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Another NAPT Analysis on the Comparative Effectiveness of the Medical Treatments Program: The Program Shifts from Congress to the Administration

Unlike several western European nations, the U.S. has no national health board to make decisions about whether to cover new technologies and treatments or set limits and conditions on the utilization of existing procedures. But the inclusion of \$1.1 billion in the recent economic stimulus package enables the Obama Administration to move forward to develop the bureaucratic process necessary to conduct comparative effectiveness research.

A little more than two months into the process, it's a work in progress. The confirmation of HHS Secretary nominee Kathleen Sebelius is on hold for at least another two weeks or more while Congress is on Easter recess. Once approved, which is expected to happen, she will attempt to move quickly to take control of the government's largest department and the comparative effectiveness program that has strong support at the highest levels of the Obama Administration. Still unanswered are questions about what types of research will be required, who will conduct the research, and how will cost-effectiveness research be used by Medicare and other payers and decision makers.

During Sebelius's nomination hearing before Chairman Edward M. Kennedy's Health, Education, Labor and Pensions Committee, she made some news for the medical provider community. Repeatedly pressed by Senators Tom Coburn and Pat Roberts, Sebelius promised not to link Medicare coverage decisions to comparative effectiveness determinations, but she did commit to "redesign the Medicare payment system." Options on the table include bundling inpatient and outpatient services under a single diagnosis, using a reviewer to approve expensive procedures, and more widespread use of National Coverage Determinations (NCDs).

While Sebelius was on Capital Hill, the White House announced the appointment of HHS's Federal Coordinating Council for Comparative Effectiveness Research. Its 15 members include health policy officials mostly unknown outside of Washington. The most notable member is Dr. Ezekiel "Zeke" Emanuel, brother of the White House chief of staff (Rahm Emanuel of Illinois) and close Obama confidant. Dr. Emanuel, 51, is an oncologist specializing in breast cancer and chair of bioethics at NIH. At a recent American Medical Association conference in Washington, he called for fundamental health system changes including mentioning **proton therapy for prostate cancer** among the treatment modalities that needed to be looked at and evaluated. In addition to his advisory job at HHS, Dr. Emanuel is special adviser for health policy at the Office of Management and Budget (OMB) under Director Peter Orszag. In his new roles, Dr. Emanuel is expected to live up to his reputation as one who speaks his mind. Naturally, he has the ear of Rahm, as the two brothers talk every day.

HHS's Federal Coordinating Council for Comparative Effectiveness Research "will not recommend clinical guidelines for payment, coverage or treatment," according to Administration spokespersons, but rather offer advice on research priorities for the \$400 million allotted to the Office of the Secretary for comparative effectiveness studies, \$300 million allotted to the Agency for Healthcare Quality and Research (AHRQ) and \$400 million to NIH. The 15-member council will meet for the first time on April 14 to form its priorities for research. Members include Dr. Thomas B. Valuck, medical officer and senior advisor for Medicare management at CMS; Dr. Carolyn M. Clancy, director of AHRQ; Dr. Garth N. Graham, deputy assistant secretary for minority health at HHS; and Dr. Michael Kilpatrick, director of strategic communications for the military health system at DOD.

No such priority list has ever existed at HHS, but one was developed in December 2004 when the department compiled a list of conditions of special importance to the Medicare program. The list, which consists primarily of chronic, long-term conditions, includes arthritis and non-traumatic joint disorders, cancer, chronic obstructive pulmonary disease/asthma, dementia including Alzheimer's disease, depression and other mood disorders, diabetes mellitus or Type 2 diabetes, ischemic heart disease, peptic ulcer/dyspepsia, pneumonia and stroke including control of hypertension.

The HHS advisory council will take into account the recommendations of the Institute of Medicine (IOM), which has traditionally performed quasi-governmental functions as Congress' official health policy advisory body. IOM held a public forum on March 20 to gather recommendations from over 60 organizations for research priorities. IOM's recommendations on how HHS should spend the \$1.1 billion are due in a report to Congress by June 30.

At the IOM public forum, the Advanced Medical Technology Association (AdvaMed), issued a statement saying that the HHS coordinating council's focus should be on clinical effectiveness, not cost effectiveness. So far the biggest opposition to comparative effectiveness is the newly formed Partnership to Improve Patient Care headed by former Congressman Tony Coelho. He warns that comparative effectiveness data that are only applicable to broad populations groups will lead to rationing. Some groups representing specific diseases, women's health or minorities, are arguing that comparative effectiveness studies that are population based will fail to address specific needs of individual patients.

AHRQ, which has been measuring what works in medicine since the late 1980s, will play a leadership role in deciding what studies to fund and how the results are promulgated. AHRQ's interest in comparative effectiveness research has its roots in the 2003 Medicare Prescription Drug Improvement and Modernization Act that required HHS to support research on the outcomes, comparative clinical effectiveness and appropriateness of health care items and services including prescription drugs.

How large a role AHRQ will play in relation to NIH to building a comparative effectiveness research bureaucracy is undetermined. AHRQ Director Carolyn Clancy was widely quoted in the news media when the HHS coordinating council was named, but her political clout is currently limited to the health policy community. While pressed about how HHS will use comparative effectiveness research, she repeatedly, said: “how it will be used I don’t think we can talk about until we have more information.”

NIH Acting Director Raynard Kington on March 26 told the House Labor-HHS appropriations subcommittee that the agency may use some of the \$10.4 billion it received from the economic stimulus package to fund comparative effectiveness research. That statement has already riled conservative lawmakers who oppose using comparative effectiveness funds for cost comparisons, arguing it will lead to rationing of care. Kington explained that NIH would use part of the \$10 billion in general funding for “high quality applications” that would include cost comparisons. He added that NIH may not fund them with the \$400 million set-aside for comparative effectiveness research which “would depend upon the ultimate decision about the definition that will apply to that pool of funds.” An Obama Administration spokesman later clarified that double speak by saying the NIH’s \$400 million set aside for comparative research could be used to fund comparative effectiveness research that includes cost comparisons but that these research findings could not be used by Medicare as the basis for coverage decisions.

We know that whatever happens at HHS will be driven by OMB director Peter Orszag, formerly director of the Congressional Budget Office, where he initiated a study of over 100 policy options to deal with unregulated federal health spending. Orszag has often said that using financial incentives to encourage doctors to use services and products identified by research as the treatments that work best would eventually bring down spending growth.

One of the changed features of the 2009 health reform political landscape has been the surge in interest among large employers in comparative effectiveness research. Press releases are issued weekly about new coalitions involving large corporations calling for reform including comparative effectiveness research which they see as a tool to get inside of the “black box” of coverage decisions made by insurers. Employers have been pushing insurers for years for hard data to justify the benefits of health and productivity programs --such as screening-- to become transparent for the employers. Employers want to make fair comparisons among the effectiveness of alternative programs and to make sure the method used by insurers are not locked up in a “black box” of complex coverage decisions.

The bottom line:

- It will take time to establish a bureaucracy to run these studies.
- Needing immediate cuts in the Medicare budget, Administration officials are likely to use regulations to cut Medicare spending.
- HHS will have the mandate it needs to rearrange Medicare spending priorities. The provider community will certainly resist cuts in Medicare.