other funds.
- **Repeal of Maintenance of Effort Requirement on State Supplementation of SSI Benefits** -- The Ways and Means Committee repeals the MOE which would let States significantly cut, or even eliminate, benefits to nearly 2.8 million poor elderly, disabled, and blind persons. The proposal also could put at risk low-income elderly and disabled individuals who could lose SSI entirely and thereby lose Medicaid coverage as well. The Administration opposed this proposal during last year's welfare reform debate.
- **Debt Limit extension should be included in the spending bill.** Currently it is only in the revenue bill reported by Ways and Means.
- **Expect consideration of two bills in the House.**

## SENATE

### Items Contrary to the Bipartisan Budget Agreement

- **Immigrant benefit restorations** -- The Finance bill fails to fully restore coverage for legal immigrants who were in the United States when the welfare law was signed but who become severely disabled after that date as called for in the Budget Agreement. The Committee adds SSI disability benefits for immigrants who were in the country before August 23 1996 who become severely disabled and who apply for benefits before September 30, 1997. This has a total cost of \$10.4 billion. It still falls short of the coverage under the Budget Agreement.
- **Medicaid investments** -- The Finance bill includes the Medicaid investments (a higher Federal matching payment for the Medicaid program in the District of Columbia and inflation adjustments for the Medicaid programs in Puerto Rico and the territories), but at spending levels below those in the Budget Agreement.
- **Assistance for Low-Income Medicare Beneficiaries** -- The Finance Committee bill fails to include the proposal in the agreement to spend \$1.5 billion over five years to ease the impact of increasing Medicare premiums on low-income Medicare beneficiaries.
- **Medicaid benefits for disabled children** -- The Finance bill fails to include the proposal in the Budget Agreement to restore Medicaid for approximately 30,000 disabled children who will lose SSI benefits under the new definition of childhood disability.
- **Home Health Reallocation** -- The Finance bill phases in the home health transfer from Part A to Part B, which takes two years away from the additional years of Part A Trust Fund solvency that would result from policies in the Agreement. (The Commerce Committee provision is consistent with the agreement.)
- **Spectrum** -- The Commerce Committee bill is estimated to save approximately \$16.8 billion, or \$9.5 billion short of the level in the agreement. While Senate bill is much improved over the House bill, the Senate bill does not include a hard date for analog termination. In addition, the bill does not include two proposals agreed to in the agreement: (1) auction of vanity toll free telephone numbers; and (2) spectrum penalty fee. (Since the agreement, CBO has changed its scoring methodology to require specificity in the directed reallocation which is causing reductions of several billion dollars in scoring.)
- **Welfare to Work Grants to Cities** -- House Ways and Means fulfills the terms of the Budget Agreement by targeting funds to urban areas through its split between formula (50 percent) and competitive (50 percent) grants; its formula grant sub-State allocation factors and method of administration; and its reservation of 65 percent of competitive grants for cities. The Finance bill reduces the competitive funding share from 50 percent to 25 percent. Additionally, the Finance Committee bill would provide for local administration

of funds only through the TANF agency, rather than mayors and other chief local elected officials working with private industry councils (PICs). The Administration strongly prefers the Ways and Means proposal.

## SENATE

### Other Major Objectionable Items

- **Privatization** -- The Finance Committee bill allows the State of Texas to privatize functions for all federal and state health and human services benefit programs -- including Medicaid, Food Stamps, and WIC. The Administration opposes privatization of the certification of eligibility for benefits and related operations (such as obtaining and verifying information about income and other eligibility factors).
- **Medicare Medical Savings Accounts** -- Although an improvement over the House version, the Finance Committee bill includes an MSA demonstration that exposes beneficiaries to any additional charges providers choose to levy without limitation. The Administration strongly believes that the current law limits on balance billing should be applied to this demonstration and that it should be limited geographically for a trial period.
- **Private Fee-For-Service Plans in Medicare Choice** -- Finance includes an objectionable provision that would allow private fee-for-service plans to participate in Medicare Choice without any balance billing protections. The Administration opposed this provision in the vetoed Balanced Budget bill.
- **Student loans** -- Labor and Human Resources includes an objectionable provision regarding administrative cost allowances (ACAs) to guaranty agencies in the Federal Family Education Loan Program (FFELP). The provision would mandate ACAs to be paid at a rate of 0.85% of new loan volume from mandatory funding authorized under Section 458 of the Higher Education Act of 1965 (HEA), up to a cap of \$170 million in FY 1998 and 1999 and \$150 million in FY 2000-2002. This provision represents a new entitlement to these agencies not included in the Budget Agreement.
- **Children's Health** -- The Administration would like to work to improve the Finance bill to achieve further improvements along the lines of the Chafee/Rockefeller proposal.
- **Children's health (abortion)** -- The Finance bill extends the Hyde amendment to the \$16 billion children's health investment. The Administration opposes the Hyde Amendment.
- **Unemployment Insurance Integrity** -- Senate Finance does not include the provision of the budget agreement that achieves \$763 M in mandatory savings over 5 years through an increase in discretionary spending for unemployment insurance "program integrity" activities of \$89 M in 1998 and \$467 M over five years. The House Ways and Means proposal includes this language.

The following provisions should be considered in the context of long-term reforms to Medicare:

- **Home Health Copayments** -- Finance imposes a Part B home health copayment of \$5 per visit, capped at an amount equal to the annual hospital deductible. These savings are not necessary to balance the budget.
- **Medicare Eligibility Age** -- Finance raises the eligibility age for Medicare from 65 to 67. These savings are not necessary to balance the budget.
- **Means Testing the Medicare deductible** -- Finance includes a new means testing provision for the Medicare deductible. These savings are not necessary to balance the budget and introduce significant administrative complexities for millions of Medicare recipients.

