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001. letter	Anne Mehler to Ira Magaziner re: phone number (partial) (2 pages)	07/08/1998	P6/b(6)

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Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
Speaking Engagements (February - July 1998) [4]

2011-0747-S
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RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
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b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

American Enterprise Institute for Public Policy Research

July 8, 1998

Christopher Jennings
Deputy Assistant to the President
Health Policy Development
Domestic Policy Council
212B Old Executive Office Building
Washington, D.C. 20502

Not available. How about Mike Hash of HCFA.

Dear Mr Jennings:

The American Enterprise Institute would like to invite you to participate in our next Health Policy Discussion on Monday, July 20, 1998. This session will be held in the Wohlstetter Conference Center at AEI from 9:15 until 11:00 a.m.

The program will feature a presentation by John Hoff on a monograph that he has just completed for AEI and which we will be releasing at this meeting. The title of the study is *Medicare Private Contracting: Paternalism or Autonomy*. The study provides a legislative and legal history of Medicare private contracting, a critical analysis of arguments for and against the passage of Section 4507 of the Balanced Budget Act of 1997, and a review of HCFA's policy against private contracting. The study is critical of both Congress and HCFA for the way they have handled this controversial issue.

We would like for you be a discussant of John Hoff's presentation and present the Clinton Administration's position on Medicare private contracting. Robert Moffit of the Heritage Foundation has agreed to be a discussant and we have also invited Martin Corry of AARP to be a discussant. The monograph is currently at the printers but we will be glad to send you a copy of the manuscript if you would like to see it.

AEI's objective with this series of Health Policy Discussions is to present an informed and fact-based discussion of important policy-related research. We feel your participation in this discussion would add greatly to the quality of the discussion. If you would like to discuss this in any way, please give me a call at 202/862-5877.

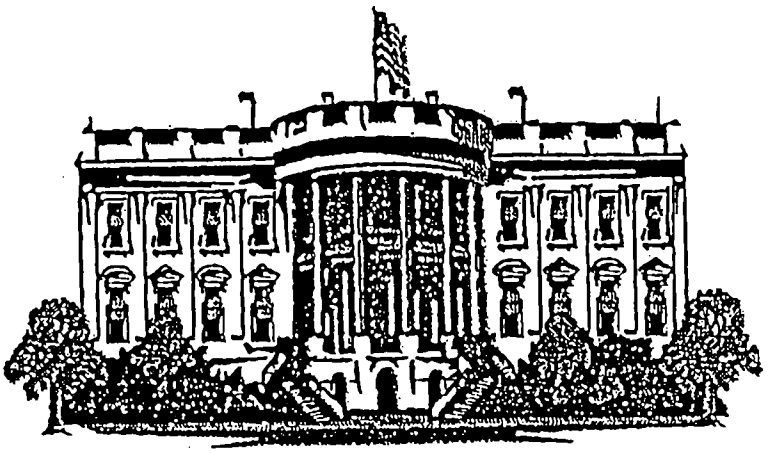
Sincerely,

Robert B. Helms
Director, Health Policy Studies

1150 Seventeenth Street, N.W., Washington, D.C. 20036-4670 202.862.5800 Fax 202.862.7177

Bob Helms FAX. to Mike
Director of Health
studies for AEI
wants to know about
Mr. Jennings's avail
for panel on July 20.
He called an invitation
867-5877 last
Mon.

THE WHITE HOUSE



Christopher C. Jennings
Deputy Assistant to the President for Health Policy
216 Old Executive Office Building
Washington, DC 20502
phone: (202) 456-5560
fax: (202) 456-5557

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Donna

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American Enterprise Institute for Public Policy Research

July 8, 1998

Christopher Jennings
Deputy Assistant to the President
Health Policy Development
Domestic Policy Council
212B Old Executive Office Building
Washington, D.C. 20502

Mike Hast

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Sincerely,

Bob Helms

Robert B. Helms
Director, Health Policy Studies

1150 Seventeenth Street, N.W., Washington, D.C. 20036-4670 202.862.5800 Fax 202.862.7177

American Enterprise Institute for Public Policy Research

HEALTH POLICY DISCUSSION

Medicare Private Contracting: Paternalism or Autonomy?

Monday, July 20, 1998, 9:15–11:00 a.m.
Wohlstetter Conference Center, Twelfth Floor, AEI

Buried in the Balanced Budget Act of 1997 is a provision that amends the Medicare law to set out the circumstances in which Medicare beneficiaries and their doctors may make their own private arrangements regarding payment for medical services. Is this a minor change in the law that patients, physicians, the Health Care Financing Administration (HCFA), and the Congress can ignore, or is this provision at the center of a more fundamental debate about the future of Medicare?

Author John Hoff will discuss this and other issues that he addresses in his monograph that AEI will be releasing at this meeting. The study describes section 4507 of the Balanced Budget Act and the regulatory history that led to it. The study also describes how Congress dealt with a confused policy developed by HCFA—and increased the confusion. The study discusses the justifications that have been given for the infringement of personal freedom caused by section 4507 and the status of responses in Congress and the courts.

8:45 a.m.	Registration and Continental Breakfast	
9:15	Introduction and Opening Remarks ROBERT B. HELMS, AEI	
	Speaker:	JOHN S. HOFF
	Discussants:	MARTIN CORRY, American Association of Retired Persons ROBERT E. MOFFIT, The Heritage Foundation CHRISTOPHER JENNINGS,* Domestic Policy Council
	Moderator:	ROBERT B. HELMS, AEI
11:00	Adjournment	

* Invited

1150 Seventeenth Street, N.W., Washington, D.C. 20036 202.862.5800 Fax 202.862.7178 http://www.aei.org

American Enterprise Institute for Public Policy Research

AEI

Registration Form

HEALTH POLICY DISCUSSION

Medicare Private Contracting: Paternalism or Autonomy?

Monday, July 20, 1998
9:15–11:00 a.m.
Wohlstetter Conference Center, Twelfth Floor, AEI

Name _____

Title _____

Affiliation _____

Address _____

City/State/Zip _____

Telephone _____ FAX _____

E-mail _____

Send this form to : Seminars and Conferences
American Enterprise Institute
1150 17th Street, N.W.
Washington, D.C. 20036

Or FAX to Seminars and Conferences at 202.862.7171.

Contact Sharon Utz with any questions at 202.862.5933.

JL
JK 7/6
ok

Atlantic Fellowships in Public Policy

The Commonwealth Fund, One East 75th Street, New York, NY 10021-2692
212.606.3809 Fax 212.606.3875

Robin Osborn
Director

June 3, 1998

Christopher Jennings
Special Assistant to the President for Health Policy Development
Office of Policy Development
Executive Office of the President
212 Old Executive Office Building
17th and Pennsylvania Avenue, N.W.
Washington, DC 20500

Ask Jeanne Lambrew or Jim Klein if interested. Pl. show them your material

Dear Mr. Jennings:

It is my pleasure to invite you to nominate a candidate for the *1999 Atlantic Fellowships in Public Policy*, a prestigious exchange program established by the British Government in partnership with the private sector in June 1994, to commemorate the fiftieth anniversary of D-day and the contribution of the United States to the liberation of Europe. The Fellowships, give outstanding American professionals the opportunity to study, travel and gain practical experience in public policy in the United Kingdom, and to receive a firsthand introduction to the European Union.

We request that you identify someone in any of the public policy fields listed in the enclosed information for candidates, whom you think would be a strong candidate. Up to ten Atlantic Fellows, drawn from a wide range of public and social policy areas, are selected each year.

The program is administered in the United States on behalf of the British Government by The Commonwealth Fund, a New York City-based private independent foundation. Further details about the program are provided in the enclosed materials.

