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Federal Purchasers

Divider Title: _____

John Whyte
Health Care Financing Administration



Medicare's Coverage Policy: Evaluating Technologies

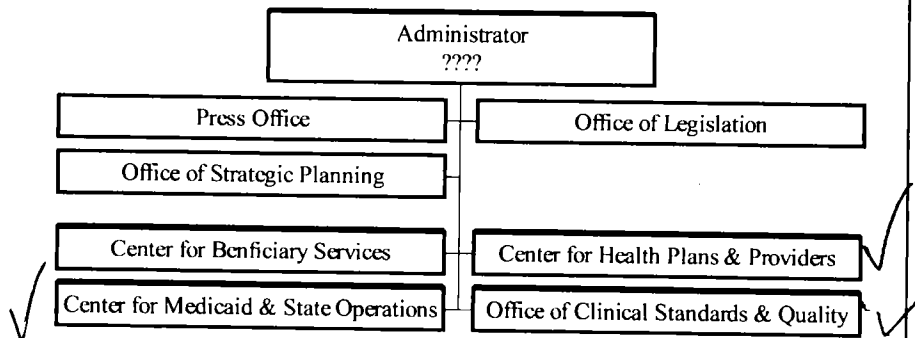
John Whyte, MD, MPH
Acting Director,
Division of Medical Items and Devices
White House Task Force on Complementary
and Alternative Medicine

May 14, 2001



Result of HCFA's Reorganization

The Health Care Financing Administration





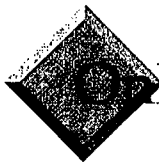
Structure

Coverage and Analysis Group
Sean Tunis, M.D.

Division of Operations
Connie Conrad

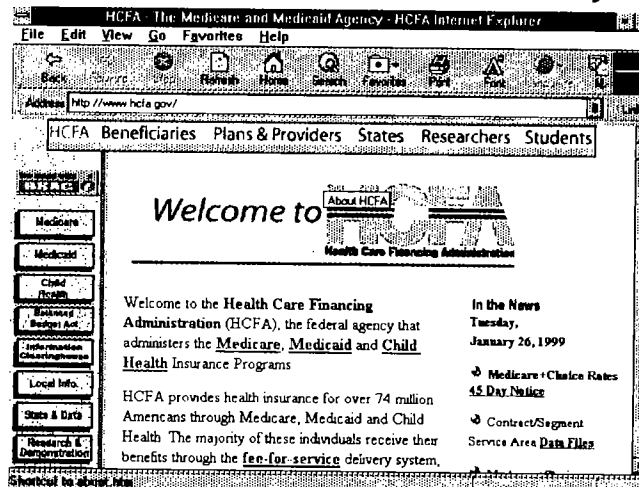
Division of
Medical/Surgical Services
Steve Sheingold, PhD

Division of
Medical Items & Devices
John Whyte, MD, MPH

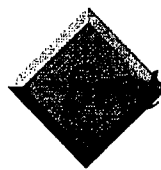


Online Access to HCFA

www.hcfa.gov



Social Security Act
Does not cover
Preventive -
Services
Providers must
be recognized
by HCFA before
reimbursement



Section 1862 (a)(1)(A)

- ❖ "...no payment may be made . . . For expenses incurred for items or services . . . [which] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."



General Methods by which Coverage Decisions are Made

43 Commercial
Federal Level
Local Coverage
Decisions

- ❖ Medicare contractors may develop coverage policies, known as Local Medical Review Policies (LMRPs) -- www.lmrp.net *
- ❖ HCFA may develop national coverage policies
- ❖ Most new items and services covered by the first process, with about 10% covered by second
- ❖ Both rely upon evidence of medical effectiveness

6000 LMRP

250-350 policies

Congress determine
Coverage



Coverage of Services, General

- ❖ Medicare is a defined benefit program
 - A service must fall into one of 55 statutorily-defined "benefit categories" as a first step toward coverage
- ❖ A service must then satisfy HCFA's process for determining whether it can be considered "reasonable and necessary"

FDA approval or
FDA clearance is a
prerequisite not
a certain requirement

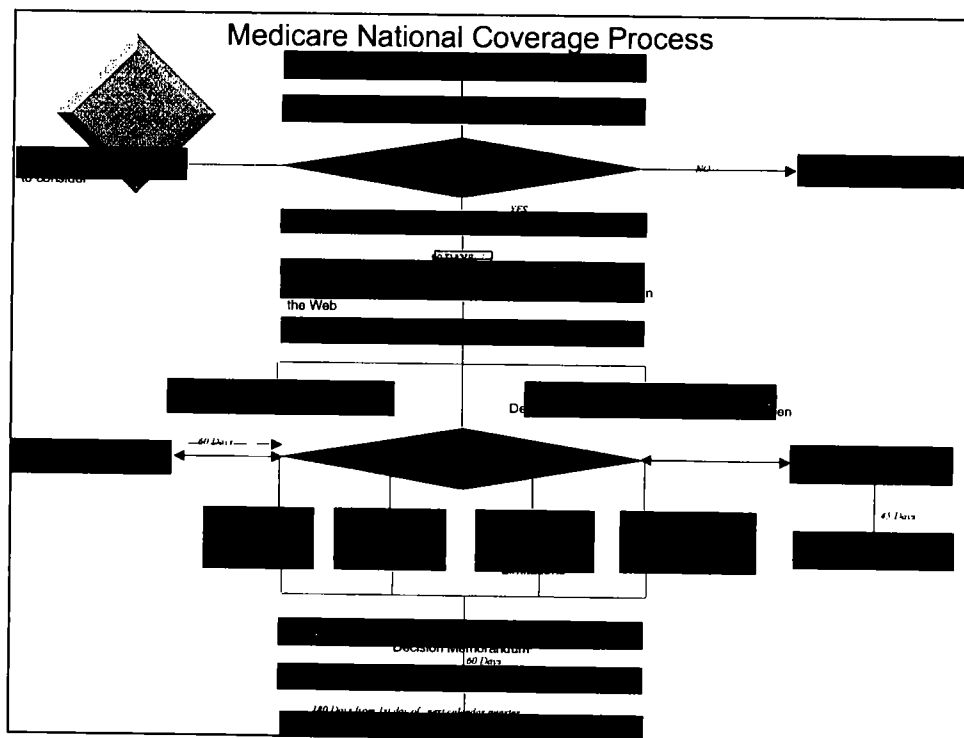


HCFA Methods for Determining Reasonable and Necessary

- ❖ HCFA currently changing its process for making national coverage policy
 - Seek to make the process more understandable, open and responsive
 - April 27, 1999 *Federal Register Notice* outlines new process, attempts to explain how an issue enters the national process and how it is handled through to a coverage decision

HCFA's Methods for Determining Reasonable and Necessary (cont.)

- ❖ Review will remain evidence-based with continued emphasis upon authoritative evidence and demonstrated medical effectiveness
 - benefits outweigh reasonably-anticipated risks
 - evidence of improved health outcomes
 - complies with all regulatory requirements





Formal Requests

- ❖ Internal vs External
- ❖ Formal Requests
 - Request must be in writing
 - Must identify the request as a “formal request for a national coverage decision”
 - Supporting documentation
- ❖ Respond to request in 90 days



Supporting Documentation

- ❖ Full description of service in question, including benefit category
- ❖ Compilation of medical/scientific information currently available
- ❖ Description of clinical trials underway
- ❖ Status of FDA activity



*Hierarchy of
clinical
evidence*
*Need for a
"Body of literature"*
*Some standards
in needed*



evidence

- ❖ RCT's
- ❖ Cohort studies
- ❖ Controlled case series
- ❖ Case reports
- ❖ Consensus statements



Technology Assessments

Nominations to Committee
AKR 9
13 Practice Panel
Peroral Care



Medicare Coverage Advisory Committee: Panels

Executive Committee

Medical/Surgical

Drugs/Biologics/Therapeutics

Laboratory

Medical Devices

DME

Diagnostic Imaging



Decisions

- ❖ National Noncoverage
- ❖ No National Coverage Decision
 - left to carrier discretion
- ❖ National Coverage Decision with limitations
- ❖ National Coverage Decision without limitations



ision Implementation

- ❖ Within 180 days from the first day of the next full calendar quarter, payment change will be effective



Clinical Trials

*Reimbursement costs
for chemical + units
are reimbursed*



Contact Information

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410-786-9668



**Health Care Financing Administration**[Site Index](#) | [Feedback](#) | [Help](#)[Medicare](#)[Medicaid](#)[SCHIP](#)[What's New](#)[Spotlight](#)

Site Search:

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Quality of Care ~ National Projects

Quality Site**Medicare Lifestyle Modification Program Demonstration**[Home](#)[Projects](#)[Standards](#)[Measures](#)[Priorities](#)[PROs](#)[Esrd Network](#)[OCSQ](#)[Software](#)[Links](#)[Index](#)**Summary of Demonstration**

(For more information contact Armen Thounmaian or Debbie Grossblatt.)

The Health Care Financing Administration (HCFA), Office of Clinical Standards and Quality (OCSQ) is implementing the Medicare Lifestyle Modification Program Demonstration.

Recent research has suggested that aggressive risk factor reduction may slow, stop, or even reverse the progress of coronary artery disease. Lifestyle modification programs are increasingly becoming an approach to the secondary prevention of coronary disease morbidity. Participation in these programs may lead to improved health outcomes for Medicare beneficiaries with cardiovascular disease and potentially reduce Medicare costs.

The demonstration is designed to test the effectiveness of providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries with moderate to severe coronary artery disease. The treatment outcomes of Medicare beneficiaries who complete the lifestyle modification program will be compared to those of similar patients who receive more traditional services under the Medicare program.

The demonstration will include two multiple site, cardiovascular lifestyle modification program models that offer a twelve-month, multi-disciplinary, clinical outpatient treatment program. Each lifestyle program model can enroll up to 1800 Medicare Part B eligible beneficiaries who meet the clinical enrollment criteria and voluntarily elect to participate in the demonstration. The two program models selected are:

✓ The Dr. Dean Ornish Program for Reversing Heart Disease? developed by Dr. Dean Ornish and offered through the joint efforts of the Preventive Medicine Research Institute, Sausalito, California and Lifestyle Advantage, Pittsburgh, Pennsylvania; and

✓ The Cardiac Wellness Extended Program developed by Dr. Herbert Benson and offered through the Mind/Body Medical Institute, Boston, Massachusetts.

All Medicare certified medical facilities licensed to provide either program are eligible to participate as demonstration sites during the demonstration period. The demonstration period began on October 1, 1999, and will provide a multi-year enrollment period ending on November 12, 2003, with payment through November 12, 2004.

November 12, 2004.

Medicare payment is based on a negotiated amount reached with the parent or licensing entity for the multi-site lifestyle modification program and applies to all sites offering that program model. The demonstration sites will receive 80 percent of the total payment amount for their 12-month program for each beneficiary who completes the treatment program.

Demonstration sites providing the Dr. Dean Ornish Program for Reversing Heart Disease? will receive 80% of \$7,200 or \$5,760. Sites offering the Cardiac Wellness Extended Program will receive 80% of \$4,800 or \$3,840. The beneficiary is responsible for paying the remaining 20%. A demonstration site may waive the amount due from the beneficiary, but it must do so for all beneficiaries.

Payments to sites will be made on a quarterly basis at 35%, 15%, 15%, and 35% of the total rate, respectively, for each enrolled beneficiary. However, if the beneficiary's dis-enrolls from the program prior to completion, the demonstration site will receive a pro-rated portion of the total payment.

The Delmarva Foundation for Medical Care, Inc., a Medicare Peer Review Organization, has been contracted to provide quality monitoring and review of the treatment provided to Medicare patients enrolled at the demonstration sites.

The Schneider Institute for Health Policy, Brandeis University has been contracted to provide an independent evaluation of the demonstration. The evaluation will focus on a comparison of clinical outcomes of Medicare beneficiaries enrolled in the demonstration with those of a matched-paired control group consisting of Medicare patients with similar demographic characteristics and disease severity. The evaluation will also assess the quality of care delivery and patient satisfaction under the demonstration as well as the potential savings of lifestyle modification treatment services to the Medicare program.



Medicare Lifestyle Modification Program

MEDICARE PHYSICIAN FEE SCHEDULE

Background

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments were based on the charging patterns of physicians. This system was inherently inflationary and resulted in large unjustifiable differences among types of services, geographic payment areas, and physician specialties. Recognizing this, Congress in the Omnibus Budget Reconciliation Act (OBRA) of 1989 added section 1848 to the Social Security Act. This section replaced the reasonable charge system with the Medicare physician fee schedule effective January 1, 1992. The law provided for a gradual 5-year transition from the reasonable charge system with the fee schedule becoming fully effective in all areas on January 1, 1996.

Development of Fee Schedule

Section 1848 requires that each of the over 7,000 services paid under the physician fee schedule be divided into 3 components--physician work, practice expenses (rent, employee wages, medical equipment and supplies, utilities, etc.), and malpractice insurance. The law further requires that uniform national relative value units (RVUs) be established for each of the 3 components--physician work (WRVU), practice expenses (PERVU), and malpractice expenses (MRVU)--of every physician fee schedule service. The law prohibits any specialty payment differential. The component RVUs are uniform everywhere, and payments vary among the 89 geographic fee schedule payment areas only to the extent that the resource costs of providing services vary as measured by the area geographic practice cost indices or GPCIs. The GPCIs are required by law to measure area cost differences compared to the national average for each of the 3 fee schedule components.

Fee schedule payments are the product of the national relative value for a service, the area component GPCIs, and the national dollar conversion factor or CF. The calculation is expressed as follows:

$$\text{Payment} = [(WRVU)(WGPCI) + (PERVU)(PEGPCI) + (MRVU)(MGPCI)][\$CF]$$

The physician work values are primarily based on a study of physician work conducted for HCFA by the Harvard School of Public Health. The study valued each service on the basis of the relative physician work--time, effort, skill--required to perform the service. The proposed work values were published in the Federal Register for public comment on June 5, 1991. After reviewing about 95,000 comments, interim final values were published in the Federal Register on November 25, 1991. Values for new and revised service codes are established each year through public notice and comment in the Federal Register. The law also requires that a comprehensive review of all work values be done every 5 years. The first 5 year review became effective in 1997. Values for new and revised codes each

year and for the 5 year review are primarily based on the recommendations of the American Medical Association's (AMA) Specialty Society Relative Value Update Committee or RUC. The RUC's recommendations are subject to review by HCFA staff physicians, carrier medical directors, and specialty refinement panels of physicians.

Practice expense and malpractice values were based on a statutory formula from 1992 to 1998. Historical practice expense and malpractice expense percentages, weighted among the specialties providing a service, were applied to the 1991 national average Medicare allowed charge for the service to determine the practice expense and malpractice relative values. In effect, the percentages of Medicare payments for a service representing practice expenses and malpractice expenses in 1991 were passed through to the fee schedule in 1992. Thus, while the work relative values were resource- based, the practice expense and malpractice relative values were still charge-based. Implementation of resource-based practice expense RVUs was begun in 1999 and will be fully implemented in 2002. The resource-based practice expense RVUs are based on AMA data on physician practice expenses, physician time per service, and expert panel review of practice expenses of individual services. Resource-based malpractice RVUs based on actual malpractice premium data will be implemented in 2000.

The initial dollar conversion factor in 1992 was required to be budget-neutral. That is, a conversion factor was calculated that yielded the same total payments for physician services in 1992 that would have been made had the the previous reasonable charge system been retained. The conversion factor is updated each year taking into account various factors including inflation, increase in the number of beneficiaries, changes in law and regulations, and allowable increases in the volume and intensity of services.

Changes in Fee Schedule Payments Must be "Budget Neutral"

The law (section 1848 (c)(2) requires that changes in the relative values must be done in a budget neutral manner. This means that in order to increase the payment for a service, we must reduce payments for all other physician services. We generally make these budget neutral adjustments through reductions in the fee schedule conversion factor which is applied to all services. In order to meet the statutory requirements, and also provide for a process that is equitable to all physicians and practitioners paid under the fee schedule, we make changes in the fee schedule payments through the regulatory process.

Impact of Fee Schedule

The implementation of the fee schedule showed that surgical and procedural services (e.g., endoscopies, x-rays) were overvalued while primary care services (e.g. office visits) were undervalued under the prior reasonable charge system. With the implementation of the fee schedule payments thus tended to flow from surgical specialties and procedural specialties such as gastroenterology and radiology to primary care specialties such as

Abby L. Block
Assistant Director for Insurance Programs

Abby L. Block is the Assistant Director for Insurance Programs at the Office of Personnel Management (OPM). The Office administers the health and life insurance programs for Federal employees and retirees. The Federal Employees Health Benefits (FEHB) Program is a \$21.5 billion a year program that provides coverage for 9 million employees and retirees and their families. The Federal Employees' Group Life Insurance Program (FGLI) is a \$2.1 billion a year program that provides coverage for 4 million employees and retirees and their families. In addition to negotiating and administering contracts with 250 insurance carriers, the Office also provides extensive information to participants so they can make informed decisions about their benefits.

Before becoming Assistant Director, Ms. Block was Chief of the Insurance Policy and Information Division in the Office of Insurance Programs. The division develops policy and provides guidance on all matters relating to insurance benefits for Federal employees and retirees. It participates in the agency's work with the Congress on legislative issues, publishes regulations to implement legislative and administrative policy, and provides information to a broad range of customers. While she headed the Division, Ms. Block played a major role in the effort that led to enactment of the Long-Term Care Security Act.

Since coming to OPM as a Presidential Management Intern in 1979, she has been involved in every functional area of the Retirement and Insurance Service. Her knowledge of the laws and regulations governing the insurance programs, along with her operational experience, have made her a recognized expert on employer-provided insurance benefits. She has taken the lead in developing ways to enhance performance and quality in the Federal Employees Health Benefits Program.

Before coming to Washington, DC, Ms. Block worked for 10 years in Substance Abuse Prevention Programs in Nassau County and New York City. She has an MA, an MSW, and an MBA from Columbia University.



Federal Employees Health Benefit Program

presented by:
Abby L. Block
Assistant Director of Insurance Programs
U.S. Office of Personnel Management



Federal Employees Health Benefit Program

- February 1954, President Eisenhower calls for health program for Federal employees
 - in line with best practices of progressive private employers
 - should be part of a well-rounded personnel program
- Public Law 86-382, Federal Employees Health Benefits Act of 1959 enacted 9/28/59



THE ACT

The legislation gave the Civil Service Commission – now OPM – authority to contract with

- certain types of health benefit plans
- for a broad range of services
 - hospital benefits
 - surgical benefits
 - ambulatory patient benefits
 - pharmaceuticals
 - other medical supplies and services

OPM

THE ACT (Continued)

- Specified those eligible for coverage:
 - employees: 2.2 M
 - retirees: 1.9 M
 - retirees with Medicare: 1.3 M
 - family members: 4.6 M
 - includes former spouses
- the method of determining the government's contribution to the program

OPM

THE ACT (Continued)

- Legislation did not specify benefit levels for the range of services
- OPM provides direction to carriers
 - annual Call Letter
 - regular Carrier Letter mailings
 - annual health plan conference
 - day-to-day interaction with contract specialists

OPM

TYPES OF HEALTH PLANS

- Open FFS plans
 - e.g. BCBS, GEHA, Mail Handlers
 - Open to all; nationwide
 - Covered Lives: 5.7 M
 - Employees: 1.3 M
 - Retirees: 1.5 M
 - Retirees w/ Medicare: 1.1 M
 - Family Members: 2.9 M

For Review

TYPES OF HEALTH PLANS (continued)

- **Closed FFS Plans**
 - e.g. Secret Service, Foreign Service
 - Open only to specific groups; nationwide
 - Covered Lives: 209,000
 - Employees: 42,000
 - Retirees: 59,000
 - Retirees w/ Medicare: 34,000
 - Family Members: 108,000

TYPES OF HEALTH PLANS (continued)

- **HMOs**
 - e.g. Kaiser, PacifiCare, Aetna U.S Healthcare
 - Serves particular geographic area
 - Covered Lives: 2.7 M
 - Employees: 879,000
 - Retirees: 307,000
 - Retirees w/ Medicare: 161,000
 - Family Members: 1.6 M

TYPES OF HEALTH PLANS (continued)

- **# of plans available**
 - minimum = 7
 - maximum = 31
- **Definitions are broad and flexible**
- **Government-wide plans and employee organization plans now have PPO component**
- **In-network services are most often used by consumers**

*Blue Cross / B.C. - Affinity process
 Individual implementation as consumer responsibility
 consumer benefits*

OPM

BENEFITS

- Contracts negotiated bilaterally with each plan on an annual basis
- Each contract must contain detailed statement of benefits which includes:
 - maximums
 - limitations
 - exclusions
 - other definitions of benefit as OPM deems necessary or desirable
 - for example, immunizations for children or mammography screening

OPM

BENEFITS

- Once contract negotiations complete, consumers given extensive benefits information
 - FEHB Guide to Plans
 - Individual plan brochures
 - Web site information
 - Decision support tool
 - Access to printed materials (Guide, brochures)
 - Policy and background information

OPM

BENEFITS: Alternative Medicine

- In April 2001 Call Letter (OPM's annual policy guidance to FEHB plans), OPM stated:
 - "Where there is demonstrated medical effectiveness, and consistent with your overall strategy for benefit design, we encourage you to consider services such as chiropractic, acupuncture, biofeedback and others that are being used increasingly for pain management and as alternative treatments."

