DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

FEB 21 1995

NOTE TO HILLARY RODHAM CLINTON

FROM: Bruce Vladeck
Administrator

SUBJECT: HCFA's Actions to Combat Medicare Fraud and Abuse

Chris Jennings has asked me to write to you with respect to our activities designed to combat fraud and abuse in the Medicare program. As you know, some key members on the Hill are very interested in this issue. This memo outlines the administrative and legislative proposals to address this serious problem.

I. Senator Harkin's Concerns

As you know, Senator Harkin is interested in the appropriateness of Medicare payment for certain items and services such as, oxygen, surgical dressings, and ambulance services.

- Senator Harkin maintains that Medicare's payment for oxygen is inappropriately high by comparison to that of other payors. We agree. Unfortunately, we are not allowed by law to change our price for oxygen except by using a lengthy and administratively cumbersome authority called "inherent reasonableness." In response to the Senator, HCFA has set the inherent reasonableness authority process in motion to change our price. The process requires us to gather data on payment rates of other payors, such as private insurance companies and the VA, and to then go through full notice and comment rule-making. Because of the detailed statutory requirements of this process, we expect two years will be necessary to arrive at a new payment methodology for oxygen.

  Because of the time that it takes to publish a regulation, we think it is important to submit to this Congress a legislative proposal to simplify our inherent reasonableness authority. Such a change would streamline the unnecessarily cumbersome process for achieving the best prices available for durable medical equipment. We estimate that potential savings would be less than $100 million over five years.

- Senator Harkin also raised concerns about the possibility of inappropriate payments being made for surgical dressings. Based on substantial comments from beneficiaries and the industry, we recently modified our coverage policy for surgical dressings so that beneficiaries receive the items they need. Medicare will now pay for dressings used not only for surgical wounds but also for bed sores and other

decubitus ulcers. With this change in policy has come the potential for abuse. The regional durable medical equipment carriers are minimizing the abuse by incorporating specific computer edits for surgical dressings into their claims processing systems. When overuse occurs, carriers are able to more fully examine the claims and deny them when inappropriate. Because of this electronic claims screening, the number of surgical dressing claims has decreased dramatically since the change in our coverage policy but at the same time, beneficiaries are receiving the needed dressings.

- At present, Medicare pays for ambulance services based on the type of equipment used. Thus, we pay for trips using advanced life support (ALS) equipment even when not required by the patient's condition. While we do not dispute the value of ALS services when needed, we must revise our regulations to change our payment policy and thus to provide a strong incentive to curb excessive ALS billings when these services are not medically necessary. We are now developing a new regulation with industry input that will address this concern by basing ambulance payment on the patient's condition. We expect that the publication of the Notice of Proposed Rulemaking to be the Spring of 1996. Due to the public comment and review process, the regulation will not be in final form before 1997.

II. Additional Efforts to Control Fraud and Abuse

The growth of the Medicare and Medicaid programs has been unfortunately accompanied by an overall increase in instances of health care fraud and program abuse. We have taken a very aggressive stance to protect Medicare and our beneficiaries from fraudulent activities by identifying and preventing such activities before prosecution of the bad actors becomes necessary. I have recently hired a Senior Advisor on Fraud and Abuse to spearhead our efforts and to liaison with the States and the enforcement agencies.

- HCFA is increasingly applying state-of-the-art techniques in analyzing our claims data to detect aberrant patterns that might reveal fraudulent behavior. To further improve HCFA's ability to screen Medicare claims for errors and fraud, the Medicare Transaction System, will standardize Medicare claims processing in a single, fully-automated system. In January of 1994, GTE was awarded the design contract which will take several years to complete. The system will be phased-in in 1997 and will be fully implemented in 1999.

- To better monitor fraud and abuse in a particularly problematic area, HCFA has changed the way durable medical equipment claims are handled. Suppliers no longer can game

the system by sending claims to the carrier that paid the highest amount or subjected them to the least scrutiny. They must now bill the regional carrier that services the area where the beneficiary lives.

- HCFA has provided funding to 22 of our claims processing contractors to hire Medicare Fraud and Abuse Information Coordinators. These coordinators identify new forms of fraudulent activity. They then alert each other and their partners, such as HCFA, Federal and State law enforcement agencies, provider and beneficiary organizations, Medicaid State agencies, and Medicare contractors.

- HCFA uses several systems to ensure that payments are appropriate. For example, claims processing contractors examine the reasonableness of the costs incurred by providers and disallow costs that are unreasonable or are not related to the Medicare program. In addition, medical review units of each contractor analyze claims data, to identify providers with aberrant billing and utilization practices and, to intervene where appropriate.

- HCFA is also expanding and strengthening efforts to root out fraud and abuse and to vigorously pursue those who commit such illegal activities. HCFA has strengthened relationships not only with the DHHS Office of the Inspector General, but also with the Department of Justice (including the FBI), State and local law enforcement agencies, and our contractors. Furthermore, we are increasingly exercising our authority to suspend payments to suppliers or providers when we discover reliable evidence of fraud.

- To address widespread fraud in South Florida, HCFA has formed a special fraud and abuse work group to concentrate on this region, involving HCFA regional staff, our Medicare contractors, and the State Medicaid agency. This group works closely with a law enforcement task force made up of Federal, State, and local law enforcement officials and the U.S. Attorney's office. The effort has achieved extremely productive and apparently unprecedented degrees of coordination among the various agencies. The work group will report in March on innovative policy and procedural changes that HCFA can implement quickly to prevent fraud and recommend longer-range changes.

III. Further Steps

While most of our initiatives have been implemented under current law, others may require legislative action. HCFA and the DHHS Inspector General have developed two innovative legislative proposals which Secretary Shalala and Director Rivlin have agreed will be included in the next "reinventing government" bill.

These proposals would create the Benefit Quality Assurance Program and the Fraud and Abuse Control Fund. Using funds recovered from anti-fraud and abuse activities, these programs would permit investment in new activities to combat fraud and abuse. While not scored by CBO, we believe that this proposal will generate an 8 to 1 return.

- The Benefit Quality Assurance Program will strengthen our existing medical and utilization review activities, coordination of benefits with other insurers, auditing of provider cost reports, and other anti-fraud and abuse activities.

- The Fraud and Abuse Control fund is similar to that envisioned in the President's Health Security Act. This fund would receive and retain civil monetary penalties, assessment amounts, and restitution payments. Money from this fund would be available to the Office of the Inspector General and to HCFA to carry out subsequent fraud and abuse enforcement responsibilities.

We welcome your advice on how to best publicize these anti-fraud efforts and to ensure that the administration gets the credit it deserves. Please let us know how we can best assist you. We think that working together on the mammography initiative has given the issue a new level of public attention. We would like to build on our relationship and look forward to working with Chris Jennings if you have further interest.

COORDINATION WITH MEDIGAP PLANS

Medigap plans (i.e. supplemental insurance policies that complements Medicare coverage) establish 30-day uniform open-enrollment period for coverage beginning after 1995. Medigap plans participate in a coordinated open-enrollment period with Medicare HMOs.

Medigap plans cannot discriminate applicants based on their age, health status, claims experience, receipt of health care or medical condition. Moreover, policies no longer contain pre-existing condition limits, elimination periods, or probationary periods.

EXPANDED COVERAGE FOR PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, AND CLINICAL NURSE SPECIALISTS.

Medicare reimburses directly for health care services provided by physician assistants, nurse practitioners and clinical nurse specialists in most settings. Coverage only applies to those services that these practitioners legally may provide in the state in which the services are delivered.

COORDINATION WITH ADMINISTRATIVE SIMPLIFICATION AND QUALITY MANAGEMENT INITIATIVE

- The Medicare Peer Review Organization Program is repealed with the implementation of national quality management program.

- Physicians, suppliers and other providers who obtain reimbursement for any services covered under Medicare Part B may no longer "extra bill" by charging patients amounts in excess of the amount allowable by Medicare.

- The Secretary of the Department of Health and Human Services takes measures to consolidate the administration of Medicare Parts A and B.

- Peer Review Organization Precertification requirement for secondary opinion for certain surgical procedures is repealed.

- The Secretary of the Department of Health and Human Services is required to limit the implementation of changes in billing and claim processing rules for Medicare payments to a semi-annual basis.

- When major changes in Medicare billing procedures occur, Fiscal Intermediaries and Carriers are required to notify health care providers who participate in Medicare at least 120 days in advance of their implementation.

Although not formally part of the Health Security Act, there will be additional streamlining of Medicare through regulation including:

- Process for settling cost reports.
- Elimination of physician requirement to sign an acknowledgement of awareness of penalties associated with falsifying claims information on an annual basis.
- Elimination of pre-billing requirement for attestation.

MEDICARE COVERAGE OF SERVICES PROVIDED BY THE DEPARTMENTS OF DEFENSE AND VETERANS AFFAIRS

Beginning Jan. 1, 1998, the Secretary of Health and Human Services makes payments on behalf of certain individuals entitled to Medicare benefits who are enrolled in a health plan sponsored by the Department of Defense or Department of Veterans Affairs, if those Departments are not required to pay the cost of care for otherwise Medicare eligible individuals.

SAVINGS IN MEDICARE PROGRAM: SUMMARY OF TITLE IV, SUBTITLE B

SAVINGS RELATED TO MEDICARE PART A

- Reduction in update for inpatient hospital services.
- Reduction in adjustment for indirect medical education.
- Reduction in payments for capital-related costs for inpatient hospital services.
- Revisions to payment adjustments for disproportionate share hospitals in participating states.
- Moratorium on designation of additional long-term care hospitals.
- Extension of freeze on updates to routine service costs of skilled nursing facilities.

SAVINGS RELATED TO MEDICARE PART B

- Establishment of cumulative expenditure goals for physician services.
- Use of real Gross Domestic Product to adjust for volume and intensity; repeal of restriction on maximum reduction permitted in default update.
- Reduction in conversion factor for physician fee schedule for 1995.
- Limitations on payment for physicians' services furnished by high-cost hospital medical staff.
- Medicare incentives for physicians to provide primary care.
- Elimination of formula-driven overpayments for certain outpatient hospital services.

- Imposition of coinsurance on laboratory services.
- Application of competitive bidding process for Part B items and services.
- Application of competitive acquisition procedures for laboratory services.

SAVINGS RELATED TO MEDICARE PARTS A AND B

- Medicare secondary payer adjustments.
- Payment limits for HMOs and CMPs with risk-sharing contracts.
- Reduction in routine cost limits for home health services.
- Imposition of copayment for certain home health visits.
- Expansion of centers of excellence.

this is from 10/28/93 + is probably the most useful.

When the new standards are in place, agencies charged with certifying health institutions focus their attention on institutions with problematic records, responding to complaints and randomly selected validation sites.

~~By January 1, 1996,~~ Within three years of enactment, the National Quality Management Program completes demonstration projects for new performance standards and revises standards according to the findings. Demonstration projects evaluate the impact of these standards in assuring quality of care, reducing cost and burdens on providers.

Current standards are retained until new ones are tested, promulgated, evaluated and implemented. In the interim, government agencies responsible for licensing and certifying health care institutions coordinate inspections, reduce paperwork and control the number of inspections except those conducted in response to complaints.

Medicare Peer Review Organizations. The peer review organization system under Medicare continues until the new quality system is implemented and the Secretary of the Department of Health and Human Services determines that Medicare enrollees are protected adequately through National Quality Management Program. PROs end at that time.

During the interim, the PRO program is streamlined. (See Administrative Simplification)

The Clinical Laboratory Improvement Act. Regulation of clinical laboratory testing refocuses to emphasize quality protection while reducing administrative burdens.

Regulation continues for labs that:

a) Perform a comprehensive menu of tests; or

b) Perform a large volume of tests (50,000 or greater); or

c) Engage in critical testing (a test is critical if an answer is needed quickly or an error can result in serious harm to an individual); or

d) Conduct testing to monitor care while it is being delivered.

1. • Ease regulatory burden on laboratories performing simple tests.

Exempt laboratories performing waived tests and microscopy from ~~all~~ requirements under CLIA, including registration and payment of fees ~~to the Department of Health and Human Services~~. Approximately 79,000 labs will be

exempt.

Add more simple tests to the list of waivered tests when those tests meet CLIA approved criteria for waived testing.

In accordance with recommendations by the Clinical Laboratory Improvement Advisory Committee (CLIAC), the physician-performed microscopy category are expanded to include tests performed by midlevel health care providers ~~advanced practice nurses and physicians' assistants~~ midlevel health care providers (e.g. nurse practitioners, physician's assistants, nurse midwives, etc.).

2. • Ease regulatory burden on laboratories performing moderate complexity tests.

Create a new category of moderately complex tests performed using FDA-approved equipment subject to less stringent inspection requirements.

By January 1, 1996, the Secretary of the Department of Health and Human Services issues a report on the extent to which regulation of laboratories performing moderately complex tests should continue. Within six months, the Secretary determines, based on the report, the need for cost regulation for these laboratories.

3. • Revise personnel standards to relieve in urban and rural areas.

In accordance with recommendations by ~~the~~ CLIA~~C~~, the Secretary will publish regulations that will allow all individuals who are currently engaged in laboratory testing or supervision to continue to perform such testing in the absence of evidence of demonstrated poor performance.

To address the concerns of rural and underserved areas, the Department of Health and Human Service modifyies personnel requirements for certain laboratory positions.

4. • Focus proficiency testing primarily on education.

   Department of Health and Human Services only takes proficiency-related enforcement actions ~~if~~ in cases in which a laboratory's performance is ~~extremely~~ poor or it ~~has~~ failed~~s~~ to take corrective action after proficiency problems are identified.

   Department of Health and Human Services works with congressional committees to develop a modified approach to cytology proficiency testing.

5. • Streamline inspections.

   Department of Health and Human Services targets on-site inspections at high-volume, high-risk ~~labs~~ laboratories for inspection first, followed by the inspection of other laboratories that perform fewer, less risky tests. Complaints against laboratories prompt immediate inspection, and laboratories with poor performance histories are targeted for more frequent inspections. Those with sustained good performance are inspected less frequently. Inspections are announced.

6. • Expand information and education activities.