Please complete and return the enclosed nomination form as soon as possible, giving us the individual's name, current position, and contact details. You can fax your nomination form to us at (212) 606-3875. We will send your nominee an application pack right away. You may wish to consider individuals within your own organization or to search more widely. **The deadline for receipt of applications for the 1999 awards is November 16, 1998.**

Yours sincerely,

Robin Osborn

Enclosures

Atlantic Fellowships in Public Policy
1995 – 1998 Fellows

1998 Fellows

Paul G. Burnet, M.S.
Assistant to the Director
Oregon Department of Environmental Quality
Project: Comparison of Incentive-based Regulations for Environmental Management

Marek D. Gootman, M.A.
Special Advisor on Community/Economic Development Policy
Office of Community Services
U.S. Department of Health and Human Services
Project: Regional Approaches to Renewal in the United Kingdom: Lessons on Metropolitan Solutions to Urban Problems

Julie A. Grohovsky, J.D.
Assistant Director of Training
U.S. Attorney's Office for the District of Columbia
Project: A Comparative Study of the Investigation and Prosecution of Sexual Offenses in England and the United States

Valerie J. King, M.D., M.P.H.
Clinical Instructor in Family Medicine
University of North Carolina
Project: Informed Choice: An Evaluation of Evidence Based Maternity Care Education Strategies for Providers and Consumers

Thomas J. Long, J.D.
Senior Telecommunications Attorney
The Utility Reform Network
Project: The Future Role of Regulation in a Transformed Telecommunications Industry

Glenn E. McGee, Ph.D.
Assistant Professor of Bioethics & Senior Fellow
Wharton School
University of Pennsylvania
Project: Having or Making Babies: Culture and New Reproductive Technology

Joyce E. Mitchell
Chair
HHS Committee, Maine State Legislature
Senior Policy Analyst
National Academy for State Health Policy
Project: Why Did We Do That? Cultural Values and Their Place in Health and Welfare Policy

Anita G. Ramasastry, J.D.
Assistant Professor of Law
School of Law
University of Washington
Project: The Role of Super Regulators in Financial Markets: An Analysis of the Financial Services Authority as a Blueprint for U.S. Reform Efforts

Nancy Wolff, Ph.D.
Assistant Professor and Associate Director
Center for Research on the Organization and Financing of Care for the Severely Mentally Ill
Rutgers University
Project: Interactions between Mental Health and Law Enforcement Agencies: Design and Policy Issues

1997 Fellows

Annette Castro
Chief of Staff
Seventh Council District, Los Angeles
Project: Re-Inventing Government: The Challenge Facing Local Governments
Host Institution: University of Birmingham

Constantine Georges
Chief
Violent Crimes Task Force, U.S. Attorney's Office, New Orleans
Project: Jury Selection and Jury Science
Host Institution: Queen Mary and Westfield College

Mark Greenberg
Senior Staff Attorney
Center for Law and Social Policy
Project: Current Perspectives in the U.K. on Causes and Policies to Address Poverty Among Families with Children
Host Institution: University of York

Edward Jurith
General Counsel
Office of National Drug Control Policy
Project: The British Experience Addressing Heroin Abuse: Implications for U.S. Policy
Host Institution: University of Manchester

Lisa Klein
Assistant General Counsel
Federal Election Commission
Project: Comparison of Political Financing: Ensuring the Integrity of the Political Process
Host Institution: King's College

Timothy Marshall
Park Manager/Landscape Architect
Central Park Conservancy, New York, NY
Project: Management and Funding of Parks and Public Spaces: New Directions
Host Institution: The University of York

Richard Moore
Senior Litigation Counsel
Department of Justice, U.S. Attorney's Office, Mobile
Project: A Comparison of U.S. and U.K. Jury Verdicts in Complex and Lengthy Cases
Host Institution: University of Oxford

Nikolas Theodore
Project Director
Chicago Urban League
Project: Welfare-to-Work Strategies in the UK: An Analysis of Current Ppractice
Host Institution: University of Manchester

Virginia Towler
Trial Attorney
Office of International Affairs, U.S. Department of Justice
Project: Identifying the Complexities in a Global Approach to Fighting Nigerian White Collar Crime
Host Institution: University of London

Michael Wilkes
Director/Physician
UCLA Doctoring Curriculum, UCLA School of Medicine
Project: Innovation in Medical Education - Cross Cultural Perspectives
Host Institution: University of Newcastle

1996 Fellows

Fabienne Brooks
Police Captain
King County Police Department
Project: Gender and Racial Diversity in Police Forces in the U.K. and the U.S.
Host Institution: Office for Public Management, London

Lynda Edwards
Senior Research Associate and Lecturer
Graduate School of Public Affairs
University of Maryland
Project: Study of The British Budget Process and the Lessons for the U.S.
Host Institution: Balliol College, University of Oxford

Neal Finkelstein
Assistant Director
Policy Analysis for California Education (PACE)
Project: Intergovernmental Relationships in English and Welsh School Systems
Host Institution: Institute of Education, University of Warwick

Thomas Judge
Chairman
Maine Emergency Medical Services Board
Project: Study of the NHS Ambulance Service and NHS Trust Models for Emergency Medical Rescue
Host Institution: Medical Care Research Unit, University of Sheffield

Robin Juni
Trial Attorney
Environment and Natural Resources Division
U.S. Department of Justice
Project: Dispute Resolution Processes in Setting Environmental Policy and Enforcing Regulation
Host Institution: Centre for Socio-Legal Studies, University of Oxford

James Leitzel
Associate Professor of Public Policy and Economics
Terry Sanford Institute of Public Policy
Duke University
Project: Firearm Regulation, Informal Markets for Firearms, and Gun-related Violence in the United Kingdom
Host Institution: Department of Economics, University of Essex

Jeffrey Prottas
Research Professor and Deputy Director
Institute for Health Policy, Heller Graduate School of Social Welfare
Brandeis University
Project: The Procurement, Rationing, and Allocation of Human Organs and Tissue for Medical Care in the U.K.
Host Institution: Oxford Radcliffe Hospital and Brunel University, Middlesex

Paul Shekelle
Research Associate
West Los Angeles Veterans Affairs Medical Center
Senior Natural Scientist
Rand Corporation
Project: Structural Changes in Britain's National Health Service and Their Effect on the Quality of Primary Care
Host Institution: National Primary Care Research and Development Centre, University of Manchester

Timothy Westmoreland
Senior Policy Fellow
Georgetown University Law Center
Project: Governmental and Social Responses to AIDS in the U.S. and the U.K.
Host Institution: The Jefferiss Research Trust Laboratories, St. Mary's Hospital Medical School, London

Steven Woolf
Consultant on Clinical Practice Guidelines
Project: Clinical Practice Guideline Development and Implementation in the U.K. and Europe
Host Institution: University of York

1995 Fellows

Dwayne A. Banks
Assistant Professor of Public Policy
University of California at Berkeley
Project: NHS Rationing of Life-Extending Technologies
Host Institution: The King's Fund

Linda J. Candler
Office of International Affairs
US Department of Justice
Project: Procedures for Tracing and Recovering Proceeds of Crimes
Host Institution: Serious Fraud Office, London

Robert J. Delahunty
Office of Legal Counsel
U.S. Department of Justice
Project: Asylum Law
Host Institution: University of Oxford

Marc Freedman
Vice President
Public/Private Ventures
Project: Use of Older Persons as Community Resources
Host Institution: Community Service Volunteers

Ron Glensor
Deputy Chief of Police
Reno, Nevada Police Department
Project: Situational Crime Prevention; Repeat Victimization
Host Institution: Police Research Group

Kathleen Hoye
Chicago Association of Neighborhood Development Organizations
Project: Micro-Economic Approaches to Economic Development in Northern Ireland
Host Institution: Northern Ireland Economic Research Centre

Sandra Lowe
Executive Director
Fairfax County Department of Community Action
Project: Early Intervention and Comprehensive Medical Care for Children
Host Institution: University of Kent at Centerbury

Meg Lundsager
Office of Asian and Near East Nations
US Department of the Treasury
Project: Economic Integration Through Capital Markets
Host Institution: London School of Economics

Jim Miller
Terry Sanford Institute of Public Policy
Duke University
Project: Government Decision-Making in Contexts Involving Risk to Human Life
Host Institution: Balliol College, Oxford

Jim Riccio
Manpower Demonstration Research Corporation
Project: Strategies for Moving Single Parents from Welfare to Work
Host Institution: Policy Studies Institute

ATLANTIC FELLOWSHIPS IN PUBLIC POLICY

INFORMATION FOR CANDIDATES

1999

Atlantic Fellowships

The Atlantic Fellowships were established by the government of the United Kingdom in June 1994, to commemorate the fiftieth anniversary of D-day and the contribution of the United States to the liberation of Europe. They give outstanding American professionals the opportunity to study, travel and gain practical experience in the United Kingdom and to receive a firsthand introduction to the European Union.