SCMB Done File**United States Senate**

WASHINGTON, DC 20510

June 19, 1997

The Honorable Trent Lott  
Majority Leader  
United States Senate  
Washington, DC 20510

Dear Trent:

Now that the Finance Committee has completed its work on the Medicare and Medicaid provisions of the budget reconciliation bill, we are writing to express our strong concern that the legislation does not provide the \$1.5 billion/five years for assistance to low income elderly Americans who will face higher Medicare premiums under the balanced budget agreement.

We note that the Conference Report to the Fiscal Year 1998 Budget Resolution assumed in Function 550 that there would be \$1.5 billion available for this purpose, which reflected the identical provisions in the House and Senate budget resolutions implementing this historic bipartisan balanced budget plan.

We are advised that there are about 8 million elderly Americans with incomes below 150 percent of the federal poverty line (up to \$11,835 annual income) who will face higher Medicare premiums if the reconciliation bill becomes law. Seniors with annual incomes from 100 percent to 125 percent of the poverty line are already spending 31 percent of their annual incomes on out-of-pocket expenses for health care. Within the group we are trying to help, two-thirds are women, one half are over the age of 75, and one half live alone. Many of these people will be unable to handle the Medicare premium increases without assistance from our government.

As the Senate prepares to consider budget reconciliation legislation next week, we urge you to take steps to ensure that the \$1.5 billion is added to the bill in order to keep our commitments to America's senior citizens.

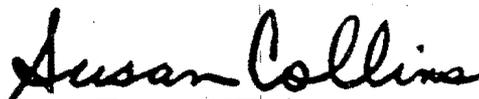
Sincerely,



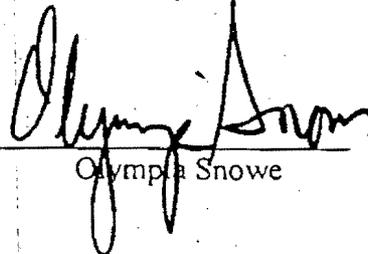
Rick Santorum



Arlen Specter



Susan Collins



Olympia Snowe

THE WHITE HOUSE

WASHINGTON

June 17, 1997

Dear Mr. Chairman:

I urge the Senate Finance Committee to adopt the bipartisan children's health amendment proposed by Senators Chafee, Rockefeller, Jeffords, and Hatch. As you know, I am extremely committed to using the \$16 billion for children's health to provide meaningful coverage for as many uninsured children as possible. The bipartisan amendment offers an opportunity to do just that.

It is critical that we continue to work together in this Congress to find ways to provide health care coverage for millions of uninsured children. As you know, over ten million children lack health care coverage -- and the impact on their families is profound. A recent study showed that nearly 40 percent of uninsured children go without the annual check-ups that all children need. One in four uninsured children do not have a regular doctor. And throughout the country, too many parents are living in fear that they may be forced to make the impossible choice between buying medicine for a sick child or food for an entire family.

Because of the importance of this problem, we need to work together to design the most effective way to invest the \$16 billion. The bipartisan amendment takes a major step toward this goal. This plan rationalizes Medicaid so that children in the same family are eligible for the same coverage. Children under 6 years old and under 133% of poverty -- about \$21,000 for a family of four -- are already eligible for Medicaid. The bipartisan plan provides incentives for states to cover older children up to this same income level. The plan also gives states the option of choosing Medicaid or a more flexible grant approach for uninsured, middle-class children. Resources and flexibility are needed because, unlike low-income children, middle class uninsured children are difficult to target with a single program. In addition, this bipartisan plan offers meaningful coverage that protects vulnerable children from excessive costs.

The bipartisan initiative -- which balances protections for vulnerable children with flexibility to target middle-class children -- stands in sharp contrast to the Commerce Committee's proposal. The plan to simply put out a block grant, with few rules and no benefits requirements, will not result in meaningful coverage for many uninsured children. While your proposal improves

The Honorable William V. Roth, Jr.  
Page Two

on the Commerce Committee's plan, the claim that it provides a choice between Medicaid and a grant approach is exaggerated. Given the incentives in the proposal, no rational state would choose Medicaid.

The bipartisan amendment merits strong and favorable support from the full Finance Committee. We should take advantage of this opportunity to significantly reduce the number of uninsured children. I look forward to working with you and others on the Finance Committee and in the Congress to achieve this end.

Sincerely,

A handwritten signature in black ink that reads "Bill Clinton". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

The Honorable William V. Roth, Jr.  
Chairman  
Committee on Finance  
United States Senate  
Washington, D.C. 20510



THE DIRECTOR

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

1997  
Reconciliation KIR letter

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June 11, 1997

The Honorable Tom Bliley, Jr.  
Chairman  
Committee on Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

I am writing to express the views of the Administration on the Medicare, Medicaid, and children's health provisions that were approved by the Subcommittee on Health and the Environment on June 10, for inclusion in the FY 1998 budget reconciliation bill.

Overall, the Administration finds much to support in the bill. It incorporates many of the proposals from the FY 1998 President's Budget and is generally consistent with the Bipartisan Budget Agreement. It proposes Medicare structural reforms that constrain growth, extends the life of the Hospital Insurance Trust Fund for at least a decade, and improves preventive care benefits. All of these changes will help strengthen and modernize Medicare for the 21st century. It also allocates the full \$16 billion for children's coverage policies within the Commerce Committee's jurisdiction, and thus, none of this important investment is dedicated to an inefficient tax approach.

