Citizens' Council on Health Care
CCHC POLICY BRIEF
May 2005

MN Proposes "Bureaucrats at the Bedside" Plan - HF 1422

Questions and Answers

Q: What is the primary concern of the proposed legislation?

A: If the "evidence-based health care" proposals becomes law, Minnesota government officials will be authorized to set the standard of care for Minnesota and direct the practice of medicine. Government bureaucrats working with HMOs and politically-minded groups and individuals, will tell doctors how to practice medicine. Micromanagement of medical decisions (managed care and health care rationing) will be supported by law.

Q: What process will be used?

The Minnesota Department of Health (MDH) will designate certain treatment protocols as the MN standard of care. At their own discretion, they will decide which protocols will be called "evidence-based" and approved for use. MDH will collect data on physician adherence to these government-issued protocols and publicly report compliance rates on their website. Physicians with low compliance rates may be financially penalized.

Q: Wasn't this law passed in 2004?

A: In 2004, a cost containment law dubbed "best practices" was enacted. However, after CCHC delivered a huge stack of citizen petitions opposing the legislation, legislators added a 6/30/06 expiration date. Although the opposition remains, the 2005 legislature proposes to repeal the expiration date—making this controversial law permanent. It also changes"best practices" to "evidence-based health care guidelines" and lists criteria for MDH.

Q: It seems logical to practice medicine according to evidence. Why should I be concerned?

A: There is no one-size-fits-all way to practice medicine because there are no one-size-fits-all patients. There are many other reasons. Here are a few: 1) "EBM [evidence-based medicine] is the sine qua non of managed care, the whole foundation of it." (Princeton health economist, Uwe Reinhardt, 1999); 2) Evidence can be in the eye of the beholder. Guideline developers choose from approximately 2 million studies done each year reported in 20,000 journals; 3) "Guidelines allow narrow interest groups to impose their priorities on the health service." (BMJ, 1999); and 4) "[EBM] has quickly advanced to evidence-based decision-making and evidence-based rationing." (Lancet, 1998)

Q: Isn't "evidence-based" medicine based on science?

A: Science is not immutable or universally agreed upon, as the recent hormone replacement therapy debate has proven. According to NYU professor Gary Belkin, MD, "We need to explain how a given version of scientific credibility is embraced to sustain influence and power in society." He argues that analyzing patient data, measuring physician performance, and calling the process "scientific" is a technocratic process being used by managed care organizations and government to shift power and control away from physicians. (*"The Technocratic Wish: Making Sense and Finding Power in the 'Managed' Medical Marketplace"* 1997)

At a 2001 workshop sponsored by a federal agency, University of Pennsylvania professor Arnold Rosoff said managed care's "technocratic wish takes the form of a search for a (seemingly, at least) objective and verifiable rationale to justify the shift of control from an entrenched medical elite to a new cadre of health services researchers, MCO [managed care organization] executives, and government policy makers." Or as he later stated, "In Belkin's view, managed care has embraced the technocratic wish in its desire to find a rationale and a mechanism for standardizing medical practice and reining in physicians' natural inclination to treat each patient as a special case."

Q: So if this law passes, will my doctor no longer be able to treat me according to my individual health care needs?

A: The law does not require your doctor to follow the government-issued treatment protocols. However, it makes it difficult for him or her not to. There may be direct and indirect financial consequences. Government reporting of the doctor's adherence rate will subject your doctor to outside pressures that could influence treatment decisions. Low conformance rates could mean exclusion from a health plan's network (less access to patients and thus less income), higher malpractice insurance premiums, and lower reimbursements. The public may also equate low scores with poor quality of care, reducing the doctor's patient volume—and income. Patients could begin to question the doctor's judgment or perceive him or her to be a "bad doctor."

Importantly, as Linda Peeno, M.D., former HMO medical director, wrote last year, physicians subject to profiling by managed care organizations "reported difficulties with making appropriate medical decisions for their patients." (*TRIAL*, May 2004)

Q: Who supports this "evidence-based medicine" proposal?

A: Key supporters: MN Chamber of Commerce, Minnesota Business Partnership, MDH, BHCAG, managed care organizations, and the Institute for Clinical Systems Improvement—a HMO-funded group that develops treatment protocols.

