American Hospital Association

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January 4, 2008

The Honorable Michael Leavitt
Secretary
The U.S. Department of Health and Human Services
200 Independence Avenue, S.W., Room 615F
Washington, D.C. 20201

Dear Mr. Secretary:

In a December 30 New York Times op-ed piece (attached), Dr. Atul Gawande raises important questions about a misguided and potentially dangerous policy of the Office for Human Research Protections that would impose an unprecedented deterrent to quality improvement efforts across the country. I am writing to ask you to immediately retract any statements from the Office of Human Research Protections that imply that quality improvement efforts should undergo review by Institutional Review Boards (IRBs), and that consent should be obtained from all patients before changes could be incorporated.

As you know, hospitals across the nation are engaged in a variety of activities aimed at redesigning health care delivery systems to ensure that our patients get the best possible care we can deliver. Some of these activities are organized by hospitals, such as the Michigan Health and Hospital Association's Keystone project that Dr. Gawande cites. Others include projects initiated by the Institute for Healthcare Improvement, the Quality Improvement Organizations funded by the Centers for Medicare & Medicaid Services, and the work of several professional societies and organizations such as the American College of Surgeons and the American College of Cardiology.

As Dr. Gawande points out, research to determine which drugs or procedures will benefit patients requires appropriate oversight by an IRB and informed consent by the patients. However, those efforts are far different from the quality improvement efforts exploring the use of checklists, computerized reminders, teamwork training, and other steps to ensure that the care we intend to deliver is actually delivered.

It is worth noting that hospitals and health care professionals are not the only ones engaged in such projects. The quality transparency efforts in which the AHA, the Department of Health and Human Services (HHS), and several other organizations have spearheaded, the local value exchanges your department has fostered, and the value-based purchasing initiatives you have championed are other examples. Yet, HHS has, quite reasonably, sought no IRB review or informed consent for these changes, because they, too, are intended simply to improve the delivery of care.

As quality improvement efforts become more standardized and rigorous, and as the data collection efforts that support this work become more extensive, it would be right and appropriate to contemplate how we can collaborate to ensure that the welfare of patients remains the central concern and that patient privacy is protected. It also would be appropriate to consider effective ways for hospitals and other providers to communicate with the public about their quality improvement efforts. However, it would be wholly inappropriate and detrimental to the patients and communities we serve if the measures apparently championed by the Office for Human Research Protections were to force hospitals and others to discontinue their quality improvement efforts.

On behalf of America's hospitals and the patients who depend on us, I urge you to ensure that the essential quality improvement efforts underway across the nation continue unabated.

Sincerely,

Rich Umbdenstock
President and CEO

Enclosure