However, as I noted in my letter to the Chairman and Ranking Member of the Health and the Environment Subcommittee, the Administration has concerns with several of the Medicare, Medicaid, and children's health provisions that your Committee will consider, including the following:

### Medicare

#### MSAs

While we have agreed to work to develop a demonstration of this concept for the Medicare population, we have concerns about the size and scale of the demonstration in the market. The Subcommittee's bill provides for a demonstration with 500,000 participants at a cost of approximately \$2 billion over five years, which is much larger than any other Medicare demonstration. In addition, the Subcommittee approved an amendment that extends the MSA demonstration from 4 years to 5 years. Moreover, the demonstration exposes beneficiaries to any additional charges providers choose to levy without limitation. We strongly believe that the current law limits on balance billing should be applied to this demonstration. We have suggested

limiting the demonstration to two states for a three-year period. We believe the demonstration should be limited geographically for a trial period, which will enable us to design the demonstration to answer key policy questions.

### **Medical Malpractice**

We believe that the malpractice provisions in the Subcommittee's bill are extraneous to the agreement. As you know, the Administration opposed the malpractice provisions in the vetoed Balanced Budget bill, as well as those adopted in the House version of the Health Insurance Portability and Accountability Act (HIPAA). We find these provisions highly objectionable, and we oppose them.

### **Preventive Benefits**

While the preventive benefits are largely the same as those advanced in the President's Budget, we bring to your attention the failure to waive coinsurance for mammograms. As you know, mammography saves lives, yet many Medicare beneficiaries fail to use this benefit. Research has found that copayments hinder women from fully taking advantage of this benefit. Thus, we continue to support waiving copayments for mammograms.

### **Prudent Purchasing**

As you know, the Medicare program is governed by a strict set of provider payment rules that limit the ability of the Federal government to secure the most competitive terms available to other payers in the marketplace. We have advanced a set of proposals to allow Medicare, the nation's largest health insurer, to also take advantage of lower rates providers offer to other payers. At a time when we all agree that Medicare spending has been growing too quickly and the Federal budget faces increasing pressures for scarce resources, we do not understand why the Subcommittee would not want to take advantage of all these proposals to allow Medicare to be a more prudent purchaser. We propose adopting practices that work in the private sector. We should let them work in the public sector as well. These practices can work well to save taxpayers money and promote quality.

We are pleased that our proposal to expand the "Centers of Excellence" program is included in the bill, but we urge the inclusion of the other proposals. We also note that the Subcommittee has added a durable medical equipment competitive bidding demonstration to the bill. However, we continue to believe that the rapid escalation of costs in this area would be more appropriately addressed by the President's proposal to authorize competitive bidding on a permanent basis across the country.

## **Commission**

We note that the Subcommittee's bill includes a Medicare commission. Establishing a process that is mutually agreeable is essential to successfully address the challenges facing Medicare. We look forward to working with you on the development of the best possible bipartisan process to address the long-term financing challenges facing Medicare while simultaneously ensuring the sound restructuring of the program to provide high-quality care for our nation's senior citizens.

## **Medicaid**

### **Investments**

After extended negotiations that preceded the Bipartisan Budget Agreement, the Administration and the Congressional leadership agreed to specified savings and investments in the Medicaid program over five years. The agreement clearly calls for a higher Federal matching payment for the Medicaid program in the District of Columbia and inflation adjustments for the Medicaid programs in Puerto Rico and the territories, but the Subcommittee failed to include these provisions. We strongly urge the Committee to include these proposals.

The bill does include a provision to ease the impact of increasing Medicare premiums on low-income beneficiaries as specified in the agreement. However, we are concerned that because of the way the proposal in the bill was drafted, low-income Medicare beneficiaries are not likely to be protected, as was intended in the agreement. The proposal in the Subcommittee's bill for the Federal government to pay 100 percent of the "extra" amount of premium due to the home health reallocation is too administratively complex for the value of the benefit provided. The cost of this provision, according to preliminary reports, is \$600 million, approximately one-third of the \$1.5 billion investment specifically included in the agreement. The Committee should include the full \$1.5 billion investment to ease the impact of higher Medicare premiums on low-income beneficiaries.

### **Disproportionate Share Hospital Savings**

We have concerns about the allocation of the disproportionate share hospital (DSH) payment reductions among States included in the bill. Although we agree that there have been abuses of this program in the past, taking such large reductions in certain states whose Medicaid programs are particularly dependent on DSH spending will likely affect their ability to cover services. We recommend that you revisit the FY 1998 President's Budget proposal, which ensures that the States with the highest DSH spending are not bearing most of the impact of the savings policy.

We are very concerned that your bill does not include retargeting of DSH funds. As the Administration has stated previously, we believe that significant savings from DSH payments

should be linked to an appropriate targeting mechanism. It is for this reason that we support proposals that assure that some DSH funds are directed to hospitals that serve a high proportion of low-income and uninsured patients.

### **Boren Amendment**

The Subcommittee bill does not repeal the Boren Amendment. The Nation's Governors have supported repeal of the Boren Amendment for many years, and the repeal was included in both the FY 1998 President's Budget and in the agreement. We are concerned that the Subcommittee's failure to include the repeal of the Boren Amendment will result in higher DSH cuts that could harm hospitals that serve a high proportion of low-income and uninsured patients. We want to work with the Committee to develop an acceptable compromise on this important issue.

### **Children's Health**

We believe that the \$16 billion investment in children's health should be used for health insurance coverage. It is for this reason that the Administration does not support the direct services option in the Subcommittee bill. We are concerned that a State could spend all of its money on one benefit or to offset the effects of the DSH cuts on certain hospitals, and children would not necessarily get meaningful coverage.

We are also concerned that the bill may not be the most cost-effective manner possible to expand coverage to children, as required by the agreement. The bill includes both a Medicaid and a grant option; however, the incentives in the bill could discourage States from choosing the Medicaid option. We believe that Medicaid is a cost-effective approach to covering low-income children, and would like to work with you on strengthening this option. We also believe that the grant program should be designed to be as efficient as possible. The provision that allows States to use funds for "other methods specified under the plan" with no details on what this means implies that States may use funds for purposes other than the intent of the agreement (e.g., to offset States' share of Medicaid). We would oppose this.