   To eliminate confusion and misinformation about CLIA requirements, the Department of Health and Human Services works with professional groups to ~~provide information and education.~~educate and inform providers.

ADMINISTRATIVE SIMPLIFICATION

SUMMARY

To address waste and inefficiency caused by excessive administrative burden, the Health Security Act calls for the adoption of standard forms for routine transactions in the health care system, both financial and clinical.

The Health Security Act simplifies the complexities that plague the existing system. It reduces the tangle of forms, the rules and regulations that weigh the system down, the generation of excessive costs and the consumption of time and energy in non-productive tasks.

In addition, the Health Security Act envisions an era in which government regulations and inspections of health care institutions pursue this vital mission of protection without over burdening doctors, nurses, clinics and hospitals.

To that end, the National Health Board contracts for the development and implementation of:

- Standard forms to record enrollment, clinical encounters and insurance reimbursement.
- Automation of insurance transactions and industry-wide adoption of standard forms.
- Simplified coordination of benefits.
- The creation of "standard and unique" identification numbers for all health care providers, health plans, employers and enrolled consumers.

In addition, the Medicare program steps up efforts to streamline its administration.

ADMINISTRATIVE SIMPLIFICATION: PROGRAM SPECIFICATIONS

After consultation with providers, plans, employer groups, and others, standard forms for insurance reimbursement, health plan enrollment and to record clinical encounters are adopted. Standard information requirements include coding, content and data elements.

By January 1, 1995, all health plans adopt a single, standard form for reimbursement according to the following classes of providers:

- The UB-92 for institutional providers
- The Standard Health Insurance Claim Form (similar to the HCFA-1500) for all non-institutional providers except pharmacies and dentists
- HCFA 1500 for dentists
- The Universal Drug Claim Form developed by the National Council on Prescription Drug Programs for pharmacies that seek reimbursement.

The standard claim form serves the secondary purpose of collecting information required for state monitoring, accountability and the measurement of quality outcomes.

All health plans and employers also adopt a national, standard enrollment form. In conjunction with standard claim reimbursement and encounter information, enrollment data is used for monitoring accountability and performance.

INSURANCE TRANSACTIONS

The National Health Board oversees the development of standards for the automation of insurance transactions, including claims payments and status reports, remittance advice, eligibility, coordination of benefits and utilization management.

Standard coding and content requirements eliminate multiple, conflicting requirements on health providers for information, formats and definitions.

The National Health Board identifies and consolidates existing standards in the health care industry, working from prototypes developed by the American National Standards Institute.

The Board reviews standards in consultation with groups such as the Workgroup for Electronic Data Interchange, the American National Standards Institute, the National Institute of Standards and Technology~~, and with professional associations representing physicians, nurses and other providers~~.

Within one year of enactment, the National Health Board designates national standards that providers, plans, alliances and employers adopt as a condition of participation in the health system. The Board establishes requirements related to content, definitions and a strategy for implementation no less than six months before the requirement for standardized transactions takes effect.

All government health programs, including the Department of Defense, CHAMPUS, Department of Veterans Affairs, Medicare and Medicaid adopt national standards immediately. All private payers, including purchasers of health insurance through regional and corporate alliances, adopt national standards for electronic transactions after January 1, 1995.

Major public and private payers, hospitals, major employers and corporate alliances, as well as clinics and group practices of 20 or more professionals automate the core transaction set within six months of adoption. States may deny payments to plans that have not automated transactions by that date.

To speed implementation, the National Health Board provides technical assistance to health alliances and plans.

UNIQUE IDENTIFICATION NUMBERS

The National Health Board undertakes a process to determine, adopt and enforce unique identification numbers for consumers in health plans.

STREAMLINING MEDICARE

The Medicare program participates in the implementation of standard forms, uniform billing, electronic claims submission, remittance notices, coordination of benefits, unique identification numbers and streamlining of utilization review~~ as required under health reform~~.

In addition, the Medicare program consolidates current roster of 80 insurance companies that act as contractors; it contracts separately for different functions (e.g. claims processing using a common system across contractors, provider profiling, provider relations,

audit, fraud and abuse prevention).

Medicare eliminates extra billing for Part B providers such as durable medical equipment providers, orthotic and prosthetic suppliers and ambulances. The program simplifies its claims processes by:

- Deleting information related to Medicare as a secondary payer from claim form and incorporating into national eligibility file.

  The Department of Health and Human Services develops and mandate model coordination of benefit rules immediately for Medicare, workers' compensation, auto insurance and other non-alliance health coverage.

  Additional coordination of benefits reforms occurs when the national enrollment file is developed and operational (January 1, 1996) After the enrollment file is operational, insurers are required to forward coordination of benefits claims to appropriate insurers, through the enrollment file if necessary.

- Deleting Medigap reporting requirement from the claim form; supplemental insurance becomes part of the national eligibility file.

The Health Care Financing Administration also:

- Gives physicians presumptive waivers from collecting or filing for beneficiary cost sharing in cases ~~where~~ in which the cost sharing would pose a financial hardship on the beneficiary or in cases of professional courtesy.

- Incorporates evaluations from physicians and their representatives into annual performance evaluations of carriers, expanding the current five-state pilot project nationally.

- Eliminates complexities caused by dual funding sources and rules for Medicare Part A and Part B claims.

  Efforts already underway by HCFA eliminate some complexities. In 1996, the Health Care Financing Administration begins to implement national, standard, integrated claims processing system for all Medicare claims, with the goal of full

implementation by 1998.

- Streamlines the process for settling cost reports, working through the Medicare-Technical Advisory Group on Hospital Administrative Issues.

- Eliminates the requirement for physicians to sign an acknowledgement of awareness of penalties associated with falsifying claims information on an annual basis and replaces with a single acknowledgement when granted hospital privileges.

- Eliminates pre-billing requirement for attestation by physician of diagnoses and major procedures performed in the hospital.

- Simplifies the "Important Letter to Medicare Patients" in consultation with the Medicare-Technical Advisory Group.

- Repeals legislation requiring review of at least ten surgical procedures.

- Improves upkeep of data in "Common Working File."

- Limits system changes for Medicare and Medicaid programs to once every six months and notifies health care providers 120 days in advance of any major change in billing procedures.

- Consistent with the 4th Scope of Work, the PRO program will continue to move toward analysis and improvement of patterns of health care and outcomes, and away from individual case review, as appropriate.

The National Health Board explores developing standards for a single annual inspection of health care institutions to replace multiple inspections performed by federal, state, local and private accreditation, survey and certification agencies, while allowing inspections in response to complaints from consumers, family members or other member of the public. ~~, while allowing for inspections to be conducted as often as necessary in response to complaints from consumers, family memebers, staff members or other members of the public.~~

- Develops methodology standards for practice guidelines, an evaluation and voluntary certification process for guidelines developed by the private sector.

- Operates a clearinghouse and dissemination program for practice guidelines.

- Disseminates information documenting clinically ineffective procedures and treatments.

- Supports research on topics central to quality management and improvement, including outcomes research, dissemination methods, ways of measuring quality and design of electronic information systems and new ways of organizing work systems.

- Establishes scientific standards and procedures for evaluating the clinical appropriateness of protocols used to manage health service utilization.

- With the advice of the national quality advisory committee, defines priorities for health-care evaluation research and recommends projects. The priorities will target diagnoses with the highest level of uncertainty in treatment decisions, widest variation in practice patterns, significant costs and incidence.

STREAMLINING REGULATORY ACTIVITIES

Minimum Standards for Health Care Institutions. The National Quality Management Programs develops uniform standards for licensing of health care institutions that focus on essential performance requirements related to patient care. As they are developed, those standards replace current regulations except in areas of fire safety, sanitation and patient rights and without undermining recent reforms in nursing home care.

When the new standards are in place, agencies charged with certifying health institutions focus their attention on institutions with problematic records, responding to complaints and randomly selected validation sites.

By January 1, 1996, the National Quality Management Program completes demonstration projects for new performance standards and revises standards according to the findings. Demonstration projects evaluate the impact of these standards in assuring quality of care, reducing cost and burdens on providers.

Current standards are retained until new ones are tested, promulgated, evaluated and implemented. In the interim, government agencies responsible for licensing and certifying health care institutions coordinate inspections, reduce paperwork and control the number of inspections.

Medicare Peer Review Organizations. The peer review organization system under Medicare continues until the new quality system is implemented and the Secretary of the Department of Health and Human Services determines that Medicare enrollees are protected adequately through National Quality Management Program. PROs will end at that time.

During the interim, the PRO program is streamlined. (See Administrative Simplification)

The Clinical Laboratory Improvement Act. Regulations of clinical laboratory testing are refocused to emphasize quality protection while reducing administrative burdens.

Regulation will continue for labs that:

a) perform a comprehensive menu of tests; or

b) perform a large volume of tests (50,000 or greater); or

c) engage in critical testing (a test is critical if an answer is needed quickly or an error can result in serious harm to an individual); or

d) conduct testing to monitor care while it is being delivered.

- Ease regulatory burden on laboratories performing simple tests

  Exempt laboratories performing waived tests and microscopy from all requirements under CLIA, including registration and payment of fees to the DHHS. Approximately 79,000 labs will be exempted. (under review)

  Add more simple tests to the list of waivered tests.

  In accordance with recommendations by the Clinical Laboratory Improvement Advisory Committee (CLIAC), the physician-performed microscopy category will be expanded to include those tests performed by midlevel health care providers (e.g. nurse practitioners, physician's assistants, nurse midwives, etc.).

- Ease regulatory burden on laboratories performing moderate complexity tests

  Create a new category of moderately complex tests that are performed using FDA-approved, highly reliable equipment that would be subject to less stringent inspection requirements.

  By January 1, 1996, the Secretary of the DHHS issues a report on the extent to which regulation of laboratories performing moderate complexity tests should continue. Within six months, the Secretary determines, based on the report, where continued regulation for these laboratories is necessary.

- Revise personnel standards to provide needed relief in urban and rural areas

  In accordance with recommendations by the CLIAC, all individuals who are currently engaged in laboratory testing or supervision will be able to continue to perform such testing (in the absence of evidence of demonstrated poor performance).

  To address the concerns of rural and underserved areas, the DHHS will modify personnel requirements for certain laboratory positions.

- Focus proficiency testing primarily on education

  DHHS will only take proficiency-related enforcement actions where a laboratory's performance is extremely poor or it has failed to take corrective action when proficiency testing problems are identified.

  DHHS will work with Congressional committees to develop a modified approach to cytology proficiency testing.

- Streamline inspections

  DHHS will target on-site inspections at high-volume, high-risk labs, and they will be announced. (under review)

- Expand information and education activities

  To eliminate confusion and misinformation with respect to CLIA requirements, DHHS will work with professional groups to expand activities in information and education.

ADMINISTRATIVE SIMPLIFICATION

The National Health Board enters into contracts for the development and implementation of:

- Standard forms to record enrollment, clinical encounters and insurance reimbursement.
- Automation of insurance transactions and industry-wide adoption of standard forms.
- Simplified coordination of benefits.
- The creation of "standard and unique" identification numbers for all health care providers, health plans, employers and enrolled consumers.
- Steps to streamline the administration of the Medicare program.

STANDARD FORMS

After consultation with providers, plans, employer groups, and others, standard forms for insurance reimbursement, health plan enrollment and to record clinical encounters are adopted. Standard information requirements include coding, content and data elements.

By January 1, 1995, all health plans adopt a single, standard form for reimbursement according to the following classes of providers:

- The UB-92 for institutional providers
- The Standard Health Insurance Claim Form (similar to the HCFA-1500) for all non-institutional providers except pharmacies and dentists
- HCFA 1500 for dentists
- The Universal Drug Claim Form developed by the National Council on Prescription Drug Programs for pharmacies that seek reimbursement.

The standard claim form serves the secondary purpose of collecting information required for state monitoring, accountability and the measurement of quality outcomes.

All health plans and employers also adopt a national, standard enrollment form. In conjunction with standard claim reimbursement and encounter information, enrollment data is used for monitoring accountability and performance.

INSURANCE TRANSACTIONS

The National Health Board oversees the development of standards for the automation of insurance transactions, including claims payments and status reports, remittance advice, eligibility, coordination of benefits and utilization management.

Standard coding and content requirements eliminate multiple, conflicting requirements on health providers for information, formats and definitions.

The National Health Board identifies and consolidates existing standards in the health care industry, working from prototypes developed by the American National Standards Institute.

The Board reviews standards in consultation with groups such as the Workgroup for Electronic Data Interchange, the American National Standards Institute, the National Institute of Standards and Technology.

Within one year of enactment, the National Health Board designates national standards that providers, plans, alliances and employers adopt as a condition of participation in the health system. The Board establishes requirements related to content, definitions and a strategy for implementation no less than six months before the requirement for standardized transactions takes effect.

All government health programs, including the Department of Defense, CHAMPUS, Department of Veterans Affairs, Medicare and Medicaid adopt national standards immediately. All private payers, including purchasers of health insurance through regional and corporate alliances, adopt national standards for electronic transactions after January 1, 1995.

Major public and private payers, hospitals, major employers and corporate alliances, as well as clinics and group practices of 20 or more professionals automate the core transaction set within six months of adoption. States may deny payments to plans that have not automated transactions by that date.

To speed implementation, the National Health Board provides technical assistance to health alliances and plans.

UNIQUE IDENTIFICATION NUMBERS

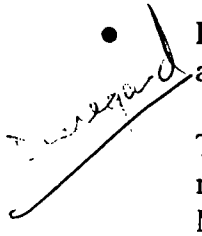
The National Health Board undertakes a process to determine, adopt and enforce unique identification numbers for consumers in health plans.

STREAMLINING MEDICARE

The Medicare program participates in the implementation of standard forms, uniform billing, electronic claims submission, remittance notices, coordination of benefits, unique identification numbers and streamlining of utilization review as required under health reform.

In addition, the Medicare program consolidates current roster of 80 insurance companies that act as contractors; it contracts separately for different functions (e.g. claims processing using a common system across contractors, provider profiling, provider relations, audit, fraud and abuse prevention).

