Chairman's Modifications To:
The Prescription Drug and Medicare Improvements Act of 2003

Title I - Medicare Prescription Drug Benefit

(1) Section 1860D-5. Beneficiary Protections (page 5)

The appeals process would include an external appeal as under Medicare+Choice.

(2) Section 1860D-6. Prescription Drug Benefits (page 7)

In 2006, "standard coverage" would be defined as having a $275 deductible, 50% cost-sharing for drug costs between $276 and the initial coverage limit of $4,500, then no coverage, except that beneficiaries would have access to negotiated drug prices, until the beneficiary had out-of-pocket costs of $3,700; and 10% cost-sharing thereafter.

The limitation on the deductible and out-of-pocket expenditures would be the same as under standard coverage.

(3) Section 1860-9. Premium and Cost-Sharing Subsidies for Low-Income Individuals. (page 16)

Eligibility for low-income individuals would be determined by states and the Social Security Administration. A BIPA requirement that the Commissioner of Social Security would identify and notify individuals entitled to benefits under the Medicare Savings Program would be amended to include individuals eligible for low-income assistance under Part D.

(4) NEW SECTION (page 18)

Medicaid Coverage Maintenance

Any State that has above expanded coverage above the minimum income level for low-income Medicare beneficiaries for aged, blind, and disabled Medicaid coverage would

have the federal government assume the cost of Medicare Part A cost-sharing for the beneficiaries that fall into the expanded eligibility category. The Part A costs would be assumed so long as the State maintains the expanded coverage. This provision would only be applied to states who have expanded eligibility levels prior to the enactment of this legislation.

(4) NEW SECTION (page 19)

Trustees' Report on Medicare's Unfunded Obligations

This provision requires the Board of Trustees of the Federal Hospital Insurance Fund and the Federal Supplementary Medicare Insurance Trust Funds to include in their 2004 Annual Report an analysis of the Medicare program's total unfunded obligations. This provision would require the Trustees to include an analysis of the program's long term obligations compared to the program's dedicated funding sources (not including general revenue transfers). This would include the combined obligations of the HI trust fund, the SMI trust fund and the new Prescription Drug Account.

(5) NEW SECTION (page 20)

Study on a National Medicare Prescription Drug Premium

This provision would require a study to look into payments to prescription drug plans being geographically adjusted in a budget-neutral manner to account for differences in utilization across services areas.

(6) Section 104. Medicaid Amendments. (page 22)

This modification would provide $30 million to Puerto Rico and the territories to help provide prescription drugs for low-income seniors. This allocation would be indexed annually by prescription drug spending**.**

(7) Section 1807A. Transitional Prescription Drug Assistance Card Program for Eligible Low-Income Beneficiaries. (page 25)

This modification clarifies that the entire $600 benefit would be available for the entire year. In addition, any balance left on the card in year one could be carried forward.

Title II - MedicareAdvantage

(1) Section 201. Establishment of the MedicareAdvantage Program. (page 32)

To enroll in a MedicareAdvantage plan, beneficiaries must be entitled to Part A and enrolled in Parts B and D. MedicareAdvantage plans include county-based coordinated care plans, private fee-for-service and medical savings account options, as well as regional preferred provider organizations (PPOs). The modification would allow beneficiaries who choose a private fee-for-service plan to forego enrollment in Part D and still participate in this option under Medicare Advantage.

(2) Section 202. Benefits and Beneficiary Protections. (page 33)

Providing Consumer Protections in Health Plans

This provision would give the Secretary the authority to disapprove a health plan's bid for the MedicareAdvantage program if the Secretary determines that the deductibles, coinsurance, or copayments applicable under the plan discourage access to covered services.

Consumer Education and Counseling

This modification would provide reliable, more adequate funding of existing state health insurance ombudsmen, advice, and counseling services. The Secretary would transfer $1 per Medicare Part A, B, or C enrollee into a Consumer Ombudsman account. This account would be authorized to be appropriated for purposes of funding the State Health Insurance Program counseling programs established by section 4360 of OBRA 1990.

(3) NEW SECTION (page 38)

Expanding the Work of Medicare Quality Improvement Organizations in the New Medicare System.