As the Administration has stated many times, we do not support limiting access to medically necessary benefits, including abortion services. We would like to work with the Congress to resolve this issue.

The Bipartisan Budget Agreement reflects compromise on many important and controversial issues, and challenges the leaders on both sides of the aisle to achieve consensus under difficult circumstances. It is critical that we do so on a bipartisan basis.

I look forward to working with you to implement this historic agreement.

Sincerely,

A handwritten signature in black ink, appearing to read 'Franklin D. Raines', written in a cursive style.

Franklin D. Raines  
Director

Identical letter sent to the Honorable John Dingell

## **Addendum**

### **MedicarePlus**

The Subcommittee's bill permits beneficiaries to be locked into a MedicarePlus plan for as long as 9 months, after a lengthy transition period. We continue to support the monthly disenrollment option as an important safety valve for managed care enrollees who are dissatisfied with their managed care plan. Moreover, we would support the ability of these enrollees to opt to purchase any Medigap plan of their choice upon disenrollment.

### **Medigap Reforms**

The President's bill advanced a number of important Medigap reforms including annual open enrollment (as well as including information about Medigap plans in the annual open enrollment season informational materials), community rating, open enrollment for disabled and ESRD beneficiaries when they become entitled to Medicare, and portability protections similar to those enacted last year in HIPAA for the under 65 population. Many of these important protections were also advanced by bipartisan bills including those sponsored by Representatives Johnson and Dingell. We urge your reconsideration of the merits of these proposals. They ensure that Medicare beneficiaries are able to purchase affordable Medigap policies to fill in the many areas not covered by Medicare. Medicare beneficiaries should be able to choose which Medigap plans to purchase, or MedicarePlus plans to enroll in, without artificial constraints.

### **Survey and Certification User Fee Proposal**

The Subcommittee bill does not contain a provision allowing HCFA to require state survey agencies to impose fees on health care providers for initial surveys required as a condition of participation in the Medicare program. This provision would authorize states to collect and retain fees from health care providers to cover the cost of initial surveys. Under the agreement, the discretionary funding level for HCFA Program Management assumes enactment of this mandatory, government receipt fee proposal.

### **Medicare Secondary Payer (MSP)**

The Subcommittee's bill limits the time period that Medicare can recover mistaken primary payments from the primary insurer to three years. Unfortunately, because we must utilize information from tax returns which is then matched against information from the Social Security Administration, by the time we receive data it is already one year, and sometimes two years, old. We must then match this information against Medicare files before a questionnaire can be sent to identified employers to determine if a Medicare beneficiary (or their spouse) had coverage through the group health plan of an employer. Thus, a three year limit on when Medicare could recover mistaken payments would effectively mean that no mistaken primary payments could be collected.

### **Hospital Outpatient Department (OPD) Coinsurance Waiver**

While we support allowing hospitals to reduce coinsurance for beneficiaries without being charged with a kickback violation, we would urge the Committee to include language barring such hospitals from charging the Medicare program for bad debt for such waived coinsurance. We suggest that hospitals make an election with the Secretary where they choose on an across-the-board basis for all beneficiaries to waive coinsurance and consequently do not bill Medicare for the waived coinsurance. Such a policy will permit proper monitoring on bad debt.

### **Mark-up of Drugs**

The Administration package contains a proposal to eliminate physician and supplier mark-ups for covered Medicare drugs. We made this proposal to eliminate excessive Medicare payments -- Medicare often pays 15 to 20 percent more than the physician's acquisition cost for the drug -- and to protect beneficiaries from excess charges. We appreciate the Subcommittee's interest in this issue, but we believe that the bill does not go far enough to eliminate excessive Medicare payments and does not contain the beneficiary protections that we believe are essential.



THE DIRECTOR

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

June 10, 1997

The Honorable Michael Bilirakis  
Chairman  
Subcommittee on Health and the Environment  
Committee on Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

I am writing to express the views of the Administration on the Medicare, Medicaid, and children's health provisions that will be considered by the Subcommittee on Health and the Environment on June 10, for inclusion in the FY 1998 budget reconciliation bill.

Overall, the Administration finds much to support in the Subcommittee's mark. It incorporates many of the proposals from the FY 1998 President's Budget and is generally consistent with the Bipartisan Budget Agreement. It proposes Medicare structural reforms that constrain growth, extends the life of the Hospital Insurance Trust Fund for at least a decade, and improves preventive care benefits. All of these changes will help strengthen and modernize Medicare for the 21st century. It also allocates the full \$16 billion for children's coverage policies within the Commerce Committee's jurisdiction, and thus, none of this important investment is dedicated to an inefficient tax approach.

However, based on our review of the June 6 version of the Chairman's mark, the Administration has concerns with several of the Medicare, Medicaid, and children's health provisions that the Subcommittee will consider, including the following:

Medicare

MSAs

While we have agreed to work with you to develop a demonstration of this concept for the Medicare population, we have concerns about the size and scale of the demonstration in the mark. The Subcommittee's mark provides for a demonstration with 500,000 participants, which is much larger than any other Medicare demonstration. Moreover, the demonstration exposes beneficiaries to any additional charges providers choose to levy without limitation. We strongly believe that the current law limits on balance billing should be applied to this demonstration. We also believe the demonstration should be limited geographically for a trial period, which will enable us to design the demonstration to answer key policy questions.

### **Medical Malpractice**

We believe that the malpractice provisions in the Subcommittee's mark are extraneous to the Bipartisan Budget Agreement. As you know, the Administration opposed the malpractice provisions in the vetoed Balanced Budget bill, as well as those adopted in the House version of the Health Insurance Portability and Accountability Act (HIPAA). We find these provisions highly objectionable, and we oppose them.