Medicare eliminates extra billing for Part B providers such as durable medical equipment providers, orthotic and prosthetic suppliers and ambulances. The program simplifies its claims processes by:



- Deleting information related to Medicare as a secondary payer from claim form and incorporating into national eligibility file.

  The Department of Health and Human Services develops and mandate model coordination of benefit rules immediately for Medicare, workers' compensation, auto insurance and other non-alliance health coverage.

Additional coordination of benefits reforms occurs when the national enrollment file is developed and operational (January 1, 1996) After the enrollment file is operational, insurers are required to forward coordination of benefits claims to appropriate insurers, through the enrollment file if necessary.

- Deleting Medigap reporting requirement from the claim form; supplemental insurance becomes part of the national eligibility file.

The Health Care Financing Administration also:

- Gives physicians presumptive waivers from collecting or filing for beneficiary cost sharing in cases where the cost sharing would pose a financial hardship on the beneficiary or in cases of professional courtesy.

- Incorporates evaluations from physicians and their representatives into annual performance evaluations of carriers, expanding the current five-state pilot project nationally.

- Eliminates complexities caused by dual funding sources and rules for Medicare Part A and Part B claims.

  Efforts already underway by HCFA eliminate some complexities. In 1996, the Health Care Financing Administration begins to implement national, standard, integrated claims processing system for all Medicare claims, with the goal of full implementation by 1998.

- Streamlines the process for settling cost reports, working through the Medicare-Technical Advisory Group on Hospital Administrative Issues.

- Eliminates the requirement for physicians to sign an acknowledgement of awareness of penalties associated with falsifying claims information on an annual basis and replaces with a single acknowledgement when granted hospital privileges.

- Eliminates pre-billing requirement for attestation by physician of diagnoses and major procedures performed in the hospital.

- Simplifies the "Important Letter to Medicare Patients" in consultation with the Medicare-Technical Advisory Group.

- Repeals legislation requiring review of at least ten surgical procedures.

- Improves upkeep of data in "Common Working File."

- Limits system changes for Medicare and Medicaid programs to once every six months and notifies health care providers 120 days in advance of any major change in billing procedures.

- Consistent with the 4th Scope of Work, the PRO program will continue to move toward analysis and improvement of patterns of health care and outcomes, and away from individual case review, as appropriate.

The National Health Board explores developing standards for a single annual inspection of health care institutions to replace multiple inspections performed by federal, state, local and private accreditation, survey and certification agencies.

This is from 12/93 + is an overview of the bill, not reg changes, although some are included. (See highlighted areas)

MEDICARE

OVERVIEW

Since its inception, the Medicare program has offered older Americans and, since 1972 the disabled, the security of health care coverage. The Health Security Act continues current benefits unchanged, except for the addition of outpatient prescription drug coverage beginning January 1, 1996 and more choice of health plans.

Prescription Drugs: Prescription drugs are frequently the most cost-effective intervention to treat medical conditions. However, these potentially life-saving products are often inaccessible because of increases in costs and inadequate insurance coverage. Until very recently, prescription drug price increases dwarfed increases in the rest of the economy. Between 1980 and 1992, while the general inflation rate increased by 22 percent, drug prices increased 128 percent.

For older Americans and the disabled, the high cost of prescription drugs and heavy reliance on medications cause a significant financial burden. Medicare does not cover outpatient prescription drugs, and less than half of all drug costs for seniors are paid for by public or private insurance plans. As a result, prescription drug costs are the highest out-of-pocket medical costs for 3 out of 4 older Americans.

As the Medicare program expands its coverage, the program also becomes one of the world's largest purchaser of medication. With its market power, the program effectively receives discounts for prescription drugs currently on the market and gives the Secretary of Health and Human Services the authority to negotiate the price of new drugs for Medicare. This assures affordable coverage to all Medicare beneficiaries.

Additional Choice of Plans: Medicare beneficiaries interested in joining new health delivery systems, such as health maintenance organizations and preferred provider organizations, have a wider range of choices under an improved Medicare managed care program.

As health alliances form, Americans who become eligible for Medicare will have the option of continuing in many alliance health plans or enrolling in the Medicare program. Individuals eligible for Medicare who continue to work and their families obtain coverage through regional alliances. A Medicare beneficiary who is a spouse of a worker also receives coverage through the alliance.

Once states fully implement reform, they may elect to integrate the Medicare program into the alliance system. However, strict Federal requirements safeguard the benefits, financial liability, and choices of Medicare beneficiaries in states that undertake integration.

Slowing the Rate of Growth in Medicare: The Health Security Act commits the federal government to slowing the rate of growth in Medicare spending over the next decade.

To achieve that goal, the Act proposes specific changes to reduce the rate of growth of current program spending and redirect projected savings towards more direct benefits including new coverage for prescription drugs.

In the past, attempts to rein in double-digit rates of growth in both Medicare and Medicaid programs proved difficult -- to a large extent because they occurred outside the context of comprehensive health reform.

Outside the context of system-wide reform, reductions in the projected rate of growth of major public programs raise concerns about the access to care for Medicare beneficiaries. In the context of national reform, parallel reductions in growth in the public and private sectors are feasible without diminution of access. Certain changes that reduce the rate of growth in Medicare spending are appropriate in the context of reform.

- More Americans over age 65 who continue to work receive employer-paid insurance, reducing financial obligations in the Medicare program.

- Federal payments to hospitals that serve disproportionate number of low-income persons can be reduced in the context of reform.

MEDICARE: SUMMARY OF TITLE IV, SUBTITLE A AND TITLE II, SUBTITLE A

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

Two years after enactment but no later than January 1, 1996, the Medicare program expands to cover outpatient prescription drugs.

The Medicare drug benefit covers all drugs, biological products and insulin approved by the Food and Drug Administration (FDA). The benefit also covers drugs used in home infusion treatment. The Secretary of Health and Human Services may establish maximum quantities per prescription, may limit the number of refills and decide not to cover certain pharmaceutical products.

Medicare pays 80 percent of the cost of each prescription after a $250 annual deductible for each individual. Beneficiaries pay no more than $1,000 out-of-pocket in 1996. For brand name drugs, reimbursement is set at the lower of the actual charge, 90th percentile of actual charges in a previous period or the estimated acquisition cost plus dispensing fee.

For generic drugs, Medicare pays the lower of the pharmacist's actual charge or the median of the estimate acquisition costs all generic prices (times the number of units dispensed) plus a dispensing fee. The dispensing fee is $5 in 1996.

As with other Part B benefits, the Medicare prescription drug benefit is funded by both general federal revenues and premiums paid by beneficiaries. In addition to any normal annual increase in premiums, in the year that coverage for prescription drugs begins, the Part B premium increases to cover 25 percent of the cost of the new benefit -- approximately $11-a-month.

As a condition of participation in Medicare, drug manufacturers agree to pay quarterly rebates to the Medicare program based on the greater of 17 percent of the average manufacturer price or the difference between the average manufacturers price and the average non-retail price.

An additional rebate is required from any manufacturer who increases drug prices at a rate higher than inflation. If a manufacturer refuses to negotiate or the Secretary of the Department of Health and Human Services is unable to negotiate agreement, the Secretary may exclude the drug from Medicare coverage.

No rebate is required for generic drugs.

Under the Medicare rebate agreement, manufacturers of prescription pharmaceutical products must offer discounts to all purchasers on equal terms. Manufacturers are precluded from providing discounts to purchasers based solely on class of trade.

All pharmacists provide information to consumers regarding the appropriate use of prescription drugs, and potential interactions between medications.

MEDICARE AND THE ALLIANCE SYSTEM

State Integration: After a state fully implements reform, a request can be made to the Secretary of the Department of Health and Human Services to integrate Medicare beneficiaries into the alliance system with the assurance that:

- Medicare beneficiaries are assured of equal or better coverage.
- Financial liability for Medicare beneficiaries or the program does not increase.
- Each regional alliance offers at least one fee-for-service health plan that provides a benefit package at least as good as the Medicare benefit.

If only an enhanced benefit package is available, the cost to the beneficiary may not exceed the cost of the traditional Medicare benefit. Once integration occurs, federal spending for Medicare is limited to the pre-integration level of per-capita spending for each beneficiary adjusted by the state's regional alliances inflation factor for each year.

Individual Election to Continue in Alliance: When health alliances are established, newly eligible Medicare beneficiaries may remain in an alliance health plan that has a risk contract with the Medicare program or is eligible to enter into such a contract with Medicare.

Individuals who remain in alliance health plans continue to receive the nationally guaranteed comprehensive benefit package and pay the difference between the premium and the amount paid by Medicare. Medicare pays the amount that it would normally pay to a risk contractor. The health plan premium for beneficiaries is community-rated adjusted by a factor determined by the Secretary of the Department of Health and Human Services that reflects the difference in utilization between the Medicare beneficiaries and non-Medicare beneficiaries.

Medicare Secondary Payer: Medicare eligible individuals, or their spouses, who work more than 40 hours a month for two consecutive months with the expectation of working the third month receive coverage for themselves and their family members through the regional alliance system. Medicare continues, as it does today, as secondary payer to alliance health plans — paying Part A cost sharing for all beneficiaries, and Parts A and B cost-sharing for Medicare beneficiaries who pay the Part B premium. In addition, Medicare pays the remainder of the employers share of the premium when a Medicare beneficiaries work part-time.

Medicare beneficiaries who stop working mid-year continue with their alliance health plan coverage until open-enrollment, with Medicare paying the employer share of the premium. During open-enrollment, the beneficiaries switches to Medicare coverage or elects alliance coverage under the individual election rules.

INCREASING OPTIONS FOR MEDICARE MANAGED CARE

The Medicare program establishes an annual open-enrollment period for Medicare managed care plans and Medigap plans, and provides informational material on the plans. It also authorizes the Secretary to establish point-of-service (POS) networks that beneficiaries may use to obtain care at reduced out-of-pocket costs. Medicare beneficiaries may elect to enroll in Medicare-approved HMOs, POS or to remain in traditional fee-for-service arrangement, with or without Medigap coverage.

COORDINATION WITH MEDIGAP PLANS

Medigap plans (i.e. supplemental insurance policies that complements Medicare coverage) establish 30-day uniform open-enrollment period for coverage beginning after 1995. Medigap plans participate in a coordinated open-enrollment period with Medicare HMOs.

Medigap plans cannot discriminate applicants based on their age, health status, claims experience, receipt of health care or medical condition. Moreover, policies no longer contain pre-existing condition limits, elimination periods, or probationary periods.

EXPANDED COVERAGE FOR PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, AND CLINICAL NURSE SPECIALISTS.

Medicare reimburses directly for health care services provided by physician assistants, nurse practitioners and clinical nurse specialists in most settings. Coverage only applies to those services that these practitioners legally may provide in the state in which the services are delivered.

COORDINATION WITH ADMINISTRATIVE SIMPLIFICATION AND QUALITY MANAGEMENT INITIATIVE

- The Medicare Peer Review Organization Program is repealed with the implementation of national quality management program.
- Physicians, suppliers and other providers who obtain reimbursement for any services covered under Medicare Part B may no longer "extra bill" by charging patients amounts in excess of the amount allowable by Medicare.
- The Secretary of the Department of Health and Human Services takes measures to consolidate the administration of Medicare Parts A and B.
- Peer Review Organization Precertification requirement for secondary opinion for certain surgical procedures is repealed.
- The Secretary of the Department of Health and Human Services is required to limit the implementation of changes in billing and claim processing rules for Medicare payments to a semi-annual basis.
- When major changes in Medicare billing procedures occur, Fiscal Intermediaries and Carriers are required to notify health care providers who participate in Medicare at least 120 days in advance of their implementation.

Although not formally part of the Health Security Act, there will be additional streamlining of Medicare through regulation including:

- Process for settling cost reports.
- Elimination of physician requirement to sign an acknowledgement of awareness of penalties associated with falsifying claims information on an annual basis.
- Elimination of pre-billing requirement for attestation.

MEDICARE COVERAGE OF SERVICES PROVIDED BY THE DEPARTMENTS OF DEFENSE AND VETERANS AFFAIRS

Beginning Jan. 1, 1998, the Secretary of Health and Human Services makes payments on behalf of certain individuals entitled to Medicare benefits who are enrolled in a health plan sponsored by the Department of Defense or Department of Veterans Affairs, if those Departments are not required to pay the cost of care for otherwise Medicare eligible individuals.

SAVINGS IN MEDICARE PROGRAM: SUMMARY OF TITLE IV, SUBTITLE B

SAVINGS RELATED TO MEDICARE PART A

- Reduction in update for inpatient hospital services.
- Reduction in adjustment for indirect medical education.
- Reduction in payments for capital-related costs for inpatient hospital services.
- Revisions to payment adjustments for disproportionate share hospitals in participating states.
- Moratorium on designation of additional long-term care hospitals.
- Extension of freeze on updates to routine service costs of skilled nursing facilities.

SAVINGS RELATED TO MEDICARE PART B

- Establishment of cumulative expenditure goals for physician services.
- Use of real Gross Domestic Product to adjust for volume and intensity; repeal of restriction on maximum reduction permitted in default update.
- Reduction in conversion factor for physician fee schedule for 1995.
- Limitations on payment for physicians' services furnished by high-cost hospital medical staff.
- Medicare incentives for physicians to provide primary care.
- Elimination of formula-driven overpayments for certain outpatient hospital services.

QUALITY AND CONSUMER PROTECTION

OVERVIEW

Many Americans worry that strong action to restrain costs will compromise the quality of health care. The goal of the Health Security Act is to build attention to quality into all levels of health care. To that end, a national quality management program creates performance measures focused on continuous improvement.

Traditional quality assurance depends on after-the-fact checks, relying primarily on external reviews, forms and process checks. Insurance companies, peer review organizations, state and federal regulatory agencies audit the work of hospitals, professional offices, clinics and laboratories, searching for infractions and punishing rule breakers.

Patients play a minor role, lacking reliable information to compare treatment options or the quality of health plans and providers. Yet rational choice among treatments depends on shared decisionmaking between physician and patient.