This provision would expand the Medicare Quality Improvement Organizations (QIOs) in the new Medicare system. It would provide that Medicare QIO's responsibility be amended to include new sections of Medicare that create Medicare Advantage Plans, Medicare Prescription Drug Plans and the Prescription Drug Assistance Cards. QIOs currently have responsibility for beneficiary protection and clinical improvement in all other parts of the system. They abide by strict confidentiality requirements that allow them access to patient identifiable information in the medical records, Part A & B claims

data and information from M+C organizations. They are currently charged with helping to improve care in hospitals, physicians' offices, nursing homes and home health agencies. Access to basic outpatient prescription drugs claims data and the authority to work with Medicare Advantage plans would complete their ability to improve the quality of care for Medicare beneficiaries across the entire continuum of the care.

Title IV - Medicare Fee-For-Service Provisions

(1) Section 401. Equalizing Urban and Rural Standardized Payment Amounts Under the Medicare Inpatient Hospital Prospective Payment System. (page 48)

The Secretary would compute a standardized amount equal to that for hospitals in large urban areas to pay hospitals in any area within the United States by FY 2005 and thereafter.

(2) Section 402. Adjustment to the Medicare Inpatient Hospital PPS Wage Index to Revise the Labor-Related Share of Such Index. (page 48)

For cost reporting periods beginning on October 1, 2003, the Secretary would be required to decrease the labor-related share to 68% of the standardized amount, and to 62% for cost reporting periods beginning on and after October 1, 2004. This provision would be applied without regard to certain budget-neutrality requirements.

(3) Section 404. Fairness in the Medicare Disproportionate Share Hospital (DSH) Adjustment for Rural Hospitals. (page 50)

Starting for discharges after October 1, 2004, a hospital that qualifies for a DSH adjustment when its DSH patient percentage exceeds the 15% DSH threshold would receive the DSH payments using the current formula that establishes the DSH adjustment for a large urban hospital. A Pickle hospital receiving a DSH adjustment under the alternative formula would not be affected.

(4) Section 413. Increase in Renal Dialysis Composite Rate For Services Furnished in 2003 and 2004. (page 56)

The composite rate would be increased by 1.6% for services furnished in 2005 and 2006.

(5) Section 414. Interim Payments and Study for Covered OPD Drugs and Biologics. (page 57)

With respect to covered drugs and biologics furnished in hospital outpatient departments, directs CMS to commission a new, independent survey of hospital acquisition costs on a per product basis, to report the survey findings to Congress, and to consider those findings in establishing annual reimbursement rates for such drugs and biologics. On an interim basis until 2006, the provision would establish product-specific reimbursement rates for single source, innovator multi-source and non-innovator multi-source products.

(6) Section 416. Increase for Ground Ambulance Services Furnished in a Rural Area. (page 58)

The payments for ground ambulance services originating in a rural area or a rural census tract would be increased by 5% for services furnished on or after January 1, 2005 through December 31, 2007. These increased payments would not affect Medicare payments for covered ambulance services in subsequent periods.

(7) Section 418. Treatment of Certain Clinical Diagnostic Laboratory Tests Furnished By a Sole Community Hospital. (page 59)

SCHs that provide clinical diagnostic laboratory tests covered under Part B in 2005 and 2006 would be reimbursed their reasonable costs of furnishing the tests.

(8) Section 419. Improvement in Rural Health Clinic Reimbursement Under Medicare. (page 60)

The RHC upper payment would be increased to $80.00 for calendar year 2004. The MEI applicable to primary care services would be used to increase the payment limit in subsequent years.

(9) Section 421. Freeze in Payment for Items of Durable Medical Equipment and Certain Orthotics. (page 61)

Class III devices would be exempt from the DME freeze.

(10) Section 422. Application of Coinsurance and Deductible for Clinical Diagnostic Laboratory Tests. (page 61)

This provision would require Medicare to pay all clinical laboratories 80% of the applicable fee schedule. Hospital-based, physician office and independent clinical laboratories would be able to charge beneficiaries a 20% coinsurance amount. The Medicare Part B deductible would apply to all tests furnished across all settings. The provision also strikes the Comptroller General study in the original Chairman's mark.