*Response to Call Letter May 31
 Proposals to be submitted
 All proposals must be cost neutral*

*Consumer Interest is
 Depending*

Barriers to Change
 ○ Resistance to Change in the Barrier
 ○ Inflation Rate

* *FEHBP* - *on separate state*
monitors - assume
Base of Services

PREMIUMS

- Rates set by negotiations between OPM and carriers
- Two rating methodologies
 - Experience Rating
 - Community Rating
- Regardless of the rating methodology used, all enrollees within a plan pay the same premium (varies by self vs. self & family and sometimes by high vs. standard option)

* *HMO's in state must follow*
state mandates - those people
enrolled in PPO are not
mandated

PREMIUMS (continued)

- Fair Share formula
 - Weighted average of all plans
 - Cannot exceed 75% of a plan's actual premium
 - Government share is 72% of weighted average premium
- Balance paid by employee or retiree
- Agencies collect premiums by payroll deduction and remit to OPM

* *advisory committee members*
need people involved in
Health Services Research
Not refer to CDM but
at her specialty for
Evidence Based Approach

CONTRACTING CYCLE

Annual Timeline of OPM Activities

- Feb/March: review and accept/deny new plan applications
- June-August: negotiate benefits and rates for next contract year
- June-September: collaborate with carriers on plan brochure language
- Nov/Dec (4-5 weeks): conduct annual open season

Carrier Contact - 1-1 contact
Just 28 plans



OPEN SEASON

OPM

- designs and distributes Open Season Guides
- provides agencies Open Season guidance through Benefits Administration Letters
- provides plan information and links to comparative information and decision tools on FEHB Open Season web site www.opm.gov/insure



OPEN SEASON

Agencies

- make guides and brochure information available to employees
- conduct health fairs
- counsel employees
- process enrollment changes



YEAR ROUND

- OPM monitors plan performance
- Responds to customer concerns
- Resolves disputed claims
- Monitors industry trends
- Consults with carriers
- Develops guidelines for next contract year

Or must
- no specific ~~the~~ benefits (BIPA) Benefit Category
- need medical Pts for results

Generalizations

- Demonstration Authority - not a lot of \$ -
- where is greatest data
- National Coverage Program

Congress can say we want to provide a benefit program in a service category

↓ Incident & provision

Place in existing benefit category? or any

applicable to CAM practice/products -

- not sure due to wide range of CAM practices.

Question is who is eligible to provide service.

- Definition of a Physician provide

- Congress can mandate coverage

Coverage Analysis done

While Pending Determinations vs Completed Review

some

Acupuncture
Proposed bad for
many practitioners



White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

April 16, 2001

Chair

James Gordon, MD

Commissioners

George Bernier, Jr, MD

David Bresler, PhD, LAc, OME

Thomas Chappell

Effie Chow, PhD, RN, DiplAc

George DeVries, III

William Fair, MD

Joseph Fins, MD, FACP

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Maureen Miller, MPH, RN

James Swyers, MA

Michael McMullan
Acting Administrator
Health Care Financing Administration
200 Independence Ave., SW
Room 314G
Washington, D.C. 20201

Dear Ms. McMullan:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request testimony from you or an appropriate HCFA representative(s) on the morning of May 14th.

The Commission was established in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. The Commission will submit a final report to the President in March 2002. Additional information on the Commission is available at its Web site at www.whccamp.hhs.gov.

The Commission will meet May 14th and 15th to discuss topic areas related to coverage and reimbursement for CAM. As part of its deliberations, the Commissioners need to understand the role of the Health Care Financing Administration, particularly regarding coverage and payment for health services. If you have information not specifically requested below but related to the scope of the Commission, please include the additional information. Please address the Medicare and the Medicaid programs separately in your testimony.

In your testimony, or supporting documentation, please address the following:

Coverage and Reimbursement

- Describe the legislative and regulatory framework related to coverage and payment of health benefits for Medicare and for Medicaid.
- Describe how coverage policy is made for the Medicare program, such as national coverage determinations and carrier decisions. In your estimation, what portion are national coverage decisions and what portion are local medical review decisions at the carrier level?
- Describe coverage of chiropractic medicine under Medicare and Medicaid. Describe coverage, if any, under Medicare of common CAM therapies. Do you have any information about the coverage of CAM under Medicaid?
- Does HCFA have plans to pursue or incorporate any CAM benefits? Does HCFA consider any CAM therapies as potentially promising for the health care of the elderly, the disabled, the poor, or individuals with End Stage Renal Disease?
- Describe relevant payment methodologies under original Medicare, particularly RBRVS, that may be used if CAM therapies are added to the Medicare benefit package. If a CAM therapy becomes a covered service under Medicare, how would HCFA determine payment?
- Briefly describe how CAM benefits may be covered and paid under the Medicare+Choice program. Do you have any information as to the types and extent of CAM therapies covered by M+C organizations?
- What ideas, issues, and concerns regarding coverage and payment for CAM can HCFA provide the Commission as it develops its policy recommendations and report to the President and Congress?

Questions Related to Research

- Briefly describe HCFA's research and demonstration program.
- Describe the two demonstration projects currently underway on CAM programs.
- Does HCFA participate in the coordination of federal CAM research efforts?

- What are the most promising areas of research on CAM interventions that may have an impact on the elderly, the disabled, persons with ESRD, and vulnerable populations?
- What are the obstacles (conceptual or otherwise) and possible solutions to accomplishing integration of CAM benefits into health services research?
- What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional areas of research, e.g., nutrition, wellness/health promotion and disease prevention, pain management, women's health, self care, care for the terminally ill, etc.?
- What ideas, issues, and concerns regarding health services research and biomedical research on CAM can HCFA offer for the Commission's consideration as it develops its policy recommendations and report to the President and Congress?

We would appreciate your response as soon as possible, and no later than May1, regarding who will speak at the upcoming meeting in Washington. You may email me at GroftS@mail.nih.gov or send a fax to 301-480-1691. Specific questions may be addressed to Maureen Miller of my staff, at 301-435-2211 or millemau@mail.nih.gov.

Thank you for your assistance and we look forward to working with HCFA.

Sincerely,



Stephen C. Groft, Pharm. D.
Executive Director

Enclosure

MEDICARE AT A GLANCE

February 2001

What Is Medicare and How Is It Financed?

Medicare is the federal health insurance program that covers 34 million Americans aged 65 and older and another 5 million younger adults with permanent disabilities. Like Social Security, Medicare is a social insurance program. It serves all eligible beneficiaries without regard to income or medical history. Medicare has played a central role in the U.S. health system since it was established in 1965. Today it provides health insurance coverage to one in seven Americans.

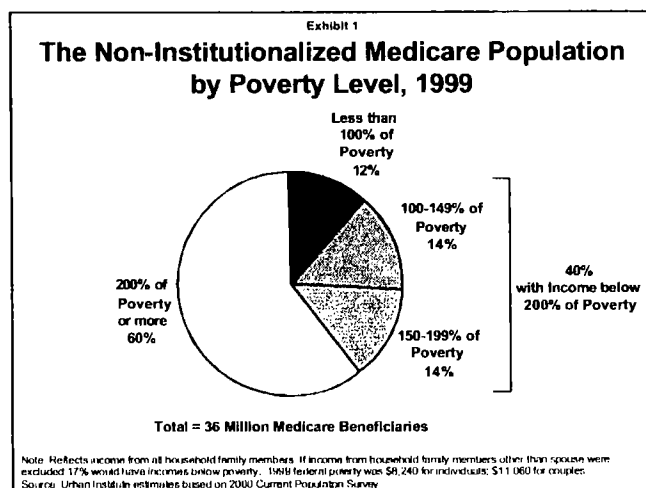
Medicare consists of two parts: Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B). Part A is financed mainly by a 1.45% payroll tax paid by both employees and employers. Revenue from the payroll tax is held in the Hospital Insurance Trust Fund and used to pay Part A benefits. Part B is financed by both beneficiary premiums (\$50 per month in 2001) and general revenue. Premiums cover about a quarter of total Part B spending.

Most individuals 65 and older are automatically entitled to Medicare Part A if they or their spouse are eligible for Social Security payments. People under 65 who receive Social Security cash payments because they are disabled become eligible for Medicare usually only after a 2-year waiting period. People with end-stage renal disease (ESRD) are entitled to Part A regardless of their age. Part B is voluntary, but 95% of all Part A beneficiaries enroll in Part B.

Who Is Covered Under Medicare?

Medicare covers a diverse population:

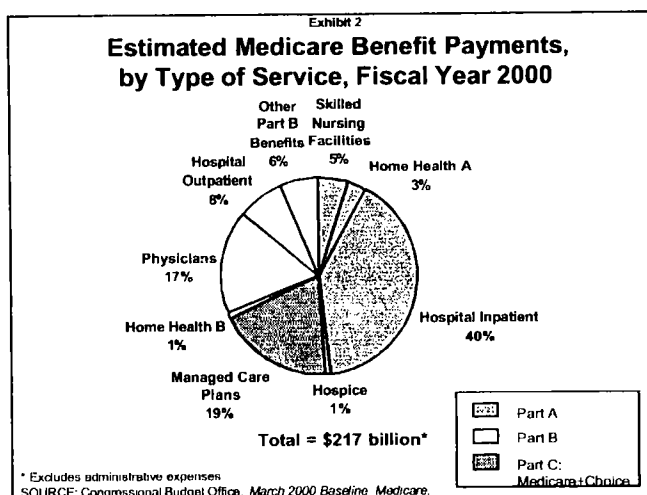
- Most beneficiaries (76%) are ages 65 to 84, but the under-65 disabled (13%) and those 85+ (11%) are growing rapidly.
- Four in ten beneficiaries (40%) have incomes at or below twice the poverty level (\$16,700 individuals; \$22,120 couples) (Exhibit 1).



- Nearly one in three (30%) say their health is fair or poor
- About one in four (23%) have difficulty with mental functioning

What Benefits Does Medicare Cover?

Medicare provides broad coverage of basic benefits, but does not generally cover prescription drugs or long-term care. Medicare Part A, which finances 49% of benefits, covers inpatient hospital services, skilled nursing facility (SNF) benefits, home health visits following a hospital or SNF stay, and hospice care (Exhibit 2). Inpatient hospital services are subject to a deductible (\$792 per benefit period in 2001) and a daily coinsurance beginning after the 60th day of a hospital stay. SNF care is limited to 100 days, subject to a 3-day prior hospitalization requirement, with coinsurance (\$99 per day in 2001) for days 21-100. No copayments apply to



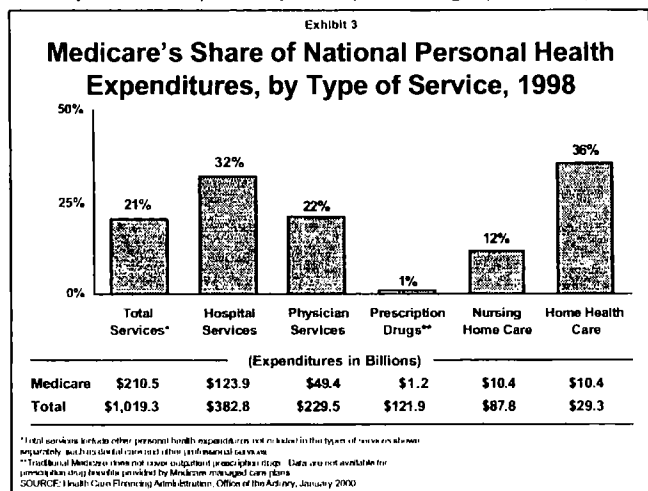
home health services.

Part B, which accounts for 32% of Medicare benefit spending, covers physician and outpatient hospital services, home health visits not covered under Part A, annual mammography and other cancer screenings, and services such as laboratory procedures and medical equipment. After the \$100 Part B deductible, a 20% coinsurance is required for almost all services. Over time, an increasing share of home health visits will be covered under Part B.

Under Medicare Part C, managed care plans contract with Medicare to provide both Part A and B services to enrolled beneficiaries. About 19% of Medicare benefit payments are made to managed care plans.

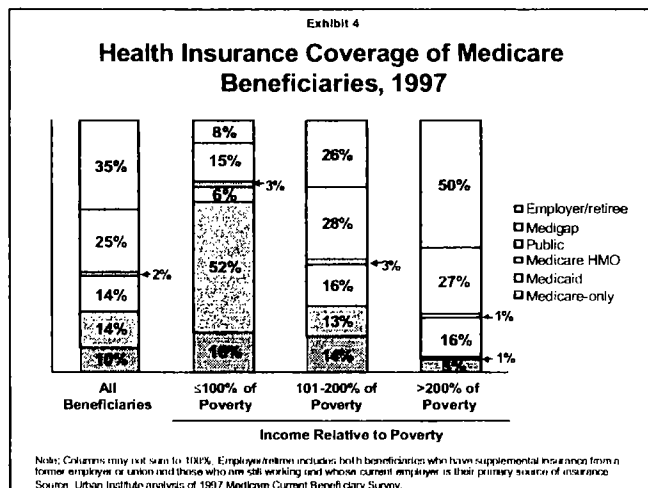
Medicare benefit payments were approximately \$217 billion in 2000, accounting for 12% of the federal budget and 21% of national spending for health services. Medicare finances 32%

of the nation's hospital services, 22% of physician services but only 1% of outpatient prescription drugs (Exhibit 3).



Gaps in Medicare: Implications for Beneficiaries

Because Medicare does not generally cover outpatient prescription drugs and has high cost-sharing requirements, most beneficiaries (90%) have some form of supplemental insurance (Exhibit 4). In 1997, over a third had employer-sponsored benefits, a quarter (25%) owned Medigap policies, and 14% had Medicaid, the major public financing program for low-income Americans. Another 14% were enrolled in Medicare HMOs. Supplemental coverage varies by income level. Those with low incomes are more likely than higher income beneficiaries to be without supplemental coverage and substantially less likely to have retiree benefits.



Despite the prevalence of supplemental insurance, one-third of all beneficiaries have no drug coverage. With average drug spending at \$1,263 in 2000, lack of drug coverage can result in high out-of-pocket spending and under-utilization of needed medications. Drug coverage is expected to decline further due to the erosion of retiree benefits, the rise in Medigap premiums, and recent Medicare HMO withdrawals.

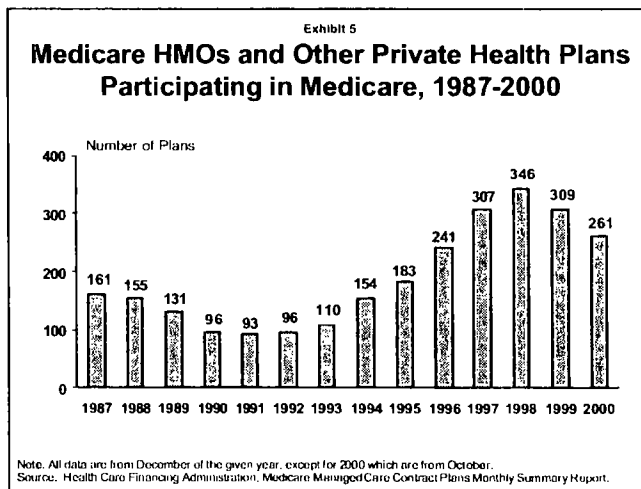
The elderly spend an estimated 22% of their income, on average, for health care services and premiums. The most vulnerable spend an even higher percentage. For example, elderly individuals in poor health without supplemental insurance spend about 44% of their income on health care.

Out-of-pocket spending is projected to rise significantly over the next 25 years.

Medicare Managed Care

Medicare HMOs have been around since the mid-1980s. Beginning in the early 1990s, the number of Medicare HMOs grew rapidly, as did the number of enrollees. Today, 6 million Medicare beneficiaries (16%) are enrolled in Medicare HMOs, more than four times the 1990 enrollment level.

However, the number of enrollees appears to be leveling off due to a drop in plan participation (Exhibit 5). More than 100 plans are expected to withdraw from the Medicare market or reduce their service area by the end of 2000, disrupting coverage for nearly 1 million beneficiaries. Declining plan participation has been attributed to changes in Medicare payments to plans, administrative requirements, and other challenges that affect profitability.



Medicare Expenditures and Financial Outlook

Medicare spending has recently grown slowly, increasing by an average of about 1.4% over the last three years (1998-2000) compared with average yearly growth of almost 10% over the preceding decade (1987-1997). This turnaround is associated with changes enacted under the Balanced Budget Act of 1997, intended to slow growth in payments to providers and plans and to promote provider compliance with payment rules. Combined with a strong economy, this downturn has extended the expected life of Medicare's Hospital Insurance Trust Fund to 2025.

While the recent slowdown will produce long-term savings, Medicare spending is expected to grow at a faster pace in coming decades. Even with continued improvements in program efficiency, Medicare will face significant financing challenges. A doubling of program enrollment coupled with the expected rise in national health care costs will likely necessitate greater resources to maintain and improve Medicare benefits such as drug coverage and to secure the financial outlook of the program. Additional challenges ahead include strengthening protections for Medicare's most vulnerable, including those with low incomes, and stabilizing the Medicare managed care market so that it works well for beneficiaries. These key issues will remain critical to the focus of the Medicare policy agenda as the program moves forward.

For additional free copies of this fact sheet (#1066b) call 1-800-656-4533.

The Health Law Resource



The Medicaid-Medicare Relationship

Provided by the Health Care Financing Administration ("HCFA")

NOTE: These summaries are very brief, simple versions of complex subjects. They should be used only as general overviews and guides to the Medicare and Medicaid programs.

The Medicaid - Medicare Relationship

Most aged and/or disabled persons who are very poor are covered under both the Medicaid and Medicare programs. These persons may receive the Medicare services for which they are entitled as well as other services available under that State's Medicaid program. As each State elects for its Medicaid Plan, services (such as hearing aids, eyeglasses and nursing facility care beyond the 100 days covered by Medicare) may be provided to these persons by the Medicaid program. And the Medicaid program pays all of the cost-sharing portions of Medicare Part A and B for these fully-eligible persons.

In addition, there are other Medicare beneficiaries (QDWIs, QMBs or SLMBs - see below) who are **not** fully eligible for Medicaid, but who do receive **some** help through a State Medicaid program's payment of part or all of the person's Medicare premiums and cost-sharing expenses. Persons identified as Qualified Disabled and Working Individuals ("QDWIs") who lost Medicare benefits because of their return to work are allowed to purchase Medicare HI and SMI coverage. However, the HI premium (but not the SMI premium) must be paid by the State Medicaid program for QDWIs with incomes below 200 percent of the Federal Poverty Level.

Other Medicare beneficiaries who may receive some assistance are those known as Qualified Medicare Beneficiaries ("QMBs") and those known as Specified Low-Income Medicare Beneficiaries ("SLMBs"). For the QMBs, (those Medicare beneficiaries who have incomes below the FPL and resources at or below twice the standard allowed under the SSI program), the State pays all the Medicare cost-sharing expenses and premiums for Medicare HI and SMI. For the SLMBs, (beneficiaries with resources like QMBs, but with slightly higher incomes: less than 110 percent of FPL in 1993 and 1994, and less than 120 percent in 1995), the Medicaid program pays (only) the SMI premiums.

Medicaid is always to be the "payor of last resort"; thus if a person is a Medicare beneficiary, then payments for any services covered by Medicare are made by the Medicare program before any payments are made by the Medicaid program.

Acknowledgements: The written portions, including the summaries of the Medicaid and Medicare programs, were prepared by Mary Onnis Waid in the Office of the Actuary, Health Care Financing Administration, N3-01-23, 7500 Security Blvd. Baltimore, MD 21244-1851. Phone (410)-786-6921. The national health expenditures data and estimates were prepared by the Office of National Health Statistics, also in the Office of the Actuary, HCFA. Historical information was extracted from the Vol. 56, No. 4, Winter, 1993 edition of the *Social Security Bulletin*.



Medicaid

Ten Basic Questions Answered

1. What is the Medicaid program?

Medicaid is the primary source of health care for low-income families with children, the low-income elderly, and disabled persons. In 1994, the program spent \$137 billion on a wide range of basic health and long-term care services for more than 34 million people. Medicaid covers 46 percent of the poor and near-poor in this country.

2. How is it administered and financed?

Medicaid is financed jointly by the federal government and the states. States administer the program, but federal guidelines require states to cover specific categories of people and types of benefits. States meeting these guidelines receive federal matching payments based on a state's per capita income. In the richest states, the federal government finances 50 percent of total Medicaid expenditures for the state; in the poorest states, 80 percent.

3. Who is eligible for Medicaid?

Historically, Medicaid eligibility has been tied to eligibility for cash assistance, mainly through the Aid to Families with Dependent Children (AFDC) and Supplemental Security Income (SSI) programs. In recent years, however, Congress and many states have expanded Medicaid coverage to poor children and pregnant women who do not qualify for cash assistance. Some states have also expanded coverage to nondisabled adults without children who are poor and have high medical expenses. The recently enacted Temporary Assistance to Needy Families program (TANF) replaces AFDC. The new program scarcely changes the current rules for Medicaid eligibility.