The Health Security Act provides the professions with resources they need to improve quality in the Nations's health care system. Patient-focused continuous improvement raises quality by improving the outcomes of care and assuring that patient needs are met. A sophisticated information system utilizing routinely collected data provides concrete measures of performance. It reports the performance of health plans on such measures as the rate of survival among patients who suffer heart attacks, the number of children who receive immunizations, the number of new mothers who receive prenatal care, and the level of patient satisfaction with the plan. The quality management program delivers useful information to consumers through annual performance reports on health plans and providers.

QUALITY AND CONSUMER PROTECTION:SUMMARY OF TITLE V, SUBTITLE A

NATIONAL QUALITY MANAGEMENT COUNCIL

The Health Security Act establishes a national quality management program overseen by the National Quality Management Council. The Council consists of 15 members including representatives of consumer groups, health plans, states, purchasers of care and experts in publish health and quality of care. The Council sets national goals for performance on selected quality measures and evaluates the impact of reform on the quality of health care and access to services.

PERFORMANCE REPORTS

The National Quality Management Council develops a core set of quality and performance measures and updates them over time. It reports annually to Congress on the performance of each regional and corporate alliance and health plans on those measures and reviews state and national quality trends. Each health alliance also makes available to the public a performance report that includes the performance of each health plan offered in the alliance.

Performance reports include information on access to care, appropriateness of care, health outcomes, health promotion, disease prevention and satisfaction with care. The reports provide information on a subset of measures for health care institutions, doctors and other practitioners if the available information is statistically meaningful.

CONSUMER SURVEYS

The National Quality Management Council conducts periodic surveys of consumers to gather information about access to care, use of health services, health outcomes and patient satisfaction. It disseminates its findings and includes the results in annual performance reports.

CLINICAL PRACTICE GUIDELINES

The National Quality Management Council directs the Administrator for Health Care Policy and Research to: develop and periodically review clinical practice guidelines that may be used by health care providers to assist in the prevention, diagnosis, and treatment of disease; oversee a clearing house and dissemination program for practice guidelines; develop standards relating to the methodologies for developing guidelines; and establish a procedure by which entities may have guidelines evaluated and certified in accordance with the standards developed.

THE KNOWLEDGE BASE TO IMPROVE QUALITY OF CARE

The National Quality Management Council disseminates information documenting clinically ineffective treatments and procedures. The Council establishes priorities for research with respect to the quality, appropriateness and effectiveness of health care and make recommendations concerning research projects. It also supports research related to the development of performance measures.

REGIONAL PROFESSIONAL FOUNDATIONS

Representatives of academic health centers, schools of public health, health professional schools, health plans, alliances and providers form private non-profit regional professional foundations across the United States. The regional professional foundations:

- Develop programs in lifelong learning for health professionals to ensure the delivery of quality care.
- Foster collaboration among health plans and providers to improve quality.
- Disseminate information about successful quality improvement programs, practice guidelines, innovative uses of health professionals and research findings.
- Develop patient education programs that promote patient involvement in treatment decisions.

NATIONAL QUALITY CONSORTIUM

A National Quality Consortium oversees and advises the National Quality Management Council and Regional Professional Foundations:

- Establishes programs for continuing education for health professionals.
- Advises the Council and the Agency for Health Care Policy Research on priorities.
- Consults with the National Quality Management Council on the selection of national measures of quality performance.
- Oversees the development of Regional Professional Foundations.
- Advises the National Health Board.

ROLE OF ALLIANCES

Regional and corporate alliances:

- Ensure through negotiations that health plans pursue continuous improvement in their performance on national quality outcome measures.
- Disseminate to consumers annual performance reports for each health plan, the results of consumer-satisfaction surveys and other information.

- Conduct educational programs through regional quality foundations to assist consumers in using quality information in choosing health plans.

ROLE OF HEALTH PLANS

Each competing health plan measures and discloses information related to performance on quality measures required by participating states, regional and corporate alliances and the National Quality Management Council

ELIMINATION OF SELECTED CLIA REQUIREMENT

The need for a certificate of waiver for simple laboratory examinations and procedures required under the Clinical Laboratories Inspection Act is repealed for laboratories that perform only such procedures.

Although not formally part of the Health Security Act, there will be additional streamlining of CLIA through regulation.

UNIFORM STANDARDS FOR HEALTH CARE INSTITUTIONS

Within three years of enactment the National Health Board develops uniform standards for licensing health care institutions that address essential performance requirements relating to patient care except in the areas of fire, safety, sanitation and patient rights. Standards must not undermine nursing home reform. Demonstration projects are completed by January 1, 1996. Standards, once tested and revised, replaces existing standards except where changes in Federal statutes are required. The Council also undertakes efforts to develop a single consolidated audit and inspection.

HEALTH INFORMATION SYSTEMS, PRIVACY PROTECTION, AND ADMINISTRATIVE SIMPLIFICATION

OVERVIEW

Health Information Systems: Quality improvement depends on information that is useful to consumers and providers. The Health Security Act envisions a national information system that will simplify the administration of health coverage, support quality improvement and protect the privacy of patients. Using standard forms, uniform data sets, electronic networks and national standards for electronic data transmission, the new information system is built on these principles:

- Protection of privacy and confidentiality.
- Partnerships between the public and private sectors.
- National standards for clinical and administrative information.
- Appropriate links to the information infrastructure programs.
- Electronic transfer of data to ensure the timely availability of reliable information.

The health care information system focuses on the production of useful comparative information on health plans and providers, analysis of outcomes and patterns of care to support health providers and evaluation of the health care system.

Protection of Privacy: The Health Security Act institutes critical safeguards to protect the privacy, security and confidentiality of patient records, including:

- The establishment of a national privacy framework and safeguards.
- New mechanisms of enforcement.
- A system of universal identification numbers.
- Security standards.

Administrative Simplification: To correct waste and inefficiency caused by excessive administrative burden, the Health Security Act calls for the adoption of standard forms for routine transactions in the health care system, both financial and clinical. In addition, the Health Security Act envisions an era in which government regulations and inspections of health care institutions carry out their vital mission of protection without overburdening doctors, nurses, clinics and hospitals. To that end, the National Health Board develops:

- Standard forms to record enrollment, clinical encounters and insurance reimbursement.
- Automation of insurance transactions and industry-wide adoption of standard forms.
- Simplified systems for coordination of benefits.
- "Standard and unique" identification numbers for all health care providers, health plans, employers and enrolled consumers.
- The Medicare program steps up efforts to streamline its administration.

HEALTH INFORMATION SYSTEMS

ESTABLISHMENT OF HEALTH INFORMATION SYSTEM (TITLE V, SUBTITLE B)

The National Health Board establishes a health information system governing the collection, reporting and dissemination of health care information.

Information collected are used for the following purposes:

- Health care planning, policy development and evaluation, research.
- Establishing and monitoring payments for health services
- Assessing and improving the quality of health care
- Measuring and improving access to health care
- Evaluating the cost of clinical or administrative functions
- Supporting public health functions and objectives
- Improving the capacity of health plans, providers and consumers to improve and make choices about health care.
- Managing and containing costs at the plan and alliance level.

Health care information to be collected includes:

- Enrollment and disenrollment in health plans, on clinical encounters and other items and services provided by health care providers, and administrative and financial transactions.

- The characteristics of populations in regional and corporate health alliances and terms of agreement between plans and providers.

- Payment of benefits, utilization management, quality management, and such other information as the Board determines.

The health care information system is developed in consultation with federal agencies, states, alliances, health plans, representatives of health care providers, employers, consumers, experts in public health and health care information and technology, and representatives of organizations furnishing health care supplies, services and equipment.

The National Health Board determines the form, manner, content and frequency of information to be reported to the system. In addition, the Board establishes standards for paper forms, uniform health data sets, and electronic data interchange. In general, data standards issued by the Board preempt state law.

ESTABLISHMENT OF ELECTRONIC DATA NETWORK

As part of the health information system, the National Health Board oversees the establishment of an electronic data network consisting of regional data centers which electronically link plans, alliances, states and the federal government for the purpose of exchanging information.

The electronic data network is developed in consultation with federal agencies, states, the National Quality Management Program, regional and corporate alliances, and health plans. Implementation of the network is preceded by adequate demonstration and testing activities.

HEALTH SECURITY CARD

The National Health Board establishes the form and standard content of Health Security cards issued to eligible individuals.

Each health plan, health provider, employer and eligible individual is assigned a unique identification number that assures ready access to basic identification and enrollment information.

PRIVACY AND SECURITY OF HEALTH INFORMATION

OVERVIEW

Individually identifiable health information poses a dilemma for health care reform: accurate, timely data is essential to delivering the highest quality and most efficient care, yet information about a person's medical history is among the most sensitive information our society maintains.

Today, no comprehensive privacy standards for health information exist. Legal protection of this information is primarily left to state laws which provide varying degrees of protection. These protections are no longer adequate due to the growing movement of information (often in electronic form), and of individuals and organizations, across state lines.

The Health Security Act emphasizes the importance of protecting patient privacy while sharing information among the National Health Board, health alliances, and accountable health plans and for other permitted health system purposes.

National Privacy Standards

- No later than two years after the enactment of the Health Security Act, the National Health Board establishes national privacy safeguards that cover individually identifiable records generated by the new health system.

- Within three years, the National Health Board develops a detailed proposal for legislation to provide a comprehensive scheme of federal privacy protection for all individually identifiable health information (whether or not they are part of the new health care system and regardless of the form in which these records are kept).

Principles Protecting Patient Rights

- The new privacy safeguard requires the informed consent of persons regarding the use of personal data, grants persons the right to know how data about them is used, grants persons the right to review and correct personal data, and limits the use of data.

- Where disclosure of information is made to law enforcement officials for enforcement of the Act, the minimum amount of information necessary to accomplish required purposes is disclosed.

- The National Board is given the authority to:

- Conduct research relating to the privacy and security of individually identifiable health information.

- Develop technology for implementing security standards.

- Develop consent forms governing disclosure of information.

Health Data Protected from Other Uses

- The Health Security Act prohibits the use of the health security card except for the purposes of obtaining the services in the guaranteed national benefit package.

- Data collected as part of the operation of the new health care system is used only for that purpose, and may not shared with any other entity.

- Individually identifiable health care information may not be used as a basis for employment decisions.

ADMINISTRATIVE SIMPLIFICATION

INTERIM REQUIREMENTS FOR ADMINISTRATIVE SIMPLIFICATION

Within one year of enactment, the Board promulgates and publishes standard forms to simplify administration of health care, including insurance claims forms, enrollment forms, and records of clinical encounters. Health providers and plans use standard forms developed by the Board.

HCFA ADMINISTRATIVE STREAMLINING

December 14, 1994

Contents

HCFA ADMINISTRATIVE STREAMLINING
December 14, 1994

Communication with Medicare Beneficiaries

Issue: The Medicare program is increasingly complex and confusing. It is very important that we maintain good communication with our primary customers, the beneficiaries, so as to mitigate any confusion about the program.

Discussion: HCFA is implementing a number of initiatives towards improving communications with our primary customer, the beneficiary. In the Medicare program, the following activities are underway in terms of planning, pilot testing, or implementation:

- A combined Part A/Part B Medicare Summary Notice which will consolidate into a single, easy-to-read, monthly statement of all of a beneficiary's claims activity for the month. We will be eliminating the multiple forms that Medicare intermediaries and carriers currently use.

- The Medicare Summary Notice will allow the beneficiary to more easily request a review of their Medicare determination rather than the current process of making a separate request.

- The physician can be a patient advocate and we want to promote this important beneficiary service. Consequently, we are exploring the release of beneficiary claims data (the Explanation of Your Medicare Part B Benefits (EOMB)) to physicians who do not accept Medicare assignment (those that accept assignment already get this information).

- Recognizing diversity in the Medicare program is important to our communication efforts, we will be expanding the use of Spanish EOMBs and testing their success at effectively informing Hispanic beneficiaries.

Though these are just some of our communication ideas, HCFA is continually seeking and implementing other improvements to our communication vehicles with beneficiaries. Many of these ideas are provided to us by beneficiaries.

Status:

o Combined EOMB Notice. In December 1994, HCFA will be developing prototype notices. In February 1995, HCFA will be using beneficiary focus groups to gain feedback on the prototypes. The implementation target date is October 1995.

- Releasing EOMB Information to Non-Assignment Physicians. Release of this information was pilot tested in two regions, Kansas City and New York. The pilots were successfully completed in July 1994 and HCFA is planning for nationwide implementation.

- Spanish EOMB. Spanish EOMB's will be pilot tested in Florida beginning in April 1995.

Budget Impact: Each of these proposals has minimal budget impact.

Eliminate Fraud and Abuse

Issue: As a major payer of health care services in the country, the Medicare and Medicaid programs are natural targets for those wishing to gain financial rewards through fraudulent and abusive activities.

Discussion:

- Detection.

  We have consolidated payment of durable medical equipment (DME) into four carriers in order to enable us to focus claims review on this problem area. One of the four has responsibility for analyzing patterns within all DME claims to highlight problem areas.

  Working with carriers and intermediaries, we are developing advanced computer systems to detect fraudulent patterns of billing in all types of claims. This will enable us to intervene early when problems are suspected.

  In problem areas such as South Florida, we are combining Medicare claims with those from Medicaid to provide a more robust data base on which to detect unusual patterns. We plan to expand to include private claims with cooperation of several existing carriers.

  We are undertaking an education program to inform employees and beneficiaries of their responsibility to report suspicious practices.

  State surveyors who visit home health agencies and nursing homes will be trained to detect and report evidence of fraud. They will also be provided with information from claims analysis which indicates quality problems.

  The Medicare Transaction System (MTS), a uniform, national system for processing Medicare claims, will replace the diverse existing systems and provide HCFA with improved capability for identifying fraud.

- Prevention and Enforcement.

  We have initiated stricter standards for suppliers under Medicare and Medicaid and are working with States to trace repeat offenders who create new organizations in order to continue in the program.

  We are developing methods to ensure that both suppliers and providers who have engaged in fraudulent activities will not be able to move to another state and resume practice.

We are actively coordinating the enforcement activities of carrier fraud units, HCFA staff, the Office of the Inspector General and the Department of Justice in areas where high rates of fraud are suspected.