1999 Fellowships

1999 will be the fifth award year. Up to ten Fellowships will be awarded for three to ten months of study, practical experience and travel in the United Kingdom, starting in late August 1999.

Objectives

The aims of the Atlantic Fellowships program are:

* to reinforce United Kingdom/United States links by enabling Americans of high intellectual ability and leadership potential to come to Britain to gain experience, first hand exposure to U. K. policy thinking and initiatives, and build contacts in the field of public policy;
* to establish long-lasting bridges and ties between the United Kingdom and United States, on a personal level, and understanding of and appreciation for the other country's social and professional values, and way of life;
* to help improve the practice of public policy in the United States and the United Kingdom by the cross-fertilization of ideas and experience in the two countries;
* to build up a network of public policy experts on both sides of the Atlantic and encourage ongoing policy exchange and collaboration.

Eligibility

Atlantic Fellowships are open to mid-career individuals active in any part of the public, business or philanthropic sectors. The program seeks candidates who: demonstrate exceptional personal and intellectual qualities, and professional achievement; are interested in learning from their experiences in the United Kingdom and capable of putting to effective use in the United States any lessons learned; show potential as leaders and opinion formers in their chosen fields; and have a commitment to advancing international understanding.

Applicants must be U.S. citizens with at least five years experience in their professions. There are no formal age limits, but the focus of the fellowship is on mid-career development and successful candidates are likely to be aged between their late twenties and early forties. Applications are welcome equally from men and women, from members of any ethnic group, and regardless of physical abilities.

Program Focus

Atlantic Fellowships are offered for study and practical experience in any field of public policy. Eligible policy areas for project proposals **include**, but are not limited to:

- health care
- welfare reform
- "reinventing government"
- local government and urban policy
- criminal justice and crime prevention
- race relations
- science and technology
- public utilities
- the arts
- youth and families
- education and training
- workplace and employment issues
- information technology
- environmental
- tax policy
- community development
- banking policy and regulations
- telecommunications

Candidates should show that their chosen programs will contribute something of value to the study of issues of general importance, such as: encouraging innovation and managing change; equal opportunities, civil liberties and human rights; the relationship of enterprise to quality of life; or the distribution of power between different levels of government. (N.B. these are merely *examples*. It is for candidates to choose issues that they think important.)

Project Criteria

Attention will be paid to the quality of the suggested projects. A carefully thought out project is therefore an important part of the application. Criteria to be applied in evaluating each project include:

* the intention to combine thought, study and practical experience;
* the candidate's grasp of the subject matter and issues;
* the relevance of the project to the United States - and the candidate's potential to apply findings and/or impact policy upon return;
* the value of pursuing the proposed study in the United Kingdom;
* the feasibility of the proposal in the time available.

Atlantic Fellowships are not awarded to support basic research or to enable study for an academic degree.

Tenure

Support is available for stays of between three to ten months. Fellows are encouraged to stay for at least seven months or longer to allow time to acquire an indepth understanding of the United Kingdom that is not possible in shorter visits.

Placement

Each Fellow will be based at a "host" institution, typically an academic- type setting- e.g. a university, research institute or "think tank," but it could be a public agency or other body. Candidates are free to indicate the institutions to which they would prefer to be attached and to contact the institution of their choice, but the final decisions on placement will be made by the Atlantic Fellowships office, after full consultation with Fellows, host institutions and the program's expert advisors.

Candidates should bear in mind that, as a matter of policy, Fellows will be based in different parts of the United Kingdom. Stated preferences for well-known centers like London or Oxford will be considered but candidates are strongly encouraged to give careful thought to the merits of host institutions in Scotland, Wales, Northern Ireland and the various English regions.

Practical Experience

Fellows will be expected to spend a substantial part of their time in contact with relevant organizations outside their host institutions to gain practical experience of their fields in the United Kingdom. These contacts will normally include an extended or part-time placement.

Fellowship Activities

While in the United Kingdom, Fellows will be required to take part in several fellowship meetings including orientation, mid-term and reporting events. These occasions will enable Fellows to interact with each other and with recent Harkness Fellows (see separate section), and to develop collaborations. They will also offer opportunities to explore broader aspects of public policy in the United Kingdom. All Fellows (unless prevented by limited tenure) will participate in a one-week study visit to Brussels under the sponsorship of the European Commission.

Final Report

At the conclusion of their Fellowships, before returning to the United States, Fellows will be required to prepare a written report, for submission to the Atlantic Fellowships office and, where relevant, their employing organizations. These reports should be written with a view to publication and documentation in the United States and United Kingdom. Before submitting the final written report, Fellows will be required to make an oral presentation to an invited audience, including their peers, Harkness Fellows (see separate section), and an expert U.K. respondent.

Supervision

Organization of Fellows' individual programs will be left largely to themselves and their host institutions, with oversight by the Atlantic Fellowships office and consultation, where necessary. Fellows will be assigned carefully identified mentors in their host institutions and linked to other individuals as appropriate.

Administration

Atlantic Fellowships is administered on behalf of the British government by The Commonwealth Fund, a New York City-based private independent philanthropic foundation that has sponsored and administered the Harkness Fellowships since 1925. The Director of the Atlantic Fellowships Program is Robin Osborn. Arrangements for U.K. placement and fellowship activities in the United Kingdom are managed by William Plowden, Associate Director, who is based in London.

Fellowship Links

The Atlantic Fellowships in Public Policy resemble closely the current Harkness Fellowships in Health Care Policy and it's predecessor the Harkness Fellowships, which afford outstanding professionals from the United Kingdom, the opportunity to travel to the United States and undertake a policy-oriented research project. Linkages between the programs offer substantial benefits to the participants. Atlantic Fellows receive direct professional and personal support in the United Kingdom from assigned Harkness Fellows. They are also be able to access the wider network of Harkness Fellows, many of whom occupy key positions in the United Kingdom or work in fields that will be relevant to Fellows' interests.

Further gains are anticipated over time, through continuing links between alumni of the Atlantic and Harkness programs, and Atlantic Fellows are expected to actively participate in and contribute to this community of continuing international exchange . Atlantic Fellows will be encouraged to provide reciprocal assistance, in the future, to Harkness Fellows in Health Care Policy on tenure in the United States.

Conditions

Approval of all Fellowship awards is given by the British Embassy and is also conditional upon: possession of a valid U.S. passport, a satisfactory medical examination, arrangements approved by the Atlantic Fellowships office for length of tenure, appropriate program and placement in the United Kingdom, and an agreed plan for families.

Fellows are required to begin their tenure on an appointed date in late August 1999.

While on tenure, Fellows may not perform services for an employer from whom they are on paid or unpaid leave of absence.

It is a condition of appointment that Fellows not seek permanent employment or residence in the United Kingdom for at least two years following their Fellowships.

Awards and Allowances

Where possible, candidates are expected to obtain paid leave. The basic and award is not intended to match Fellows' U.S. salaries. Fellows on paid leave will receive an allowance of £500 per month (£600 in London) on top of their salaries and will also be entitled to family allowances and other allowances described below.

Fellows unable to obtain paid leave will receive a monthly living allowance of £1,300.00 (£1,700.00 per month in London), intended to cover the basic expenses of residence in the United Kingdom.

Further allowances, available to all Fellows, are detailed below:

Travel to and from United Kingdom: travel from home to U.K. base and return, for a Fellow, spouse and children aged under 18 years.

Institutional fees: direct payment will be made to host institutions for provision of a desk and use of telephone, fax, computer and office equipment.

Family allowances: spouse's allowance of £150 per month (not payable to Fellows whose spouses are employed or receiving a grant or fellowship), and £50 per month for each of two children under the age of 18 years. Please note: eligibility for family allowances is based on a Fellow's family status at the time of interview and will remain unchanged throughout tenure.