### **Preventive Benefits**

While the preventive benefits are largely the same as those advanced in the President's Budget, we bring to your attention the failure to waive coinsurance for mammograms. As you know, mammography saves lives, yet many Medicare beneficiaries fail to use this benefit. Research has found that copayments hinder women from fully taking advantage of this benefit. Thus, we continue to support waiving copayments for mammograms.

### **Prudent Purchasing**

As you know, the Medicare program is governed by a strict set of provider payment rules that limit the ability of the Federal government to secure the most competitive terms available to other payers in the marketplace. We have advanced a set of proposals to allow Medicare, the nation's largest health insurer, to also take advantage of lower rates providers offer to other payers. We are pleased that one of these proposals (expansion of the "Centers of Excellence" program) is included in the Subcommittee's mark, but we urge the inclusion of the other proposals.

At a time when we all agree that Medicare spending has been growing too quickly and the Federal budget faces increasing pressures for scarce resources, we do not understand why the Subcommittee would not want to take advantage of these proposals to allow Medicare to be a more prudent purchaser. We propose adopting practices that work in the private sector. We should let them work in the public sector as well. These practices can work well to save taxpayers money and promote quality.

### **Commission**

We note that the Subcommittee's mark includes a Medicare commission. Establishing a process that is mutually agreeable is essential to successfully address the challenges facing Medicare. We look forward to working with you on the development of the best possible bipartisan process to address the long-term financing challenges facing Medicare while simultaneously ensuring the sound restructuring of the program to provide high-quality care for our nation's senior citizens.

## Medicaid

### **Investments**

After extended negotiations that preceded the Bipartisan Budget Agreement, the Administration and the Congressional leadership agreed to specified savings and investments in the Medicaid program over five years. The Agreement clearly calls for a higher Federal matching payment for the Medicaid program in the District of Columbia and inflation adjustments for the Medicaid programs in Puerto Rico and the territories. We would urge the Subcommittee to include these proposals.

The mark does include a provision to ease the impact of increasing Medicare premiums on low-income beneficiaries as specified in the Agreement. However, we are concerned that because of the way the proposal in the mark was drafted, low-income Medicare beneficiaries are not likely to be protected, as was intended in the Agreement. The proposal in the mark for the Federal government to pay 100 percent of the "extra" amount of premium due to the home health reallocation is too administratively complex for the value of the benefit provided. The cost of this provision, according to preliminary reports, is \$300 to \$500 million, one-fifth of the \$1.5 billion investment specifically included in the Bipartisan Budget Agreement. The Subcommittee should include the full \$1.5 billion investment to ease the impact of higher Medicare premiums on low-income beneficiaries.

### **Disproportionate Share Hospital Savings**

We have concerns about the allocation of the disproportionate share hospital (DSH) payment reductions among States included in the mark. Although we agree that there have been abuses of this program in the past, taking such large reductions in certain states whose Medicaid programs are particularly dependent on DSH spending will likely affect their ability to cover services. We recommend that you revisit the FY 1998 President's Budget proposal, which ensures that the States with the highest DSH spending are not bearing most of the impact of the savings policy. We are also concerned that your mark does not include any retargeting of DSH funds. We support proposals that assure that some DSH funds are directed to needy hospitals.

## Children's Health

The Administration does not support the direct services option in the Subcommittee mark. We are concerned that a State could spend all of its money on one benefit or to offset the effects of the DSH cuts on certain hospitals, and children would not necessarily get meaningful coverage.

We are also concerned that the mark may not be the most cost-effective manner possible to expand coverage to children, as required by the Agreement. The mark includes both a Medicaid and a grant option; however, the incentives in the mark could discourage States from

choosing the Medicaid option. We believe that Medicaid is a cost-effective approach to covering low-income children, and would like to work with you on strengthening this option. We also believe that the grant program should be designed to be as efficient as possible. The provision that allows States to use funds for "other methods specified under the plan" with no details on what this means implies that States may use funds for purposes other than the intent of the Agreement (e.g., to offset States' share of Medicaid). We would oppose this.

Finally, we strongly oppose the sunset of the children's health provisions in the mark. It appears that the mark's funding for children's health expires in 2003. The Agreement includes \$38.9 billion in spending for children's health over ten years.

The Bipartisan Budget Agreement reflects compromise on many important and controversial issues, and challenges the leaders on both sides of the aisle to achieve consensus under difficult circumstances. It is critical that we do so on a bipartisan basis.

I look forward to working with you to implement this historic Agreement.

Sincerely,



Franklin D. Raines

Identical letter sent to the Honorable Sherrod Brown

## **Addendum**

### **MedicarePlus**

The Subcommittee's mark permits beneficiaries to be locked into a MedicarePlus plan for as long as 9 months, after a lengthy transition period. We continue to support the monthly disenrollment option as an important safety valve for managed care enrollees who are dissatisfied with their managed care plan. Moreover, we would support the ability of these enrollees to opt to purchase any Medigap plan of their choice upon disenrollment.

### **Medigap Reforms**

The President's bill advanced a number of important Medigap reforms including annual open enrollment (as well as including information about Medigap plans in the annual open enrollment season informational materials), community rating, open enrollment for disabled and ESRD beneficiaries when they become entitled to Medicare, and portability protections similar to those enacted last year in HIPAA for the under 65 population. Many of these important protections were also advanced by bipartisan bills including those sponsored by Representatives Johnson and Dingell. We urge your reconsideration of the merits of these proposals. They ensure that Medicare beneficiaries are able to purchase affordable Medigap policies to fill in the many areas not covered by Medicare. Medicare beneficiaries should be able to choose which Medigap plans to purchase, or MedicarePlus plans to enroll in, without artificial constraints.