Status: These programs are all ongoing. GTE was awarded the design contract for the MTS in January 1994. HCFA plans to begin implementation in 1997.

Budget Impact: Significant savings are expected. Each additional dollar spent on payment safeguards activities, including fraud and abuse activities, would result in at least eight dollars of savings to the Medicare Trust Funds. The Department and HCFA continue to work to establish a secure source of funding for this important type of investment in program integrity.

Billing and Payment Improvements

Issue: Providers are increasingly frustrated with the perceived administrative burden and complexity of Medicare's billing procedures.

Discussion: HCFA has undertaken several actions under current law to streamline our billing and payment procedures. In addition, we are considering some legislative proposals as part of the 1996 budget and legislative process.

- Eliminating Pre-Billing Attestation Requirement.

  HCFA is eliminating pre-billing requirements for attestation by physicians of diagnoses and major procedures performed in the hospital. This will lessen the administrative burden on physicians who provide services to Medicare beneficiaries.

- Providing Uniform Identification Numbers to all Providers.

  HCFA is leading an effort involving other Federal payers of health services, including the Department of Veterans' Affairs, the Department of Defense, and State Medicaid agencies to provide unique provider identification numbers to all providers of government health services. Having uniform provider numbers for all government health programs will make it easier for physicians to complete billing forms.

- Simplifying the "Important Message from Medicare".

  HCFA plans to simplify the content of this message and to simplify the way hospitals distribute it.

Status: Work is underway on all three administrative actions. We expect to begin assigning new provider numbers by the end of 1996, before implementation of MTS.

Budget Impact: Minimal budget impact.

Medicare Transaction System

Issue: At present, Medicare and its providers must cope with 14 different claims processing systems operated by 79 insurance companies at 62 sites. Information flow from Medicare to providers, and vice versa, is unnecessarily slow, complex, and costly.

Discussion: HCFA has awarded a contract for the development, testing, and implementation of a new Medicare Transaction System (MTS). This uniform, national system for processing Medicare claims will replace the diverse existing systems and significantly simplify administrative operations for beneficiaries, providers, and Medicare. Implementation of the MTS will begin in 1997. Benefits that will flow from the new system include:

- Improved service for beneficiaries
- Improved service for providers
- Improved management of program expenditures
- Greater uniformity in coverage and payment decisions
- Enhanced capability to identify fraud
- Improved coordination of benefits

While MTS is being developed for the Medicare program, we acknowledge that MTS will have implications well beyond Medicare. MTS will well shape the environment for information transaction in Medicaid, public health, other government programs, and private industry. In the development of MTS, we are being sensitive to the needs of all industry participants, and are working to ensure that providers and payers are not caught between incompatible systems. HHS has moved to set up a steering committee to coordinate information policy within HHS and to ensure ongoing coordination with the private sector as data systems for HCFA and the Public Health Service are integrated and streamlined.

Status: GTE was awarded the design contract for the MTS in January 1994. HCFA plans to begin implementation in 1997.

Budget Impact: Without MTS, HCFA would have difficulty managing claims processing in an era of shrinking administrative budgets. By enhancing HCFA's ability to detect and prevent fraud, MTS will protect the integrity of the Medicare Trust Funds.

Changes Affecting Providers

Issue: The Medicare program has many administrative requirements that often burden and constrain providers.

Discussion:

- Facility Conditions.

  We are revising the conditions of participation for hospitals, end stage renal disease facilities, and home health agencies to make them more easily understandable, outcomes-based, and less process-oriented.

- HMO Organizational Structure and Services (OMC-007-F).

  This regulation will provide organizations which operate HMOs that are federally qualified under title XIII of the Public Health Service Act with greater flexibility in operating other health benefit plans. It would also authorize, with certain limitations, federally qualified HMOs to offer out-of-plan physician services and require a reasonable deductible for those services. Further, this regulation would permit the HMO to use assets of the parent organization to meet fiscal soundness and insolvency protection requirements.

Status: The hospital and the ESRD revisions are in the developmental stage. The Notice of Proposed Rulemaking for the home health agency conditions of participation is expected to be published in November 1995. The HMO final rule is scheduled to be published in 1995.

Budget Impact: No budget impact.

Transforming Medicare Peer Review

Issue: HCFA, through contractor Peer Review Organizations and ESRD Networks (hereafter referred to as Quality Improvement Programs (QIPs)), has historically monitored quality through a detection program. This was accomplished primarily through the intensive review of individual case records (physician or provider records) that had been selected as part of random samples and outlier focused samples.

Discussion: Under the Health Care Quality Improvement Program (HCQIP), HCFA has reinvented, and is continuing to reinvent, Medicare's quality assurance programs. Over the next five years, HCQIP is expected to encompass an integrated quality management system that is emerging as part of HCFA's strategic plan.

HCQIP is based on the principle that QIPs can do more to improve the quality and cost effectiveness of care by bringing typical care into line with best practices than by inspecting to identify erred treatment in individual cases. The key HCQIP objectives are to:

- Build a community of those committed to improving quality;
- monitor and improve quality of and access to care;
- communicate with beneficiaries and providers of care so as to promote informed health choices;
- protect beneficiaries from poor care; and
- create a supporting infrastructure to make these achievements possible.

Among the primary HCQIP initiatives are:

o Local and National Improvement Projects.

As part of HCQIP local cooperative projects, QIPs work with the local health care community to identify and interpret scientifically sound parameters of practice to measure the quality of care. These parameters of care are often based on practice guidelines developed by the Agency for Health Care Policy and Research (AHCPR) as well as other authoritative clinical bodies. QIPs use statistical quality surveillance to examine variations in both the processes and outcomes of care. QIPs share these data with providers and physicians and work cooperatively with them to interpret and apply findings. HCQIP gives QIPs and HCFA a chance to demonstrate that health care provided to Medicare beneficiaries can be measurably improved.

Status: To date, QIPs have reported on 514 collaborative improvement projects. Of these, 60 have been completed, 222 are in progress and another 154 are in development. QIPs have abandoned 78 projects to date. Approximately 20 percent of projects address the use of pharmaceuticals, such as antibiotics and ACE inhibitors. Another 10 percent address the accuracy of diagnostic and procedure coding. Other projects that involve multiple PROs include blood transfusions and cardiac catheterization. In January 1995, all PROs will begin the cooperative cardiovascular project. This project will focus exclusively on the treatment of heart attacks.

- o Clinical Data Quality Surveillance.

  Under this initiative, QIPs will measure processes and outcomes of care against community-accepted clinical standards of quality and practice guidelines. Upon identifying and assessing statistical variations, QIPs will intervene and work collaboratively with hospitals and physicians to improve the delivery of care. In instances of provider incompetence and negligence, QIPs will have a stronger role in notifying licensing and certifying agencies and making sanction recommendations to the Inspector General.

  Status: Implementation is underway.

- o Investigation of Beneficiary Complaints.

  Under this initiative, revised regulations will allow for a more aggressive posture in soliciting and investigating beneficiary complaints to the QIPs and provide a more thorough and sensitive follow-up to these complaints.

  Status: Initial planning work is underway.

- o Beneficiary Education.

  HCFA will improve educational beneficiary outreach programs in health promotion and disease prevention to help beneficiaries make better health choices, and ensure that they are fully aware of their rights to quality care under Medicare.

  Status: Initial work is underway.

Budget Impact: Budget neutral. HCFA anticipates that this program change will significantly improve the quality of care provided to Medicare beneficiaries.

Use of Quality Indicators in the Medicare/Medicaid Survey and Certification Program

Issue: The current process by which HCFA can ensure provider compliance with Federal health and safety requirements involves labor-intensive, expensive, on-site "snapshot" performance surveys. Through routine site visits, over 7,000 surveyors observe, interview, and review records of 22 different Medicare and Medicaid provider and supplier categories.

Discussion: HCFA has been developing quality indicators (QIs) in nursing homes and home health agencies for use in the survey and certification process. QIs are tested, validated and reliable data-driven "markers" of outcomes of care, or processes of care, that have been shown to be predictors of outcomes of care. QI data will be collected, analyzed and shared with providers, States, HCFA, and beneficiaries.

The ability to use QI data in the survey process and provider-based internal quality improvements depends on requiring standard assessment and reporting of the critical QI data, the implementation and maintenance of a State and national data system and the development of a reliable complete data base of information reported by the facilities on individual clients.

QIs have multiple beneficial uses:

- Use by regulators in the survey process;
- use by providers in internal quality improvement;
- use by beneficiaries to inform themselves as they make critical choices for health care;
- use by professionals, researchers, social and health policy experts to inform care practices and policy; and
- use by payment policy experts to help inform payment policy.

Status: Quality indicators for nursing homes and home health agencies (HHAs) have been developed and are now being piloted in use. New HHA conditions of participation are under development, as is a new standard assessment tool for HHAs. Computerization of the existing nursing home assessment tool information is in progress. Full implementation of the nursing home project will occur in 1 to 2 years, and the home health project will be implemented in 3 to 4 years. Plans are being made to develop quality indicators for end stage renal disease facilities, hospices, and intermediate care facilities for the mentally retarded as well.

Budget Impact: The use of QI data will not replace the on-site inspection, but will enable the State survey agencies to assess provider performance throughout the year and across all the providers without actually being there all the time. This will allow diminishing survey resources for on-site inspections to be targeted to problem providers and used more efficiently.

Quality Improvement Programs Procurement Process

Issue: The procurement process in contracting with Peer Review Organizations and End Stage Renal Disease Networks (hereafter referred to as Quality Improvement Programs, or QIPs) has been time and labor intensive for both government and contractor personnel, leading to delays in completing procurement actions. On the average, it takes about 18 months to complete any major procurement action.

Discussion: HCFA has analyzed delays in the procurement process and determined ways to streamline and improve the procedure. Delays were found to occur mostly at the scope of work development stage. For example, current procedures used in developing the independent government cost estimates (IGCE) are cumbersome and difficult to use.

HCFA has determined, and will embark on, ways to streamline and improve the procurement procedure. With respect to developing IGCEs, HCFA will soon award a contract for a user friendly computer program. Other areas of improvement will include:

- Effective communication of negotiation positions among all HCFA teams prior to negotiations;
- procedures to ensure receipt of proposals by all neutral panel members for noncompetitive procurement;
- elimination of the confusion and problems resulting from having too many versions of the Requests for Contracts/Proposals;
- ways to increase administrative support during peak periods in the procurement process;
- elimination of inconsistent submission of Justification for Other Full and Open Competition.

In addition, the Social Security Act allows QIP contracts to be non-competitively renewed. HCFA has developed a streamlined procurement process for noncompetitive renewal of QIP contracts. HCFA is working with the QIPs to develop pricing principles and contract provisions based on a common understanding of the Statement of Work. HCFA intends to apply this collaborative model to other contractors and agents. Benefits derived from this approach include: reduced acquisition processing time; elimination of the need for technical proposal review for contractors who have met the renewal criteria; cost savings realized by both the QIPs and the government in the procurement process; improved understanding of contract expectations; and greater uniformity in QIPs' contract execution.

Status: Vendor proposals for the contract to develop a user-friendly program for the IGCE have been received and are under evaluation. Award of the contract will take place soon. Implementation on other areas of improvement has commenced.

Budget Impact: Cost savings have not been quantified. Full implementation of the above recommendations should reduce the processing time for PRO and ESRD procurement from 18 to 12 months.

Modifications to Requirements Under the Clinical Laboratories Improvement Amendments (CLIA)

Issue: Current CLIA requirements are burdensome, particularly for the more than 130,000 laboratories that have not been regulated previously. Burdens include: meeting comprehensive quality requirements based on the complexity of the testing performed in the laboratory, registration and other paperwork requirements, and fee payments. State survey agencies are also burdened with conducting biennial on-site surveys of approximately 40,000 laboratories to determine compliance with the complex and comprehensive CLIA requirements.

Discussion: HCFA has embarked on, or will pursue, various administrative actions to reduce unnecessary burdens.

- Categorization of Tests and Personnel Modification (HSQ-216-FC). This regulation will expand the category of microscopy tests which are exempt from inspection, and this would effectively double the number of laboratories exempt from routine survey under this provision. The rule would also give flexibility to laboratories by expanding the list of professionals who may perform moderate complexity microscopy procedures. This should reduce the burden to rural and medically underserved areas in having to compensate and recruit health personnel who are in short supply.

  Status: This rule is in the final stages of clearance prior to OMB review.

  Budget Impact: Approximately 10,000 laboratories would be exempted from routine inspections.

- CLIA Deeming Notices: HCFA has approved, as deeming certification agencies, the Commission on Office Laboratory Accreditation, the Joint Commission on Accreditation of Health Care Organizations, and the American Society for Histocompatibility and Immunogenetics. Applications from the American Osteopathic Association, the College of American Pathologists, and the American Association of Blood Banks have been received. Furthermore, the Washington State exemption from CLIA was recently re-approved for 2 years.

  Budget Impact: The deeming arrangement will reduce the number of laboratories surveyed by HCFA by 20,000 laboratories.

- Categorization and Certification Regulations for "Accurate and Precise Technology" (APT) Tests (HSQ 222-P). By creating a new subcategory of lab procedures called "accurate and precise technology" tests, this rule would reduce the burden on laboratories to comply with all of the moderate complexity testing requirements.

  Status: The Notice of Proposed Rulemaking is being prepared.

- Flexible Surveys for Small Laboratories. HCFA has devised a flexible survey which accounts for the great variability among laboratories in lab test volumes and degree of lab test complexity. Approximately 1,000 laboratories (those that are low volume or that perform only simple screening or preventive tests for ambulatory patients) will be surveyed once every four years. Laboratories will be required to respond to specific questions regarding the types of testing conducted and how they are meeting the corresponding CLIA quality requirements. Based on this information, surveyors can determine the necessity of on-site surveys.

  Status: Evaluation of the survey process is currently underway.

  Budget Impact: A flexible survey process will enhance surveyor efficiency and better utilize resources. It is expected to significantly reduce administrative costs in the first two years of the program.

- Outcome-Oriented, Performance-Based Surveys. Plans are underway to develop a more outcome-oriented, performance-based CLIA survey process.