U.K. travel allowances: Fellows are expected to travel extensively within the U.K. to further their study programs and, with their families, to discover the country. Each Fellow will be provided with a combination of travel pass and funds to be spent at his or her discretion (to a total value of £250 per month). In addition, travel to participate in group activity and other arranged meetings (including the study visit to Brussels) will be paid direct by the Atlantic Fellowships office or reimbursed on a cost basis.

Setting-up allowance: £600 will be provided for household goods.

Fellows will not be responsible for paying U.K. income tax on the above allowances and awards.

Medical Treatment

Fellows awarded tenure of six months or more are accepted as ordinarily resident and are therefore entitled to free medical attention under the British National Health Service while in the United Kingdom. Specialist advice is provided free when it is required; dental and optical treatment are provided inexpensively.

Fellows awarded tenure of less than six months are responsible for assuring themselves that they will be covered in the U.K. by their continuing U.S. health insurance policies. In cases of difficulty, tourist insurance packages may be purchased. The Atlantic Fellowships office may advise and assist Fellows, but has no responsibility for ensuring coverage.

Insurance

The Atlantic Fellowships office, The Commonwealth Fund and the British government have no responsibility for insurance against sickness, accident or death either for candidates in the United States or for Fellows and their families traveling to or from or residing in the United Kingdom. Although some Fellows and their families are eligible for medical treatment in the United Kingdom (see above), all Fellows are advised to maintain continuing health insurance in the United States during their period of tenure. Fellows are also advised to make adequate arrangements for insurance of personal possessions when traveling to or from or residing in the United Kingdom.

Application and Inquiries

In order to apply, interested individuals must complete a formal application package, including a project proposal, which is available from the Atlantic Fellowships in Public Policy, One East 75th Street, New York, NY 10021-2692.

Completed applications must reach The Commonwealth Fund in New York by **4:00 p.m. on Monday, November 16, 1998.** Late applications will not be accepted.

For further information and questions regarding the program, eligibility or the application process, please contact Robin Osborn, Director, Atlantic Fellowships, at the above address, or by telephone: 212 606-3809; fax: 212 606-3875; or email: ro@cmwf.org.

Selection Process and Timetable

All applications for Atlantic Fellowships will be reviewed by regional screening committees. Applicants who are shortlisted will be interviewed in Washington, D.C., on Saturday, February 27, or Sunday, February 28, 1999. The selection committee includes senior British diplomats as well as prominent Americans. Formal approval of Fellows will be given by the British Embassy.

Neither the Atlantic Fellowships office nor offices of the U.K. government can discuss unsuccessful applications.

Candidates should plan to be available to be in Washington, DC from Friday evening February 26, beginning at 6:oo pm through Sunday afternoon, February 28, if invited for an interview. Travel expenses to Washington, D.C. for applicants will be reimbursed by The Commonwealth Fund.

November 16, 1998	Deadline for receipt of applications
January 22, 1999	Notification to applicants Shortlisted applicants invited for interviews
February 26, 1999	Reception for finalists at the British Embassy, Washington, D.C.
February 27-28, 1999	Interviews and selection of 1999 Fellows, Washington, D.C.
March 19, 1999	Orientation and project meeting for the 1999 Atlantic Fellows, at The Commonwealth Fund, New York City

Application Deadline and Submission

The deadline for receipt of applications is 4:00 p.m. on Monday, November 16, 1998. Completed applications should be mailed to:

Robin Osborn
Atlantic Fellowships in Public Policy
The Commonwealth Fund
One East 75th Street
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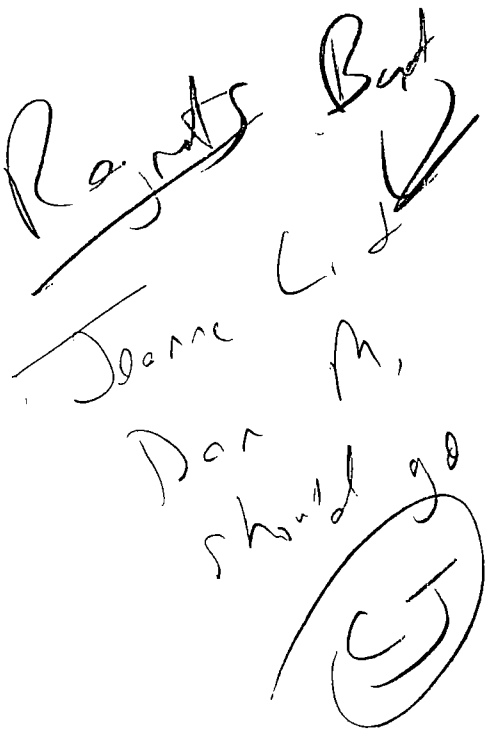
No. 722

ISSUE BRIEF

NATIONAL HEALTH POLICY FORUM

Medicare Coverage and Technology Diffusion: Past, Present, and Future

Thursday, July 9, 1998
8:00 to 8:30 am - Continental Breakfast
8:30 am to 12:30 pm - Discussion
Holiday Inn on the Hill
415 New Jersey Avenue, N.W.
Federal Ballroom North



A discussion with

Donald A. Young, M.D.
Senior Vice President for Policy and Clinical Services
American Association of Health Plans

Michael B. McCulley, Esq.
Assistant General Counsel
Johnson & Johnson

Jeffrey L. Kang, M.D., M.P.H.
Director
Office of Clinical Standards and Quality, and
Chief Clinical Officer
Health Care Financing Administration

and a Capitol Hill panel featuring

Allison Giles, J.D.
Professional Staff
Subcommittee on Health
House Committee on Ways and Means

Peter Hasselbacher, M.D.
Robert Wood Johnson Health Policy Fellow
Senate Committee on Finance

Alexander Vachon, Ph.D.
Chief Social Security Analyst
Senate Committee on Finance

Registration: Please call **Dagny Wolf at 202/872-1392** as soon as possible.

The George Washington University
WASHINGTON DC

Medicare Coverage and Technology Diffusion

In 1989 the National Health Policy Forum held a session entitled "Medicare Coverage: Translating Process into Practice." Now, nine years later, it is holding another meeting looking at the same proposed rule, issued in 1989 by the Health Care Financing Administration (HCFA), on Medicare coverage of services and products and exploring a process that has changed little over the past decade. The issues remain fundamentally the same. Only now the issue of coverage—for Medicare as well as for private plans—has become more complex as the market has fractured into a range of health plans. As Medicare dips its toes into the managed care waters through its Medicare + Choice program, it will have to resolve the dilemma all plans are facing: balancing risk with coverage policy. Under managed care, as more risk is shifted to providers, the coverage issue changes its character. Providers no longer have the clear incentives to adopt new technology they once had under fee-for-service reimbursement. Today, those incentives are more diluted.

Criticisms of the Medicare coverage process include lack of openness, lack of public participation, lack of predictability, lack of precise definitions of key terms and criteria, and lack of an adequate appeals process. In part, these criticisms are a manifestation of the tension Medicare faces in balancing the encouragement of innovation and quality of care against the proliferation of inappropriate services and the escalation of health care costs. The challenge lies in providing Medicare beneficiaries with access to the newest medical technologies whose costs are justified by improvements in health outcomes while limiting access to technologies of lesser or unknown value.

Medicare coverage is critical for successful technology diffusion. Complicating this process, however, is the nonlinear, incremental nature of innovation in medical technology. For example, before a device is deemed effective enough for coverage, it may need to be used by patients and physicians and improved over a period of time as it diffuses into everyday medical practice. On the other hand, successful diffusion may depend on whether or not the device is covered. Thus, coverage determination and technology innovation can become ensnared in a classic catch-22.

Coverage determination does not occur in a vacuum. It is part of a continuum that includes technology assessment, payment determination (for example, method, site, and level of payment), and the demand for evidence (for example, quality of life data, economic outcomes, and societal costs). Medicare coverage, which involves different levels of decision making, highlights the important role the physician plays in determining medical necessity. This Forum session will look at the Medicare coverage process, examine its strengths and weaknesses, and review options for its improvement.