4. Why do Medicaid coverage and expenditures vary so much from state to state?

Within federal guidelines, states have considerable flexibility in setting their own financial eligibility criteria, benefit packages, and payment policies. Large state-to-state variations in coverage and expenditures reflect this flexibility,

as well as income differences among states. In 1994, for example, state coverage of low-income populations ranged from under 40 percent to 60 percent. Total per capita Medicaid expenditures varied from a high of more than \$4,800 per low-income person in the highest-spending state to a low of just under \$1,000.

5. Which groups are the largest Medicaid beneficiaries?

Children come first. They comprised about half of the 34 million people who received Medicaid in 1994. Nondisabled, low-income adults—mainly adults with children receiving cash assistance and low-income pregnant women—are the second largest group, at 7.9 million. Blind and disabled beneficiaries come next (5.4 million), followed by low-income elderly persons (3.8 million).

6. Which groups receive the greatest proportion of Medicaid funds?

Children in low-income families and nondisabled low-income adults account for about one-third of all direct Medicaid spending; the elderly and the disabled account for two-thirds.

7. What services does Medicaid cover?

Federal guidelines require coverage of a broad range of services, including in-patient and out-patient hospital physician services; laboratory and X-ray services; nursing homes and home health care; early and periodic screening, diagnosis, and treatment for children under 21; family planning; and rural health clinics and federally qualified health centers.

8. Which services absorb most Medicaid spending?

Of Medicaid's \$137 billion direct expenditures in 1994, acute care services accounted for just over half and long-term care services for one-third. The remaining 12 percent was spent on disproportionate share hospital (DSH) payments, which go to hospitals that serve more than their "share" of low-income and Medicaid beneficiaries. Among acute care services, in-patient services receive the most funds; among long-term services, nursing home care ranks first.

9. How much does service spending differ by enrollment group?

Greatly. For nondisabled children, for example, most funds go to acute care, with hospital in-patient care and HMO

payments together accounting for over half of the total. For nondisabled adults, virtually all direct Medicaid spending goes to acute care services. For people with disabilities and the elderly, however, only 57 percent of spending went for acute care in 1994, while 43 percent went to long-term care. For the elderly, the amount spent on long-term services (mostly nursing home care) is 77 percent of total direct expenditures in 1994.

10. What might happen if pressures to cut Medicaid spending result in eligibility restrictions or limits on spending on certain beneficiaries?

Low-income children and adults in families with children rely on Medicaid as their major public source of health care coverage. If the downward trend in employer-based health insurance coverage continues, tightening eligibility for these groups would probably increase the numbers of uninsured in this country. Since 60 percent of total program expenditures go to the elderly and disabled, efforts to reduce Medicaid expenditures will most likely require states to control expenditures for these groups by using managed care and restructuring the way long-term care is financed and delivered.

Sources

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The Health Law Resource



Overview of The Medicaid Program

Provided by the Health Care Financing Administration ("HCFA")

Brief Summary of TITLE XIX

of the Social Security Act

as of 6/24/95 (with 1994 data)

NOTE: These summaries are very brief, simple versions of complex subjects. They should be used only as general overviews and guides to the Medicare and Medicaid programs.

Contents

- Medicaid: A Brief Summary
 - Basis of Eligibility and Maintenance Assistance Status
 - Scope of Medicaid Services
 - Amount and Duration of Medicaid Services
 - Payment for Medicaid Services
 - Medicaid Trends and Summary
-

Medicaid: A Brief Summary

Overview

Title XIX of the Social Security Act is a Federal-State matching entitlement program which provides medical assistance for certain individuals and families with low incomes and resources. This program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of more adequate medical care to eligible needy persons. Medicaid is the largest program providing medical and health-related services to America's poorest people.

Within broad national guidelines which the Federal government provides, each of the States: (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program. Thus, Medicaid programs vary considerably from State to State, and within each State over time.

Basis of eligibility and maintenance assistance status

Medicaid does not provide medical assistance for all poor persons. Even under the broadest provisions of the Federal statute, Medicaid does **not** provide health care services even for very poor persons **unless** they are in one of the groups designated below. And low income is only one test for Medicaid eligibility for those within these groups; their resources and assets also are tested against established thresholds (as determined by each State, within Federal guidelines).

States generally have broad discretion in determining which groups their Medicaid programs will cover and the financial criteria for Medicaid eligibility. However, to be eligible for Federal funds, States are **required** to provide Medicaid coverage for most individuals who receive Federally assisted income-maintenance payments, as well as for related groups not receiving cash payments.

The following displays the mandatory Medicaid eligibility groups:

- Recipients of Aid to Families with Dependent Children (AFDC);
- Children under age 6 who meet the State's AFDC financial requirements or whose family income is at or below 133% of the Federal poverty level (FPL);
- Pregnant women whose family income is below 133% of the FPL (services to the woman are limited to pregnancy, complications of pregnancy, delivery and three months of postpartum care);
- Supplemental Security Income (SSI) recipients (or those aged, blind and disabled individuals who qualify in States that apply more restrictive eligibility requirements);
- Recipients of adoption assistance and foster care who are under Title IV-E of the Social Security Act;
- All children born after September 30, 1983 in families with incomes at or below the FPL. (They must be given full Medicaid coverage until age 19. This phases in coverage, so that by the year 2002, all poor children under age 19 will be covered);
- Special protected groups (typically individuals who lose their cash assistance from AFDC or SSI due to earnings from work or increased Social Security benefits, but who may keep Medicaid for a period of time); and
- Certain Medicare beneficiaries (described later).

States also have the **option** to provide Medicaid coverage for other "categorically needy" groups. These optional groups share the characteristics of the mandatory groups, but the eligibility criteria are somewhat more liberally defined. The broadest optional groups that States will receive Federal matching funds for coverage under the Medicaid program include:

- Infants up to age one and pregnant women not covered under the mandatory rules whose family income is no more than 185% of the FPL (exact percentage of FPL is set by each State);
- Children under age 21 who meet the AFDC income and resources requirements, but who otherwise are not eligible for AFDC;
- Recipients of State supplementary income payments;
- Certain aged, blind or disabled adults who have incomes above those requiring mandatory coverage, but below the FPL;
- Persons receiving care under home and community-based waivers;
- TB-infected persons who would be financially eligible for Medicaid at the SSI income level (but eligibility is only for TB-related ambulatory services and for TB drugs);
- Institutionalized individuals with income and resources below specified limits; and
- "Medically needy" persons (described below).

The option to have a "medically needy" (MN) program allows States to extend Medicaid eligibility to additional qualified persons with significant health care expenses who have income in excess of the mandatory or optional categorically needy levels. Such persons may "spend down" to Medicaid eligibility by incurring medical and/or remedial care expenses to offset their "excess" income, -- thereby reducing it to a level below the maximum income allowed by that State's Medicaid plan. States may also allow families to establish eligibility for MN coverage by paying monthly premiums to the State in an amount equal to the difference between the threshold allowance for income eligibility, and a family's income (reduced by any unpaid expenses incurred for medical care in previous months).

The "medically needy" Medicaid program does not have to be as extensive as the "categorically needy" program in a State, but there are certain requirements. If a State has **any** MN program, certain services **must** be provided as a minimum (the State may also **choose** to include additional services); and in any MN program, a State is **required** to provide coverage to certain children under age 18 and pregnant women who are MN. A State may **elect** to provide eligibility to certain other MN persons also: aged, blind, and/or disabled persons; caretaker relatives of children deprived of parental support and care; and certain other financially eligible children up to age 21. In 1994, there were 40 MN program which provided at least some services for at least some recipient groups.

The Medicare Catastrophic Coverage Act (MCCA) of 1988 made some significant changes which affected Medicaid. Although much of the MCCA was repealed, the Medicaid portions remain in effect. For Medicaid nursing facility recipients, the MCCA protects enough of the institutionalized spouse's income and resources to assure a moderate level of support for the spouse in the community. As a result, less income and resources remain available to contribute to the cost of the nursing facility care. Thus, the institutionalized spouse qualifies for Medicaid earlier than would have been true previously.

Once eligibility for Medicaid is determined, coverage generally is retroactive to the third month prior to application. Medicaid coverage generally stops at the end of the month in which a person no longer meets the criteria of any Medicaid eligibility group. In addition to the Medicaid program, most States have additional "State-only" programs to provide medical assistance for specified poor persons who do not qualify for Medicaid. Federal matching funds are **not** provided for these State-only programs.

Scope of Medicaid services

Title XIX of the Social Security Act requires that, in order to receive Federal matching funds, a State **must** offer certain **basic** services to the categorically needy populations:

- inpatient hospital services;
- outpatient hospital services;
- prenatal care;
- physician services;
- nursing facility (NF) services for persons aged 21 or older;
- family planning services and supplies;
- rural health clinic services;
- home health care for persons eligible for skilled-nursing services;
- laboratory and x-ray services;
- pediatric and family nurse practitioner services;
- nurse-midwife services;

- certain Federally-qualified ambulatory and health-center services; and
- early and periodic screening, diagnostic, and treatment (EPSDT) services for children under age 21.

States may also receive Federal assistance for funding if they elect to provide other approved optional services. A few of the optional services under the Medicaid program include:

- clinic services;
- nursing facility services for the aged and disabled;
- intermediate care facilities for the mentally retarded (ICFs/MR);
- optometrist services and eyeglasses;
- prescribed drugs;
- prosthetic devices;
- dental services; and
- TB-related ambulatory services & drugs for qualifying persons.

States may provide home and community-based care to certain persons with chronic impairments. Another option allowed eight States (as a demonstration project) to establish and provide community-supported living arrangement services for persons with mental retardation or a related condition.

Amount and duration of Medicaid services

Within broad Federal guidelines, States determine the amount and duration of services offered under their Medicaid programs. They may limit, for example, the number of days of hospital care or the number of physician visits covered. However, States are prohibited from limiting the duration of coverage for medically necessary inpatient hospital services provided to Medicaid-eligible children under age six who are in "disproportionate share hospitals" (defined below) and to infants in all hospitals.

With certain exceptions, a State's Medicaid Plan must allow recipients to have freedom of choice among participating providers of health care. States may provide and pay for Medicaid services through various pre-payment arrangements, such as health maintenance organizations (HMOs).

In general, States are required to provide comparable amounts, duration and scope of services to all categorically-needy eligible persons. But there are two important exceptions:

1. Health care services identified under the EPSDT program as being "medically necessary" for eligible children must be provided by Medicaid, even if those services are not included as part of the covered services in that State's Plan (i.e., only these specific children might receive those specific service); and
 2. States may request "waivers" for home and community-based services (HCBS) under which they offer an alternative health care package for persons who might otherwise be institutionalized under Medicaid (i.e., only those persons so designated might receive HCBS). States are not limited in the scope of services they can provide under such waivers as long as they are cost effective (except that, other than as a part of respite care, they may not provide room and board for such recipients).
-

Payment for Medicaid services

Medicaid operates as a vendor payment program, with States paying providers directly. Providers participating in Medicaid must accept the Medicaid reimbursement level as payment in full. With a few specific exceptions, each State has broad discretion in determining (within Federally-imposed upper limits and specific restrictions) the reimbursement methodology and resulting rate for services.

States may impose nominal deductibles, coinsurance or copayments on some Medicaid recipients for certain services. However, certain Medicaid recipients must be excluded from cost sharing: pregnant women, children under age 18, hospital or nursing home patients who are expected to contribute most of their income to institutional care, and categorically needy enrollees in HMOs. In addition, emergency services and family planning services must be exempt from co-payments for all recipients.

The portion of each State's Medicaid program which is paid by the Federal government, known as the Federal Medical Assistance Percentage (FMAP), is determined annually by a formula that compares the State's average per capita income level with the national income average. By law, the FMAP cannot be lower than 50 percent nor higher than 83 percent. The wealthier States have a smaller share of their costs reimbursed. In 1994, the FMAPs varied from 50 percent (paid to 11 States and D.C.) to 78.9 percent (to Mississippi), with the average Federal share among all States being 57.5 percent.

The Federal government also shares in the State's expenditures for administration of the Medicaid program. Most administrative costs are matched at 50 percent for all States. However, depending on the complexities and the need for incentives for a particular service, higher matching rates are authorized for certain functions and activities.

Federal Medicaid payments to States have no set limit (cap); rather, the Federal government matches (at FMAP rates) the State payments for the mandatory services plus the optional services that the individual State decides to provide for eligible recipients. Reimbursement rates must be sufficient to enlist enough providers so that Medicaid care and services are available under the State Plan at least to the extent that comparable care and services are available to the general population within that geographic area.

States also must augment payment to qualified hospitals that provide inpatient services to a disproportionate number of Medicaid recipients and/or to other low-income persons under what is known as the "disproportionate share hospital" (DSH) program. Under this program -- which was coupled with refundable donations and provider taxes -- some States made large DSH payments in order to get higher Federal matching monies with little or no increase in the State's share. However, under legislation passed in 1991, these DSH payments are now limited.

Medicaid Trends and Summary

Medicaid was initially formulated as a medical care extension of Federally funded income maintenance programs for the poor, with an emphasis on dependent children and their mothers. Over the years, however, Medicaid has been diverging from a firm tie to eligibility for cash programs. Recent legislation assures Medicaid coverage to an expanded number of low-income pregnant women, poor children and to some Medicare beneficiaries who are not eligible for any cash assistance program. Such persons would not have been eligible for Medicaid under earlier legislation. Legislative changes also focused on increased access, better quality of care, continuation of specific benefits, enhanced outreach programs,

and fewer limits on services.

Medicaid policies for eligibility and services are complex, and vary considerably even among similar-sized and/or adjacent States. A person who is eligible for Medicaid in one State might not be eligible in another State. Services provided by one State may differ considerably in amount, duration, or scope from services provided in a similar or neighboring State. And Medicaid eligibility and/or services within a State can change during the year.

The Managed Care concept, which is growing rapidly within the Medicaid program, seeks to enhance access to quality care in a cost effective manner. As of June 30, 1994, 7.8 million Medicaid recipients had enrolled in Medicaid Managed Care programs, and the number of participants is increasing rapidly.

The biggest change from the original Medicaid program has been the growth of Medicaid's substantial role in long-term care. An average of almost 45 percent of care for persons using nursing facility or home health services in the U.S. in recent years was paid for by the Medicaid program. A much larger percentage is paid by Medicaid for those persons who used more than four months of such long-term health care. Medicaid payments for institutional and community-based long term care in 1994 totaled almost \$46 billion.

Since its inception, increases in expenditures for the Medicaid program have exceeded the consumer price index, and have exceeded the increase in total numbers of persons served and the increase in services provided. This continually increasing growth in Medicaid expenditures seems primarily due to four factors:

1. the increase in rates of payments to providers of medical and health care services, when compared to general inflation;
2. the results of technological advances to keep more very low birth-weight babies and other critically ill or severely injured persons alive, but in need of continued extensive and very expensive care;
3. the increase in the numbers of very old and disabled persons requiring extensive acute and/or long term health care and various related services; and
4. the increase in the size of the Medicaid-covered populations (a result of the economic recession and Federal mandates).

Most Medicaid recipients require relatively small expenditures per person, per year. For example, the data for 1994 indicate that Medicaid vendor payments for over 17 million children under age 21 averaged only \$1,006 per child. Other groups, comprised of far fewer persons, have much larger per-person expenditures; e.g., the 158,800 recipients of ICFs/MR care in 1994 who averaged \$55,300 per person in Medicaid payments to ICFs/MR (plus the cost of acute care and other services they received outside of the ICF/MR facility). And at least 40 percent of persons with AIDS have their health care (estimated in 1992 to be about \$40,000 per person per year) paid for by Medicaid.

Although the recipient numbers are relatively very small, some individual patients (e.g., severely burned patients, accident or violence victims with multiple severe head and brain injuries, medically fragile very premature babies, organ transplant patients, and others requiring very specialized, extensive and intensive medical care) can cost over \$4,000 per day/per person. And a few persons require continuing extensive and very complex health care for many years, costing several hundreds of thousands of dollars per person, year after year.

Data indicate that over 40 million persons were enrolled in Medicaid in 1994. Of these, 35.5 million received at least some health care service in 1994 through the Medicaid program. Total 1994 outlays for the Medicaid program include: vendor payments of \$109 billion, payments for various premiums (for HMOs, Medicare, etc.) of almost \$11 billion, payments to disproportionate share hospitals of nearly \$17 billion, plus administrative costs. Total increase was from \$126 billion for 1993 to \$137 billion for 1994 (\$79 billion in Federal and \$58 billion in State monies). This meant an average 1994 Medicaid payment to vendors of \$3,070 per Medicaid recipient.

Medicaid's compound rate of growth for the existing program is now projected to be nine percent per year between the years 1994 and the year 2000. Thus, if current expenditure trends continue, and there are no significant changes to the Medicaid program, then payments for the total (Federal and State) Medicaid programs may exceed \$230 billion by the year 2000.

The U.S. Congress, the Department of Health and Human Services and the individual States continually seek to make improvements in the Medicaid programs' quality, effectiveness and extent of health care services. The need for expanded eligibility and more extensive and enduring services is obvious. However, the Medicaid programs must function within the various Federal and State constraints of economic, social, and political factors. As a balance for these factors is sought, revisions continue to occur in Federal laws, in HCFA regulations, and in the States' Medicaid Plans. Thus, the Medicaid programs are continually changing.

Acknowledgements: The written portions, including the summaries of the Medicaid and Medicare programs, were prepared by Mary Onnis Waid in the Office of the Actuary, Health Care Financing Administration, N3-01-23, 7500 Security Blvd. Baltimore, MD 21244-1851. Phone (410)-786-6921. The national health expenditures data and estimates were prepared by the Office of National Health Statistics, also in the Office of the Actuary, HCFA. Historical information was extracted from the Vol. 56, No. 4, Winter, 1993 edition of the *Social Security Bulletin*.

For Related Information:

- [HCFA's Medicaid Information](#)
- [Search State Laws by Topic](#)

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Quality of Care ~ National Projects

Medicare Lifestyle Modification Program Demonstration Summary of Demonstration

(For more information contact Armen Thoumaian or Debbie Grossblatt.)

The Health Care Financing Administration (HCFA), Office of Clinical Standards and Quality (OCSQ) is implementing the Medicare Lifestyle Modification Program Demonstration.

Recent research has suggested that aggressive risk factor reduction may slow, stop, or even reverse the progress of coronary artery disease. Lifestyle modification programs are increasingly becoming an approach to the secondary prevention of coronary disease morbidity. Participation in these programs may lead to improved health outcomes for Medicare beneficiaries with cardiovascular disease and potentially reduce Medicare costs.

The demonstration is designed to test the effectiveness of providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries with moderate to severe coronary artery disease. The treatment outcomes of Medicare beneficiaries who complete the lifestyle modification program will be compared to those of similar patients who receive more traditional services under the Medicare program.

The demonstration will include two multiple site, cardiovascular lifestyle modification program models that offer a twelve-month, multi-disciplinary, clinical outpatient treatment program. Each lifestyle program model can enroll up to 1800 Medicare Part B eligible beneficiaries who meet the clinical enrollment criteria and voluntarily elect to participate in the demonstration. The two program models selected are:

The Dr. Dean Ornish Program for Reversing Heart Disease? developed by Dr. Dean Ornish and offered through the joint efforts of the Preventive Medicine Research Institute, Sausalito, California and Lifestyle Advantage, Pittsburgh, Pennsylvania; and

The Cardiac Wellness Extended Program developed by Dr. Herbert Benson and offered through the Mind/Body Medical Institute, Boston, Massachusetts.

All Medicare certified medical facilities licensed to provide either program are eligible to participate as demonstration sites during the demonstration period. The demonstration period began on October 1, 1999, and will provide a multi-year

enrollment period ending on November 12, 2003, with payment through November 12, 2004.

Medicare payment is based on a negotiated amount reached with the parent or licensing entity for the multi-site lifestyle modification program and applies to all sites offering that program model. The demonstration sites will receive 80 percent of the total payment amount for their 12-month program for each beneficiary who completes the treatment program.

Demonstration sites providing the Dr. Dean Ornish Program for Reversing Heart Disease? will receive 80% of \$7,200 or \$5,760. Sites offering the Cardiac Wellness Extended Program will receive 80% of \$4,800 or \$3,840. The beneficiary is responsible for paying the remaining 20%. A demonstration site may waive the amount due from the beneficiary, but it must do so for all beneficiaries.

Payments to sites will be made on a quarterly basis at 35%, 15%, 15%, and 35% of the total rate, respectively, for each enrolled beneficiary. However, if the beneficiary's disenrolls from the program prior to completion, the demonstration site will receive a pro-rated portion of the total payment.

The Delmarva Foundation for Medical Care, Inc., a Medicare Peer Review Organization, has been contracted to provide quality monitoring and review of the treatment provided to Medicare patients enrolled at the demonstration sites.

The Schneider Institute for Health Policy, Brandeis University has been contracted to provide an independent evaluation of the demonstration. The evaluation will focus on a comparison of clinical outcomes of Medicare beneficiaries enrolled in the demonstration with those of a matched-paired control group consisting of Medicare patients with similar demographic characteristics and disease severity. The evaluation will also assess the quality of care delivery and patient satisfaction under the demonstration as well as the potential savings of lifestyle modification treatment services to the Medicare program.