U.S. Department of Labor

Pension and Welfare Benefits Administration
Washington, D.C 20210

Kim - Look at this
& make
suggestions
for
improvements

November 22, 1994

MEMORANDUM FOR: CHRIS JENNINGS
Senior Health Policy Analyst Special Assistant to the President!

FROM: MEREDITH MILLER
Deputy Assistant Secretary, PWBA

SUBJECT: Health Care Related Regulatory & Administrative Initiatives - Retirement Income Security Act (ERISA)

The attached document is in response to your request to outline the scope of potential Department of Labor (the Department) regulatory projects with respect to section 3(40) of the Employee Retirement Income Security Act (ERISA) and other possible administrative initiatives and their potential impact with regard to health care coverage of American workers and their families.

Standards Under Section 3(40) of ERISA Regarding Collectively Bargained Plans

For the past several years, the Department and state insurance departments have had to dedicate significant resources to problems of fraud, mismanagement, and abuse in the provision of health care benefits to American workers. Many of these problems are a direct result of the activities of unscrupulous entrepreneurs seeking to market employee health care coverage to employers without complying with financial solvency and other state insurance regulatory requirements.

In 1983 Congress amended ERISA to make clear that an arrangement that constitutes a "multiple employer welfare arrangement" (MEWA), as defined in the statute, is subject to state insurance regulation without regard to whether the arrangement is an ERISA-covered plan. The 1983 amendments specifically excepted from the MEWA definition plans that are established or maintained under, or pursuant to, one or more agreements that the Department finds to be collective bargaining agreements. This exception is now being exploited by MEWA operators, who through the use of sham unions and collective bargaining agreements, market fraudulent insurance schemes under the guise of collectively bargained welfare plans exempt from state insurance regulation.

Administrative Action/Description of the Regulatory Project

- The regulatory project will establish standards for determining whether an employee benefit plan is established or maintained pursuant to one or more collective bargaining agreements for purposes of their exclusion from the MEWA definition in section 3(40) of ERISA and, thus, exempted from state regulation.

- It will clarify the scope of the exception from the MEWA definition for plans maintained under or pursuant to one or more collective bargaining agreements by providing criteria which will serve to distinguish plans maintained by legitimate unions pursuant to bona fide collective bargaining agreements from health insurance scams promoted and marketed by illegitimate unions.

- This project is currently under development and efforts are now underway to coordinate our views on this project with other executive agencies that may be affected by our actions.

Other Possible Regulatory Projects

The Department is also exploring whether the Pension and Welfare Benefits Administration (PWBA) may develop and undertake the following three regulatory projects under ERISA that could address issues raised in the health reform debate.

Amend the Section 503 Regulations to Add Urgent Request Procedure

PWBA is considering whether to amend ERISA section 503 to give more specific guidance regarding timeframes for processing claims procedures that involve urgent requests for preauthorization of items and services. This particular procedural change could be put forward in a proposed rulemaking. The reason for proceeding by way of a proposed rule on this particular procedure is the widely documented growth in managed care plans, many of which require preauthorization of services.

Such urgent requests would only be made when the health of the individual could be in serious jeopardy if he or she did not receive the item or service. The new procedure could stipulate that:

- the request must be accompanied by a certification that the item or service is urgently needed
- the plan must approve or deny the request within a very limited period of time
- if the request is denied the claimant could have an equally fast review of the denial

RFI on Timeframes for Benefit Claims Procedures

We are considering a project that could include a Request for Information (RFI) to ascertain whether there is also a need to update the current broad language on timeframes for processing routine claims with more specific requirements.

At present the regulations under section 503 require that claimants be notified of decisions regarding claims "within a reasonable period of time" after the plan receives the claim. Absent special circumstances, current regulations specify that the period of time in which to notify the claimant will be deemed unreasonable if it exceeds 90 days. Several of the major health care reform bills, including the Administration's Health Security Act, sought to significantly reduce the amount of time that a plan could take to render its decision.

- The Department's rational for proposing such changes could be the improved and faster technology for claims processing now available some 15 years after the present regulation was written as well as the changes in how benefits are now provided.

- The advantage of opening up this regulatory area would be to help some participants and beneficiaries receive faster and more efficient responses to their benefit claims.

- One potential disadvantage is that sponsors and administrators will argue that any new rules are overly bureaucratic and burdensome and may cause plan sponsors to terminate plans, thus eliminating coverage.

Amend the Section 503 Regulations to Add Standards Plans Should Use When Reviewing Benefit Claims Denials

PWBA is considering whether to amend the ERISA benefits claim procedures under the section 503 regulations to establish standards a plan must use when reviewing its initial decision to deny a claim, such as interpreting ambiguous language against the drafter. This rule would fill in the void that presently exists since judicial review of benefit claims decisions grants judicial deference to the fiduciary's decision.

Such standards could be required in all cases or only in situations where the plan chooses not to have an independent fiduciary review the claims appeals. Alternatively, the regulation could be drafted so that a plan could avoid having to meet the standards, even if it did not use an independent fiduciary, by offering participants the opportunity to pursue claims through ADR procedures such as mediation after exhausting all plan procedures.

PWBA Reinvention Goals

The PWBA has established certain reinvention goals for FY 1995 that reflect the priorities of the Assistant Secretary and the Secretary to improve customer service and enhance the protection of participants and beneficiaries of employee benefit plans, including health plans. The following health care related goals have been adopted:

- Establish a coordinated enforcement program to ensure that health care promises made by employers to their employees are fulfilled.

- Continue to implement the decentralized litigation process with the Solicitor's office to assure early involvement and better service to participants by decentralizing litigation to all field offices.

- Continue to streamline the enforcement process and procedures by eliminating unnecessary levels of review and internal reports and by reducing the number of overaged cases, i.e., those cases pending for more than 18 months. During FY 1994, through reinvention & streamlining, PWBA eliminated 50% of its field enforcement reports and 33% of the national office enforcement reports. As of August 30, PWBA had closed 1250 overaged cases.

- Initiate by January 1995, a pilot project with the American Bar Association in Washington, DC, providing pro bono legal services to indigent benefit plan participants.

- Initiate by January 1995 (subject to OMB approval), a delinquent filer voluntary compliance program designed to encourage non-filers and late filers to come into compliance and resolve their filing penalties at a reduced amount.

- Develop and submit to OMB for consideration an ERISA enforcement bill by June 1995 that strengthens private and governmental remedies to include such possible components as Mertens, 502(l), MEWAs, ADR, and audit provisions.

- Prepare recommendations for legislative and regulatory changes to enhance and facilitate reporting to the department and disclosure to participants by June 1995.

- Technical assistance staff will respond to written inquiries from participants and beneficiaries in employee benefit plans within 30 days of receipt, and respond to telephone inquiries by the end of the business day following the day on which the call is received.

HCFA LEGISLATIVE SUMMARY

November 30, 1994

SOCIAL SECURITY ACT AMENDMENTS OF 1994
(P.L. 103-432)

On October 31, 1994, the President signed into law H.R. 5252, the Social Security Act Amendments of 1994 (P.L. 103-432). The law makes numerous miscellaneous and technical corrections to various titles of the Social Security Act. This summary describes only those changes that pertain to the Medicare program and (indirectly) Medicaid eligibility requirements.

Debbie I. Chang

Debbie I. Chang
Director
Office of Legislative and Inter-Governmental Affairs

TITLE I -- MEDICARE

SUBTITLE A -- PROVISIONS RELATING TO PART A

SUBTITLE B -- PROVISIONS RELATING TO PART B

Part I -- Physicians' Services

TITLE I -- MEDICARE

SUBTITLE A -- PROVISIONS RELATING TO PART A

Section 101. Provisions Relating to Adjustments to Standardized Amounts for Wages and Wage-Related Costs

Under prior law, the Medicare Geographic Classification Review Board (MGCRB) guidelines were based on a reclassification system using metropolitan statistical areas as the definition of labor market areas. This amendment allows the Secretary to change the guidelines for the MCCRB if the hospital wage index is changed so that metropolitan statistical areas are no longer the basis for the labor market areas. Effective upon enactment. The section also makes other minor technical changes.

Section 102. Essential Access Community Hospital (EACH) Amendments

Under prior law, grants were provided to facilities in seven States to design networks around the concept of a limited service hospital. These small facilities, Rural Primary Care Hospitals (RPCHs), are linked in referral networks with the larger referral EACH hospitals. Both of these facility types, once certified, become part of the operating program under Medicare. This amendment (beyond making minor technical corrections):

- Re-authorizes EACH/RPCH program appropriations through fiscal year (FY) 1997 at the current annual level of $25 million;

- Changes the 72 hour limit on inpatient admissions to an <u>average</u> of 72 hours;

- Qualifies urban hospitals as EACHs, although these providers will not receive a change in Medicare payment as a result of this new designation;

- Authorizes a RPCH that had a swing bed agreement (at the time that it applies to be a RPCH) to retain all of its licensed beds for extended care services in addition to the 6-12 beds it is allowed under the RPCH program;

- Prohibits RPCHs from providing surgery or other services that require general anesthesia, unless the attending physician certifies that the risk of transfer to another facility outweighs the benefits;

- Changes the date for implementation of inpatient and outpatient rural primary care hospital prospective payment is from January 1, 1993 to January 1, 1996.

This section is effective upon enactment.

Section 103. Provisions Relating to Rural Health Transition Grant Program

This provision extends the Rural Health Transition Grant Program through FY 1997 and authorizes $30 million annually. It also changes the reporting frequency from six months to once a year. Rural Primary Care Hospitals would be eligible to receive grants. Effective upon enactment.

Section 104. Psychology Services in Hospitals

This amendment allows clinical psychologists to supervise the care of Medicare patients in a hospital if they are authorized to do so under State law. Effective upon enactment.

Section 105. Medicare-Dependent, Small Rural Hospitals and Sole Community Hospitals

This provision makes minor technical amendments to OBRA-1993, effective upon enactment.

Section 106. Skilled Nursing Facilities

- Construction of Wage Index.

  This amendment requires the Secretary to begin to collect SNF wage data within one year of date of enactment for the purposes of constructing a SNF wage index.

- Clarification of Repeal of Utilization Review Requirements.

  OBRA-1987 amendments created confusion about whether or not a utilization review plan is required for skilled nursing facilities (SNFs) and other providers of extended care services. Section 1819 enumerates quality assurance and other requirements for SNFs, but does not explicitly require utilization review activities. However, other sections of the Act (sections 1866(d) and 1814(a)(5)) do make reference to SNFs and extended care services in the context of utilization review requirements. This amendment eliminates all references to SNFs and post-hospital extended care services in sections 1866(d) and 1814(a)(5), and thereby clarifies that utilization review plans and activities for SNFs and extended care services are permitted, but not required. The effective date is as if included in the enactment of OBRA-1987.

- Conforming Amendments to Nursing Home Reform.

  Under prior law, the Secretary could prohibit approval of a nurse aide training program offered by a S.F if, within the previous two years, the SNF had been subject to an extended recertification survey. This section clarifies that such a prohibition is not authorized if the extended survey shows that the SNF is in compliance with the Medicare participation requirements of section 1819. This amendment also makes other technical and conforming amendments to correspond to Medicaid Nursing Home Reform.

  This section also increases the minimum amount required for separate deposit of personal funds from $50 to $100.

  This section also clarifies that a State shall not include, in a nurse aide registry, allegations of resident abuse or neglect or misappropriation of resident property unless such allegations are specifically documented by the State.

Section 107. Notification of Availability of Hospice Benefit

This provision requires hospitals to notify beneficiaries, as part of the discharge planning process, of the availability of hospice services. The effective date is the first day of the first month beginning more than one year after date of enactment.

Section 108. Clarifying Expertise of Individuals to Serve on the Prospective Payment Assessment Commission

This amendment changes the qualifying expertise for ProPAC commissioners to permit appointment of persons with other than hospital backgrounds. Effective upon enactment.

Section 109. Authority for Budget Neutral Adjustments for Changes in Payment Amounts for Transfer Cases

This amendment gives the Secretary authority to make budget neutral adjustments to the prospective payment system (PPS) standardized amounts when changes are made to transfer payment policy. Effective upon enactment.

Section 110. Clarification of DRG Payment Window Expansion; Miscellaneous and Technical Corrections

Under prior law, the DRG payment window of 3 days applied to all hospitals, PPS and otherwise. This amendment changes the payment window to one day for non-PPS hospitals. The provision also makes other technical corrections to Part A. Effective upon enactment.

SUBTITLE B -- PROVISIONS RELATING TO PART B

Part I -- Physicians' Services

Section 121. Development and Implementation of Resource-Based Methodology for Practice Expenses

This section requires the Secretary to develop a methodology for implementing a resource-based system for determining practice expense relative value units for all physicians' services. The Secretary must report to Congress on the methodology by June 30, 1996. The methodology must be implemented by January 1, 1998.

Section 122. Geographic Cost of Practice Index Refinements

This amendment requires the Secretary to consult with appropriate representatives of physicians in the periodic review of geographic cost of practice indices (GPCIs). This section also requires the use of the most recent data in establishing GPCIs. Finally, it requires a report to Congress, within one year from enactment, on the availability, limits, and costs of collecting GPCI data.

Section 123. Extra-Billing Limits

- Enforcement of Limits.

  This provision: (1) clarifies rules applicable to non-participating physicians and suppliers regarding beneficiary liability and physician sanctions, and (2) requires timely refunds for non-participating physicians (effective upon enactment), and timely refunds for non-participating suppliers or other persons (effective January 1, 1995).

- Clarification of Mandatory Assignment Rules for Certain Practitioners.

  This amendment clarifies that mandatory assignment applies to <u>all</u> services furnished by non-physician practitioners who bill Medicare on a fee-for-service basis, effective January 1, 1995.

- Information on Extra-Billing Limits.

  Effective July 1, 1995, this section requires carriers to include, in the Explanation of Medicare Benefits (EOMBs), information regarding the applicable limiting charge (including information concerning the right to a refund) if the limiting charge was exceeded.

Also, effective for contracts as of January 1, 1995, this section requires carriers to: determine, prior to making payment, if the limiting charge was exceeded; notify the physician periodically of excess charges; and provide for prompt response to physician inquiries concerning the accuracy of limiting charges.