THE PAST: LEGISLATING AND REGULATING MEDICARE COVERAGE

Congress established the Medicare program in 1965 with the enactment of title XVIII of the Social Security Act. While the law provides for the coverage of broad categories of benefits, such as inpatient hospital care, it does not include a specific list of services actually covered. It was inevitable that, over time, particularly with the development of new technologies, questions would arise requiring individual coverage determinations. Congress anticipated this need and provided the secretary of health and human services with the authority to make these decisions. Section 1862 (a)(1)(A) of the Act states:

> Notwithstanding any other provisions of this title, no payment may be made under Part A or Part B for any 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.

ISSUE BRIEF/No. 722

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The regulations implementing the "reasonable and necessary" section of the law are quite general [42 CFR 405.310 (k)]. Although the criteria that a health care technology must meet in order to be considered reasonable and necessary are specified, precise definitions do not exist. Historically, reasonable and necessary has been largely defined by the local physician community.

Determinations about whether services are reasonable and necessary and, therefore, covered under Medicare have wide-felt repercussions. They have, for example, considerable impact on the shape of the health care marketplace. A negative coverage decision may slow down or even halt the diffusion of a new technology, in turn limiting the services physicians may feel free to use. From the patient's point of view, he or she may be denied needed services for which technology does exist but coverage—and therefore payment—does not.

On April 29, 1987, HCFA published a notice (52 FR 15560) in the *Federal Register* announcing its process for making coverage decisions. This notice was the result of *Jameson v. Bowen*, a lawsuit in which the plaintiff sued to have HCFA reimburse him for a percutaneous transluminal coronary angioplasty (PTCA) procedure performed before a coverage determination had been made. In addition to reimbursing the plaintiff, HCFA agreed to publish the notice. On January 30, 1989, HCFA published another proposed rule expanding upon this 1987 description of the process. The 1989 proposed rule moved to clarify some of the uncertainty, explaining that

> Although the process by which we make Medicare coverage decisions on health care technology has been in place for many years, we believe there are segments of the population that may still benefit from a complete description of the coverage decision making process. We also believe the process should be more open and that the review of breakthrough technologies should be streamlined. It is for these reasons that we are now presenting the coverage decisions process as a public document.

Many experts, however, argued that HCFA's proposed rule did not go far enough. Further, some of its elements, such as the cost-effectiveness component, were highly controversial. A modest effort to issue the 1989 regulation in final form died in 1996, highlighting again the controversial nature of coverage decision making.

THE PRESENT: THE MEDICARE COVERAGE PROCESS EXPLAINED[1]

Coverage involves deciding whether or not to pay for a particular service or product, while *reimbursement* involves determining the methods and amounts of payment for covered services and products. To be paid by the Medicare program, all services and products must be covered by HCFA, the agency that administers the program. That is, the services or procedures and the products used in them must be deemed to be reasonable and necessary for diagnosing or treating a patient. They must also fit into particular statutory categories, such as hospital services, surgical dressings, durable medical equipment, prosthetics and orthotics, or supplies incident to a physician's services.

The vast majority of Medicare coverage decisions are made by its contractors, known as fiscal intermediaries for Medicare Part A (inpatient) services and carriers for Medicare Part B (outpatient, physician, clinical laboratory, and medical supplier) services. These contractors are private insurance companies that contract with Medicare to process claims from beneficiaries, providers, and suppliers.

Medicare coverage is carried out at three levels: local, regional, and national. Figure 1 (see last page of issue brief) depicts the local and national coverage decision-making process for Medicare.

Local Coverage

In deciding whether to cover a medical service or technology, contractors review applicable manuals for specific product- or procedure-related policies supplied by HCFA or apply general criteria such as the following: Is the product safe and effective? Is it reasonable and necessary? Is it appropriate? Is it experimental or investigational?

Many carriers maintain medical advisory committees comprising local specialists to advise them on new procedures and technologies. These advisory committees, along with medical directors and medical policy staff of the carriers, play an important role in reviewing new technologies and making local coverage decisions. Such decisions are often printed in local carrier bulletins or newsletters.

Local coverage decision making has been viewed as a double-edged sword by many. On the one hand, decisions are not standardized, since each contractor makes separate decisions. What is covered in one locality may not be in another. From a manufacturer, physician, and patient point of view, this process, while sometimes confusing and frustrating, allows for coverage in some circumstances as the new technology diffuses. A national decision, on the other hand, while uniform and standard, can be a death sentence for a

technology if a national noncoverage determination is handed down by HCFA's central office.

Regional Coverage

In 1993 and 1994, Medicare Part B claims processing for certain products was transferred from 34 local carriers to four regional carriers, known as durable medical equipment carriers (DMERCs). These carriers process claims for durable medical equipment, prosthetics, orthotics, surgical dressings, and a wide array of supplies used in the patient's home. Each DMERC has issued a manual with detailed coverage and payment policies on particular product areas, such as infusion pumps, wheelchairs, and orthopedic support devices.

National Coverage

Under certain circumstances, HCFA may decide that a technology requires a national coverage decision —that is, one that applies to all contractors. Such a decision may be warranted, for example, if a device is likely to result in a major increase in Medicare costs or provide important therapeutic benefits.

Manufacturers, health care providers, beneficiaries, HCFA contractors and others may request that HCFA issue a national coverage decision for a technology. HCFA then conducts an initial review to determine whether such a decision should be considered. At this point in the process, HCFA can refer to the Office of Health Technology Assessment (OHTA) within the Agency for Health Care Policy and Research (AHCPR) for a full assessment or inquiry. Alternatively, HCFA's staff can conduct a special study of its own (as was the case with heart transplants). HCFA can issue a national coverage decision without referring to OHTA, or it can decline to make a national coverage decision and leave it to the discretion of its contractors. Beneficiaries, providers, and manufacturers have limited opportunities to appeal HCFA's coverage decision, but they may ask for reconsideration, especially based on new scientific data. HCFA's coverage issues manual contains approximately 200 national coverage decisions. Local contractors must abide by national coverage decisions.

MEDICARE COVERAGE OF EXPERIMENTAL OR INVESTIGATIONAL PRODUCTS

HCFA has historically interpreted "experimental" devices or procedures to be outside the scope of the reasonable and necessary clause. Included in the agency's definition of experimental is whether the product has been cleared by the Food and Drug Administration (FDA).

In early 1994, the Department of Health and Human Services, Office of Inspector General sent subpoenas to more than 135 hospitals asking for information about products billed to Medicare and Medicaid that had been used in services covered by the program but had not been approved for those purposes by the FDA. By the second half of 1994, HCFA was rigorously enforcing the practice of not paying for services in which medical devices that had not received an FDA premarket approval were used. (This practice is not required by the Medicare statute and is not contained in the HCFA regulatory manual.) The development raised significant questions about the precise role of FDA approval in Medicare coverage determinations, as well as about the use of a product outside the scope of its labeled indications.

The Regulation of Medical Devices: The Role of the FDA

In the United States, the FDA is responsible for regulating medical products for *safety* and *effectiveness*, while HCFA reviews technologies to determine whether they will be available (that is, covered) through the Medicare program for eligible beneficiaries. How Medicare pays for these products is a separate issue and depends upon the item.

While some define technology as all-encompassing —that is drugs, devices, and biologics—the FDA regulates each of these categories differently. The FDA's duties regarding devices fall into two general categories: review of a device before it reaches the market and postmarket control after it has been cleared by the FDA. This description is limited to the premarket process.

Both the type of premarket review and the degree of regulation a medical device undergoes depend, in large measure, upon the potential risk presented to patients. The landmark Medical Device Amendments of 1976 introduced a systematic premarket regulation of medical devices, classifying products into one of three categories:

- *Class I*—products that pose the least risk, such as elastic bandages. Class I devices must meet certain general controls that assure, among other things, that the product is not adulterated or misbranded, that it is properly labeled, that it is manufactured in a manner that meets all specifications, and that the FDA is notified prior to marketing.
- *Class II*—products that pose a moderate degree of risk, such as catheters and hypodermic needles. In

addition to meeting Class I general controls, Class II devices must meet any standards or other special controls developed by the FDA for that type of device.

- *Class III*—products that pose the most significant potential risk, such as replacement heart valves and extended-wear contact lenses. In addition to the Class I and II controls, these devices must undergo detailed and often lengthy premarket evaluation to determine if they are *safe* and *effective.*

The product approval process. With the exception of some custom devices and certain Class I devices, the FDA conducts a premarket review of all medical devices before they can be introduced into the market. This is done either through a detailed premarket review of the device (known as a premarket approval, or PMA) or through a more routine premarket notification, or 510(k).

