MEDICARE COVERAGE CRITERIA: THE EXPERTS SPEAK

On the need for criteria

"For purposes of coverage policy, we have never explicitly stated...what the operable definitions are."

- Grant Bagley, former Director of HCFA's Coverage Group HCFA committee meeting, July 1998

Evaluating cost

"Insisting that new medical devices, drugs and procedures be cost-effective from the start is a dangerous approach. If handled clumsily, it runs the risk of chilling promising research. [I]n their zeal to cut costs, Federal officials may cripple American medical technology, the world's best."

- The New York Times editorial, May 18, 1991.

"I feel very strongly that HCFA's coverage policy...must very explicitly not include absolute cost effectiveness criteria at all. Whether Medicare pays for something or not...should be a purely clinical and scientific determination."

-Former HCFA Administrator Bruce Vladeck, M.D., March 24, 2000.

"Let me be clear: HCFA does not and will not refuse to cover a service simply becaus e it is costly."

- HCFA Administrator Nancy-Ann DeParle March 1998 testimony before Senate Labor Committee

"Unfortunately, health policy too often starts out being budget policy rather than starting from the premise that we have these dramatic new advances in medicine and the capability to keep people healthy."

> - Christine Cassel, MD, Mount Sinai School of Medicine Joint Economic Committee hearing, September 29, 1999

Recognizing the full spectrum of coverage data

"Those who conduct technology assessments should be as innovative in their evaluations as the technologies themselves...The randomized trial is unlikely to be replaced, but it should be complemented by other designs that address questions about technology from different perspectives."

> - John M. Eisenberg, MD, Administrator, Agency for Healthcare Research and Quality Journal of the American Medical Association, Nov. 17, 1999

"There is an opportunity in addition to hearing evidence, an opportunity for medical consensus" through the Medicare Coverage Advisory Committee. "Sometimes the evidence can be short, but the consensus is overwhelming."

- Jeffrey Kang, MD, Director, HCFA Office of Clinical Standards and Quality February 1999 congressional briefing

Getting Input from Patients and Providers

"The HCFA coverage decision-making process must allow for input [from] medical specialty societies, other provider organizations and patient advocacy groups with an interest in the coverage issue."

> - Eleanor Kinney, J.D., M.P.H., Professor of Law and Co-Director The Center for Law and Health Indiana University School of Law

"In the real world, we don't have controlled clinical trials on most of the things we do." Services worthy of coverage are those "deemed appropriate by physicians practicing in the same clinical specialty."

> - William Mahood, MD, American Medical Association Board of Trustees member July 1998 HCFA committee meeting

Improving Access to Clinical Trials

"Reimbursement should not be denied solely because the care is delivered as part of a clinical trial."

- Institute of Medicine report to Congress, December 15, 1999

"Finally, we've recognized that you need a source of sufficient funding for experimental therapy."

 Dr. Henry E. Simmons, President of the National Coalition on Health Care, commenting on private health insurers recent decisions to pay for experimental cancer therapies. *New York Times* article, December 19, 1999

March 2000