Federal Employees Health Benefit Program

presented by:

Abby L. Block

**Assistant Director of Insurance Programs
U.S. Office of Personnel Management**

Federal Employees Health Benefit Program

- **February 1954, President Eisenhower calls for health program for Federal employees**
 - **in line with best practices of progressive private employers**
 - **should be part of a well-rounded personnel program**
- **Public Law 86-382, Federal Employees Health Benefits Act of 1959 enacted 9/28/59**

THE ACT

The legislation gave the Civil Service Commission – now OPM – authority to contract with

- **certain types of health benefit plans**
- **for a broad range of services**
 - **hospital benefits**
 - **surgical benefits**
 - **ambulatory patient benefits**
 - **pharmaceuticals**
 - **other medical supplies and services**

THE ACT (Continued)

- Specified those eligible for coverage:
 - employees: 2.2 M
 - retirees: 1.9 M
 - retirees with Medicare: 1.3 M
 - family members: 4.6 M
 - includes former spouses
- the method of determining the government's contribution to the program

THE ACT (Continued)

- **Legislation did not specify benefit levels for the range of services**
- **OPM provides direction to carriers**
 - **annual Call Letter**
 - **regular Carrier Letter mailings**
 - **annual health plan conference**
 - **day-to-day interaction with contract specialists**

TYPES OF HEALTH PLANS

- **Open FFS plans**
 - e.g. BCBS, GEHA, Mail Handlers
 - Open to all; nationwide
 - Covered Lives: 5.7 M
 - Employees: 1.3 M
 - Retirees: 1.5 M
 - Retirees w/ Medicare: 1.1 M
 - Family Members: 2.9 M

TYPES OF HEALTH PLANS (continued)

- **Closed FFS Plans**
 - e.g. Secret Service, Foreign Service
 - Open only to specific groups;
nationwide
 - Covered Lives: 209,000
 - Employees: 42,000
 - Retirees: 59,000
 - Retirees w/ Medicare: 34,000
 - Family Members: 108,000

TYPES OF HEALTH PLANS

(continued)

- **HMOs**

- e.g. Kaiser, PacifiCare, Aetna U.S Healthcare
- Serves particular geographic area
- **Covered Lives: 2.7 M**
 - **Employees: 879,000**
 - **Retirees: 307,000**
 - Retirees w/ Medicare: 161,000
 - **Family Members: 1.6 M**

TYPES OF HEALTH PLANS (continued)

- **# of plans available**
 - minimum = 7
 - maximum = 31
- **Definitions are broad and flexible**
- **Government-wide plans and employee organization plans now have PPO component**
- **In-network services are most often used by consumers**

BENEFITS

- **Contracts negotiated bilaterally with each plan on an annual basis**
- **Each contract must contain detailed statement of benefits which includes:**
 - **maximums**
 - **limitations**
 - **exclusions**
 - **other definitions of benefit as OPM deems necessary or desirable**
 - **for example, immunizations for children or mammography screening**

BENEFITS

- **Once contract negotiations complete, consumers given extensive benefits information**
 - **FEHB Guide to Plans**
 - **Individual plan brochures**
 - **Web site information**
 - **Decision support tool**
 - **Access to printed materials (Guide, brochures)**
 - **Policy and background information**

BENEFITS:

Alternative Medicine

- **In April 2001 Call Letter (OPM's annual policy guidance to FEHB plans), OPM stated:**
 - **“ Where there is demonstrated medical effectiveness, and consistent with your overall strategy for benefit design, we encourage you to consider services such as chiropractic, acupuncture, biofeedback and others that are being used increasingly for pain management and as alternative treatments.”**

PREMIUMS

- **Rates set by negotiations between OPM and carriers**
- **Two rating methodologies**
 - **Experience Rating**
 - **Community Rating**
- **Regardless of the rating methodology used, all enrollees within a plan pay the same premium (varies by self vs. self & family and sometimes by high vs. standard option)**

PREMIUMS (continued)

- **Fair Share formula**
 - **Weighted average of all plans**
 - **Cannot exceed 75% of a plan's actual premium**
 - **Government share is 72% of weighted average premium**
- **Balance paid by employee or retiree**
- **Agencies collect premiums by payroll deduction and remit to OPM**

CONTRACTING CYCLE

Annual Timeline of OPM Activities

- **Feb/March: review and accept/deny new plan applications**
- **June-August: negotiate benefits and rates for next contract year**
- **June-September: collaborate with carriers on plan brochure language**
- **Nov/Dec (4-5 weeks): conduct annual open season**

OPEN SEASON

OPM

- **designs and distributes Open Season Guides**
- **provides agencies Open Season guidance through Benefits Administration Letters**
- **provides plan information and links to comparative information and decision tools on FEHB Open Season web site www.opm.gov/insure**

OPEN SEASON

Agencies

- **make guides and brochure information available to employees**
- **conduct health fairs**
- **counsel employees**
- **process enrollment changes**

YEAR ROUND

- **OPM monitors plan performance**
- **Responds to customer concerns**
- **Resolves disputed claims**
- **Monitors industry trends**
- **Consults with carriers**
- **Develops guidelines for next contract year**



White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

April 6, 2001

Chair

James Gordon, MD

Commissioners

George Bernier, Jr, MD

David Bresler, PhD, LAc, OME

Thomas Chappell

Effie Chow, PhD, RN, DiplAc

George DeVries, III

William Fair, MD

Joseph Fins, MD, FACP

Veronica Gutierrez, DC

Wayne Jonas, MD

Linnea Larson, LCSW, LMFT

Tieraona Low Dog, MD, AHG

Charlotte Kerr, RSM

Dean Ornish, MD

Conchita Paz, MD

Joseph E. Pizzorno, Jr, ND

Buford Rolin

Julia Scott

Xiaoming Tian, MD, LAc

Donald Warren, DDS

Executive Staff

Stephen Groot, PharmD

Executive Director

Michele Chang, CMT, MPH

Executive Secretary

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Corinne Axelrod, MPH

Joseph Kaczmarczyk, DO, MPH

Doris Kingsbury

Geraldine Pollen, MA

Consultant Staff

Kenneth Fisher, PhD

Maureen Miller, MPH, RN

James Swyers, MA

Nicheole Amundsen, RNMS
(112) Chief, Primary Care
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, D.C. 20420

Dear Ms. Amundsen:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request certain information in preparation for an upcoming meeting.

The President established this Commission in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at www.whccamp.hhs.gov.

The Commission will meet May 14th through the 16th to discuss coverage and reimbursement for CAM, as well as further discussion of CAM research – an area addressed by Dr. John Demakis (for Dr. James Burris) at the Commission's October 2000 meeting. At this time, we are seeking information related to the role of the Veterans Administration (VA) in coverage and reimbursement for CAM therapies. To guide you in providing information of interest to the Commission, we have developed the questions outlined below. If in preparing your response you find information not specifically requested but related to the scope of the Commission, please provide us with the additional information.

To assist you in fulfilling this request, we have enclosed a listing of health care modalities that are generally considered to be CAM to serve as guidance. This list is not intended to be all-inclusive and does not reflect the consensus or opinion of the Commission regarding a definition CAM. If there are other health care practices that you consider to be unconventional and wish to include with your response, please do so.

Questions Related to Coverage and Reimbursement

- What are the legislative, regulatory, and administrative parameters related to coverage of health benefits for veterans? How does the VA determine which benefits to add to its health care programs?
- Does the VA include any CAM services and products at its health care facilities, or through contracted providers? Describe.
- Does the VA have plans to incorporate new or additional CAM benefits? Explain, including budgetary options or concerns.
- What does the VA consider as the most promising areas of CAM practice to incorporate into its health care programs? Explain.
- For CAM services provided by the VA, if any, how are the costs of such services addressed, i.e., payment policies, budgeting, etc.
- For any CAM service provided outside of a VA facility, does the VA (or a contractor) determine whether to pay for the service and, if so, how is this done? Explain any relevant coverage processes.
- For CAM services provided outside of a VA facility, how is the payment amount determined? Describe any pertinent payment policies and processes used by the VA
- What ideas and suggestions does the VA have for health services research related to access, coverage, and payment for CAM services and products?
- For CAM services covered, has the VA established standards (e.g., education, training, licensure) for the practitioners providing such services? Are any other quality monitors utilized?
- What ideas, issues, and concerns regarding coverage and payment for CAM can the VA provide the Commission as it develops its policy recommendations and report to the President and Congress?

We would appreciate your response **by May 7** either by email or fax so that the Commissioners will have time to review it before the May meeting. You may email your response to Maureen Miller at millemau@mail.nih.gov or send a fax to 301-480-1691. Specific questions may be addressed to her at 301-435-7592, or to me at 301-435-6199. Thank you for your attention to this request.

Sincerely,



Stephen C. Groft, Pharm. D.
Executive Director

Enclosure

Common CAM Therapies

Acupuncture
Acupressure
Alexander Technique
Applied Kinesiology
Anthroposophic Medicine
Aromatherapy
Autogenic Training
Ayurvedic Medicine
Energy Medicine
Chiropractic
(Sacral) Cranial Osteopathy
Environmental Medicine
Herbal Medicine
Homeopathy
Hypnosis
Guided Imagery
Massage Therapy
Meditation
Naturopathy
Nutritional Therapy (Nutrition)
Reflexology
Relaxation and Visualization
Shiatsu
Spiritual Healing
Therapeutic Touch
Traditional Chinese and Oriental Medicine
Yoga

Adapted from Zollman C, Vickers A. What is Complementary Medicine?
British Medical Journal 1999, 319; 693-696



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

APR 27 2001

In Reply Refer To:

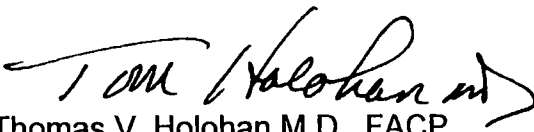
•
Ms. Maureen Miller R.N., M.P.H.
White House Commission
on Complementary and Alternative Medicine Policy
6701 Rockledge Drive
Suite 1010, MS-7707
Bethesda, MD 20817

Dear Ms. Miller:

As we discussed, you will find enclosed copies of the FR notice of 1999 addressing medical benefits for veteran patients, my testimony before Congressman Burton, and the results of a recent informal voluntary field survey of CAM practices within VA. The reliability of this polling is, of course, undetermined, and we cannot represent that it accurately reflects the current state of use of those various practices.

The Office of the Under Secretary for Health and the Office of Patient Care Services believe that any intervention provided to our veteran patients should be supported by evidence of safety and effectiveness. At the same time, medical research is one of the mandated missions of the Department of Veterans Affairs. Thus patients may be afforded the opportunity to participate in clinical research, subject to appropriate requirements for protection of human subjects and Institutional Review Board approval for provision of unproven interventions.

Thank you for your willingness to discuss these issues in detail. We look forward to working with you and your office on these challenging issues.


Thomas V. Holohan M.D., FACP
Chief, Patient Care Services

**Testimony of Thomas V. Holohan M.D., FACP
Chief, Patient Care Services, VHA
For
The House Committee on Government Reform**

Public interest in, and use of, unconventional or alternative medical practices (AM) is increasing. Contemporary observers have offered many reasons for the phenomenon, including dissatisfaction with limitations of conventional medicine, desire for treatment directed toward the "whole person", distrust of drugs and side effects, and awareness of linkages between disease and emotional and lifestyle factors. Added to this is the recognized frustration and search for "cure" on the part of patients afflicted with chronic or fatal disorders which have not responded well to available therapy. Other factors likely include the reduction in time physicians are able or willing to spend with individual patients, as productivity concerns in medical practice assume greater importance. A recent Washington Post article reported a survey that alleges the average time a patient has to present their complaints to a physician is less than 25 seconds. Several recent publications have indicated that up to \$27 billion are spent each year on AM, and that up to a third of persons surveyed have used at least one modality that may be defined as "alternative". Interest in the conventional medical community is evidenced by the fact that the entire November 11 issue of the Journal of the American Medical Association was devoted to AM. In 1993, the National Institutes of Health (NIH) established the Office of Alternative Medicine (OAM) to facilitate the evaluation of alternative therapies. This Office currently has an annual budget of \$50 million.

The heterogeneous treatments employed by the many schools of alternative practices cannot be encompassed within a single paradigm. When we refer to AM, we are using a nonspecific term to describe a variable group of practices

which include botanical therapies, mind-body interactive approaches, nutritional interventions, various physical or manual therapies, some chemical entities or biologics which have not been evaluated by the Food and Drug Administration (FDA) on the bases of clinical trials, and similar modalities. Still others are rooted in cultural or religious belief systems which may be foreign to contemporary North American and Western European society. Their single commonality is that their underlying philosophies or the manner in which their agents and techniques are employed diverge from mainstream Western medical principles and practices. However, that separation is not distinct and absolute, as we shall later elaborate.

VA recently awarded a contract to survey alternative practices as they might apply to our system of healthcare. Elements of the report were to include: the current state of use and familiarity with alternative practice within our system; a review of VA's patient database and a literature-based assessment of the applicability of alternative practices to VA patients; an evaluation of the state of alternative practices in the private sector; and an appraisal of the cost-effectiveness of alternative practices. At present, the report has not been completed. We do, however, have some survey data regarding the state of alternative practices in VA facilities. While knowledge, and even awareness, of alternative practices varies widely among providers and facilities, most facilities provide some such treatments. These have generally included modalities such as acupuncture, dietary therapy, yoga, biofeedback, relaxation, music therapy, and Native American therapies (e.g., "sweat lodges"). These practices usually reflected the presence of practitioner advocates and managerial willingness to accept the implementation of those programs. Most facility management teams were reported as pragmatically oriented, and described as having no biases for or against alternative treatments. The main concerns expressed related to the highly variable training and credentialing of practitioners, the lack of sound scientific evidence supporting use of many alternative therapies, and uneasiness

about budgetary impact of alternative practice in an environment of constrained resources.

We would call to the Committee's attention that to a significant extent, many practices often considered as alternative medicine have been, or are, also in the armamentarium of "conventional" medicine. For example, physical/manual treatments (e.g., massage therapy) significantly overlap with physical therapy modalities widely used in the current practice of physical medicine and rehabilitation. Many nutritional therapy models have counterparts in allopathic medicine, such as the use of hyperalimentation as an adjunct to conventional cancer treatment. In addition, the mainstream medical literature contains numerous studies of vitamin C supplementation, zinc for treatment of viral respiratory infections, and the use of vitamin E as an antioxidant, among many others. Many drugs widely used by conventional practitioners are in fact botanical preparations which have been evaluated in clinical trials and approved for marketing by FDA. These include vincristine (from the periwinkle plant), digitalis (foxglove), and taxol (originally extracted from Pacific yew tree bark). Many metallic elements have been employed by conventional practitioners including cis-platinum (for cancer), mercury (syphilis), magnesium (eclampsia of pregnancy) and others. Indeed, it was not very long ago, certainly within my medical career, that maggots were sometimes used in lieu of surgery to successfully treat putrifying wounds and soft tissue infections, based on observations made in the First World War that maggot infected wounds rarely became gangrenous.

The mind-body interaction is not a phenomenon only realized by alternative practitioners. There is a long history in medicine of appreciation of those mutual effects. A significant body of mainstream research – both old and new - has provided compelling data that indicate the prognosis for coronary disease patients with depression is worse than for those without; that breast cancer patients who attend a support group had measurably better outcomes than those

who did not; that single male cancer patients had worse prognoses than married patients; that cancer patients who were optimistic and who had stronger religious feelings tended to fare better than patients not so inclined. Indeed, it is no accident that the Chaplains' service is an integral part of our Office of Patient Care Services, and not attached to administrative programs. We see their ministry as part and parcel of clinical care. I should here note that my attendance at the VA Chaplains' recent national convocation convinced me that they strongly believe their mission to be both pastoral and medical. Further, we are currently developing a formal VA-wide strategy to fully integrate mental health and medical services throughout our system of care, based upon our belief that all diseases or disorders exist within a person, that the patient is the unit of care, and that one treats a whole patient, not simply an organ system.

At the same time, one cannot ignore a portion of the spectrum of alternative or unconventional care that is truly extreme. There are a number of therapies whose advocates have proposed unduly optimistic claims and whose treatments have been unequivocally demonstrated as ineffective and often harmful. Such treatments include immunoaugmentative therapy for cancer, offered in the Bahamas for many years. In this genre are also administrations of coffee enemas as cancer therapy, and the sale of laetrile, the latter having been legalized by the legislatures of 24 states. Indeed, in the early 1980's, the late Congressman Claude Pepper's committee published a lengthy, depressing yet remarkable report on the wide variety of ineffective or fraudulent treatments being provided to the public. We do not mean to imply that all unconventional treatments are *ipso facto* suspect. The critical point to be made is that the advocate of any treatment, conventional or unconventional, allopathic or homeopathic, surgical or psychological, has an obligation to provide high quality evidence that satisfactorily demonstrates the treatment is effective and that the benefit is clearly proportionate to the risk. This is in accord with the intent of the Kefauver Commission which in 1962 determined that pharmaceuticals must be shown by their manufacturers to be effective for their intended purpose.

The ethical and moral obligation of an advocate of any treatment is to demonstrate effectiveness and acceptable safety of that therapy. It is important to emphasize claims that scientific research standards are inappropriate or irrelevant to alternative practices are bankrupt. Science is neither an entity nor a belief system, but merely a method of investigation. It is a tool that enables one to formulate and then test a hypothesis; as such its applicability is virtually universal. It stands in distinction to behaviors which accept opinion, however highly placed or impressive the source, as determinative. It is the only instrument that permits a mathematically sound statement of the probability that a particular cause will result in a specific effect. A casual and unsystematic linkage of cause and effect is easily erroneous in biological systems. For those reasons, prudent clinicians are loath to accept anecdotal evidence or a few cases as proof of efficacy. For example, medicine has come to understand that the so-called the placebo effect is real, and is potent. Patients often experience what they expect to experience. For example, the Physician's Desk Reference (PDR) includes data on adverse effects reported by patients during trials in which drugs were compared with placebo. For pilocarpine hydrochloride (used to treat salivary gland dysfunction), nine percent of patients given placebo reported increased sweating, eight percent reported headache, and seven percent rhinitis. For diltiazem (used to treat hypertension), of patients on the placebo arm, five percent reported headache, three percent dizziness, and remarkably, 2.3% had abnormalities of their electrocardiogram (versus 1.6% of those treated with the active drug). Suggestion is powerful, as has repeatedly been demonstrated in hypnotherapy since the 19th century.

Consequently, treatments should be offered patients only after there has been provided convincing evidence of effectiveness and acceptable adverse effects. This is no less true of conventional than of alternative practices. Ignoring this tenet does not served patients well. During the 1960's an operation to prevent stroke by connecting the external carotid to the internal carotid artery (EC-IC

bypass) was developed and widely applied based upon a number of reports of small series of patients. Because of the outspoken skepticism of some in the medical community, despite the prestige of the advocates, the NIH sponsored an international, multicenter prospective randomized trial comparing the surgery with medical therapy. The results demonstrated that not only did the procedure fail to prevent stroke, but that operated patients died sooner and in greater proportion than did patients treated with drugs. Currently, federal law requires that the FDA approve drugs only on the basis of well-controlled clinical trials; similar requirements exist for some medical devices (those implanted or used for life-threatening conditions). There are no such standards for surgical procedures or for alternative medical therapies.

VA believes that we have a serious responsibility to demand evidence of benefit and safety for treatments we provide to veteran patients, and we have invested considerable resources to that end. We have recently established a Technology Recommendations Panel, to add to our Technology Assessment Program, with the view of aiding such evaluations; the Panel has already reviewed the use of a neurosurgical operation (pallidotomy) for Parkinson's disease, and an investigational device used to repair blood vessels without requiring an open surgical procedure.

We believe that expert opinion or beliefs do not constitute scientific evidence; anecdotes, case reports, and small series of patients represent the weakest forms of evidence and best serve to provide a hypothesis which may be tested in a well-designed clinical trial. While such positions are not in accord with the opinions of some in both the conventional and alternative medical fields, they certainly are in agreement with how most of us, tacitly or overtly, rely on the scientific method in our daily lives. When we step on an airplane, we are aware of our dependence upon the engineers' theories, the experimentation supporting those theories, and repeated testing of the materials and the design of the airframe, engine, and controls. We expect the Federal Aviation Administration to

provide serious oversight in aircraft manufacture, and that design and construction will not be based solely on an engineer's opinions or beliefs. Likewise, we expect that our automobile brakes and tires will be the products of materials research, carefully controlled testing, and standardized components and construction. In both of those venues, we also expect that the design and construction will be accomplished by technical experts qualified by training and experience and certified as competent by reliable and responsible authorities, such as universities or governmental agencies.