- *Premarket notification*—A company intending to market a product that is "substantially equivalent" to an earlier, legally marketed device, can submit a premarket notification application, often referred to as a 510(k) application, to the FDA. The idea behind premarket notification is to expedite incremental adjustments in health care technologies through the regulatory process. 510(k)s are typically used for Class I and II devices, and, in some cases, for Class III devices for which the FDA has not required a more detailed PMA submission. With a 510(k), the company must show that the device has the same technological characteristics and the same intended use as the earlier device already in the market. If the device represents different characteristics, the company must show that it is just as safe and effective as the earlier device. Once the company receives clearance from the FDA, it can market the product.
- *Premarket approval*—The FDA conducts a rigorous premarket review for those devices that represent a potentially great risk. These include Class III products, such as implantable devices or those representing potentially significant risk of injury or illness. Class III products also include all products that are not substantially equivalent to an earlier device —that is, they represent a new kind of technology whose risk and reliability are unknown. In this case, the FDA requires a premarket approval, or PMA, application, which involves a wide range of physical, scientific, biological, and engineering testing and information. In order for a company to collect these data on patients, it must obtain approval of an institutional review board.

  In addition, a company must also submit a plan to the FDA explaining, among other things, how it will conduct the testing, what types of patients it will use, what results it expects, and what risks and precautions it believes are involved. If the FDA considers the request to be sound, it will grant an investigational device exemption or IDE. The IDE allows for the device to be used in patients for the purpose of gathering data. (An approved IDE is also required for clinical testing of devices that undergo marketing clearance through 510[k]).

Linking Product Safety and Efficacy to Product Coverage and Reimbursement

Payers today have become increasingly sophisticated and are demanding far more information beyond FDA approval, information such as outcomes and cost-effectiveness. The FDA imprimatur alone is not enough to assure commercial success. Overwhelmingly, however, payers look to see whether, at a minimum, a product has received FDA approval or clearance (that is, PMA or 510[k]).

This "FDA stamp of approval" is typically the first criterion applied, because, without it, a product may be considered experimental or investigational. However, these products, under limited conditions, *may* be considered for coverage. "Deciding when an innovative new therapy has moved from experimental to standard treatment is an issue with which insurers, providers, and public policymakers all struggle."[2]

Generally, Medicare carriers will not cover experimental or investigational technologies, although much has happened over the past few years, including the recent growing attention to the relationship between a technology's FDA review status and Medicare coverage determination. Most important was the publication of HCFA's "Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services" final rule in the September 19, 1995, *Federal Register*. The rule specifically "sets forth the process by which the FDA will assist HCFA in identifying non-experimental investigational devices that are potentially covered under Medicare."

Medicare coverage of IDEs. The September 19, 1995, rule established in regulations that certain devices involved in trials approved by the FDA under an IDE as well as certain services related to those devices *may* be covered under Medicare. Specifically, the rule outlines the process by which the FDA will assist HCFA in

identifying non-experimental investigational devices that are potentially covered under Medicare.

Historically, the term experimental has been used synonymously with the term investigational. Therefore, a device categorized by the FDA as being investigational served as an indication that it was not reasonable and necessary within the meaning of the Medicare program. The following is noted in the final rule:

> There is increasing recognition, however, that there are devices that are refinements of existing technologies or replications of existing technologies by other manufacturers. The FDA places many of these devices within the IDE category as a means of gathering the scientific information necessary to establish the safety and effectiveness of the particular device, even though there is scientific evidence that similar devices can be safe and effective. Arguably, these devices could be viewed as reasonable and necessary under Medicare and recognized for payment if it were possible to identify them in the FDA's process.

The fundamental policy issue addressed by this rule is the need for a mechanism to prevent HCFA from automatically excluding from Medicare coverage all devices that the FDA considers investigational.

IDE categorization. To that end, the rule set out a new categorization system. To assist HCFA in its coverage decision process, the FDA follows a categorization process that differentiates between the clinical assessment of novel, first-of-a-kind devices and newer generations of legally marketed devices. The policy changes in this rule reflect the categorization of investigational devices that are the subject of FDA-approved IDEs.

Under the new categorization process, the FDA assigns each device with an FDA-approved IDE to one of two categories: experimental/investigational (Category A) devices, or non-experimental/investigational (Category B) devices. A Category A device is "an innovative device in Class III for which 'absolute risk' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective.)" HCFA is, according to the rule, to exclude from Medicare coverage a Category A device.

A Category B device is a

> device believed to be in Class I or II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

HCFA will now *consider* covering Category B devices and related services (also spelled out in the rule). Even if an IDE device receives a Category B determination from the FDA, Medicare coverage is not guaranteed or mandated. Rather, HCFA will not automatically exclude the device from Medicare coverage consideration.

Alternative Options for Crossover Technologies

In a Summer 1994 *Health Affairs* Perspectives piece, "How Can Medicare Keep Pace with Cutting-Edge Technology?"—in which she expressed her individual opinion and not her agency's—deputy director of HCFA's Center for Health Plans and Providers Kathleen Buto wrote that

> Therapies that are evolving from experimental to standard practice pose some of the most difficult coverage issues for Medicare.... The Medicare program could go on as it is, basing coverage decisions on technology assessments and limiting coverage of crossover[3] therapies until they become part of standard practice. But HCFA could consider changes that will make promising therapies available earlier and lead to better data on use and patient outcomes. Any changes should provide more options for providers and patients and greater flexibility for the Medicare program to revise coverage policy.
>
> Two alternatives meet these goals: (1) broader use of limited coverage approaches (coverage of a technology or therapy that is limited by certain criteria or conditions) and (2) a clinical research fund or set-aside (similar to the Blue Cross/Blue Shield fund used to support breast cancer clinical trials). The fund could be used to pay for services not otherwise covered and would allow Medicare to support studies of potentially beneficial treatments for the elderly or persons with disabilities.

THE FUTURE: MEDICARE COVERAGE POLICY CHALLENGES—OPTIONS FOR CHANGE

According to a March 1998 white paper, "Medicare Coverage: Time for a Public Policy Dialogue," by the Medical Technology Leadership Forum (MTLF),

> The Health Care Financing Administration has experimented with some aspects of coverage policy, primarily on an *ad hoc* basis using informal guidelines and directives. The result is that there are pressing issues of timeliness, flexibility, and accountability in the Medicare coverage process. In

addition, major public policy issues about technology and Medicare have not been addressed explicitly in an open forum. It is time for a serious reevaluation of the Medicare coverage policy.

The MTLF paper lays out four key policy issues:

- *What standard of evidence should be applied to Medicare coverage decisions?* What criteria or standards should be applied? Are they appropriate for medical devices and procedures? What methodologies are acceptable to meet the standards? Who defines the elements of that standard, including concepts such as "authoritative evidence," "demonstrated evidence," or "relative effectiveness?" Should HCFA defer to the FDA's finding of safety and effectiveness? Should cost-effectiveness be considered? If so, how should costs and effectiveness be defined? Who should pay for the costs of developing the data?
- *What is the appropriate balance between national coverage decisions and those of local carriers?* How important is uniformity for the program? Are there some decisions that are best left to local decision making? What role should the opinions of medical specialty societies play in Medicare coverage decisions? What role should producers of technology play?
- *Should Medicare have a responsibility to support and encourage medical innovation?* How does this change as Medicare transforms itself from an administrator of health care into a provider of health care through its Medicare + Choice program?
- *Who should participate in coverage decisions and how can the process be improved?* Should it be more open? More flexible? More predictable? Where should the locus of decision making reside? What role, if any, should cost-effectiveness play? When should a technology be assessed? By whom? Are there adequate appeals processes in place?

Options under Consideration

Several stakeholders have spent a great deal of time analyzing the intricacies of the Medicare coverage process and circulating proposals around Capitol Hill and throughout the various federal agencies, including HCFA, OHTA, AHCPR, and the National Institutes of Health. Most of these proposals call for greater predictability, openness, and flexibility in the process.