### **Survey and Certification User Fee Proposal**

The Subcommittee mark does not contain a provision allowing HCFA to require state survey agencies to impose fees on health care providers for initial surveys required as a condition of participation in the Medicare program. This provision would authorize states to collect and retain fees from health care providers to cover the cost of initial surveys. Under the Bipartisan Budget Agreement, the discretionary funding level for HCFA Program Management assumes enactment of this mandatory, government receipt fee proposal.

### **Medicare Secondary Payer (MSP)**

The Subcommittee's mark limits the time period that Medicare can recover mistaken primary payments from the primary insurer to three years. Unfortunately, because we must utilize information from tax returns which is then matched against information from the Social Security Administration, by the time we receive data it is already one year, and sometimes two years, old. We must then match this information against Medicare files before a questionnaire can be sent to identified employers to determine if a Medicare beneficiary (or their spouse) had coverage through the group health plan of an employer. Thus, a three year limit on when Medicare could recover mistaken payments would effectively mean that no mistaken primary payments could be collected.

### **Hospital Outpatient Department (OPD) Coinsurance Waiver**

While we support allowing hospitals to reduce coinsurance for beneficiaries without being charged with a kickback violation, we would urge the Subcommittee to include language barring such hospitals from charging the Medicare program for bad debt for such waived coinsurance. We suggest that hospitals make an election with the Secretary where they choose on an across-the-board basis for all beneficiaries to waive coinsurance and consequently do not bill Medicare for the waived coinsurance. Such a policy will permit proper monitoring on bad debt.

### **Mark-up of Drugs**

The Administration package contains a proposal to eliminate physician and supplier mark-ups for covered Medicare drugs. We made this proposal to eliminate excessive Medicare payments -- Medicare often pays 15 to 20 percent more than the physician's acquisition cost for the drug -- and to protect beneficiaries from excess charges. We appreciate the Subcommittee's interest in this issue, but we believe that the proposal does not go far enough to eliminate excessive Medicare payments and does not contain the beneficiary protections that we believe are essential.

### **Institutions for Mental Diseases**

We are concerned that the mark includes a proposal to allow States to cover services in Institutions for Mental Diseases (IMDs) for people between the ages of 21 and 65 under the 1915(b) waiver authority. We believe that covering services in IMDs has significant Federal costs and could not meet the cost effectiveness requirements of these waivers.



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

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The Honorable James M. Jeffords  
Chairman, Committee on Labor  
and Human Resources  
United States Senate  
Washington, D.C. 20510

JUN 11 1997

Dear Senator Jeffords:

For the past several months the Administration has been working with the Senate Labor and Human Resources Committee on legislation to improve the performance and accountability of the Food and Drug Administration (FDA or the Agency), while preserving and enhancing the Agency's ability to protect and promote the public health. I appreciate the efforts that you, Senator Kennedy, and the other members of the Committee have made in this regard and believe that considerable progress has been made toward these goals.

The Food and Drug Administration Modernization and Accountability Act of 1997, S. 830, includes approximately 20 provisions that represent significant consensus reforms. Among the provisions that we all agree on are those that set forth the Agency's mission, codify reforms to the regulation of biotechnology products, provide expedited authority for the adoption of third party performance standards for device review and for the classification of devices, and streamline submission requirements for manufacturing changes and marketing applications for drugs and biologics.

I must emphasize that these provisions represent very significant reform, on which all parties have worked hard to reach consensus, and which I hope will not be jeopardized by insistence on other provisions on which we have not reached agreement.

Unfortunately, the Chairman's substitute to S. 830, also includes a number of provisions which as drafted do not reflect consensus and about which I have very significant concerns. Also, the current version is not "balanced" in that it does not take advantage of significant opportunities to strengthen current law so FDA can more effectively protect the public health. The most significant of the non-consensus provisions, summarized on the enclosed list, would undermine the public health protections that the American people now enjoy, by: 1) lowering the review standard for marketing approval; 2) allowing distribution of experimental therapies without adequate safeguards to assure patient safety or completion of research on efficacy; 3) allowing health claims for foods and economic claims for drugs and biologic products without adequate scientific proof; 4) requiring third party review even for devices that require clinical data; and 5) burdening the Agency with extensive new regulatory requirements that will detract resources from critical Agency functions without commensurate enhancement of the public health. Another significant nonconsensus item is the set of adjustment provisions in sections 703 and 704, which together require significant increases in FDA's appropriations levels over FY 1998 through 2002 (almost \$100 million above the FY 1998 Budget with

levels rising thereafter). We recognize that the ability of the FDA to commit to specific performance goals under PDUFA depends on the resources it will have available. We would support a user fee proposal that is consistent with our FY 1998 Budget proposal, but we are concerned that the proposal to collect user fees in this legislation imposes additional pressure on the fixed level of discretionary resources agreed to under the Bipartisan Budget Agreement.

We note the inclusion of the provision on pediatric labeling in the most recent version of the Committee mark. We believe it should be revised to assure a more appropriate system for testing drugs for pediatric use before they are prescribed for children.

I want to commend you and members of the Committee on both sides of the aisle on the progress we have made together to develop a package of sensible, consensus reform provisions that are ready for consideration with reauthorization of the Prescription Drug User Fee Act (PDUFA). We are interested and prepared to continue working with the Committee to reach consensus on additional issues — and have proposed acceptable alternative approaches to many of the objectionable provisions. My concern is the time for reauthorization of PDUFA is running perilously short. As I indicated in my recent letter to you, I am concerned that the inclusion of non-consensus issues in the Committee's bill will result in a protracted and contentious debate. This would not serve our mutual goal of timely reauthorization of PDUFA and passage of constructive, consensus bipartisan FDA reform.