**COMPLEMENTARY AND ALTERNATIVE THERAPIES
CURRENTLY PROVIDED
BY NETWORK**

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
1 (no informati on provided)	<u>104 CPT Visits</u>			<u>2,506 Massage CPT</u> <u>62 Acupuncture CPT</u> (Not just for pain clinic)		<u>No Use in 2000 CPT</u>
2	<u>227 CPT Visits</u> -Bath -Buffalo, sparingly at Rochester	None	According to Network, NO According to Nursing SHG, VISN 2 provides Planetree concept – use of complementary therapies, Aroma Therapy, Reiki, hypnotherapy, Humor, music and labyrinth therapy, therapeutic touch and massage (Not all done by nursing staff and Planetree requires certification and ongoing education)	<u>3,148 Massage CPT</u> <u>827 Acupuncture CPT</u> (Not just for pain) -Buffalo –acupuncture, relaxation and biofeedback -Syracuse –acupuncture all medical centers have biofeedback available	No	<u>No Use in 2000 CPT</u> No

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
3	<u>160 CPT Visits</u> -Hudson Valley, used for pain management, stress reduction, smoking cessation) -New York Harbor uses	None	-New York Harbor, nurses familiar with but don't officially use. Reiki, therapeutic touch, therapeutic massage, craniosacral therapy, magnet therapy and ariculotherapy practiced by one CT - Northampton (Therapeutic touch per HQ Nursing SHG)	<u>3,281 Massage CPT</u> <u>1904 Acupuncture CPT</u> (Not just for pain) -Bronx- Acupuncture -Hudson Valley –use acupuncture fairly frequently -New Jersey- Soft tissue manipulation, did acupuncture until two years ago, practitioner left -New York Harbor – acupuncture by on anesthesiologist and contract for acupuncture one day per week -Northport -Acupuncture	No	<u>1 Use in 2000 CPT</u> -New York Harbor – used in Podiatry, just started recently.
4	<u>63 CPT Visits</u> -Clarksburg -for chronic PTSD -Lebanon- one psychologist uses with 40% of patients -Wilmington – one nurse	None	Erie –Psychiatric NPs and RNs use therapeutic touch daily	<u>3,292 Massage CPT</u> <u>No Acupuncture CPT</u> -Clarksburg – Visualization for chronic PTSD -Erie – BH uses visualization and relaxation techniques -Lebanon – Massage through PT -Philadelphia – Massage, visualization, Eye Movement Desensitization Reprogramming - Wilmington - Music therapy. Relaxation, visualization, relaxation	No	<u>1 Use in 2000 CPT</u> -Lebanon – one case referred to Community -Philadelphia – 7 referrals to local facilities for wound healing -Pittsburgh – Referral for radical neck wound healing.

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
5	<u>55 CPT Visits</u> -Baltimore – some	None	Some, Not sure how many	<u>1,194 Massage CPT</u> <u>539 Acupuncture CPT</u> (Not just for pain) Baltimore – Acupuncture ½ day a week in clinic BH – virtual Reality for PTSD	No	<u>No Use in 2000 CPT</u> Washington – 5 treatments through contract
6	<u>109 CPT Visits</u> -Asheville – 2 licensed hypno- therapists -Hampton – for chronic pain -Richmond – tx pain, smoking cessation and to facilitate psychotherapy -Salem – 5 psychologists for pain management -Salisbury – one psychologist	- Richmond -yes	-Durham, 2 nurses for therapeutic touch - Hampton – Healing touch instructor used in oncology, pain management and SCI	<u>837 Massage CPT</u> <u>207 Acupuncture CPT</u> (Not just for pain) -Durham - visualization, -Fayetteville – Acupuncture in low back pain program, Visualization for relaxation and mood anxiety disorders	No	<u>No Use in 2000 CPT</u> -Asheville – Refer to Durham -Durham – Refer to Duke

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
7	<u>3 CPT Visits</u> - Montgomery/Tusk for chronic pain management	None	None According to Nursing SHG, also perform reflexology, in the Network	<u>5,248 Massage CPT</u> <u>57 Acupuncture CPT</u> (Not just for pain) - Atlanta, Birmingham, Columbia, Charleston, Montgomery/Tuskegee use visualization, some acupuncture and minimal massage for pain management - (Some virtual reality treatment per HQ Mental Health)	None	<u>No Use in 2000 CPT</u> All can refer, use for wound care (burns, gangrene, decubitis, etc.)
8 (no informati on provided)	<u>54 CPT Visits</u>			<u>9,102 Massage CPT</u> <u>1,666 Acupuncture CPT</u> (Not just for pain)		<u>971 Hyperbaric CPT</u>
9	<u>13 CPT Visits</u> - Memphis –for pain control and relaxation	None	No	<u>1143 Massage CPT</u> <u>3 Acupuncture CPT</u> (Not just for pain) -Lexington, Acupuncture in Rehab -Mountain Home – Biofeedback - Tennessee Valley HCS (Murfreesboro and Nashville – Biofeedback, relaxation therapy, massage, stretch and spray therapy	No	<u>0 Hyperbaric CPT</u> -Memphis – contract for it occasionally for wound care and osteoradionecrosis -Mountain Home – Dental uses for post radiation therapy to treat wound infection, surgical wound breakdown and osteoradionecrosis - - Tennessee Valley HCS (Murfreesboro and Nashville – oral

						surgery treat prior to and following oral surgery and radiation is involved.
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VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
10	<u>73 CPT Visits</u>	No	No	<u>870 Massage CPT</u> <u>3 Acupuncture CPT</u> (Not just for pain) -Chillicothe – Biofeedback -Cincinnati – Massage and biofeedback (Reiki per HQ nursing) - Cleveland – Acupuncture, Biofeedback - Dayton – Massage, biofeedback aromatherapy, pet therapy,	No	<u>0 Hyperbaric CPT</u> <u>No</u>
11	<u>8 CPT Visits</u> <u>No</u>	None	No (According to Nursing SHG- there is an RN with a funded research project on Therapeutic Touch and Massage at Ann Arbor)	<u>594 Massage CPT</u> <u>0 Acupuncture CPT</u> (Not just for pain) -Ann Arbor -Biofeedback and visualization - Detroit - Massage	No	<u>0 Hyperbaric CPT</u> -Ann Arbor - For oral patients who need radiation therapy and teeth extractions - Detroit – Refer outside for wound healing occasionally
12	<u>764 CPT Visits</u> - North Chicago – for smoking cessation and Hospice			<u>1188 Massage CPT</u> <u>42 Acupuncture CPT</u> (Not just for pain) -North Chicago in hospice uses Visualization, Music Therapy and Heat and Cold Massage		<u>0 Hyperbaric CPT</u> -Hines- through contract for non- healing wounds and deep soft tissue infections

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
13	<u>0 CPT Visits</u> -Black Hills – Counseling - Minneapolis – trauma symptoms, anxiety reduction, realization training, etc.	-Black Hills – 2 sweat lodge used mainly by native Americans and for PTSD - St Cloud has one sweat lodge	-Black Hills – one nurse doing therapeutic touch one day a week. - (Per Nursing SHG, Black Hills uses Healing Touch, Guided Imagery and relaxation	<u>1734 Massage CPT</u> <u>0 Acupuncture CPT</u> (Not just for pain) - Minneapolis – uses biofeedback and relaxation techniques including guided imagery, muscle relaxation, and meditation/	No	<u>30 Hyperbaric CPT</u> -Fargo – refers patients -Sioux Falls refers patients - Minneapolis uses for treatment of maxillofacial infections and treatment of complications of radiation therapy.
14 (no informati on provided)	<u>20 CPT Visits</u>	None	No	<u>1018 Massage CPT</u> <u>0 Acupuncture CPT</u> (Not just for pain)		<u>0 Hyperbaric CPT</u>
15	<u>41 CPT Visits</u> Used in Mental Health Clinic, smoking cessation, relaxation techniques and anger management	None	No	<u>1616 Massage CPT</u> <u>15 Acupuncture CPT</u> (Not just for pain) No	No	<u>2 Hyperbaric CPT</u> - Used for radiation injury, vascular disease with non healing wounds and some infectious diseases

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
16	<u>284 CPT Visits</u> -Fayetteville – some for smoking cessation Muskogee – in Behavioral Medicine for past memories for PTSD, occasionally for smoking cessation -New Orleans – with smoking cessation program - Little Rock – for pain management only - Biloxi – limited basis for smoking cessation -Houston – for anxiety disorders - Shreveport – occasionally for chronic pain and conversion disorders	None	- -Muskogee – therapeutic touch occasionally especially with the elderly	<u>4188 Massage CPT</u> <u>426 Acupuncture CPT</u> (Not just for pain) -Fayetteville – some massage -Muskogee – Spiritual Medicine used in Behavioral Medicine, Guided Imagery for anxiety conditions, Relation techniques including biofeedback for anxiety and pain control, Music therapy, St. John's work and ginkgo biloba occasionally used, after discussion of pros and cons and patient purchases OTC. - Montgomery – Acupuncture used in Rehab - Houston – Acupuncture, hydrotherapy, imagery/relaxation, and distraction/reframing - Shreveport –desensitization, and progressive relaxation	None	<u>25 Hyperbaric CPT</u> -Alexandria – purchase some for wound healing -New Orleans – uses in Dental for anaerobic infections, or for slow or non- healing wounds. - Montgomery – for non healing wounds occasionally -Biloxi – Dental uses when surgery is planned for patients who have received head and neck radiation - Shreveport – used by Pastics for flaps, for dental procedures after radiation

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
17	<u>47 CPT Visits</u> Temple – for smoking cessation occasionally	None	No	<u>3067 Massage CPT</u> <u>3 Acupuncture CPT</u> (Not just for pain) -Cranioelectric stimulation for depression, anxiety, and insomnia for addictive disorders -Biofeedback for adult ADD -Capnometry biofeedback (breathing retaining for post MI patients -Medication, TM and other forms for pain relief -EMDR-eye movement desensitization retraining for PTSD	No	<u>2 Hyperbaric CPT</u> Contracted for wound healing by surgical and dental service

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
18	<u>175 CPT Visits</u> -Phoenix – occasionally for smoking cessation or PTSD - Albuquerque – Pain management -Tucson – smoking cessation	- Phoenix – healing ceremonies in conjunction with Navajo Nation, some ceremonies not in Sweat Lodges - Prescott – employ Native American Peer Counselor through contract in MH, provides one sweat lodge per month, two talking circles per month, and room cleansing, as requested - Tucson – Primary Care Line offers services of Native American Healer, Sweat Lodges 5-6 in last year	- Prescott – Healing touch routinely in NHCU - Tucson – Therapeutic touch in hospice and palliative care	<u>2171 Massage CPT</u> <u>0 Acupuncture CPT</u> (Not just for pain) - Albuquerque - Visualization used routinely, biofeedback for pain management - Phoenix – short term massage therapy in community at VA expense for treatment of acute musculoskeletal injuries	No	<u>1 Hyperbaric CPT</u> -Phoenix –rarely for wound infections, or carbon monoxide poisoning
19 NOTE: Salt Lake has an Integrative Health Program since 9/00: Goal to integrate what is effective and educate about what is not	<u>69 CPT Visits</u> -Cheyenne – pain management , smoking cessation and stress reduction	- Salt Lake – Sweat Lodge occasionally and 4-5 smudging of patients	No says CMO - Denver (Nursing SHG says Therapeutic touch, Reiki, message, guided imagery, and visualization	<u>716 Massage CPT</u> <u>124 Acupuncture CPT</u> (Not just for pain) - Salt Lake - acupuncture in anesthesiology, gentle stretch exercise, guided imagery, hypnosis, meditation and massage therapy. - Cheyenne – Electrostimulation acupuncture - Southern Colorado HCS - Electrostimulation acupuncture	None	<u>1 Hyperbaric CPT</u> All out on Fee Basis wound healing, surgical

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelati on Therapy for heart disease	Use hyperbaric O2? For what?
20	<u>5 CPT Visits</u> - Boise – PTSD Relaxation Techniques, stress management	- Portland – Sweat Lodges available not used often - Boise – fund Sweat Lodges - Spokane – funds Sweat Lodges and has lodge on grounds - Roseburg – Sweat Lodge - Walla Walla Fund Sweat Lodges and has a Sweat Lodge - White City – Available Puget Sound – Sweat Lodges - Alaska – Talking Circles	- Portland – Therapeutic touch in acute and long term care, in pain management, music therapy, massage relaxation - Puget Sound – Hypnotherapy, massage, visualization, art and prayer therapy on individual basis	<u>1409 Massage CPT</u> <u>0 Acupuncture CPT</u> (Not just for pain) - Portland – acupuncture in community, relaxation - Boise – Deep pressure and deep tissue massage - Puget Sound – Dry needling as an approximation of acupuncture for chronic pain, prolotherapy (akin to manipulation), local injection therapy - Alaska – Fee basis over 100 visits last year	No	<u>0 Hyperbaric CPT</u> - Portland – occasionally for osteonecrosis of mandible - Boise- Refer rarely - Puget Sound – Occasionally for ischemia

VISN	Use Hypnotherapy, For what?	Sweat lodges, or other related modalities	Nurses who <u>officially</u> provide therapeutic touch, etc	In pain management and other centers, do we use acupuncture, massage, visualization, etc.	Chelation Therapy for heart disease	Use hyperbaric O2? For what?
21 (no information provided)	<u>69 CPT Visits</u>			<u>2716 Massage CPT</u> <u>299 Acupuncture CPT</u> (Not just for pain)		<u>2 Hyperbaric CPT</u>
22 (no information provided)	<u>161 CPT Visits</u>		(Nursing SHG – Rapid Relaxation Response at San Diego)	<u>1845 Massage CPT</u> <u>15 Acupuncture CPT</u> (Not just for pain)		<u>453 Hyperbaric CPT</u>
(National FY 2000 CPT Data)	<u>2,504 CPT Visits</u>			<u>52,883 Massage CPT</u> <u>6,192 Acupuncture CPT</u> (Not just for pain)		<u>1,489 Hyperbaric CPT</u>

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations governing payment of the proceeds of checks which are returned and canceled following the death of the payee. This amendment is necessary to implement a statutory amendment that deleted the requirement for settlement by the General Accounting Office prior to payment of these proceeds to an estate. This document also makes nonsubstantive changes for purposes of clarity.

DATES: *Effective Date:* October 19, 1996.

FOR FURTHER INFORMATION CONTACT: Warren Jones, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 273-7167.

SUPPLEMENTARY INFORMATION: Section 5122 of title 38, United States Code, governs payment of the proceeds of VA benefit check(s) received by a payee but not negotiated before his or her death. VA has implemented section 5122 at 38 CFR 3.1003.

Under section 5122, VA shall upon return and cancellation of an original benefit check pay the amount represented by the check in the same manner as it pays accrued benefits under 38 U.S.C. 5121. Section 5121 requires VA to pay accrued benefits to the first living person(s) in the following order: (A) veteran's spouse; (B) veteran's children (in equal shares); and (C) veteran's dependent parents (in equal shares). Section 5121(a)(5) also provides that, "[i]n all other cases," accrued benefits may be paid only as necessary to reimburse the person who bore the expenses of the payee's last sickness and burial. Section 5122 further provides that any amount not paid in this manner shall be paid to the estate of the deceased payee, unless the estate will escheat, i.e., revert to the state because there is no one eligible to inherit it.

Prior to October 19, 1996, section 5122 required settlement by the General Accounting Office (GAO) before payment could be made to an estate. However, section 202(t) of the General Accounting Office Act of 1996, Public Law 104-316, effective October 19, 1996, amended section 5122 to delete reference to settlement by GAO. VA's Office of the General Counsel has advised that under section 5122, VA is now authorized to pay amounts due to the estates of deceased payees without reference to any other agency. We are, therefore, amending 38 CFR 3.1003(b) to bring VA's regulation into conformity

with the amended statute by removing reference to settlement by GAO.

We also are amending § 3.1003(b) to replace the legal term "escheat" with the words "revert to the state because there is no one eligible to inherit it." We believe that many will not understand the term "escheat" and have, therefore, chosen to replace it with words that express the same legal meaning but are easier for the general public to understand.

The effective date of this amendment is October 19, 1996, the effective date of section 202(t) of Public Law 104-316.

This final rule reflects statutory amendments and makes nonsubstantive changes. Accordingly, there is a basis for dispensing with prior notice and comment and delayed effective date provisions of 5 U.S.C. 552 and 553.

Because no notice of proposed rule making was required in connection with the adoption of this final rule, no regulatory flexibility analysis is required under the Regulatory Flexibility Act (5 U.S.C. 601-612). Even so, the Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act.

The Catalog of Federal Domestic Assistance program numbers are 64.102, 64.104, 64.105, 64.109, and 64.110.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Veterans, Vietnam.

Approved: September 14, 1999.
Togo D. West, Jr.,
Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

§ 3.1003 [Amended]

2. In § 3.1003, paragraph (b) is amended by removing "upon settlement by the General Accounting Office"; and by removing "escheat" and adding, in its place, "revert to the state because there is no one eligible to inherit it".

[FR Doc. 99-26066 Filed 10-5-99; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AJ18

Enrollment—Provision of Hospital and Outpatient Care to Veterans

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends VA's medical regulations. The Veterans' Health Care Eligibility Reform Act of 1996 mandates that VA implement a national enrollment system to manage the delivery of healthcare services. Accordingly, the medical regulations are amended to establish provisions consistent with this mandate. Starting October 1, 1998, most veterans were required to be enrolled in the VA healthcare system as a condition of receiving VA hospital and outpatient care. Veterans will be allowed to apply to be enrolled at any time. They will be eligible to be enrolled based on funding availability and their priority status. In accordance with statutory provisions, the final rule also states that some categories of veterans are eligible for VA hospital and outpatient care even if not enrolled. This document further establishes a "medical benefits package" setting forth, with certain exceptions, the hospital and outpatient care that will be provided to enrolled veterans and certain other veterans.

Moreover, this document announces that VA will enroll all 7 priority categories of veterans for the period October 1, 1999 through September 30, 2000, unless it is necessary to change this determination by a subsequent rulemaking document.

DATES: *Effective Date:* November 5, 1999.

FOR FURTHER INFORMATION CONTACT: Roscoe Butler, Health Administration Service, (10C3), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273-8302. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In a document published in the *Federal Register* on July 10, 1998 (63 FR 37299), we proposed to amend the medical regulations at 38 CFR part 17. Public Law 104-262, the Veterans' Health Care Eligibility Reform Act of 1996, mandates that VA implement a national enrollment system to manage the delivery of healthcare services. Public Law 104-262 also contains priority categories for determining eligibility for enrollment. Accordingly, we proposed

to amend the medical regulations to establish provisions consistent with these statutory provisions. Starting October 1, 1998, most veterans were required to be enrolled in the VA healthcare system as a condition for receiving VA hospital and outpatient care. The proposal also stated that these veterans would be allowed to apply to be enrolled at any time. In accordance with statutory provisions, the proposal further stated that some categories of veterans would be eligible for VA hospital and outpatient care even if not enrolled. In addition, we proposed to establish a "medical benefits package" setting forth, with certain exceptions, the hospital and outpatient care that would be provided to enrolled veterans and certain other veterans.

We received comments from 10 sources. The comments are discussed below. Based on the rationale set forth in the proposed rule and in this document, the provisions of the proposed rule are adopted as a final rule with certain changes explained below.

Catastrophically Disabled

The priority listing for enrollment in proposed § 17.36 provided for certain catastrophically disabled veterans to be enrolled in priority category 4 and for certain other catastrophically disabled veterans to be enrolled in priority category 7. The proposed provisions were based on an attempt to reconcile the provisions of 38 U.S.C. 1705 and 1710(a). The provisions of 38 U.S.C. 1705 include in priority category 4 "veterans who are catastrophically disabled." The provisions of 38 U.S.C. 1710(a) set forth a preference scheme for providing VA care first to "mandatory veterans" and then to "discretionary veterans." This preference scheme, if controlling, would place some catastrophically disabled veterans in a lower priority category than priority category 4. Several commenters asserted that the provisions of 38 U.S.C. 1705 must be interpreted to require that all catastrophically disabled veterans be enrolled in priority category 4. Upon further consideration, we have concluded that the statutory provisions in question are irreconcilable and that the rules of statutory construction require that deference be given to the more specific provisions in 38 U.S.C. 1705. Accordingly, except as discussed below, the final rule includes all catastrophically disabled veterans in priority category 4.

Some veterans who are catastrophically disabled must agree to make the applicable co-payment as a condition of being included in priority category 4. This is because 38 U.S.C.

1710 imposes co-payments on certain veterans, including some veterans who are catastrophically disabled. Accordingly, we amended § 17.36(b)(4) to reflect the co-payment requirement. We also made corresponding changes to § 17.36(d)(1) with respect to information to be included in the application for enrollment in the VA healthcare system.

In § 17.36(e), the definition of the term "catastrophically disabled" includes the requirement that the condition be "permanent." Some commenters opposed the inclusion of this requirement. Although we have retained the requirement that the condition be "permanent," we have made clarifying changes.