- Report on Charges in Excess of Limiting Charge.

  This amendment requires the Secretary's annual report to Congress on assignment, participation, and beneficiary out-of-pocket expenses to include information on limiting charge excesses, effective with reports beginning with 1995.

- Miscellaneous and Technical Amendments.

  This section also makes a conforming change allowing restitution to beneficiary from civil money penalties collected for violations of mandatory assignment for laboratory services, effective upon enactment.

Section 124. Relative Values for Pediatric Services

This amendment requires the development of relative values for the full range of pediatric services, including necessary refinements, by July 1, 1995. It also requires the Secretary to conduct a study and report to Congress by July 1, 1995 on whether there are significant variations in the resources used in providing pediatric and other services to different populations, and to recommend whether coding or payment changes are needed to appropriately reflect the resources involved in providing pediatric services.

Section 125. Administration of Claims Relating to Physicians' Services

- Limitation on Carrier User Fees.

  Effective upon enactment, the Secretary and carriers are prohibited from imposing user fees for five specified activities: filing claims; errors in filing claims or denied claims; appeals; obtaining a unique identifier; and responding to inquiries about physician services or providing information in response to medical review of services.

- Clarification of Permissible Substitute Billing Arrangements.

  Prior law allowed substitute billing arrangements (i.e., payment made to one physician for the services of a second physician) only for medical visits furnished on a reciprocal basis for no more than 60 days. This provision expands permissible substitute billing arrangements to include

arrangements involving per diem or other fee-for-time compensation. The provision also allows all physician services (rather than just visits) to be covered. The provision maintains the limitation that the substitute physician provide services for a period not exceeding 60 continuous days and requires that the second physician's unique identifier be reported on the first physician's claim. Effective with the first month beginning more than 60 days after enactment.

Section 126. Miscellaneous and Technical Corrections

- Overvalued Procedures.

  This amendment corrects the list of overpriced procedures as designated in section 4101 of OBRA-1990. Effective as if included in OBRA-1990.

- Radiology Services.

  This amendment corrects the radiology reductions (section 4102 of OBRA-1990) so as not to increase fees below the target. Effective as if included in OBRA-1990.

- Anesthesia Services.

  This amendment corrects the anesthesia reductions (section 4103 of OBRA-1990) so as not to increase fees below the target. Effective as if included in OBRA-1990.

- Assistants at Surgery.

  This section clarifies that the limiting charge in 1991 could not exceed the applicable percentage of the prevailing charge associated with the payment for an assistant-at-surgery. Effective as if included in OBRA-1990.

- Technical Components of Diagnostic Services.

  This provision clarifies that the list of diagnostic services capped by section 4108 of OBRA-1990 would not also be reduced under other OBRA-1990 provisions. Effective as if included in OBRA-1990.

- Statewide Fee Schedules.

  This provision mandates that Nebraska and Oklahoma be treated as statewide areas for purposes of the Medicare fee schedule (note that Nebraska and Oklahoma have already become statewide areas under the Medicare physician fee schedule), but eliminates the special OBRA-1990 conditions (section 4117) for such treatment. Effective as if included in OBRA-1990.

- Other Miscellaneous and Technical Amendments.

  This amendment also makes other technical and conforming changes to OBRA-1990 relating to physician payment, effective as if included in OBRA-1990.

- Other Corrections.

  This amendment eliminates the reporting requirement for the mandated study regarding use of time in medical visits, effective upon enactment. This amendment also repeals, effective beginning with FY 1994, the provision giving carriers bonuses equal to 1 percent of the carrier annual budget in order to increase participation of physicians and suppliers.

Part II -- Durable Medical Equipment

Section 131. Certification of Suppliers

- Requirements.

  This amendment establishes the following requirements:

  - Stipulates that, beginning on the date of enactment, no payment may be made to suppliers of medical equipment and supplies unless they obtain a supplier number and meet standards established by the Secretary. The section also requires the Secretary to establish, by January 1, 1996, additional standards related to: compliance with State and Federal licensure requirements, maintenance of a physical facility, and proof of product liability insurance. The above requirements do not apply to medical equipment and supplies furnished incident to a physician's service.

  - Prohibits the issuance of more than one supplier number to a supplier unless more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

  - Prohibits the Secretary from delegating (other than to a carrier) the responsibility of determining whether suppliers meet the supplier standards.

  - Expands the category of suppliers to whom the prohibition on completing certificate of medical necessity (CMN) forms applies, to include suppliers of prosthetics, orthotics, and other medical supplies. Allows suppliers to complete the administrative portion of forms and requires suppliers to include the charge and fee schedule amount on the form.

phone call

- Requires the Secretary to annually review the coverage and utilization of durable medical equipment (DME) items, prosthetics, orthotics, and other medical supplies to determine whether certain items should be made subject to coverage and utilization criteria.

o Use of Covered Items by Disabled Beneficiaries.

This provision requires the Secretary to study the impact of Medicare payments on the ability of disabled beneficiaries to obtain DME, including customized items. A report on the study is due to Congress one year after enactment.

o Criteria for Treatment of Items as Prosthetic Devices or Orthotics and Prosthetics.

This provision requires the Secretary to report to Congress on prosthetic devices and orthotics that do not require custom fitting and recommend an appropriate payment methodology for these items. The report is due one year after enactment.

Section 132. Restrictions on Certain Marketing and Sales Activities

With limited exceptions, this section prohibits suppliers from contacting beneficiaries by telephone regarding the provision of an item of DME, prosthetics, and orthotics. No payment may be made to a supplier for an item furnished in violation of this provision. A supplier may be excluded from the program for a pattern of violations. Suppliers are required to make refunds to beneficiaries for any amounts collected on unassigned claims for items furnished in violation of the provision.

Section 133. Beneficiary Liability for Noncovered Services

o Unassigned Claims.

Under prior law, physicians were required to make refunds to beneficiaries for unassigned claims for their services that are denied as medically unnecessary. This refund requirement for unassigned claims applied only to physician services.

This amendment expands the refund requirements to DME, prosthetics, orthotics, and medical supplies. It requires suppliers to make refunds to beneficiaries when these items are furnished on an unassigned basis if: payment is denied for lack of medical necessity; an item is furnished by a supplier who does not have a supplier number; or a prior authorization denial is made.

- Assigned Claims.

  Under prior law, beneficiaries were not liable for assigned claims (including DME, prosthetics, orthotics, and medical supplies) denied as medically unnecessary. Beneficiaries were indemnified by the program for any amounts paid, and Medicare collected amounts owed from the provider or supplier.

  This amendment expands the limitation of beneficiary liability for items of DME, prosthetics, orthotics, and medical supplies to certain situations other than medical necessity denials. Specifically, beneficiaries will not be liable when: an item is furnished by a supplier who does not have a supplier number; payment is denied because of violation of the telemarketing provisions; or a prior authorization denial is made. In these instances, suppliers are required to make refunds to beneficiaries for any amounts paid.

Section 134. Adjustments for Inherent Reasonableness

This amendment elaborates on the Secretary's authority to make adjustments to payments for an item of DME, prosthetics, and orthotics if the payment amount that would result from the application of ordinary DME payment rules would be inherently unreasonable (excessive or deficient). Specifically, new language is added that expressly refers to the issue of whether payment is inherently reasonable "on the basis of prices and costs applicable at the time the item is furnished." The section also requires that this inherent reasonableness determination be made for decubitus care equipment, transcutaneous electrical nerve stimulators (TENS), and any other item considered appropriate by the Secretary.

Section 135. Miscellaneous and Technical Corrections

- Updates to Payment Amounts.

  This section makes a minor technical correction.

- Advance Determinations of Coverage.

  Under prior law, carriers were required to make prior approval decisions for seat-lift mechanisms, TENS, motorized scooters, and other items determined by the Secretary to be frequently subject to unnecessary utilization.

  This amendment eliminates the former prior authorization provision and gives the Secretary the authority to require prior authorization for: (1) items frequently subject to unnecessary utilization, either in a carrier's entire service area or a portion of that area; and (2) items furnished by suppliers with a pattern of over-utilization or a substantial

number of claims that are denied as medically unnecessary. The provision also requires prior authorization for customized items if requested by the beneficiary or supplier. The provision is expanded to include prosthetics and orthotics in addition to DME.

o Study of Variations in DME Supplier Costs.

This provision requires HCFA to study DME cost data to determine the proportion of costs that are "service" versus "product" costs, and the extent to which these proportions vary by type of equipment and by geographic region. It also requires HCFA to submit a report to Congress which analyzes the data, recommends a geographic cost index for supplier costs, and analyzes the impact of such an index on Medicare payments. The report is due on July 1, 1995.

o Other Miscellaneous and Technical Corrections.

The amendment also makes minor miscellaneous and technical corrections.

Part III -- Other Items and Services

Section 141. Ambulatory Surgical Center Services

o Payment Amounts for Services Furnished in Ambulatory Surgical Centers.

This amendment:

- Requires surveys of the actual audited costs incurred in ambulatory medical centers (ASCs), beginning January 1, 1995 and every 5 years thereafter, to determine payment amounts.

- Beginning with FY 1996, provides for automatic Consumer Price Index for Urban Areas (CPI-U) updates for ASC services if the Secretary has not otherwise updated the payment amounts for such services.

- Requires consultation with trade and professional groups in developing the list of ASC procedures.

o Adjustments to Payment Amounts for New Technology Intraocular Lenses.

This amendment:

- Requires the Secretary to develop a process for interested parties to request review of the appropriateness of

Medicare payment amounts for a class of new technology intraocular lenses (IOLs).

- Provides that the Secretary, in determining whether a payment adjustment should be made in response to a request for review under the above process, shall take into account whether the lens would result in: reduced risk of operative complications; accelerated postoperative recovery; reduced astigmatism; and other factors.

- Requires the Secretary to publish a notice in the Federal Register, at least annually, which lists the requests made for payment adjustments for new technology IOLs and provides for a 30-day comment period. The Secretary is also required to publish a subsequent notice of the determinations made on such payment adjustments requested.

o Other Technical Corrections.

This section makes other technical corrections.

Section 142. Study of Medicare Coverage of Patient Care Costs Associated with Clinical Trials of New Cancer Therapies

This provision requires the Secretary to study the effects of Medicare coverage of the patient care costs associated with clinical trials of new cancer therapies (where the protocol for the trial has been approved by the National Cancer Institute or meets similar scientific and ethical standards). The study must include an estimate of the cost of coverage, an assessment of whether clinical trials provide the best available treatment, an assessment of whether Medicare coverage would lead to progress in developing new anticancer therapies, and an evaluation of whether there should be criteria for admission of Medicare beneficiaries. A study report is due to Congress within two years of enactment.

Section 143. Study of Annual Cap on Amount of Medicare Payment for Outpatient Physical Therapy and Occupational Therapy Services

This amendment requires the Secretary to study the appropriateness of continuing an annual limitation on payments for outpatient services of independently practicing physical and occupational therapists. A report must be submitted to Congress by January 1, 1996, and include a recommendation for making any changes in the annual limitation, as appropriate.

Section 144. Payment of Part B Premium Late Enrollment Penalties by States

This provision allows States to pay the Secretary, on a quarterly or other periodic basis, a lump sum for the total amount of the part B enrollment surcharges for a group of Medicare beneficiaries.

Section 145. Application of Mammography Certification Requirements

This provision conforms requirements for Medicare coverage of mammography services to the Mammography Quality Standards Act (MQSA) of 1992. Screening mammography services and diagnostic mammography services will be covered only if conducted by a facility that has a certificate of compliance, or provisional certificate, issued by the Public Health Service.

Section 146. Coverage of Services of Speech-Language Pathologists and Audiologists

This section defines speech-language pathology services and audiology services and makes conforming amendments.

Section 147. Miscellaneous and Technical Amendments

- Immediate Enrollment in Part B by Individuals Covered by an Employment-Based Plan.

  Under prior law, the special enrollment period (SEP) allowed individuals with employer group health plan (EGHP) coverage to enroll in Part B beginning with the first month that the individual is no longer enrolled in the EGHP and ending seven months later. This amendment revises the SEP for individuals with EGHP coverage to allow them to enroll in Part B at any time that they are still enrolled in the EGHP and up until 8 months after their EGHP coverage ends.

- Other Technical Amendments.

  The section also makes other technical corrections.

SUBTITLE C -- PROVISIONS RELATING TO PARTS A AND B

Section 151. Medicare Secondary Payer Reforms

- Improving Identification of Medicare Secondary Payer Situations.

  To improve the Secretary's identification of Medicare secondary payer (MSP) situations, this amendment:

  - Mandates that HCFA provide beneficiaries an initial enrollment questionnaire on which they identify whether Medicare would be the primary or secondary payer. Effective date is 60 days after enactment.

  - Prohibits the denial of Medicare payment solely on the grounds that the beneficiary does not return the questionnaire. Effective upon enactment.

  - Mandates denial of Part B claims if the provider does not complete the Medicare secondary payer (MSP) questions on the claim form. Civil money penalties may be levied on entities that knowingly, willfully and repeatedly fail to, or inaccurately complete, the MSP questions on the claim form. Effective date is 120 days after enactment.

- Improvements in Recovery of Payments from Primary Payers.

  This provision requires contractors (fiscal intermediaries and carriers) to submit to the Secretary annual reports describing the steps taken to recover mistaken Medicare primary payments. It further mandates that contractors be subject to standards and criteria relating to success in payment recovery in their performance evaluations. This provision is effective for contract years beginning with 1995.

- Deadline for Reimbursement by Primary Plans.

  This amendment codifies the current policy on payment of interest if recoveries are not received within 60 days of notice. Effective upon enactment.

- Miscellaneous and Technical Corrections.

  This section also makes technical corrections to OBRA-1993, OBRA-1990, and OBRA-1989.

Section 152. Physician Ownership and Referral

- Reporting Requirements.

  This amendment extends the reporting requirement, which currently applies to physician ownership arrangements, to physician investment and compensation arrangements. Effective upon enactment. The provision also makes other minor technical amendments.

- Designated Health Services List.