** References for the following information found in the CCHC Report: "How Technocrats are Taking Over the Practice of Medicine," Jan. 2005*

Questioning "Science"

"[T]echniques that people see as objective proof, when more carefully examined, are easily seen to be the result of a multitude of subjective choices (my subjectivity of objectivity). Health services research and the foundational practices of managed care that...appear to offer new scientific rigor to medicine are a perfect example of this. Measuring outcomes of medical interventions and paying for, approving, and rewarding those treatments with desirable outcomes seems obvious, straightforward, and long-delayed. But the value-laden nature of what is "desirable," the innumerable choices and disagreements as to outcome variables, interventions, and observed population definition, make the measuring of outcomes anything but straightforward." (Belkin)

Problems with Evidence:

- **Researcher Bias.** Values and biases of researchers determine "which research to pursue, which articles to read, and which patient-oriented outcomes are most important."
- **Discordant Views.** "What counts as best evidence" varies by interpreter. As a former director of the U.S. Agency for Healthcare Research and Quality writes, "Who will determine what evidence should be followed?"
- **Levels of evidence.** Evidence exists in a hierarchy of importance, and several different evidence hierarchies exist, introducing confusion.
- **Conflicting evidence.** Evidence can be "murky, dubious, narrow, conflicting, or irrelevant."
- **Source of data.** Evidence is often based on the results of clinical trials reported in peer reviewed research journals, but not all editors are qualified to distinguish between sound or flawed research protocols.
- **Insufficient reporting.** Not all results of studies, particularly negative ones, are reported or available.
- **Flawed research.** Guideline developers often fail to notice that many clinical studies have poor methodology and should not be used to draw conclusions.
- **Selection bias.** Assembly and critique of evidence is not necessarily neutral, objective, comprehensive or rooted in science.
- **Possibilities of fraud.** The principle investigator of the sole positive trial of autologous bone marrow transplant in stage II breast cancer confessed to falsifying the data.
- **Loss of compassion.** Efforts to quantify the quality of care may threaten, rather than strengthen, the physician's commitment to sick people.

Problems with Guidelines

Guidelines rapidly become outdated. In 2000, a group of researchers determined that more than 75 percent of the guidelines developed between 1990 and 1996 needed updating. In addition, they discovered that half the guidelines were outdated in 5.8 years. Of the 17 clinical practice guidelines they assessed—the entire output of a high-profile program developing practice guidelines with the assistance of the U.S. Agency for Healthcare Research and Quality (AHRQ)—13 were in need of an update. Seven needed a major update, 6 needed a minor update, 3 were judged to still be valid, and no conclusion was made about the last one.

Guidelines fail to make explicit how recommendations are devised, leaving practitioners to follow in blind faith. Dr. Shaneyfelt and colleagues took the guideline development industry to task in one study of 279 guidelines. Only 7.5 percent of the guidelines described how the developers combined evidence and expert opinion, and only 6.1 percent described the values that were used to make recommendations.

Many guidelines are of dubious quality. In one study, researchers found that only 14.7 percent of 217 drug therapy guidelines developed or endorsed by Canadian organizations over a 5-year period met half or more of their criteria for rigor in the development process. Independent reviewers rated only 9.2 percent of the guidelines as sound without modification. They noted, "The quality of the guidelines assessed varied significantly by developer, publication status and drug company sponsorship."

Other concerns surround the content and use of guidelines:

- **Conflicting guidelines.** One guideline conflicts with another guideline.
- **Individual vs. population.** What is best for patients overall, as recommended in guidelines, may be inappropriate for individuals.
- **Poor research.** "[G]uideline developers must often reckon with research that is modest in rigor, discordant, or nonexistent."
- **Comorbidities.** Many patients have more than one disease process, while guidelines focus on a single disease.
- **Special interests.** "Guidelines allow narrow interest groups to impose their priorities on the health service."
- **Researcher opposition.** Researchers in evidence-based medicine are not comfortable with prescriptive use of guidelines.
- **Selective interpretation.** Utilization managers can interpret guidelines according to their own "biases, assumptions, history, mood, distractions, and personalities."
- **Values-based.** Recommendations can be based not only on someone's personal determination of what constitutes "evidence" but also on economic considerations, values of the guideline developers and presumed values of society.
- **Not reality-based.** Guidelines are often based on ideal research situations. But day-to-day clinical practice is not a controlled environment. There are fewer resources, less patient compliance and the practice is not limited to a narrow group of patients.
- **Narrow focus on science.** Medical decisions involve not only matters of the head, but matters of the heart.
- **Reduction in care.** Eliminating variation in practice can reduce individualized care, particularly for those who have special needs.
- **Impact not studied.** Despite publishing criteria for guideline development, federal agencies provide little information or guidance on assessing the clinical impact of guidelines.
- **Hinder medical advances.** Rigid guidelines could impede adoption of new medical technologies.