We believe that a condition causing an individual to be catastrophically disabled must be a "permanent" condition. Under the provisions of 38 U.S.C. 1705, priority category 4 consists of "Veterans who are in receipt of increased pension based on a need of regular aid and attendance or by reason of being permanently housebound and other veterans who are catastrophically disabled." The words "other veterans who are catastrophically disabled" indicate that all veterans in priority category 4 are "catastrophically disabled" and are disabled to a similar extent. To be in receipt of increased pension based on a need of regular aid and attendance or by reason of being permanently housebound, a veteran must be permanently disabled (see 38 U.S.C. 1502 and 1521). We have thus construed this statutory priority category to include only veterans with permanent conditions. Our interpretation is consistent with other provisions of Pub. L. 104-262, which, as noted above, includes the mandate that VA implement a national enrollment system. In this regard, the four examples used to describe the term "disabled" in 38 U.S.C. 1706 are permanent conditions, *i.e.*, spinal cord dysfunction, blindness, amputations, and serious mental illness. Moreover, the legislative history of Pub. L. 104-262 refers to a permanent condition, spinal cord injury, to describe the type of disabilities intended to be covered by the term "catastrophically disabled" (House Report No. 690, 104th Cong., 2d Sess. 7 (1996)) and the Joint Explanatory Statement for H.R. 3118, The Proposed Veterans' Health Care Eligibility Reform Act of 1996 (142 Cong. Rec. S11642, S11646 (daily ed. Sept. 28, 1996)).

We have, however, clarified the criteria for determining when a condition is permanent. In this regard, we have revised the second sentence in § 17.36(e) to read as follows: "This definition is met if an individual has

been found by the Chief of Staff (or equivalent clinical official) at the VA facility where the individual was examined to have a permanent condition specified in paragraph (e)(1) of this section; to meet permanently one of the conditions specified in paragraph (e)(2) of this section by a clinical evaluation of the patient's medical records that documents that the patient previously met the permanent criteria and continues to meet such criteria (permanently) or would continue to meet such criteria (permanently) without the continuation of on-going treatment; or to meet permanently one of the conditions specified in paragraph (e)(2) of this section by a current medical examination that documents that the patient meets the permanent criteria and will continue to meet such criteria (permanently) or would continue to meet such criteria (permanently) without the continuation of on-going treatment." This clarifies that a veteran who previously met the criteria in § 17.36(e)(2) for establishing a permanent condition would continue to meet the criteria even if the condition has improved because of ongoing treatment. In our view, on-going treatment does not change the finding that the condition is permanent.

In § 17.36, paragraph (e) defines the term "catastrophically disabled" and includes provisions stating that the definition is met if certain conditions are met. One commenter argued that in order to be determined to be "catastrophically disabled" a veteran should be required to meet the definition or the conditions, but not both. No changes are made based on this comment. Both the definition and the specific conditions or the functional disability levels that meet the definition are necessary to ensure that the term "catastrophically disabled" is uniformly applied.

Under the provisions of § 17.36(b)(4), a veteran may be determined to be catastrophically disabled and thereby included in priority category 4 only if determined to be catastrophically disabled by the Chief of Staff (or equivalent clinical official) at the VA facility where the veteran was examined. One commenter suggested that VA include in the regulations additional information concerning examinations for determining whether veterans are catastrophically disabled, *i.e.*, how a first-time applicant could obtain catastrophically disabled status, how the examination would be conducted, and whether records of previous treatment and examination could be substituted for a current examination. No changes are made

based on this comment. We will consider a subsequent amendment to this final rule to include additional procedures as warranted. Currently, examinations could be provided based on the request of a veteran or VA. Also, the Chief of Staff (or equivalent clinical official) at the VA facility where the individual was examined would make decisions based on the criteria in the final rule for determining whether a veteran is catastrophically disabled and could use any available records in making the decision. Further, the decisionmaker could make a decision without requiring a new examination if the records are sufficient.

One commenter asserted that the determination by the Chief of Staff (or equivalent clinical official) constitutes an appeal and that the final rule should include appeal procedures and time limits for this decision. No changes are made based on this comment. The decision by the Chief of Staff (or equivalent clinical official) constitutes the initial decision. It is that decision that could be appealed.

In the proposal, the conditions for determining whether a veteran is catastrophically disabled included a finding that the veteran is "[d]ependent in 4 or more Activities of Daily Living (eating, dressing, bathing, toileting, transferring, incontinence of bowel and/or bladder), with at least 4 of the dependencies being permanent, using the Katz scale." Commenters argued that the reference to 4 should be lowered in both places to 3. We have compared the conditions with the definition of catastrophically disabled and have concluded that the definition would still be met if the number were changed to 3 in both places. Accordingly, we have made these changes in the final rule.

In the proposal, the conditions for determining whether a veteran is catastrophically disabled include a finding that the veteran scored 30 or lower using the Global Assessment of Functioning. Commenters asserted that the score for the Global Assessment of Functioning should be raised to 40. No changes are made based on these comments. Patients above 30 are in a range described as severe but less than catastrophic in that they do not require personal or mechanical assistance to leave home or bed or require constant supervision to avoid physical harm to self or others. Accordingly, they would not meet the definition of catastrophically disabled.

Commenters recommended that the list of conditions in § 17.36(e) that would establish that a veteran is "catastrophically disabled" should be

expanded to include chronic and severe mental illnesses, Amyotrophic Lateral Sclerosis, Multiple Sclerosis, a score of 5 or higher on the Kurtzke Expanded Disability Status Scale for Multiple Sclerosis, and possibly other things. No changes are made based on these comments. Conditions not specifically mentioned, including those mentioned by the commenters, would be covered when the criteria in § 17.36(e) are met. It is impractical to attempt to list all of the specific conditions that would be covered by the criteria.

The list of conditions for establishing that a veteran is catastrophically disabled includes a condition resulting from two of the specified procedures in § 17.36(e)(1) provided the two procedures were not on the same limb. The proposed procedures included "Amputation of toe (only if accompanied by V49.71 code for amputated great toe) (procedure code 84.11)." These provisions are clarified to reflect more clearly that the toe amputated must be the great toe.

The proposed list of conditions for establishing that a veteran is catastrophically disabled included permanent "unspecified hemiplegia." This is deleted. The final rule provides that a veteran is catastrophically disabled upon a finding of a score of 2 or lower on at least 4 of the 13 motor items using the Functional Independence Measure. This finding necessarily could be made if a veteran had hemiplegia that would be catastrophically disabling. This Functional Independence Measure is a more appropriate method of determining whether hemiplegia constitutes a catastrophic disability.

The proposed list of conditions for establishing that a veteran is catastrophically disabled included a score of 14 or higher on the Activities of Daily Living (ADL) Index using Resource Utilizations Group (RUG) III. This condition is deleted. The ADL section is one part of a complex multidimensional assessment tool known as the Minimum Data Set (MDS). All sections in the MDS contribute to the construction of 44 RUGs (RUG III). Therefore isolating one section and attempting to calculate a numerical score invalidates the purpose for which the instrument was designed.

Moreover, this should not have any negative effects on veterans. The category of veterans intended to meet the definition of catastrophically disabled based on the ADL criteria necessarily would also meet the definition of catastrophically disabled based on the criteria in §§ 17.36(e)(2)(i) or (iii) i.e., dependent in 3 or more

Activities of Daily Living (eating, dressing, bathing, toileting, transferring, incontinence of bowel and/or bladder), with at least 3 of the dependencies being permanent, using the Katz scale; or a score of 2 or lower on at least 4 of the 13 motor items using the Functional Independence Measure. In the ADL provision, "dependent" was intended to mean fully dependent. Being fully dependent is represented by a rating of 1 on the Katz scale. We have clarified the rule accordingly.

One commenter questioned how the definition and conditions were established for determining when an individual is "catastrophically disabled". In this regard, we note that the definition and conditions were formulated by knowledgeable VA clinical experts.

One commenter asserted that VA form 10-10 EZ should be amended to specifically ask whether a veteran is requesting an examination to determine whether the veteran is catastrophically disabled. No changes are made based on this comment. The issue of whether an individual should be examined is a complex matter (see § 17.36(e)) that does not lend itself readily to the form. Further, before a veteran would be removed from the list of enrollees based on a priority status lower than priority category 4, the veteran first would be provided a letter advising of the opportunity to request that action be taken (including an examination, if needed) to determine whether the veteran is catastrophically disabled and thereby eligible for inclusion in priority category 4.

Additional Enrollment Issues

One commenter opposed any enrollment system that could exclude any categories of veterans from access to medical care. No changes are made based on this comment. The Veterans' Health Care Eligibility Reform Act requires that we establish a system for the management of hospital and outpatient care based on priorities and available funding.

One commenter asserted that nonservice-connected Purple Heart recipients should be included in priority category 3. No changes are made based on this comment. The priority categories are established by statute, and there is no authority to include this category of veterans in priority category 3.

One commenter asserted that within priority category 7, military retirees should be given a subpriority based on the further assertion that military retirement benefits are inadequate. No changes are made based on this

comment. This final rule is not an appropriate forum for addressing military retirement benefits.

One commenter asserted that enrollment status decisions should be transferable among VA medical facilities. In response, we have added a note to § 17.36 to clarify that a veteran's enrollment status will be honored by all VA medical facilities in the United States (care abroad is covered by 38 U.S.C. 1724).

One commenter asserted that veterans should be given a presumption of entitlement to medical services when they initially apply or reapply for enrollment and should receive medical services until an appeal is decided. No changes are made based on this comment. We have no authority to include such provisions in the final rule.

One commenter asserted that enrollment should guarantee a veteran access to the "medical benefits package" for a certain period of time, e.g. until the end of the fiscal year. Commenters also asserted that after a number of years of receiving VA medical services an enrollee's right to receive medical services should become permanent. No changes are made based on these comments. It is our intent under the provisions of § 17.36 to try to predict accurately for the whole fiscal year how many priority categories will be funded. However, the regulations must include provisions for amending the determination at any time because VA can only provide services insofar as there are available funds to cover the services. Further, we have no authority to make permanent an enrollee's right to receive medical services.

Under the provisions of § 17.36(d)(4)(iii), a veteran who had been enrolled based on inclusion in priority category 5 will be disenrolled if the veteran does not return to VA a completed form VA Form 10-10EZ. One commenter asserted that this provision could cause some of the most vulnerable veterans to lose their medical benefits. No changes are made based on this comment. This will not disadvantage veterans who are disenrolled merely because they did not return the form. Under the provisions of § 17.36 such a veteran may reapply to be enrolled at any time and thereby supply the information necessary to determine their enrollment priority category.

One commenter opposed the provisions in § 17.36(d)(4)(i) which state that a veteran will be removed from the list of enrollees if the veteran submits to a VA medical center a signed document stating that the veteran no longer wishes to be enrolled. No changes are made

based on this comment. If a veteran no longer intends to obtain VA care we would like to be informed so that we can better predict the demand for VA care. However, this will not disadvantage those who wish to restore their enrollment status since, as noted above, a veteran may reapply to be enrolled at any time.

Commenters asserted that the letter that VA sends veterans concerning their enrollment status should indicate which priority group the veteran was placed in and all co-payment information. We intend to provide this information to enrolled veterans as soon as possible.

Under the provisions of Pub. L. 105-368, a veteran enrolled based on an illness associated with service in combat in a war after the Gulf War or during a period of hostility after November 11, 1998, is included in priority category 6 and is eligible for VA hospital and outpatient care provided in the medical benefits package for the illness. The final rule is amended to reflect this statutory change.

Hospital and Outpatient Care to Veterans Who are not Enrolled in the VA Healthcare System

Consistent with the provisions of Pub. L. 104-262, § 17.37 specifies when VA may provide hospital and outpatient care to veterans who are not enrolled in the VA healthcare system. One commenter asserted that this should include a statement that a veteran who is not enrolled in the VA healthcare system may receive an examination to determine whether the veteran is eligible for inclusion in priority category 4 based on a finding that the veteran is catastrophically disabled. We agree and have amended § 17.37 accordingly.

Medical Benefits Package

One commenter argued that the final rule should concern only a national enrollment system and, accordingly, should not include a medical benefits package. Although the commenter concluded that VA has inherent authority to establish a medical benefits package, the commenter asserted that the proposed rule purportedly was designed solely "to implement the Veterans' Health Care Eligibility Reform Act of 1996" and that the "medical benefits package" went beyond this statutory authority. The commenter also asserted that the statutory provisions at 38 U.S.C. 1701 and the regulations at 38 CFR 17.30 are adequate for determining what care will be provided to enrolled veterans. The commenter further asserted that we did not provide sufficient rationale or justification for the establishment of a "medical benefits

package." No changes are made based on these comments. Although the Veterans' Health Care Eligibility Reform Act of 1996 did not direct VA to create a medical benefits package, we believe that it is necessary under the requirements of the Administrative Procedure Act to inform affected individuals concerning the care that would or would not be provided to veterans enrolled in the VA healthcare system. The definitions of terms in 38 U.S.C. 1701 and 38 CFR 17.30 are not adequate by themselves to allow individuals to make such determinations. Further, the following statement in the preamble portion of the proposed rule provided the rational basis for the medical benefits package: "The Secretary has authority to provide healthcare as determined to be medically needed. In our view, medically needed constitutes care that is determined by appropriate healthcare professionals to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice. The care included in the proposed 'medical benefits package' is intended to meet these criteria."

Commenters asserted that infertility services, pregnancy and delivery, surgical implantation of penile prostheses, and membership in spas and health clubs should be included in the medical benefits package. As noted above, the medical benefits package would include "care that is determined by appropriate healthcare professionals to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice." Upon reconsideration, we conclude that pregnancy and delivery services (to the extent we have legal authority to provide such services) meet these criteria and should be included in the medical benefits package. We also conclude that membership in spas and health clubs does not meet these criteria and should not be included. Further, under these criteria, we have determined that reproductive sterilization, surgery to reverse voluntary sterilization, infertility services (other than in vitro fertilization), and surgical implantation of penile prostheses should not be excluded. Appropriate changes are made to the medical benefits package to reflect these determinations.

Commenters asserted that the "medical benefits package" should cover all emergency care for all enrolled veterans. No changes are made based on these comments. The final rule includes in the "medical benefits package" all of

the emergency care that VA is authorized to provide to enrolled veterans (see 38 U.S.C. 1703, 1728).

Priority category 6 includes veterans solely seeking care for a disorder associated with exposure to a toxic substance or radiation or for a disorder associated with service in the Southwest Asia theater of operations during the Gulf War, as provided in 38 U.S.C. 1710(e). One commenter asserted that these veterans should be eligible to receive the full "medical benefits package" because of such disorders. No changes are made based on this comment. The restrictions for this category are required by 38 U.S.C. 1710(e).

One commenter asserted that the final rule should include provision for "long-term care services." No changes are made based on this comment. The medical benefits package includes non-institutional long-term care services, such as home health care. The statutory framework for the enrollment system does not cover nursing home care.

The medical benefits package includes prescription drugs available under the VA national formulary system. Commenters argued that this is inadequate based on the assertion that this would limit drugs only to those listed and exclude any opportunity for using non-listed drugs. No changes are made based on these comments. The national formulary system includes a mechanism for the provision of drugs and medicines not listed in the formulary.

Commenters recommend that the "medical benefits package" include a statement that VA will maintain its capacity to treat disabled veterans in accordance with the provisions of 38 U.S.C. 1706. No changes are made based on these comments. The statutory provisions are adequate by themselves to provide notice of this requirement.

Commenters asserted that a determination regarding care received under the "medical benefits package" should only be made by a physician in the appropriate medical specialty and that a veteran should have direct access to the medical specialist of choice. No changes are made based on these comments. Consistent with the trends in industry practice, we believe that generally veterans should first meet with primary care healthcare professionals and then be referred to medical specialists, if necessary.

Commenters asserted that the letter that VA sends veterans concerning their enrollment status should specify what services are available to enrollees. No changes are made based on these comments. The enrollment status letter

will provide an overview of the services available and will include a toll-free telephone number for veterans to call for further information.

We also have made a clarifying change to the medical benefits package to state that it includes the completion of certain forms (e.g., Family Medical Leave forms, life insurance applications, Department of Education forms for loan repayment exemptions based on disability, non-VA disability program forms) by healthcare professionals based on an examination or knowledge of the veteran's condition, but not including the completion of forms for examinations where payment for such examinations cannot be paid to VA but can be paid to other health care practitioners. This is a medical service that generally is provided under customary medical practice.

Notice of Priority Categories Eligible for Enrollment

The proposed rule provided for the Secretary to publish notices in the notice section of the *Federal Register* announcing which categories of veterans are eligible to be enrolled. One commenter asserted that the determinations made must be published as rules and that such rules can be made only after prior notice and comment. In response, we have changed the provisions of the final rule to provide for inclusion of the announcements by the Secretary in the regulatory material at § 17.36. Determinations regarding notice and comment will be made in accordance with the provisions of the Administrative Procedure Act.

Also, the criteria in § 17.36 for determining which categories of veterans are eligible to be enrolled are clarified to more accurately reflect the elements necessary for making the determination.

Appeals

Commenters asserted that the proposed rule did not contain sufficient notice of appeal rights for enrollment determinations. In response, we have added information to § 17.36(d)(5) stating that the letter providing notification of enrollment status (enrollment or disenrollment) will include an effective date for any changes and will include a statement regarding appeal rights.

As stated in the proposal, veterans may appeal VA decisions regarding enrollment and disenrollment to the Board of Veterans' Appeals and the Court of Veterans Appeals. Commenters asserted that actions on appeals to the Board take too long and that special intermediate appeal procedures must be

established to protect veterans' access to healthcare. Most of the enrollment determinations will be based on the ministerial application of determinations made by the VA's Veterans Benefits Administration. There is already a process for obtaining reconsideration of these VBA determinations at the Regional Office level. It would be inappropriate for VA's Veterans Health Administration (VHA) which administers the National Enrollment System to provide appellate rights for these VBA issues. Further, although we are not required to do so, we are in the process of formulating voluntary intermediate reconsideration procedures for VHA decisions (63 FR 9990). In this regard, we are considering whether to apply such voluntary intermediate appeal procedures to certain VHA enrollment issues, such as decisions concerning catastrophic disabilities and means testing.

One commenter asserted that a veteran should not lose benefits for at least 90 days or until the completion of an appeal. No changes are made based on this comment. We have no authority to establish such a rule.

Commenters asserted that the Presidential Memorandum on Federal Agency Compliance with the Patient Bill of Rights requires appeal procedures for enrollment issues. No changes are made based on these comments. This Memorandum was intended to ensure additional process for medical determinations not subject to the appellate jurisdiction of the Board of Veterans Appeals, such as the need for and appropriateness of specific types of medical care and treatment for an individual. Further, as noted above, we are taking steps to establish intermediate appeal procedures as appropriate.

Commenters asserted that the final rule should specifically state that the Board of Veterans Appeals has appellate jurisdiction of VHA determinations concerning whether a veteran is catastrophically disabled. No changes are made based on these comments. We agree that under 38 CFR 20.101(b) the Board has jurisdiction over these determinations. Further, we do not believe that there is a need to include specific provisions in the final rule regarding this matter.

Miscellaneous

Non-substantive changes have been made for purposes of clarification.

Announcement Regarding Enrollment of Priority Categories

VA will enroll all 7 priority categories of veterans for the period October 1,

1999 through September 30, 2000, unless changed by a subsequent rulemaking document.

OMB

This document has been reviewed by the Office of Management and Budget under Executive Order 12866.

Paperwork Reduction Act

The collection of information contained in the notice of the proposed rulemaking was submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act (44 U.S.C. 3504(h)). The information collection subject to this rulemaking concerns:

(1) *Initial Application for Health Benefits*. Under the provisions of § 17.36(d)(1), a veteran who wishes to be enrolled must apply by submitting a VA Form 10-10EZ to a VA medical facility. Veterans applying based on inclusion in categories 1, 2, 3, 6, and 7 do not need to complete section II, but must complete the rest of the form. Veterans applying based on inclusion in priority category 4 must complete all or a portion of VA Form 10-10EZ as set forth in § 17.36(d)(1). Veterans applying based on inclusion in priority category 5 must complete the entire form. VA Form 10-10EZ is set forth in full at § 17.36(f). This information is needed to determine whether a veteran is eligible to be enrolled in the VA healthcare system and, consequently, whether the veteran is eligible for VA hospital and outpatient care;

(2) *Yearly Re-application for Health Benefits*. Under the provisions of § 17.36(d)(4)(iii), veterans enrolled based on inclusion in priority category 5 will be mailed a Form 10-10EZ on a yearly basis. They will be requested to complete the form and return the form to the address on the return envelope. VA Form 10-10EZ is set forth in full at § 17.36(f). This information is needed to determine whether a veteran is eligible to continue to be enrolled in the VA healthcare system, and, consequently, whether the veteran is eligible to continue to receive VA hospital and outpatient care;

(3) *Voluntary disenrollment*. Under the provisions of § 17.36(d)(4)(i), a veteran wishing to disenroll and forgo VA hospital and outpatient care must submit to a VA medical center a signed document stating that the veteran no longer wishes to be enrolled. This information is needed to determine the identity of those veterans wishing to disenroll and forgo VA hospital and outpatient care. This will help VA determine how to allocate available funding for hospital and outpatient care.

Interested parties were invited to submit comments on the collection of information. However, no comments were received. OMB has approved this information collection under control number 2900-0091.

VA is not authorized to impose a penalty on persons for failure to comply with information collection requirements which do not display a current OMB control number, if required.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This proposed rule would affect only individuals. Accordingly, pursuant to 5 U.S.C. 605(b), this proposed rule is exempt from the initial and final regulatory flexibility analysis requirements of §§ 603 and 604.

The Catalog of Federal domestic assistance numbers for the programs affected by this rule are 64.005, 64.007, 64.008, 64.009, 64.010, 64.011, 64.012, 64.013, 64.014, 64.015, 64.016, 64.018, 64.019, 64.022, and 64.025.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: July 16, 1999.