At the beginning of 1998, the Indiana Medical Device Association challenged HCFA's Technology Advisory Committee (TAC) as not complying with the Federal Advisory Commission Act, which calls for an open, public hearing as part of the coverage determination process. As a result of the ruling in this court case as well as a recent GAO finding, the TAC will be restructured to address concerns about due process in assuring openness.

While most agree that the process needs to be more open and public, there is less agreement as to *how* this should be accomplished. The four basic options available to policymakers are

- Constructive informal discussions with HCFA among all concerned parties.
- Notice and comment rulemaking.
- Negotiated rulemaking.
- Legislation.

Forum speakers will consider the benefits and drawbacks of each as they discuss the past, present, and future of Medicare coverage decision making.

THE FORUM SESSION

Donald A. Young, M.D., senior vice president for policy and clinical services at the American Association of Health Plans (AAHP), will open with an overview of how we got to where we are today—a history of the issues and lessons learned and implications for the private sector. Before joining the AAHP, Dr. Young was the executive director of the Prospective Payment Assessment Commission. He also served as deputy director of the Policy Bureau at HCFA, where he was responsible for Medicare and Medicaid eligibility, reimbursement, and coverage policies.

Jeffrey L. Kang, M.D., M.P.H., HCFA's chief clinical officer and director of the Office of Clinical Standards and Quality, will discuss where HCFA is today vis-à-vis the Medicare coverage process. He will look at the strengths and weaknesses of the current system as well as what changes might occur in coverage decision making as Medicare becomes a provider of health care through its Medicare + Choice program. Dr. Kang's responsibilities include developing national coverage policies and quality standards for Medicare providers, collecting clinical data to support agency initiatives, overseeing quality improvement activities, and managing Medicare's peer review program.

Michael B. McCulley, Esq., assistant general counsel of Johnson & Johnson will explain the implications of Medicare decision making on technology

innovation and adoption. His present assignments include work in the areas of general corporate and U.S. and international regulatory law, with a primary regulatory focus on matters relating to the FDA, the European Common Market, and HCFA. Before joining Johnson & Johnson, Mr. McCulley was senior regulatory counsel for the American Hospital Supply Corporation.

A panel of Capitol Hill speakers will continue the discussion. **Allison Giles, J.D.,** professional staff member of the House health subcommittee of the House Ways and Means Committee, will explore concerns of members of Congress, focusing on HCFA's Technology Advisory Committee. For more than two years before joining the health subcommittee, Ms. Giles worked on health care policy issues in the personal office of its chairman, Rep. Bill Thomas (R-Calif.). From 1992 to 1994, she was the assistant chief counsel for health policy in the Office of Advocacy at the U.S. Small Business Administration.

Alexander Vachon, Ph.D., chief social security analyst with the Senate Committee on Finance, will talk about aspects of coverage decision making included in the recent Balanced Budget Act, with a focus on laboratory coverage. In addition, Mr. Vachon will touch upon how the process affects access of care for patients. Dr. Vachon has worked on every major spending bill that has come before the committee since he joined it in 1995, including the Balanced Budget Act of 1995. Previously, he was a legislative aide to Sen. Bob Dole (R-Kans.).

Wrapping up will be **Peter Hasselbacher, M.D.,** Robert Wood Johnson Health Policy Fellow with the Senate Committee on Finance. Dr. Hasselbacher, who has served as medical director of a large multi-specialty group practice and as medical director and vice president for medical affairs of a 135,000-member managed care plan, will discuss implications of government coverage determinations on managed care programs. He will review the origins, implications, and limitations of HCFA's definitions of "safe and effective," "medically necessary and appropriate," and "investigational." He will highlight some intrinsic tensions between manufacturers and payers related to coverage determinations that will not be easy (or perhaps desirable) to resolve.

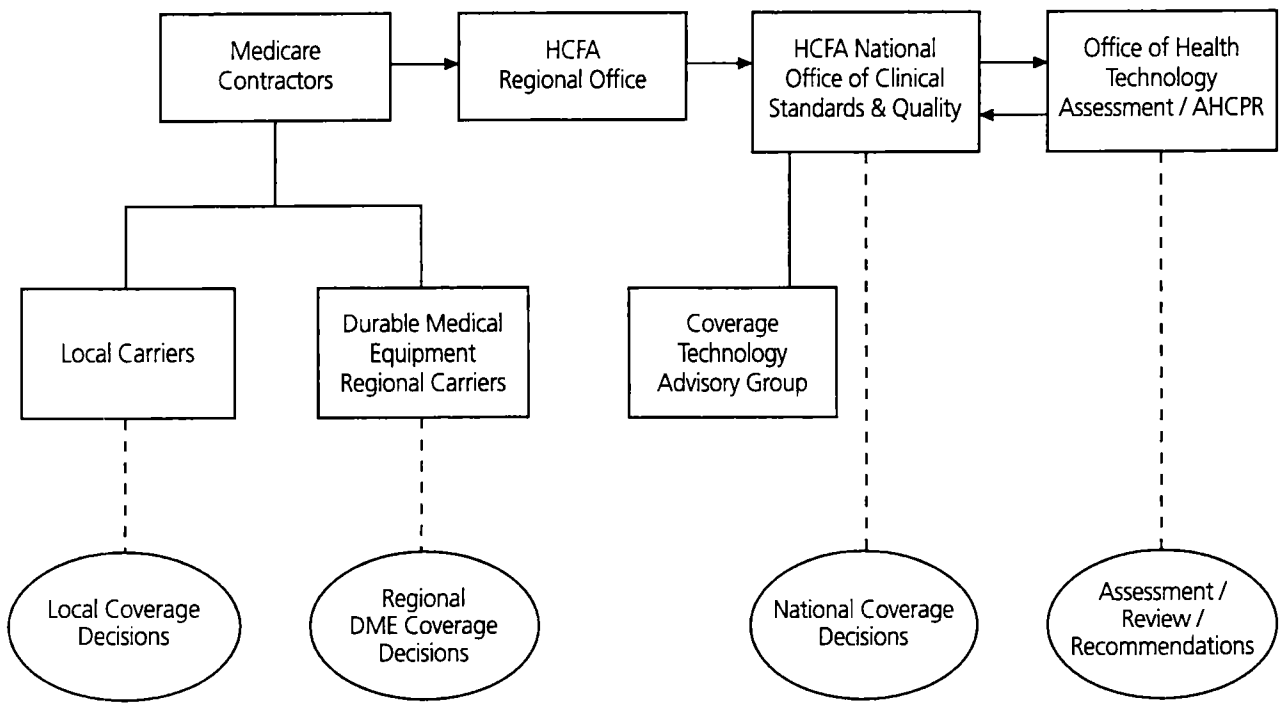
ENDNOTES

1. Much of this section was taken from the *1995 Reference Guide for the Health Care Technology Industry,* Health Care Technology Institute, Alexandria, Virginia, 22-25.

2. Stanley Joel Reiser, "Criteria for Standard versus Experimental Therapy," *Health Affairs (Medical Innovation: Risks and Rewards),* Summer 1994, 127.

3. As explained by Stanley Joel Reiser in his Summer 1994 *Health Affairs* article, "Criteria for Standard versus Experimental Therapy," crossover technologies—which are innovations that move between experimental and standard categories—can be defined in the following manner: "Therapies are like trains: They exist in an oscillating motion, shuttling back and forth between standard and experimental stations, and sometimes taking a crossover track to pause at a place in between them." To define this in-between place, Reiser offers the term "crossover therapy."

Figure 1
Medicare Local, Regional, and National Coverage



Source: Gordon B. Schatz of Reed, Smith, Shaw & McClay, Washington, DC, 1994 (updated 1998).

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MEMORANDUM

Jeanne out of town 7/17 8:45 - 10:00

3rd Friday in Sept

Do you want me to schedule?

No - Jeanne can go, if she wants. I think I should try to log on

TO: Chris Jennings

FROM: Bill Pierron
Public Affairs Associate

RE: EBRI Washington Reps Meetings

DATE: June 12, 1998

Jeanne Lambrew suggested that I send you a brief memo outlining our monthly Washington reps meetings -- if your schedule permits, we would like you and/or Jeanne to attend one to discuss the Administration's views on health care policy and take questions from the attendees.