(11) Section 423. Basing Medicare Payments for Covered Outpatient Drugs on Market Prices. (page 62)

Section 423(a). Medicare Payment Amount.

Drugs or biological furnished before January 1, 2004 would be paid at 95% of the AWP. After January 1, 2004 existing drugs would be paid the lower of the AWP or 85% of the listed AWP as of April 1, 2003.

This provision would save Medicare $16 billion over the ten-year period and would save Medicare Beneficiaries approximately $8 billion through lower cost-sharing and lower Part B premiums.

Section 423(b). Adjustments to Payment Amounts for Administration of Drugs and Biologicals.

During 2005, the ESRD composite rate would be increased by 0.05 percent per year. Beginning in 2006 and subsequently, the ESRD composite rate of the previous year (calculated without the temporary increase specified earlier in this legislation) would be increased by 0.05 percentage points.

Section 423(b). Adjustments to Payment Amounts for Administration of Drugs and Biologicals.

ADD NEW SECTION

Payment for Discarded Drugs.

Current Law:

The Secretary is not authorized to compensate physicians for chemotherapy drugs that they purchase with a reasonable intent to administer to a Medicare beneficiary but which cannot be administered despite the physician's reasonable efforts.

Explanation of Provision:

The provision would authorize the Secretary to compensate physicians for chemotherapy drugs that they purchase with a reasonable intent to administer to a Medicare beneficiary but which cannot be administered despite the physicians reasonable efforts (e.g., the beneficiary is too sick or the beneficiary's condition changes and the physician must discard the drugs. The Secretary could increase the Medicare payment amount (not including beneficiary cost sharing) across the board for all chemotherapy drugs paid by Medicare but the total amount of the increase could not exceed one percent of the payment for chemotherapy drugs.

Section 423(c). Linkage of Revised Drug Payments and Increases for Drug Administration.

Current Law:

No provision

*Explanation of Provision***:**

The Secretary shall not implement the revisions in payment amounts specified in subsection (a) for a category of drug or biological unless the Secretary concurrently implements the adjustments to payment amounts for administration of such category of drug or biological as specified in subsection (b).

(12) NEW SECTION (page 72)

Clarification of Congressional Intent in the Balanced Budget Act of 1997 (BBA) with Respect to Graduate Medical Education (GME) and a Technical Correction

This provision would clarify that to receive Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME) payments for residents in non-hospital locations, hospitals must incur all, or substantially all, the costs of the training in that site from the effective date of a written agreement between the hospital and the entity owning or operation the non-hospital site, and not from the inception of the program. The effective date of the written agreement would be determined according to generally accepted accounting principles.

Further, the provision would clarify that congressional intent was for "all or substantially all" the costs of the non-hospital site to include the resident's stipends and benefits and other costs, if any, as determined by the parties and to allow programs to be eligible for GME funding if the hospital incurs "all or substantially all" of the costs of the training in the non-hospital location, even if for certain programs "all or substantially all" of the

costs might be low because of voluntary faculty or other discounted benefits.

Lastly, it would provide for a technical amendment to provisions enacted in the BBA that created a three-year rolling average in counting residents and a one year lag in increasing IME payments. It would exempt dental and podiatric residents from these provisions in the same way these residents were exempted from the residency requirements in the BBA.

(13) NEW SECTION (page 72)

Medicare Puerto Rico Hospital Payment Parity

Under current law, hospitals in Puerto Rice receive reimbursement based on a blend of 50% of the Federal rate and 50% of the Puerto Rico regional rate. Puerto Rico is the only territory or state that receives a blended payment under the Medicare Prospective Payment System (PPS). All other hospitals were phased into a 100% PPS payment utilizing DRGs as the base payment system since 1983.

The provision would increase the blended payment rate in Puerto Rico from 50% Federal Rate / 50% Regional Rate to 100% Federal Rate, for FYs 2005, 2006, 2007, 2008 and 2009. Current law would resume in FY 2010.