A copy of this letter is also being sent to the ranking Minority member, Senator Kennedy, and the other members of the Senate Labor and Human Resources Committee.

Sincerely,



Donna E. Shalala

Enclosure

## S. 830 (Chairman's Substitute)

### A. Major Concerns

#### 1. Cumulative Regulatory Burdens/No Provisions to Promote Public Health

- many new regulatory burdens are being imposed on FDA (list enclosed) and little that can be advanced as promoting public health

#### 2. Third Party Review of Devices (Sec. 204)

- expansion of FDA's existing pilot project for review of medical devices (includes devices that require clinical data) by organizations accredited by FDA

#### 3. Approval Standard for Drugs/Biologics/Devices (Secs. 404/409/609/610/611/619)

- effectiveness standard for drugs and biologics needs further clarification; for supplements (applications for new uses) lowers standard such that they might not ever require a single investigation
- limits FDA authority to evaluate clinical outcomes for devices
- lowers approval standard for radiopharmaceuticals, including PET drugs

#### 4. Health Claims For Foods (Sec. 617)

- health claims not approved by the FDA but consisting of information published by authoritative government scientific bodies (e.g., NAS or NCI) would be permitted for use by companies in the labeling of food products, even if it is very preliminary

#### 5. Expanded Access to Investigational Therapies (Sec. 102)

- would allow drug and device companies to sell an investigational product for any serious disease or condition without FDA approval and without appropriate protections for clinical investigations

6. **Device Modifications (Sec. 601)**

- would allow companies to make manufacturing changes that affect a device's safety and effectiveness without FDA agreement

7. **Health Economic Claims (Sec. 612)**

- would allow industry to discuss health economic claims given to managed care organizations under a lower evidentiary standard and without FDA review, even if the claim compared the safety or efficacy of two drugs

8. **Pediatric Labeling**

would provide an incentive of six months of market exclusivity to encourage pharmaceutical companies to conduct necessary clinical trials for FDA approval of their products for children

- doesn't assure that necessary labeling for children will be included.
- might undercut FDA's ability to use other means such as regulations

**B. Other Significant Concerns**

1. Expanded Humanitarian Use of Devices (Sec. 103)
2. Device Collaborative Determinations/Review (Secs. 301/302)
3. Limitations on Initial Classification Determinations (Sec. 407)
4. Evaluation of Automatic Class III Designation (Sec. 604)
5. PMS (Sec. 606)

**C. Currently In The Bill - No Language Provided Yet**

1. Off-Label Use of Drugs (floor amendment expected)
2. Drug Compounding (amendment expected)

*In particular, etc*

DRAFT ----- DRAFT ----- DRAFT ----- DRAFT ----- DRAFT

Raines/Administration letter regarding S. 830

Dear Senator Jeffords,

I am writing regarding the Food and Drug Administration and Accountability Act of 1997, S. 830, which was reported by the Labor and Human Resources Committee on June 18, 1997. I understand that the bill includes a significant number of provisions that represent constructive, consensus reform designed to improve the performance and accountability of the Food and Drug Administration (FDA or Agency). We appreciate the efforts that you, Senator Kennedy and the other members of the Committee have made in this regard. As you know, improving the performance of Executive branch agencies, while preserving and enhancing our ability to protect health, safety and the environment, has been one of this Administration's highest priorities.

Unfortunately, I understand that the bill as reported contains a number of provisions which would undermine the public health protections on which the American public relies. The

*that go beyond the package of consensus reforms.*

~~provisions of greatest concern to the Administration were outlined in Secretary Shalala's letter to you dated June 11, 1997. Our concerns have not been addressed in the bill reported by the~~

*While progress has been made during the Committee's work on the bill, our concerns have not been addressed in the bill reported by the*

~~Committee. The Administration is prepared to continue to work with you, Senator Kennedy and the other members of the Committee, on a package of consensus reforms that could be enacted.~~

~~The Administration has significant concerns with some of the provisions of the Prescription Drug User Fee Act (PDUFA). Please understand,~~

*with some of the provisions of the Administration could not*

~~however, that our concerns are significant and the President could not sign this FDA reform~~

*support this bill*

~~legislation without those concerns being addressed. Moreover, I must reiterate, as the Secretary of the Prescription Drug User Fee Act noted in her letter, that time for reauthorization of (PDUFA) is running perilously short.~~

*out*

*The Prescription Drug User Fee Act*

*These provisions ~~are~~ In particular we have serious problems with (a) \_\_\_\_\_ + (b) \_\_\_\_\_*

I hope we will not jeopardize the opportunity before us to enact the PDUFA reauthorization with strong, constructive consensus reform because there continue to be issues on which consensus does not exist. Working together I am confident that we can achieve our mutual goal of FDA improvements that enhance performance and the Agency's ability to promote and protect the public health.

Sincerely,

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**MEDICAID IMPACT OF MEDICARE POLICY CHANGES WITH SLMB EXPANSION**

06-May-97

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	Total 1998-2007
<b>1 Medicare Policy</b>											
New Part B Premium	\$47.30	\$52.30	\$56.50	\$61.10	\$66.80	\$73.20	\$79.70	\$85.70	\$92.00	\$98.80	
Change from Current Law	\$1.50	\$5.20	\$8.00	\$11.10	\$15.30	\$20.20	\$25.10	\$29.50	\$34.10	\$39.10	
<b>Total Costs</b>	\$0.1	\$0.3	\$0.5	\$0.7	\$1.0	\$1.4	\$1.8	\$2.2	\$2.5	\$3.0	\$2.6
Federal Share	\$0.0	\$0.2	\$0.3	\$0.4	\$0.6	\$0.8	\$1.0	\$1.2	\$1.5	\$1.7	\$1.5
<b>2 Expand SLMB Program to 160% of Poverty - Current State FMAP</b>											
<b>Total Costs</b>	\$0.3	\$0.3	\$0.3	\$0.4	\$0.4	\$0.4	\$0.4	\$0.4	\$0.5	\$0.5	4.9
Federal Share	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.2	\$0.3	\$0.3	\$1.0
<b>Incremental Cost with New Premium</b>	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1	\$0.1	\$0.2	\$0.2	\$0.3	\$0.3	
Federal Share	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1	\$0.1	\$0.2	\$0.2	\$0.2
<b>Federal Share of Medicare Policy Changes</b>	\$0.0	\$0.2	\$0.3	\$0.4	\$0.6	\$0.8	\$1.0	\$1.2	\$1.5	\$1.7	\$1.5
<b>Total Federal Share</b>	\$0.2	\$0.4	\$0.5	\$0.7	\$0.9	\$1.1	\$1.4	\$1.6	\$1.9	\$2.1	\$2.6