Togo D. West, Jr.,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 17 is amended as set forth below:

PART 17—MEDICAL

1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

§ 17.34 [Amended]

2. The first sentence of § 17.34 is amended by removing "When an application" and adding, in its place, "Subject to the provisions of §§ 17.36 through 17.38, when an application".

3. An undesignated center heading, § 17.36, and a parenthetical at the end of the section are added to read as follows:

Enrollment Provisions and Medical Benefits Package

§ 17.36 Enrollment—provision of hospital and outpatient care to veterans.

(a) *Enrollment requirement for veterans*. (1) Except as otherwise provided in § 17.37, a veteran must be enrolled in the VA healthcare system as a condition for receiving VA hospital and outpatient care.

Note to paragraph (a)(1): A veteran may apply to be enrolled at any time. (See § 17.36(d)(1).)

(2) Except as provided in paragraph (a)(3) of this section, a veteran enrolled under this section is eligible for VA hospital and outpatient care as provided in the "medical benefits package" set forth in § 17.38.

Note to paragraph (a)(2): A veteran's enrollment status will be recognized throughout the United States.

(3) A veteran enrolled based on having a disorder associated with exposure to a toxic substance or radiation, for a disorder associated with service in the Southwest Asia theater operations during the Gulf War, or a illness associated with service in combat in a war after the Gulf War or during a period of hostility after November 11, 1998, as provided in 38 U.S.C. 1710(e), is eligible for VA hospital and outpatient care provided in the "medical benefits package" set forth in § 17.38 for the disorder.

(b) *Categories of veterans eligible to be enrolled*. The Secretary will determine which categories of veterans are eligible to be enrolled based on the following order of priority:

(1) Veterans with a singular or combined rating of 50 percent or greater based on one or more service-connected disabilities or unemployability.

(2) Veterans with a singular or combined rating of 30 percent or 40 percent based on one or more service-connected disabilities.

(3) Veterans who are former prisoners of war; veterans with a singular or combined rating of 10 percent or 20 percent based on one or more service-connected disabilities; veterans who were discharged or released from active military service for a disability incurred or aggravated in the line of duty; veterans who receive disability compensation under 38 U.S.C. 1151; veterans whose entitlement to disability compensation is suspended pursuant to 38 U.S.C. 1151, but only to the extent

that such veterans' continuing eligibility for hospital and outpatient care is provided for in the judgment or settlement described in 38 U.S.C. 1151; veterans whose entitlement to disability compensation is suspended because of the receipt of military retired pay; and veterans receiving compensation at the 10 percent rating level based on multiple noncompensable service-connected disabilities that clearly interfere with normal employability.

(4) Veterans who receive increased pension based on their need for regular aid and attendance or by reason of being permanently housebound and other veterans who are determined to be catastrophically disabled by the Chief of Staff (or equivalent clinical official) at the VA facility where they were examined; except that a veteran who is catastrophically disabled and who must agree under 38 U.S.C. 1710 to pay to the United States a co-payment as condition of receiving VA care, must agree to pay to the United States the applicable co-payment to be enrolled in priority category 4.

(5) Veterans not covered by paragraphs (b)(1) through (b)(4) of this section who are determined to be unable to defray the expenses of necessary care under 38 U.S.C. 1722(a).

(6) Veterans of the Mexican border period or of World War I; veterans solely seeking care for a disorder associated with exposure to a toxic substance or radiation, for a disorder associated with service in the Southwest Asia theater of operations during the Gulf War, or for any illness associated with service in combat in a war after the Gulf War or during a period of hostility after November 11, 1998, as provided and limited in 38 U.S.C. 1710(e); and veterans with 0 percent service-connected disabilities who are nevertheless compensated, including veterans receiving compensation for inactive tuberculosis.

(7) Veterans who agree to pay to the United States the applicable copayment determined under 38 U.S.C. 1710(f) and 1710(g). This category is further prioritized into the following subcategories:

- (i) Noncompensable zero percent service-connected veterans; and
- (ii) All other priority category 7 veterans.

(c) *Federal Register notification of eligible enrollees.* (1) It is anticipated that on or before August 1 of each year the Secretary will announce in paragraph (c)(2) of this section which categories of veterans are eligible to be enrolled. As necessary, the Secretary at any time may revise this determination by further amending paragraph (c)(2) of

this section. The preamble to a Federal Register document announcing which priority categories are eligible to be enrolled must specify the projected number of fiscal year applicants for enrollment in each priority category, projected healthcare utilization and expenditures for veterans in each priority category, appropriated funds and other revenue projected to be available for fiscal year enrollees, and results—projected total expenditures for enrollees by priority category. The determination should include consideration of relevant internal and external factors, e.g., economic changes, changes in medical practices, and waiting times to obtain an appointment for care. Consistent with these criteria, the Secretary will determine which categories of veterans are eligible to be enrolled based on the order of priority specified in paragraph (b) of this section.

(2) Unless changed by a rulemaking document in accordance with paragraph (c)(1) of this section, VA will enroll all priority categories of veterans set forth in § 17.36(b) for the period from October 1, 1999 through September 30, 2000.

(d) *Enrollment and disenrollment process*—(1) *Application for enrollment.* A veteran may apply to be enrolled in the VA healthcare system at any time. A veteran who wishes to be enrolled must apply by submitting a VA Form 10-10EZ to a VA medical facility. Veterans applying based on inclusion in priority categories 1, 2, 3, 6, and 7 do not need to complete section II, but must complete the rest of the form. Veterans applying based on inclusion in priority category 4 because of their need for regular aid and attendance or by being permanently housebound need not complete section II, but must complete the rest of the form. Veterans applying based on inclusion in priority category 4 because they are catastrophically disabled need not complete section II, but must complete the rest of the form, if: they agree to pay to the United States the applicable copayment determined under 38 U.S.C. 1710(f) and 1710(g); they are a veteran of the Mexican border period or of World War I or a veteran with a 0 percent service-connected disability who is nevertheless compensated; their catastrophic disability is a disorder associated with exposure to a toxic substance or radiation, or with service in the Southwest Asia theater of operations during the Gulf War as provided in 38 U.S.C. 1710(e); or their catastrophic disability is an illness associated with service in combat in a war after the Gulf War or during a period of hostility after November 11,

1998, as provided in 38 U.S.C. 1710(e). All other veterans applying based on inclusion in priority category 4 because they are catastrophically disabled must complete the entire form. Veterans applying based on inclusion in priority category 5 must complete the entire form. VA Form 10-10EZ is set forth in paragraph (f) of this section and is available from VA medical facilities.

Note to paragraph (d)(1): To remain enrolled based on inclusion in priority category 5, a veteran annually must return information to VA on a VA Form 10-10EZ as provided in paragraph (d)(4)(iii) of this section and otherwise meet the requirements for enrollment.

(2) *Action on application.* Upon receipt of a completed VA Form 10-10EZ, a VA network or facility director, or the Chief Network Officer, will accept a veteran as an enrollee upon determining that the veteran is in a priority category eligible to be enrolled as set forth in § 17.36(c)(2). Upon determining that a veteran is not in a priority category eligible to be enrolled, the VA network or facility director, or the Chief Network Officer, will inform the applicant that the applicant is ineligible to be enrolled.

(3) *Automatic enrollment.* Notwithstanding other provisions of this section, veterans who were notified by VA letter that they were enrolled in the VA healthcare system under the trial VA enrollment program prior to October 1, 1998, automatically will be enrolled in the VA healthcare system under this section if determined by a VA network or facility director, or the Chief Network Officer, that the veteran is in a priority category eligible to be enrolled as set forth in § 17.36(c)(2). Upon determining that a veteran is not in a priority category eligible to be enrolled, the VA network or facility director, or the Chief Network Officer, will inform the veteran that the veteran is ineligible to be enrolled.

(4) *Disenrollment.* A veteran enrolled under paragraph (d)(2) or (d)(3) of this section will be disenrolled only if:

- (i) The veteran submits to a VA medical center a signed document stating that the veteran no longer wishes to be enrolled;
- (ii) A VA network or facility director, or the Chief Network Officer, determines that the veteran is no longer in a priority category eligible to be enrolled, as set forth in § 17.36(c)(2); or
- (iii) A VA network or facility director, or the Chief Network Officer, determines that the veteran has been enrolled based on inclusion in priority category 5; determines that the veteran was sent by mail a VA Form 10-10EZ; and determines that the veteran failed to

return the completed form to the address on the return envelope within 60 days from receipt of the form. VA Form 10-10EZ is set forth in paragraph (f) of this section.

(5) *Notification of enrollment status.* Notice of a decision by a VA network or facility director, or the Chief Network Officer, regarding enrollment status will be provided to the affected veteran by letter and will contain the reasons for the decision. The letter will include an effective date for any changes and a statement regarding appeal rights. The decision will be based on all information available to the decisionmaker, including the information contained in VA Form 10-10EZ.

(e) *Catastrophically disabled.* For purposes of this section, catastrophically disabled means to have a permanent severely disabling injury, disorder, or disease that compromises the ability to carry out the activities of daily living to such a degree that the individual requires personal or mechanical assistance to leave home or bed or requires constant supervision to avoid physical harm to self or others. This definition is met if an individual has been found by the Chief of Staff (or equivalent clinical official) at the VA facility where the individual was examined to have a permanent condition specified in paragraph (e)(1) of this section; to meet permanently one of the conditions specified in paragraph (e)(2) of this section by a clinical evaluation of the patient's medical records that documents that the patient previously met the permanent criteria and continues to meet such criteria (permanently) or would continue to meet such criteria (permanently) without the continuation of on-going treatment; or to meet permanently one

of the conditions specified in paragraph (e)(2) of this section by a current medical examination that documents that the patient meets the permanent criteria and will continue to meet such criteria (permanently) or would continue to meet such criteria (permanently) without the continuation of on-going treatment.

(1) Quadriplegia and quadriparesis (ICD-9-CM Code 344.0x: 344.00, 344.01, 344.02, 344.03, 344.04, 344.09), paraplegia (ICD-9-CM Code 344.1), blindness (ICD-9-CM Code 369.4), persistent vegetative state (ICD-9-CM Code 780.03), or a condition resulting from two of the following procedures (ICD-9-CM Code 84.x or associated V Codes when available or Current Procedural Terminology (CPT) Codes) provided the two procedures were not on the same limb:

(i) Amputation through hand (ICD-9-CM Code 84.03 or V Code V49.63 or CPT Code 25927);

(ii) Disarticulation of wrist (ICD-9-CM Code 84.04 or V Code V49.64 or CPT Code 25920);

(iii) Amputation through forearm (ICD-9-CM Code 84.05 or V Code V49.65 or CPT Codes 25900, 25905);

(iv) Disarticulation of forearm (ICD-9-CM Code 84.05 or V Code V49.66 or CPT Codes 25900, 25905);

(v) Amputation or disarticulation through elbow (ICD-9-CM Code 84.06 or V Code V49.66 or CPT 24999);

(vi) Amputation through humerus (ICD-9-CM Code 84.07 or V Code V49.66 or CPT Codes 24900, 24920);

(vii) Shoulder disarticulation (ICD-9-CM Code 84.08 or V Code V49.67 or CPT Code 23920);

(viii) Forequarter amputation (ICD-9-CM Code 84.09 or CPT Code 23900);

(ix) Lower limb amputation not otherwise specified (ICD-9-CM Code

84.10 or V Code V49.70 or CPT Codes 27880, 27882);

(x) Amputation of great toe (ICD-9-CM Code 84.11 or V Code V49.71 or CPT Codes 28810, 28820);

(xi) Amputation through foot (ICD-9-CM Code 84.12 or V Code V49.73 or CPT Codes 28800, 28805);

(xii) Disarticulation of ankle (ICD-9-CM Code 84.13 or V Code V49.74 or CPT 27889);

(xiii) Amputation through malleoli (ICD-9-CM Code 84.14 or V Code V49.75 or CPT Code 27888);

(xiv) Other amputation below knee (ICD-9-CM Code 84.15 or V Code V49.75 or CPT Codes 27880, 27882);

(xv) Disarticulation of knee (ICD-9-CM Code 84.16 or V Code V49.76 or CPT Code 27598);

(xvi) Above knee amputation (ICD-9-CM Code 84.17 or V Code V49.76 or CPT Code 27598);

(xvii) Disarticulation of hip (ICD-9-CM Code 84.18 or V Code V49.77 or CPT Code 27295); and

(xviii) Hindquarter amputation (ICD-9-CM Code 84.19 or CPT Code 27290).

(2)(i) Dependent in 3 or more Activities of Daily Living (eating, dressing, bathing, toileting, transferring, incontinence of bowel and/or bladder) with at least 3 of the dependencies being permanent with a rating of 1, using the Katz scale.

(ii) A score of 10 or lower using the Folstein Mini-Mental State Examination.

(iii) A score of 2 or lower on at least 4 of the 13 motor items using the Functional Independence Measure.

(iv) A score of 30 or lower using the Global Assessment of Functioning.

(f) VA Form 10-10EZ. [insert actual photocopy of VA Form 10-10EZ]

BILLING CODE 8320-01-P

OMB Approved No. 2900-0091
Estimated Burden Avg. 20 min.

Department of Veterans Affairs		APPLICATION FOR HEALTH BENEFITS	
SECTION 1: GENERAL INFORMATION			
1A. TYPE OF BENEFIT(S) APPLIED FOR (You may check more than one)			
☐ HEALTH SERVICES ☐ NURSING HOME ☐ DOMICILIARY ☐ DENTAL ☐ ENROLLMENT			
1B. IF APPLYING FOR HEALTH SERVICES, WHICH VA MEDICAL CENTER OR OUTPATIENT CLINIC DO YOU PREFER			
2. VETERAN'S NAME (Last, First, MI)		3. OTHER NAMES USED	
5. SOCIAL SECURITY NUMBER		6. CLAIM NUMBER	
7. DATE OF BIRTH (mm/dd/yyyy)		8. RELIGION	
9A. CURRENT MAILING ADDRESS (Street)		9B. CITY	
9C. STATE		9D. ZIP	
9E. COUNTY		10. HOME TELEPHONE NUMBER	
11. WORK TELEPHONE NUMBER			
12. CURRENT MARITAL STATUS (Check one)			
☐ MARRIED ☐ NEVER MARRIED ☐ SEPARATED ☐ WIDOWED ☐ DIVORCED ☐ UNKNOWN			
13A. LAST BRANCH OF SERVICE		13B. LAST ENTRY DATE	
13C. LAST DISCHARGE DATE		13D. DISCHARGE TYPE	
13E. MILITARY SERVICE NUMBER			
14. CIRCLE YES OR NO			
A. ARE YOU A FORMER PRISONER OF WAR		YES	NO
B. DO YOU HAVE A VA SERVICE-CONNECTED RATING		YES	NO
B1. IF YES, WHAT IS YOUR RATED PERCENTAGE		%	
C. ARE YOU RECEIVING A VA PENSION		YES	NO
D. ARE YOU RETIRED FROM THE MILITARY		YES	NO
D1. WAS YOUR RETIREMENT THE RESULT OF A DISABILITY		YES	NO
D2. WERE YOU REGULARLY RETIRED - (20 + yrs.)		YES	NO
E. WERE YOU EXPOSED TO TOXINS IN THE GULF WAR		YES	NO
F. WERE YOU EXPOSED TO AGENT ORANGE		YES	NO
G. WERE YOU EXPOSED TO RADIATION		YES	NO
H. DO YOU HAVE A MILITARY DENTAL INJURY		YES	NO
I. DO YOU HAVE A SPINAL CORD INJURY		YES	NO
J. ARE YOU ELIGIBLE FOR MEDICAID		YES	NO
K. ARE YOU ENROLLED IN MEDICARE HOSPITAL INSURANCE PART A		YES	NO
L. ARE YOU ENROLLED IN MEDICARE HOSPITAL INSURANCE PART B		YES	NO
M. MEDICARE CLAIM NUMBER			
N. NAME EXACTLY AS IT APPEARS ON YOUR MEDICARE CARD			
15A. VETERAN'S EMPLOYMENT STATUS (check one)		15B. COMPANY NAME, ADDRESS AND TELEPHONE NUMBER	
☐ NOT EMPLOYED ☐ EMPLOYED ☐ RETIRED If employed or retired, complete item 15B		Date of retirement	
16A. SPOUSE'S EMPLOYMENT STATUS (check one)		16B. COMPANY NAME, ADDRESS AND TELEPHONE NUMBER	
☐ NOT EMPLOYED ☐ EMPLOYED ☐ RETIRED If employed or retired, complete item 16B		Date of retirement	
17A. VETERAN'S HEALTH INSURANCE COMPANY		17B. SPOUSE'S HEALTH INSURANCE COMPANY	
17C. NAME OF POLICY HOLDER		17D. NAME OF POLICY HOLDER	
17E. POLICY NUMBER		17F. GROUP CODE	
19A. NAME, ADDRESS AND RELATIONSHIP OF NEXT OF KIN		19B. NEXT OF KIN'S HOME TELEPHONE NUMBER	
		()	
		19C. NEXT OF KIN'S WORK TELEPHONE NUMBER	
		()	
20A. NAME, ADDRESS AND RELATIONSHIP OF EMERGENCY CONTACT		20B. EMERGENCY CONTACT'S HOME TELEPHONE NUMBER	
		()	
		20C. EMERGENCY CONTACT'S WORK TELEPHONE NUMBER	
		()	
21. I DESIGNATE THE FOLLOWING INDIVIDUAL TO RECEIVE POSSESSION OF ALL MY PERSONAL PROPERTY LEFT ON PREMISES UNDER VA CONTROL AFTER MY DEPARTURE OR AT THE TIME OF MY DEATH. (Check one) (This does not constitute a will or transfer of title.)			
☐ EMERGENCY CONTACT ☐ NEXT OF KIN			
22A. IS NEED FOR CARE DUE TO ON THE JOB INJURY (Check one)		22B. IS NEED FOR CARE DUE TO ACCIDENT (Check one)	
☐ YES ☐ NO		☐ YES ☐ NO	

APPLICATION FOR HEALTH BENEFITS, Continued		VETERAN'S NAME		SOCIAL SECURITY NUMBER
SECTION II: FINANCIAL ASSESSMENT				
IIA. DEPENDENT INFORMATION (Use a separate sheet for additional dependents)				
1. SPOUSE'S NAME (Last, First, MI)		2. CHILD'S NAME (Last, First, MI)		
3. SPOUSE'S SOCIAL SECURITY NUMBER	4. SPOUSE'S DATE OF BIRTH (mm/dd/yyyy)		5. CHILD'S DATE OF BIRTH (mm/dd/yyyy)	
6. SPOUSE'S ADDRESS (Street, City, State, ZIP)		7. CHILD'S SOCIAL SECURITY NUMBER		
8. SPOUSE'S TELEPHONE NUMBER		9. CHILD'S RELATIONSHIP TO YOU (Circle one) Son Daughter Stepson Stepdaughter		
10. DATE OF MARRIAGE (mm/dd/yyyy)		11. DATE CHILD BECAME YOUR DEPENDENT		
12. IF YOUR SPOUSE OR DEPENDENT CHILD DID NOT LIVE WITH YOU LAST YEAR, ENTER THE AMOUNT YOU CONTRIBUTED TO THEIR SUPPORT SPOUSE \$ CHILD \$		13. EXPENSES PAID BY YOUR DEPENDENT CHILD FOR COLLEGE, VOCATIONAL REHABILITATION OR TRAINING (tuition, books, materials, etc.) \$		
14. WAS CHILD PERMANENTLY AND TOTALLY DISABLED BEFORE THE AGE OF 18? ☐ YES ☐ NO		15. IF CHILD IS BETWEEN 18 AND 23 YEARS OF AGE, DID CHILD ATTEND SCHOOL LAST CALENDAR YEAR? ☐ YES ☐ NO		
II B. FINANCIAL DISCLOSURE				
You are not required to provide the financial information in this Section. However, current law may require VA to consider your household financial situation to determine your eligibility for enrollment and/or cost-free care of your nonservice-connected (NSC) conditions. If you are 0% SC noncompensable or NSC (and are not an Ex-POW, WWI veteran or VA pensioner) and your annual household income (or combined income and net worth) exceeds the established threshold, you must agree to pay VA co-payments for care of your NSC conditions to be eligible for enrollment. See Section III - Consent and Signature. ☐ YES, I WILL PROVIDE SPECIFIC INCOME AND/OR ASSET INFORMATION TO HAVE ELIGIBILITY FOR CARE DETERMINED. Complete all sections below that apply to you with last calendar year's information. Sign and date the application. ☐ NO, I DO NOT WISH TO PROVIDE MY DETAILED FINANCIAL INFORMATION. I understand I will be assigned the appropriate enrollment priority based on nondisclosure of my financial information. By checking NO and signing below, I am agreeing to pay the applicable VA co-payment. Sign and date the application.				
II C. PREVIOUS CALENDAR YEAR GROSS ANNUAL INCOME OF VETERAN, SPOUSE AND DEPENDENT CHILDREN				
1. WHAT WAS YOUR GROSS ANNUAL INCOME FROM EMPLOYMENT (wages, bonuses, tips, etc.), AS WELL AS INCOME FROM YOUR FARM, RANCH, PROPERTY OR BUSINESS		VETERAN	SPOUSE	CHILDREN
		\$	\$	\$
2. LIST OTHER INCOME AMOUNTS (Social Security, compensation, pension, interest, dividends) Exclude welfare.		\$	\$	\$
3. WAS INCOME FROM YOUR FARM, RANCH, PROPERTY OR BUSINESS (If yes, refer to page 2, Section IIC of the instructions.) ☐ YES ☐ NO				
II D. DEDUCTIBLE EXPENSES				
1. NON-REIMBURSED MEDICAL EXPENSES PAID BY YOU OR YOUR SPOUSE (payments for doctors, dentists, drugs, Medicare, health insurance, hospital and nursing home)				\$
2. AMOUNT YOU PAID LAST CALENDAR YEAR FOR FUNERAL AND BURIAL EXPENSES FOR YOUR DECEASED SPOUSE OR DEPENDENT CHILD (Also enter spouse or child's information in Section IIA)				\$
3. AMOUNT YOU PAID LAST CALENDAR YEAR FOR YOUR COLLEGE OR VOCATIONAL EDUCATIONAL EXPENSES (tuition, books, fees, materials, etc.) DO NOT LIST YOUR DEPENDENTS' EDUCATIONAL EXPENSES.				\$
II E. NET WORTH				
1. CASH, AMOUNT IN BANK ACCOUNTS (Checking and savings accounts, certificates of deposit, individual retirement accounts, etc.)		VETERAN	SPOUSE	
		\$	\$	
2. MARKET VALUE OF LAND AND BUILDINGS MINUS MORTGAGES AND LIENS. Do not count your primary home. Include value of farm, ranch, or business assets.		\$	\$	
3. STOCKS AND BONDS AND VALUE OF OTHER PROPERTY OR ASSETS (art, rare coins, etc.) MINUS THE AMOUNT YOU OWE ON THESE ITEMS. Exclude household effects and family vehicles.		\$	\$	
SECTION III: CONSENT AND SIGNATURE				
CO-PAYMENT NOTICE: If you are a 0% service-connected noncompensable or a nonservice-connected veteran (and are not an Ex-POW, WWI veteran or VA pensioner) and your household income (or combined income and net worth) exceeds the established threshold, you may be eligible for enrollment only if you agree to pay VA co-payments for treatment of your NSC conditions. By signing this application you are agreeing to pay the applicable VA co-payment if required by law.				
I CERTIFY THE FOREGOING STATEMENT(S) ARE TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND ABILITY.				DATE (mm/dd/yyyy)
SIGN HERE (Signature of applicant or applicant's representative)				
THE LAW PROVIDES SEVERE PENALTIES FOR WILLFUL SUBMISSION OF FALSE INFORMATION.				