(14) NEW SECTION (page 72)

Use of Arrangements to Provide Core Hospice Services Under Certain Circumstances

In extraordinary, exigent or other non-routine circumstances such as staffing shortages, inordinately high patient load periods, lack of availability of specialty staff or temporary travel of a patient outside the program service area, a hospice program may enter into an arrangement with another hospice program for provision of similar services. In addition, certain highly specialized services could be provided under contract with the direction and supervision of the hospice, on an as needed basis. In all circumstances, the hospice contracting for such services would continue to maintain financial and professional management responsibility for all services furnished the beneficiary, regardless of who provided services or the location in which they were furnished. Permitting a hospice to subcontract for core services under these limited circumstances assures that trained hospice staff or specially trained nurses will provide the services and that the services provided are appropriate within the context of the Medicare hospice benefit. The provision would apply to hospice care provided on or after the date of the enactment of this Act.

(15) NEW SECTION (page 72)

Clinical Psychology Training

This provision would provide payments for costs of approved education activities of clinical psychology internship training programs under the allied health professional training provisions. Such approved educational activities shall include only the provider-operated one-year clinical training portion of professional educational psychology training. This provision would begin in 2005.

(16) NEW SECTION (page 72)

Authorization for the Capital Infrastructure Loan Program

This provision would establish a Capital Infrastructure Loan Program, which would be used to help rural health care facilities improve crumbling buildings and infrastructure and update technology. This amendment would authorize $5 million in loans for these facilities. In addition, rural providers could apply to receive $50,000 planning grants to help assess capital and infrastructure needs.

(17) NEW SECTION (page 72)

Medicare Complex Clinical Care Management Payment Demonstration Project

The Secretary would be required to establish a 3-year demonstration program in 6 sites to promote continuity of care, stabilize chronic medical conditions, and reduce health outcomes. The Secretary would enter into an agreement with a principal care physician to manage beneficiaries' complex clinical conditions who would be responsible for: (1) serving as a primary contact for the beneficiary in accessing Medicare covered services; (2) maintaining medical information on care provided to the beneficiaries by other health care providers and practitioners; (3) monitoring and advocating continuity of care and the use of evidence-based guidelines; (4) promoting appropriate self-care and family caregiver involvement; (5) having appropriate staffing arrangements to conduct patient self-management and other care; and (6) meeting other requirements specified by the Secretary. The Secretary would develop a monthly complex care management fee to pay for these services. The Secretary would be able to waive Medicare and Medicaid requirements as necessary. The demonstration program would be subject to a budget-neutrality requirement. The Secretary would be required to submit to Congress a report on the demonstration project including recommendations regarding necessary statutory and administrative changes no later than 6 months after its completion.

(18) NEW SECTION (page 72)

Cost-Effective and Quality Chronic Care Coordination for Medicare Beneficiaries in Traditional Medicare

This provision would require the HHS Secretary to develop a demonstration program to provide care coordination services in the traditional fee-for-service program for Medicare beneficiaries with multiple chronic illnesses. Under this demonstration, the Secretary would contract with a range of care management organizations to provide care coordination services to eligible beneficiaries. This program would be targeted to high-risk Medicare beneficiaries who have multiple chronic conditions, functional impairments, and are at risk of poor outcomes and high health care costs.

Under this structure, beneficiaries would keep their existing physician and Medicare pays for standard services on a fee-for-service basis. A portion of the Medicare payments to care management organizations would be at risk for performance. The care management organization will be required to meet agreed-upon savings and outcomes targets in order to be paid the part of the fee that is at risk. All Medicare covered services for beneficiaries will continue to be paid on a fee-for service basis by the Medicare fiscal intermediaries or carriers.

Care management organizations would include Medicare providers such as physicians, hospice providers, Medicare + Choice organizations, and beneficiary organizations. These organizations would provide a full range of care coordination services including: comprehensive health assessments, supportive services for physicians, care conferences, and ongoing coordination and monitoring.

(19) NEW SECTION (page 72)

Indian Contract Health Services and Medicare Payments

The provision would prohibit Medicare providers from charging more than Medicare rates for inpatient hospital services provided to Indians who are eligible for contract health services from the Indian Health Service, tribally-operated health programs, and urban Indian organizations. This is similar to language regarding contract health services purchased by the Veterans Administration and the Department of Defense.