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MAY-08-97 13:17 FROM: CBO/BAD/HRCEU

**DRAFT PRELIMINARY: Estimates of the Costs of Federalizing SLMB Coverage between 120-150% of Poverty**

Based on Preliminary Estimates from the Congressional Budget Office 5/6/97

(Dollars in billions, fiscal years)

	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	1998-2002	1998-2007
<b>EXPANSION to 150% OF POVERTY</b>												
Immediately	0.4	0.4	0.5	0.6	0.6	0.6	0.8	0.8	1.0	1.0	2.5	6.6
Phased In By 2002	0.1	0.2	0.3	0.5	0.6	0.6	0.8	0.8	1.0	1.0	1.7	5.8
Percent of Poverty	126%	132%	138%	144%	150%	150%	150%	150%	150%	150%		
Phased In By 2003	0.1	0.1	0.3	0.4	0.5	0.6	0.8	0.8	1.0	1.0	1.4	5.5
Percent of Poverty	125%	130%	135%	140%	145%	150%	150%	150%	150%	150%		
Phased In By 2004	0.1	0.1	0.2	0.4	0.4	0.5	0.8	0.8	1.0	1.0	1.2	5.2
Percent of Poverty	124%	129%	133%	137%	142%	146%	150%	150%	150%	150%		

**NOTES:**

Based on premiums and cost estimates on the May 6, 1997 "Medicaid Impact of Medicare Policy Changes with SLMB Expansion"

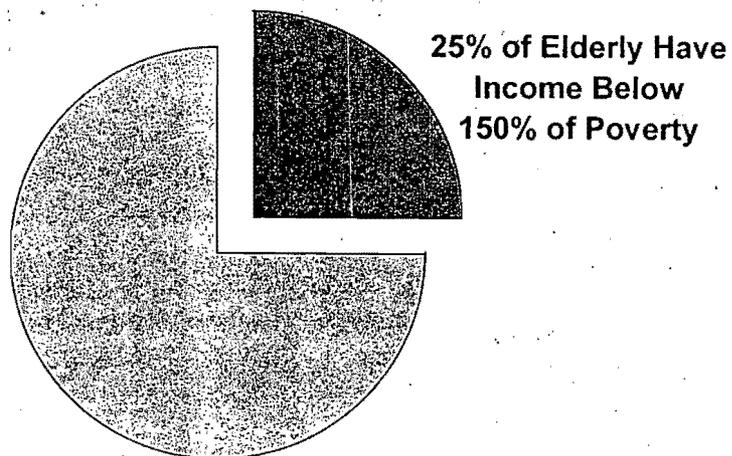
Assumes 25% increase in cost due to increased participation from full Federalization

Assumes that beneficiaries are evenly distributed in the income bands between 120 and 150% of poverty.

## MEDICARE PREMIUMS IN THE BUDGET AGREEMENT

- The Budget Agreement includes significant structural reform in Medicare. It keeps the Medicare Part B premium at its current level of 25 percent of program costs. This is far below the 31.5 percent premium that the President vetoed in 1995.
- These premiums are very reasonable and significantly below the vetoed 1995 Republican budget's premiums — around \$20 below per month in 2002 or around \$240 per year.
- The Agreement also gradually includes home health spending transferred to Part B of Medicare in the premium.
  - By phasing in the premium, home health is treated like all other Part B spending.
  - The premium only increases by about a \$1 per month per year due to the phase in.
- Medicaid's premium protection for low-income Medicare beneficiaries is expanded from its current 120 percent to 150 percent of poverty. This protects over 8 million Medicare beneficiaries.

### One In Four Medicare Beneficiaries Assisted With Medicare Premiums



**Preliminary Options to Extend Medicare Premium Assistance to  
Low-Income Beneficiaries**

The following are preliminary ideas on how Medicare premium assistance can be extended to low-income Medicare beneficiaries. All options assume (a) that the Federal spending over 5 years is \$1.5 billion and (b) the funding is given to states through either Medicaid or grants.

1. **Immediately extend SLMB program to 135% of poverty, with 100% Federal matching rate**

States would be required to cover premiums for Medicare beneficiaries between 120 and 135% of poverty. This spending would be fully matched at 100% by the Federal government.

2. **Gradually extend SLMB program to 150% of poverty, with 100% Federal matching rate**

States would be required to cover premiums for Medicare beneficiary between 120 and 150% of poverty phased in using 5% increments by 2003 (e.g., in 1998, 125% of poverty, in 1999, 130% of poverty, etc.). This spending would be fully matched at 100% by the Federal government.

3. **Gradually extend SLMB program to 150% of poverty, with current law Federal matching rate and grant**

States would be required to cover premiums for Medicare beneficiaries between 120 and 150% of poverty. This spending would be matched at the current law rates. However, states would receive a grant that would offset the full amount of the state share (this is the same as option two, except that the extra amount is administered through a grant rather than a matching rate increase).