  This provision deletes reference to "other diagnostic services" from the list of services subject to the referral ban and clarifies that radiology services include magnetic resonance imaging, computerized axial tomography scans, and ultrasound services. The effective date is for referrals made on or after January 1, 1995.

  This provision also clarifies that the referral ban applies to supplies used in conjunction with radiation therapy services, durable medical equipment, and prosthetics, orthotics and prosthetic devices. The effective date is for referrals made on or after January 1, 1995.

- Revision of Effective Date Exception.

  This amendment revises the exceptions built into the OBRA-1993 effective date provisions.

  Referrals made for clinical laboratory services before January 1, 1995 are <u>not</u> subject to the following OBRA-1993 provisions:

  - Expansion of the definition of financial relationship to include ownership or investment interest in an entity that <u>holds</u> an ownership or investment interest in an entity that provides designated health services;

  - Requirement for group practices receiving the in-office ancillary services exception that services be billed under a group practice's billing number, and that members of the group personally conduct at least 75 percent of the physician-patient encounters;

  - Rural services exception requirement that <u>substantially all</u> services provided by a rural provider are to residents living in the rural area; and

  - Prohibition on group practices receiving an in-office exception from having direct or indirect compensation arrangements based on volume or value of referrals, or

overall profits and productivity bonuses that are based on volume or value of referrals.

The following provisions are a combination of pre-OBRA-1993 exceptions and OBRA-1993 revisions:

- With regard to ownership or investment in publicly traded securities, corporations that meet the pre-OBRA-1993 total assets requirement ($100,000,000 in most recent fiscal year) are not subject to the corresponding OBRA-1993 provisions ($75,000,000 in the most recent year or this amount, on average, over the last three fiscal years).

- OBRA-1993 exceptions for compensation under personal service arrangements shall apply except to arrangements that satisfy pre-OBRA-1993 requirements either for employment and service arrangements with hospitals or for service arrangements with non-hospital entities.

The following pre-OBRA-1993 provisions remain in effect until January 1, 1995 with regard to the provision of clinical laboratory services:

- Exception for ownership and compensation arrangements with hospitals as long as the relationship does not relate to the provision of clinical laboratory services.

- Exception for ownership or investment of publicly-traded securities that are available on terms generally available to the public and are in a corporation listed on the New York Stock Exchange (NYSE), American Stock Exchange (ASE), or traded under an automated inter-dealer system operated by the National Association of Securities Dealers (NASD).

- Exception for rental of office space under the prohibited compensation arrangements.

Section 153. Definition of FMGEMS Examination for Payment of Direct Graduate Medical Education

This amendment allows the Secretary to recognize the successor exam to the Foreign Medical Graduate Examination in the Medical Sciences (FMGEMS). Successful completion of this exam is required for foreign medical graduates to be included in the full-time equivalent (FTE) count used for Medicare payment purposes.

Section 154. Qualified Medicare Beneficiary Outreach

This provision requires the Secretary to obtain information from newly eligible Medicare beneficiaries that may be used to determine their eligibility as qualified Medicare beneficiaries

(QMBs), and to report this information to their state of residence.

Section 155. Hospital Agreements with Organ Procurement Organizations

This provision requires a hospital or rural primary care hospital to have an agreement (described in section 371(b)(3)(A) of the Public Health Service Act) only with an Organ Procurement Organization (OPO) designated for the service area in which the hospital is located. Any hospital that desires to have an agreement with a non-designated (out-of-area) OPO must submit an application for a waiver to the Secretary. Furthermore, any hospital that desires to continue an existing agreement with an out-of-area OPO must submit an application for a waiver to the Secretary by January 1, 1996. The existing agreement remains in effect pending the Secretary's determination.

In granting a waiver for an out-of-area agreement, the Secretary must determine that such a waiver: (a) would be expected to increase organ donation, and (b) will assure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the out-of-area OPO. In making a waiver determination, the Secretary may consider, among other factors: (a) cost effectiveness, (b) improvements in quality, (c) whether there has been any change in a hospital's designated OPO service area due to a redefinition of metropolitan statistical areas (MSAs), and (d) the length and continuity of a hospital's relationship with the out-of-area OPO. The Secretary must publish a notice of any waiver application and offer interested parties an opportunity to comment in writing within 60 days.

The provision also mandates the Office of Technology Assessment (OTA) to study and make recommendations on the impact of the new requirements on the fairness and efficacy of organ procurement and distribution.

Section 156. Peer Review Organizations

- Repeal of PRO Precertification Requirement for Certain Surgical Procedures.

  Section 1164 of the Act, which requires 100 percent peer review for certain surgical procedures, is repealed. Other sections of the Act referencing section 1164 are revised to conform.

- PRO Notification of State Licensing and Disciplinary Boards.

  Prior law has been unclear about those circumstances where a Peer Review Organization (PRO) must notify a State licensing

or disciplinary board of findings related to a physician's performance. Section 1154(a)(9)(B) could be interpreted to require State notification whenever physician services fail to meet the broad medical necessity, quality, and appropriate setting standards. Yet, this would be operationally infeasible.

This amendment clarifies the ambiguity by requiring a PRO to notify a State board, after reasonable notice to and opportunity for discussion with the physician, in those instances where the PRO has (1) found that the physician has furnished services in violation of the medical necessity, quality and appropriate setting standards under section 1156(a), and (2) determined that the physician should enter into a corrective action plan under section 1156(b)(1). The amendment is effective as of enactment.

Section 157. Health Maintenance Organizations

- Revisions in the Payment Methodology for Risk Contracts.

  This provision requires the Secretary to submit a proposal to Congress by October 1, 1995 for the revision of the payment methodology for risk contractors. Such revised methodology would be used for payment purposes beginning in 1997. In making the revisions, the Secretary is to consider the need for adjustors for health status and demographic characteristics, and for alternative geographic classifications. Before January 1, 1996, the General Accounting Office (GAO) is to report to Congress on the appropriateness of the proposed revisions.

- Miscellaneous and Technical Corrections.

  The section also contains miscellaneous and technical corrections.

Section 158. Home Health Agencies

- Use of Most Current Data in Determining Wage Index.

  Under prior law, it was unclear what year's hospital wage index should be used to calculate the labor component of the home health agency (HHA) payment upon the completion of the cost limit freeze of OBRA-1993's section 13564(a). This provision clarifies that upon the completion of the OBRA-1993 cost limit freeze, HHA cost limits will be established by using the most recent available hospital wage index survey data. The provision applies with respect to cost reporting periods beginning on or after July 1, 1996.

- Clarification of Extension of Waiver of Liability.

  OBRA-1990 extended, until December 1, 1995, the expiring limitation on liability provision for home health service coverage denials pursuant to section 1879. OBRA-1990 neglected to extend the limitation on liability protections for home heath services denied under section 1862(a)(1)(A), which relates to services not medically reasonable or necessary. This provision corrects this omission, extending the waiver of liability for coverage denials under section 1862(a)(1)(A) until December 1, 1995. The provision is effective as if included in OBRA-1990.

Section 159. Permanent Extension of Authority to Contract with Fiscal Intermediaries and Carriers on Other Than a Cost Basis

This amendment retroactively restores, and makes permanent, the authority to enter into contracts and agreements without regard to cost reimbursement when mutually agreed to by the Secretary and the fiscal intermediaries and carriers.

Section 160. Miscellaneous and Technical Corrections

- Survey and Certification Requirements.

  This amendment:

  - Clarifies that the OBRA 1990 provision that established a prohibition on user fees under title XVIII does not apply to user fees relating to the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

  - Removes the requirement that the Secretary contract with State agencies to ensure compliance of non-Medicare clinical laboratories with CLIA. Replaces this requirement with discretionary authority allowing the Secretary to contract with State or local agencies for this purpose.

- Home Dialysis Demonstration Technical Corrections.

  This provision makes a number of technical changes to the requirements for the demonstration on staff-assisted home dialysis.

- Technical Correction to Revisions of Coverage for Immunosuppressive Drug Therapy.

  OBRA-1993 expanded coverage of immunosuppressive drugs by phasing-in an extension of the number of months of coverage between 1995 (18 months of coverage) and 1997 (36 months). The provision, however, expanded coverage in such a manner

that beneficiaries would experience lapses in coverage. This amendment eliminates these gaps in coverage by allowing the Secretary to administer the provision so that consecutive months of coverage are furnished, as long as the total number of months of coverage allowed by OBRA-1993 are the same.

SUBTITLE D -- PROVISIONS RELATING TO MEDICARE SUPPLEMENTAL INSURANCE POLICIES

Section 171. Standards for Medicare Supplemental Insurance Policies

o Preventing Duplication.

This provision clarifies and narrows the existing anti-duplication provisions. Under the revised statute, it is illegal to sell or issue the following health insurance policies to Medicare beneficiaries:

- a Medigap policy when the beneficiary already has a Medigap policy, unless the purchaser states in writing an intent to terminate the existing policy;

- a policy (other than Medigap or employer coverage) that duplicates private health benefits to which the beneficiary is already entitled, unless the policy pays benefits directly to the beneficiary without regard for other insurance coverage; and

- a policy (other than employer coverage) that duplicates Medicare or Medicaid benefits to which a beneficiary is already entitled. Exceptions under this section for Medigap policies are: (a) if a State Medicaid program pays the premiums for the policy, (b) for qualified Medicare beneficiaries (QMBs), if the policy includes prescription drug coverage, or (c) if payment of Part B premiums is the only medical assistance the individual receives from the Medicaid program. An exception is also made for other health insurance policies (e.g., dread disease policies) where the benefits are paid without regard to duplication in coverage, where applicable, and where a statement disclosing the duplication is included in the application.

Within 90 days of the enactment of this section, the National Association of Insurance Commissioners (NAIC) must, after consultation with consumer and insurance industry representatives, develop statements describing the extent of duplication for each of the types of health insurance policies and submit them to the Secretary for approval. The Secretary must approve or disapprove the statements within 30 days of

- Effective Date and Transition Provisions.

  This provision requires the NAIC to modify its 1991 Model Regulation to conform to the amendments made in this section within six months of enactment of this Act. Failure to do so will result in the Secretary making the modifications.

  Effective dates for provisions that apply refunds and credits based on loss ratios for renewed policies and that address the calculation of the loss ratio refunds or credits will be the earlier of (a) the date the State conforms its program to meet the changes in this provision, or (b) one year after the NAIC or the Secretary first modifies the 1991 NAIC Model Regulation. An exception is made for States that the Secretary determines need State legislative changes (other than fund appropriation) to conform but whose legislatures are not scheduled to meet in the time specified.

  Policies sold or issued between the effective date of OBRA-1990 and the effective date of this Act will not be subject to penalty for violation of OBRA-1990 anti-duplication provisions (with the exception of the duplication of Medigap policies). All other provisions are effective upon enactment of this Act.

- Other Minor and Technical Amendments.

  This provision also makes other minor technical amendments.

Section 172. 6-Month Extension of Period for Issuance of Medicare SELECT Policies

The Medicare SELECT demonstration was to expire at the end of 1994. This provision authorizes a six month extension.

receipt. Statements that are approved will be published by the Secretary.

If the statements are not approved or not submitted within the 90-day period, the Secretary shall develop the statements, after consultation with consumer and insurance industry representative, within 90 days of the date of disapproval or at the end of the 90-day period. Disclosure statements are only applicable to policies sold or issued more than 60 days after the disclosure statements are approved by the Secretary and published.

- Loss Ratios and Refunds of Premiums.

  This provision also applies loss ratio and refund requirements to renewed policies, in addition to new policies. It clarifies that refund and credit provisions apply to policies 12 months after issue rather than 24 months.

- Treatment of HMOs.

  This provision clarifies that health care prepayment plans and approved demonstration projects under the Social Security Amendments of 1983, the Deficit Reduction Act of 1984 (DEFRA-1984), or OBRA-1986 are not considered Medigap policies for the purposes of Federal law until after 1995.

- Open Enrollment.

  Effective January 1, 1995, this provision states that the six month open enrollment period (i.e., issuers cannot underwrite on the basis of health status) for Medigap policies begins with the first month that a beneficiary is age 65 or older and is enrolled for benefits under Part B. This clarifies that the open enrollment period applies to <u>all</u> beneficiaries who are age 65, including those who had been entitled to Part B benefits prior to age 65 as a result of ESRD or disability.

  Beneficiaries who turned age 65 after the effective date of the original open enrollment provision (November 5, 1991) and who did not receive an open enrollment period because they were previously entitled to Part B will be given a one-time six month open enrollment period beginning on January 1, 1995.

- Health Insurance Counseling.

  The provision re-authorizes the Health Insurance Information, Counseling and Assistance Grants through FY 1996 for $10 million each fiscal year. The original authorization expired in FY 1993.

TITLE II -- MEDICAID-RELATED PROVISIONS

SUBTITLE C -- SUPPLEMENTAL SECURITY INCOME

Section 221. Definition of Disability for Children Under Age 18 Applied to All Individuals Under Age 18

This provision amends, effective upon enactment, the Supplemental Security Income program under title XVI of the Act to change the references to "a child" under age 18 who is disabled to "an individual" under age 18 who is disabled. This has the effect of deleting the requirement that the individual (to whom the special disability rules are being applied) be unmarried.

SUBTITLE D -- AID TO FAMILIES WITH DEPENDENT CHILDREN

Section 231. Simplification of Income and Eligibility Verification System

This provision amends section 1137 of the Social Security Act to conform the requirements for a written declaration of citizenship or immigration status, as a condition of eligibility for Aid to Families with Dependent Children (AFDC), Medicaid, or unemployment compensation, to those adopted in 1990 with respect to benefits under the Food Stamp program. Thus, effective upon enactment, the law will allow one member to submit and sign the declaration for all family members, and permit such a declaration to be filed with respect to a newborn in the family no later than the date of the family's next redetermination of eligibility.

Section 232. Measurement and Reporting of Welfare Receipt

This amendment requires the Secretary to develop indicators of welfare dependency and predictors of welfare receipt, and to report these findings to Congress no later than two years after enactment and annually thereafter. It also establishes an Advisory Board on Welfare Indicators to advise the Secretary on the content of reports to Congress.