(20) NEW SECTION (page 72)

Tricare Access Improvement Provision

The provision would waive the late enrollment penalty for military retirees and their spouses who sign up for Medicare Part B between January 2001 and December 31, 2004. The provision would also permit year-round enrollment through 2004 so that retirees can access the new benefits immediately. Currently, individuals who do not join Medicare part B when initially eligible can only do so during the annual open enrollment season, which runs from January 1 until March 31. The Defense Authorization Act of 2000 extended TRICARE eligibility to military retirees over age 65 and provided them with a new pharmacy benefit. To participate in TRICARE for life, retirees must be enrolled in Medicare part B. This benefit would begin in 2005.

(21) NEW SECTION (page 72)

Medicare Coverage of Routine Costs Associated with Certain Clinical Trials

This provision would direct CMS to keep its commitment to cover the routine costs of clinical trials of breakthrough medical technologies. This policy would have a minimal impact on Medicare spending (breakthroughs represent only six percent of FDA-approved studies) but a huge impact on Medicare patients awaiting emerging breakthroughs like implantable artificial hearts, bioartificial livers and kidneys and "bionic eyes" to treat blindness.

This amendment would require the Secretary to deem FDA-approved clinical trails as automatically qualified for coverage fo routine costs associated with such clinical trials. Nothing in this section shall be construed as authorizing or requiring the Secretary to modify the current policy with respect to coverage of, or payment for, a medical device subject to a clinical trial subject of an FDA exemption. This would be in effect in 2005 and 2006.

(22) NEW SECTION (page 72)

Equitable Funding Adjustments for Home Health

This modification would provide for home health services occurring beginning January 1, 2005 through December 31, 2006 reductions in the wage index portion of the reimbursement formula for home health services could not exceed 3%.

Title V - Regulatory Relief

(1) NEW SECTION (page 79)

State Carrier Medical Directors (CMD) in Every State

This provision would require Medicare carriers to maintain utilization of at least one full-time physician Carrier Medical Director (CMD) in each State, or reasonable geographic area.

Title VI - Other Provisions

(1) Section 601. Continuation of BIPA Rule for Determination of Medicaid DSH Allotments for Fiscal Year 2004. (page 86)

The special DSH rule established by BIPA that raised DSH allotments, subject to the current law limit of 12% of spending for medical assistance, would be extended for the last two quarters of FY2004 and the first two quarters of FY2005. Allotments for the four specified quarters of FY2004 and FY2005 would be calculated to be equal to FY2002 allotments as under BIPA increased by the percentage change in the CPI-U for each of FYs 2002 and 2003. Allotments for the last two quarters of FY2005 would be equal to FY2002 allotments (as established by BBA 1997 and subject to the current law limit of 12% of spending for medical assistance) increased by the percentage change in the CPI-U for each of FY2002, FY2003, and FY2004. For FY2006 and thereafter, DSH allotments would be calculated based on the previous years' amount (subject to the current law limit of 12% of spending for medical assistance) increased by the percentage change in the CPI-U for the previous year.

(2) NEW SECTION (page 90)

Reimbursement to Health Providers for Uncompensated Care
The Balanced Budget Act of 1997 included a provision to help states and health providers defray the costs associated with providing federally-mandated, but uncompensated, emergency medical treatment to undocumented aliens. This modification to the Chairman's mark includes additional funds over a four year period to offset these unreimbursed expenditures.

(3) NEW SECTION (page 90)

Public Safety-Net Hospitals Purchases of Inpatient Drugs Exempted from Medicaid Best Price Calculations

This provision would amend section 1927(c)(1)(C) of the Social Security Act to also exempt public safety-net hospital's purchase of inpatient drugs from Medicaid best price calculations.

(4) NEW SECTION (page 90)

Immigrant Children's Health Improvement Program

This provision would give states the option to provide Medicaid and State Child Health Insurance Program (S-CHIP) coverage to lawfully present legal immigrant children and pregnant women for FY 2005, 2006, and FY 2007.

(5) NEW SECTION (page 90)

Health Care Fraud and Abuse Control Account for FY 2004-2006

This modification increases the amount provided to the HHS/Office of Inspector General from the Health Care Fraud and Abuse Control Account by $10 million for FY 2004, $15 million for FY 2005 and by $25 million for FY 2006.