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900-0091.)

Authority: 38 U.S.C. 101, 501, 1701, 1705, 1710, 1721, 1722.

4. A new § 17.37 is added to read as follows:

§ 17.37 Enrollment not required—provision of hospital and outpatient care to veterans.

Even if not enrolled in the VA healthcare system:

(a) A veteran rated for service-connected disabilities at 50 percent or greater will receive VA hospital and outpatient care provided for in the "medical benefits package" set forth in § 17.38.

(b) A veteran who has a service-connected disability will receive VA hospital and outpatient care provided for in the "medical benefits package" set forth in § 17.38 for that service-connected disability.

(c) A veteran who was discharged or released from active military service for a disability incurred or aggravated in the line of duty will receive VA hospital and outpatient care provided for in the "medical benefits package" set forth in § 17.38 for that disability for the 12-month period following discharge or release.

(d) When there is a compelling medical need to complete a course of VA treatment started when the veteran was enrolled in the VA healthcare system, a veteran will receive that treatment.

(e) Subject to the provisions of § 21.240, a veteran participating in VA's vocational rehabilitation program described in §§ 21.1 through 21.430 will receive VA hospital and outpatient care provided for in the "medical benefits package" set forth in § 17.38.

(f) A veteran may receive VA hospital and outpatient care based on factors other than veteran status (e.g., a veteran who is a private-hospital patient and is referred to VA for a diagnostic test by that hospital under a sharing contract; a veteran who is a VA employee and is examined to determine physical or mental fitness to perform official duties; a Department of Defense retiree under a sharing agreement).

(g) For care not provided within a State, a veteran may receive VA hospital and outpatient care provided for in the "medical benefits package" set forth in § 17.38 if authorized under the provisions of 38 U.S.C. 1724 and 38 CFR 17.35.

(h) Commonwealth Army veterans and new Philippine Scouts may receive hospital and outpatient care provided

for in the "medical benefits package" set forth in § 17.38 if authorized under the provisions of 38 U.S.C. 1724 and 38 CFR 17.35.

(i) A veteran may receive certain types of VA hospital and outpatient care not included in the "medical benefits package" set forth in § 17.38 if authorized by statute or other sections of 38 CFR (e.g., humanitarian emergency care for which the individual will be billed, compensation and pension examinations, dental care, domiciliary care, nursing home care, readjustment counseling, care as part of a VA-approved research project, seeing-eye or guide dogs, sexual trauma counseling and treatment, special registry examinations).

(j) A veteran may receive an examination to determine whether the veteran is catastrophically disabled and therefore eligible for inclusion in priority category 4.

Authority: 38 U.S.C. 101, 501, 1701, 1705, 1710, 1721, 1722.

5. A new § 17.38 is added to read as follows:

§ 17.38 Medical benefits package.

(a) Subject to paragraphs (b) and (c) of this section, the following hospital and outpatient care constitutes the "medical benefits package" (basic care and preventive care):

(i) Basic care.

(i) Outpatient medical, surgical, and mental healthcare, including care for substance abuse.

(ii) Inpatient hospital, medical, surgical, and mental healthcare, including care for substance abuse.

(iii) Prescription drugs, including over-the-counter drugs and medical and surgical supplies available under the VA national formulary system.

(iv) Emergency care in VA facilities; and emergency care in non-VA facilities in accordance with sharing contracts or if authorized by §§ 17.52(a)(3), 17.53, 17.54, 17.120-132.

(v) Bereavement counseling as authorized in § 17.98.

(vi) Comprehensive rehabilitative services other than vocational services provided under 38 U.S.C. chapter 31.

(vii) Consultation, professional counseling, training, and mental health services for the members of the immediate family or legal guardian of the veteran or the individual in whose household the veteran certifies an intention to live, if needed to treat:

(A) The service-connected disability of a veteran; or

(B) The nonservice-connected disability of a veteran where these services were first given during the

veteran's hospitalization and continuing them is essential to permit the veteran's release from inpatient care.

(viii) Durable medical equipment and prosthetic and orthotic devices, including eyeglasses and hearing aids as authorized under § 17.149.

(ix) Home health services authorized under 38 U.S.C. 1717 and 1720C.

(x) Reconstructive (plastic) surgery required as a result of disease or trauma, but not including cosmetic surgery that is not medically necessary.

(xi) Respite, hospice, and palliative care.

(xii) Payment of travel and travel expenses for veterans eligible under § 17.143 if authorized by that section.

(xiii) Pregnancy and delivery services, to the extent authorized by law.

(xiv) Completion of forms (e.g., Family Medical Leave forms, life insurance applications, Department of Education forms for loan repayment exemptions based on disability, non-VA disability program forms) by healthcare professionals based on an examination or knowledge of the veteran's condition, but not including the completion of forms for examinations if a third party customarily will pay health care practitioners for the examination but will not pay VA.

(2) Preventive care, as defined in 38 U.S.C. 1701(9), which includes:

(i) Periodic medical exams.

(ii) Health education, including nutrition education.

(iii) Maintenance of drug-use profiles, drug monitoring, and drug use education.

(iv) Mental health and substance abuse preventive services.

(v) Immunizations against infectious disease.

(vi) Prevention of musculoskeletal deformity or other gradually developing disabilities of a metabolic or degenerative nature.

(vii) Genetic counseling concerning inheritance of genetically determined diseases.

(viii) Routine vision testing and eye-care services.

(ix) Periodic reexamination of members of high-risk groups for selected diseases and for functional decline of sensory organs, and the services to treat these diseases and functional declines.

(b) *Provision of the "medical benefits package".* Care referred to in the "medical benefits package" will be provided to individuals only if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice.

(1) *Promote health.* Care is deemed to promote health if the care will enhance the quality of life or daily functional level of the veteran, identify a predisposition for development of a condition or early onset of disease which can be partly or totally ameliorated by monitoring or early diagnosis and treatment, and prevent future disease.

(2) *Preserve health.* Care is deemed to preserve health if the care will maintain the current quality of life or daily functional level of the veteran, prevent the progression of disease, cure disease, or extend life span.

(3) *Restoring health.* Care is deemed to restore health if the care will restore the quality of life or daily functional level that has been lost due to illness or injury.

(c) In addition to the care specifically excluded from the "medical benefits package" under paragraphs (a) and (b) of this section, the "medical benefits package" does not include the following:

(1) Abortions and abortion counseling.

(2) In vitro fertilization.

(3) Drugs, biologicals, and medical devices not approved by the Food and Drug Administration unless the treating medical facility is conducting formal clinical trials under an Investigational Device Exemption (IDE) or an Investigational New Drug (IND) application, or the drugs, biologicals, or medical devices are prescribed under a compassionate use exemption.

(4) Gender alterations.

(5) Hospital and outpatient care for a veteran who is either a patient or inmate in an institution of another government agency if that agency has a duty to give the care or services.

(6) Membership in spas and health clubs.

Authority: 38 U.S.C. 101, 501, 1701, 1705, 1710, 1721, 1722.

§ 17.43 [Amended]

6. In § 17.43, paragraph (a) is removed and paragraphs (b) through (e) are redesignated as paragraphs (a) through (d), respectively.

§ 17.47 [Amended]

7. In § 17.47, paragraph (h) is removed; paragraphs (i) through (l) are redesignated as paragraphs (h) through (k), respectively; and newly redesignated paragraph (h) is amended by removing "hospital or" and by removing "or hospital care in a Federal hospital under agreement,".

§ 17.93 [Amended]

8. In § 17.93, paragraph (a)(2) is amended by removing "Medical

services" and adding, in its place, "Subject to the provisions of §§ 17.36 through 17.38, medical services".

§ 17.99 [Removed]

9. Section 17.99 is removed.

§ 17.100 [Amended]

10. In § 17.100, the third sentence is amended by removing "a new application is filed, and".

[FR Doc. 99-25871 Filed 10-5-99; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300927; FRL-6382-3]

RIN 2070-AB78

Imazapic-Ammonium; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of imazapic-ammonium, (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid, applied as its ammonium salt and its metabolite (+)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-hydromethyl-3-pyridinecarboxylic acid both free and conjugated in or on grass forage at 30 ppm; grass hay at 15 ppm; milk, fat, meat, meat byproducts (except kidney) of cattle, goats, hogs, horses, and sheep at 0.10 ppm; kidney of cattle, goats, hogs, horses, and sheep at 1 ppm. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on pasture/rangeland and land in the Conservation Reserve Program. This regulation establishes a maximum permissible level for residues of imazapic-ammonium and its metabolite in these food commodities. The tolerances will expire and are revoked on December 31, 2001.

DATES: This regulation is effective October 6, 1999. Objections and requests for hearings, identified by docket control number OPP-300927, must be received by EPA on or before December 6, 1999.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each

method as provided in Unit VII. of the "SUPPLEMENTARY INFORMATION" section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300927 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703 308-9364; and e-mail address: pemberton.libby@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal productio Food manufactur Pesticide manufac- turing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the "FOR FURTHER INFORMATION CONTACT" section.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then locate the entry for this document under the "Federal Register-Environmental Documents." You can also go directly to



White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-169
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

Chair

James Gordon, MD

Commissioners

George Bernier, Jr, MD
David Bresler, PhD, LAc, OME
Thomas Chappell
Effie Chow, PhD, RN, DiplAc
George DeVries, III
William Fair, MD
Joseph Fins, MD, FACP
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Linnea Larson, LCSW, LMFT
Tieraona Low Dog, MD, AHG
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Kenneth Fisher, PhD
Maureen Miller, MPH, RN
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April 6, 2001

J. Jarrett Clinton, M.D.
Acting Assistant Secretary of Defense for Health Affairs
ASD-HA Room 3E-1082
1200 Defense Pentagon
Washington, D. C. 20301-1200

Dear Dr. Clinton:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request certain information in preparation for an upcoming meeting.

The President established this Commission in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at www.whccamp.hhs.gov.

The Commission will meet May 14th through the 16th to discuss topic areas related to research as well as to coverage and reimbursement for CAM. As part of its deliberations, the Commissioners need to understand the role of the Department of Defense in these topic areas. To guide you in providing information of interest to the Commission, we have developed the questions outlined below. If in preparing your response you find information not specifically requested but related to the scope of the Commission, please provide us with the additional information.

To assist you, we have enclosed a listing of health care modalities that are generally considered to be CAM to serve as guidance. This list is not intended to be all-inclusive and does not reflect the consensus or opinion of the Commission regarding a definition CAM. If there are other health care practices that you consider to be unconventional and wish to include with your response, please do so.

Questions Related to Research

- Does DoD, or any of the service branches, support any research on CAM practices and programs? If so, please briefly describe the research and describe why these areas of research were selected.
- Does DoD coordinate CAM research efforts 1) across services 2) with other Federal agencies, and 3) with the private sector? What is needed to create or strengthen coordination of research among these sectors?
- What are the most promising areas of research on CAM interventions funded by DoD or its service branches, or elsewhere?
- What is needed to expand DoD efforts to bring CAM practices and products into mainstream medical research, e.g., research support, methodologies, education and training, incentives, etc.?
- What are the obstacles (conceptual or otherwise) and possible solutions to accomplishing integration of CAM into mainstream medical research?
- What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional areas of research, e.g., nutrition, wellness/health promotion and disease prevention, pain management, women's health, self care, care for the terminally ill, etc.?
- What ideas, issues, and concerns regarding research on CAM can DoD offer for the Commission's consideration as it develops its policy recommendations and report to the President and Congress?

Questions Related to Coverage and Reimbursement

- What are the legislative, regulatory, and administrative parameters related to coverage of health benefits for active duty military, retirees, and dependents? How does DoD determine which benefits to add to its military/TRICARE health care programs?
- Does DoD include any CAM services and products at its military treatment facilities, or through the TRICARE program? Describe the history and use of chiropractic medicine in DOD.
- Does DoD have plans to incorporate new or additional CAM benefits? Explain. Does DOD, or any of its branches of service, cover or include on a formulary any herbs or dietary supplements?
- What does DoD consider as the most promising areas of CAM practice to incorporate into military/TRICARE health care programs? Explain.

- For CAM services provided at or through a military treatment facility, how are the costs of such services addressed? Describe any pertinent payment policies, payment procedures, budgeting, etc.
- For any CAM service provided outside of a military treatment facility, does DoD (or TRICARE or another contractor) determine whether the service is covered? Explain.
- For CAM services provided outside of a military treatment facility, how is the amount of payment determined? Describe any pertinent payment policies and procedures used by DoD or its service branches.
- What ideas and suggestions does DoD have for health services research related to access, coverage, and payment for CAM services and products?
- For CAM services covered, has DOD or its service branches established standards (e.g., education, training, licensure, certification) for the practitioners providing such services? Are any other quality monitors utilized?
- Does DoD or any of its service branches have any criteria, standards, or policies for the selection of dietary supplements available in the commissary and exchange system?
- Does DoD have any comment on the use of CAM products and services by active duty personnel?
- What ideas, issues, and concerns regarding coverage and payment for CAM can DoD provide the Commission as it develops its policy recommendations and report to the President and Congress?

We would appreciate your response by May 7 either by email or fax so that the Commissioners will have time to review it before the May meeting. You may email me at GroftS@mail.nih.gov or send a fax to 301-480-1691. Specific questions may be addressed to:

Research
Coverage/Reimbursement

Geraldine Pollen 301-435-6233
Maureen Miller 301-435-7592

Thank you for your attention to this information request.

Sincerely,



Stephen C. Groft, Pharm. D.
Executive Director

Enclosure

Common CAM Therapies

Acupuncture
Acupressure
Alexander Technique
Applied Kinesiology
Anthroposophic Medicine
Aromatherapy
Autogenic Training
Ayurvedic Medicine
Energy Medicine
Chiropractic
(Sacral) Cranial Osteopathy
Environmental Medicine
Herbal Medicine
Homeopathy
Hypnosis
Guided Imagery
Massage Therapy
Meditation
Naturopathy
Nutritional Therapy (Nutrition)
Reflexology
Relaxation and Visualization
Shiatsu
Spiritual Healing
Therapeutic Touch
Traditional Chinese and Oriental Medicine
Yoga

Adapted from Zollman C, Vickers A. What is Complementary Medicine?
British Medical Journal 1999, 319; 693-696

On the back of this page you will find the response received from the Department of Defense.

Please place it after the letter to Dr. J. Jarrett Clinton, which is the last item under the Federal Purchasers tab in the section on Agenda Topic I.

Please note that this response also relates to the same letter to Dr. Clinton that you will find as the last item under the Federal Agencies tab in the section on Agenda Topic II.



THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

MAY 11 2001

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on Complementary
and Alternative Medicine Policy
6701 Rockledge Drive, Suite 1010, MS-7707
Bethesda, MD 20817

Dear Dr. Groft:

This letter is in response to your correspondence dated April 6, 2001, requesting Department of Defense (DoD) information for your upcoming meeting on Complementary and Alternative Medicine (CAM) Policy.

Under the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 1995, Congress directed the DoD to conduct a Chiropractic Health Care Demonstration Program (CHCDP) at selected military treatment facilities (MTFs). The DoD completed that demonstration in September 1999. Section 702 of the NDAA for FY 2001 directed the DoD to implement a chiropractic care program for active duty service members at designated MTFs. This program is currently under development with an implementation plan to be submitted to Congress in the Spring of 2001.

At this time, DoD is not involved in CAM research activities, and neither does the Military Health System (MHS) benefit cover the common CAM therapies or products you delineated in your letter. Congress regulates the scope of our health care benefit and at this time we have no immediate plans to provide the CAM services and products you described.

We constantly strive to provide the best care for our beneficiaries. As scientific clinical trials and evidence-based research identify additional services and benefits to incorporate into our existing health care system, we use established procedures to modify the TRICARE benefit. My point of contact is Ms. Lynn Pahland who may be reached at (703) 681-1703.

A handwritten signature in black ink, reading "J. Jarrett Clinton", is positioned above the typed name.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on Complementary and Alternative Medicine Policy
6701 Rockledge Drive, Suite 1010, MS 7707
Bethesda, Maryland 20817

Dear Dr. Groft:

Thank you for your letter of April 11 in which you request information in advance of White House Commission on Complementary and Alternative Medicine Policy hearings on May 15-16. Because of the need for a timely response, I am providing you with a summary response at this time.

The Health Resources and Services Administration (HRSA) established the Integrative Medicine and Alternative Health Practices (IMAHP) Initiative within BPHC to address complementary and alternative medicine (CAM) in underserved populations. The IMAHP Initiative has been the focal point for CAM within HRSA. The HRSA welcomes information regarding CAM utilization at primary care organizations and within communities, and recognizes the need for additional research involving diverse populations and the use of CAM therapies. We apologize for not having more information to provide on CAM currently, and hope that we will be able to provide more information at a later date.

Your first questions address the evaluation of health services delivery and data collection. Each of the Health Resources and Services Administration (HRSA) Bureaus—Bureau of Primary Health Care (BPHC), Bureau of Health Professions, HIV/AIDS Bureau, and the Maternal and Child Health Bureau—contribute to the HRSA mission to improve the Nation's health by assuring equitable access to comprehensive quality health care for all. Each Bureau collects some data. However, since HRSA is a service delivery organization, we primarily collect data on service delivery. With the exception of the Chiropractic Demonstration Project, we do not directly fund CAM at this time. Consequently, we have not collected primary care CAM data..

The Health Center programs have major data collection systems that enable us to monitor performance and to better understand service delivery. No specific data on CAM services is collected at this time, however, it is being considered for inclusion in the near future. Several Health Centers are currently providing CAM services and we are in the process of identifying and understanding these programs.

You also have asked about conducting and coordinating health services delivery research and data with other Federal agencies. The HRSA is still gathering information and deliberating potential methods of coordination at this time. For example, BPHC is in discussions with the National Center for Complementary and Alternative Medicine (NCCAM) to increase the representation of underserved ethnic and racial minority populations in NCCAM-supported research. This collaborative effort is expected to link research and primary health care in a culturally competent manner to address ethnic and racial health disparities.

The HRSA's Bureau of Health Professions (BHPr) has previously responded to and testified before a plenary session of the Commission on February 22, 2001. The information provided at that time described the BHPr's programs, funding and other educational opportunities for complementary and alternative medicine and conventional health practitioners. During this testimony, the Chiropractic Demonstration Project Grants Program was profiled. This program supports research projects where chiropractors and physicians collaborate to identify and provide effective treatment for spinal and lower-back conditions.

If you require additional information or clarification on our response, please contact Lanardo Moody (301-594-3726) or Ezio Borchini (301-594-4464).

Sincerely,

Elizabeth M. Duke
Acting Administrator