As you probably know, EBRI is a nonpartisan, nonprofit research organization dedicated to objective research and education on all aspects of economic security and employee benefits, including health care. Our membership includes labor unions, employers, employee benefit consulting firms, financial services firms, health plans, and insurers.

We hold an informational exchange meeting for the Washington representatives of our members on the third Friday of each month, from 8:45 a.m. to 10:00 a.m., at our offices. Usually, 10-15 representatives attend. We frequently invite guests from the Hill or various agencies to discuss issues of current interest.

These meetings typically entail a brief update on EBRI activities, followed by a discussion of benefits issues. Because of the current interest in patient protection legislation, we thought it would be worthwhile for our members to hear from the Administration on what they would like to see, or expect to come out of Congress this year.

Our next meeting is scheduled for Friday, June 19. We will hold a meeting July 17, but will probably skip the month of August. I'll follow up early next week to see if you're available for either, but in the meantime please don't hesitate to call me at 202/775-6353 if you have any questions.

cc: Jeanne

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2121 K Street, NW
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20037-1896

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FAX TRANSMITTAL

To: Donna

Company: White House

Fax number: 456-5557

From: Bill Pierron

Phone: 775-6353

Number of pages (including cover sheet) 2

Message: Please forward to Chris Jennings

7/2 left msg - 775-6353
7/6 Bill called to confirm
7/13 cc: Donna

CJ 7/6 schedule?

EBRI
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To: Donna

Company: White House

Fax number: 456-5557

From: Bill Pierron

Phone: 775-6353

Number of pages (including cover sheet) 2

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NATIONAL HEALTH COUNCIL

WHERE THE HEALTH COMMUNITY MEETS

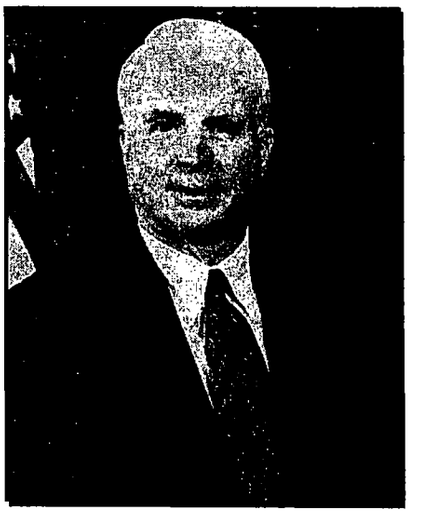
BREAKFAST BRIEFING

Regrets —

Don
Ethical Question Rec
Know about this?
Pl Forward

The Future of National Tobacco Legislation

A Breakfast Briefing with Senator John McCain (R-AZ)



The Washington Court Hotel
Grand Ballroom
525 New Jersey Avenue, NW
Washington, DC 20001

Thursday, July 30, 1998
8:30 AM to 9:30 AM

The National Health Council is honored to host Senator John McCain (R-AZ) at a July 30 Breakfast Briefing to discuss the future of national tobacco legislation. He will share his views on why comprehensive legislation was defeated in the Senate, the impact of the defeat on the prospects of passing legislation this Congressional session, and what future legislation might look like. Please join us to hear his comments about this critical public health issue.

Registrations and cancellations must be received by **noon, Tuesday, July 28, 1998.** Registrants canceling after the deadline will not receive refunds and will be responsible for any unpaid fees. Checks should be made payable to the National Health Council.

RETURN TO: **National Health Council**, 1730 M Street, NW, Suite 500, Washington, DC 20036; FAX: (202) 785-5923
Hosted by the National Health Council with an educational grant from SmithKline Beecham Pharmaceuticals.

McCAIN BREAKFAST BRIEFING

Name _____ Title _____
(as you wish it to appear on your badge)

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__MEMBER ($20-one free registration per member organization) __NON-MEMBER ($30 enclosed)

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NATIONAL HEALTH COUNCIL
1730 M Street, NW • Suite 500 • Washington, DC 20036-4505

Chris Jennings
The White House
1600 Pennsylvania Avenue
Washington DC 20036

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Anne Mehler to Ira Magaziner re: phone number (partial) (2 pages)	07/08/1998	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
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FOLDER TITLE:
Speaking Engagements (February - July 1998) [4]

2011-0747-S
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Called 7/10

TO: Donna Geisbert, please
202-456-7431

Oct 8
or
Oct 1
or
Oct 15

Jewish Community Center of Greater Washington

6125 Montrose Road Rockville, MD 20852-4857 301.881.0100 FAX: 301.881.5512 TTY: 301.881.0012

July 8, 1998

Mr. Ira Magaziner,
The White House,
fax: 202-456-5557

Dear Mr. Magaziner,

Seniors Organized for Change, the political group sponsored by the Jewish Community Center, would like to invite you to speak to us some Thursday morning in October. Although you are not now involved in health issues, to us your name will always be associated with the job you did four years ago and that would be the subject we would be pleased to have addressed.

There has been so much dissatisfaction expressed recently with HMO's and with the present system of insurers' control of medical services that it is time to think again about a better system of health care delivery. The title of the talk might be something like, "Another look at Hilary's Health Care Plan."

SOC is made up of active seniors who meet at the Center every Thursday morning, from 10:45-11:45 a.m. We usually attract 50-60 people. We address a wide variety of issues on local, state, and national levels of concern. We hear speakers and we take political action such as circulating petitions, organizing phone campaigns, and meeting with legislators and staff.

I will be in touch soon with you or with Mr. Sean Bladsvedt. If there are any questions, of course I would be pleased to hear from you at any time.

Sincerely,

Anne Mehler

Anne Mehler, Program Vice-President

Seniors Organized for Change
P6/(b)(6)

Anne would like
like an answer
ASAP.

7/15

7/15 - Michael called
If at all possible -
would accomodate
your schedule. If you
did think of going you
could go home over
Labor Day & present
or the 9th - would be
home that afternoon.

Health Policy
Grosvenor Hall
Athens, Ohio 45701

Phone 614·593·2500
FAX 614·593·0761

7/22
OK

Ohio University College of Osteopathic Medicine

Regrets b/c
Congress in
session. Could
perhaps do later
in year.
(CJ

July 2, 1998

Christopher C. Jennings
Deputy Assistant to the President for
Health Policy Development
Old Executive Office Building, Office 212
17th St. & Pennsylvania Ave., N.W.
Washington, DC 20502

Dear Mr. Jennings,

We have begun coordinating the five-day, "intensive" weekend in Athens, Ohio, for the next Health Policy Fellowship class, and Lois Kiss brought your name up as her first choice to be the keynote speaker for that session. We know that your schedule is incredibly busy, but we also realize that coming to Athens would allow you to "kill two birds with one stone," so to speak, since you could take a long weekend to visit your family. It is our understanding that you cannot accept an honorarium to speak, but we would be happy to cover your travel expenses.

Both Lois and Dean Ross-Lee were impressed with the candor of your remarks to the current Fellowship class during the April meeting in Washington, DC, and they feel that that type of presentation at the outset of the program would ground the Fellows in the reality of health policy development at the national level. If your schedule allows, we would like for you to speak to the Fellows for roughly 40 to 45 minutes, and then field questions and engage then in discussion for the remainder of a two-hour session. (The presentation you gave at lunch in Washington would be perfect.)

The program is scheduled for September 9 through September 13 this year. Judith Edinger, the new coordinator for the Fellowship program, has suggested that your presentation would be best on either Wednesday or Thursday afternoon—the 9th and 10th respectively. After that session, the Fellows, Dean Ross-Lee, and you (and your wife)—if you do not have other plans—would be invited up to my home for socializing—drinks, food, etcetera.

I hope that you can make the time to come "home" and take part in the first session for the next Fellowship class. I know that hearing your perspective on the health policy development would be the high point of the weekend for the Fellows. Please contact me with your availability at (614) 593-2380 or by e-mail at "weiser@exchange.oucom.ohiou.edu." Since you are our first choice, your timely acceptance or regrets will dictate how we proceed with our plans to fill our keynote slot. We hope that your busy schedule will allow you to join us.

Sincerely,

Michael A. Weiser
OU-COM Health Policy Writer