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EYE ON WASHINGTON

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the growing interest in a comparative clinical effectiveness center

Information will be a critical component in U.S. healthcare reform, no matter what direction it ultimately takes.

As candidates for the 2008 election are again demonstrating, there is little consensus about how to approach healthcare reform. Different proposals abound, and it is far too early to see which, if any, will dominate the political landscape.

But a consensus does seem to be developing on the need for improved information, particularly on comparative clinical effectiveness—that is, information on how various medical conditions respond to treatment using different therapeutic interventions. Driving this interest is the recognition that the current, and long-term, growth rate in healthcare spending is simply not sustainable and that, even with increased spending, problems with quality and patient safety persist.

As important as information is, better information by itself will not be enough to moderate spending or even change physician behavior. If our nation is ever to learn how to "spend smarter," we must, at the very least, change the incentive structure that influences patients' and clinicians' decisions and begin to use information on comparative clinical effectiveness to set payment rates. Given the pressing need for change, this is an opportune time to create a new national center of comparative clinical information to provide a foundation for such change.

Role of the Center

The primary purpose of this new center, as I envision it, should be to provide information that could be used to better inform clinical decision-making and to help in the design of smarter decisions regarding payment. As such, the center would not serve a decision-making function in itself. Neither should it become a mechanism for setting additional requirements for coverage. Current FDA coverage rules focusing on safety and efficacy seem quite sufficient to me.

The center would exist to fund new research and synthesize existing research on comparative clinical effectiveness, and to disseminate and otherwise make available current knowledge about the likely clinical results of using different treatment options for different subgroups of the population. The focus should be on medical conditions rather than on specific interventions or therapeutics. Also, if the information is to help moderate spending, it must include medical procedures as well as pharmaceuticals and devices.

The center's information must not only include data that are comparative across various interventions, but also take into account that outcomes may differ substantially for various subgroups of the population. Further, the center should not be construed as a one-time endeavor. Given the nature of the discovery process and the types of incremental changes associated with many innovations, investments in comparative clinical effectiveness should be seen as a dynamic, ongoing process.

Placement of the Center

The question of where the center should reside has been the subject of considerable discussion. I believe the placement of the center should be determined by the necessary defining characteristics of the center's information. The critical point, here, is that the center cannot serve the functions envisioned for it if its data are not regarded as objective, credible, and transparent—protected both from the political process as well as the interests of affected parties. The center's

information needs to be timely, span the full range of available data, and be understandable to the various parties who want to make use of it. But most important, the information must be regarded as trustworthy.

Many have argued the merits of keeping such a center directly within government, with the most commonly cited possible home being the Agency for Health, Research, and Quality (AHRQ), which is already responsible for carrying out a limited amount of comparative clinical effectiveness analysis. Others have argued the merits of keeping it outside of direct government involvement.

Although any placement will have its advantages and disadvantages, on balance, the option that I find most appealing is to set it up as a federally funded research and development center (FFRDC) attached to AHRQ. An FFRDC is an entity that is funded primarily by government (minimum of 70 percent) and sponsored by an executive branch agency, which monitors its use of funds. One of the better known FFRDCs is the Lawrence Livermore Labs. This model best reflects, for me, the spirit of "close, but not too close" to government, while it also ensures a close linkage with AHRQ, the lead agency for health services research.

Key Issues

Many other important issues would need to be addressed in establishing such a center of clinical information. Key issues include the following.

Research expertise. Much of the center's work would be contracted out to universities and other freestanding research centers, but having the center include both intramural (in-house) and extramural (contract) research would ensure that it retains an important element of expertise and hands-on research experience.

Governance. The governance of the center is almost as important as its placement—again, the key concepts are credibility, objectivity, and transparency. The governing body must be representative of all the major stakeholders, with staggered year appointments by the executive branch so that no single administration has too much control. Specialized scientific advisory boards could be created to offer advice on particular comparative effectiveness studies, particularly those involving new research.

Funding. Like any new entity, the center would require several years to reach a "steady-state," with needed funding likely to be in the amount of several billions of dollars per year. Because information is clearly a "public good" in the traditional economic use of the term, the preferred funding would be by direct appropriation. A more politically realistic funding might be to combine funding sources to include monies from direct appropriations, a contribution from the Medicare trust fund, and a small assessment of all privately covered lives. Although all would benefit, payers—both public and private—would gain a special advantage from this information.

Cost information. Monies also should be set aside to fund cost-effectiveness studies, as cost-effectiveness information could provide an important resource for setting payment strategies. In my opinion, however, the comparative clinical effectiveness center should not assume this role. Rather, this modeling should be performed elsewhere, probably in CMS. Concepts of cost-effectiveness tend to be more technically controversial and more politically contentious than concepts of clinical effectiveness. Any provision that increases the political vulnerability of a center on clinical effectiveness should be avoided because the information such a center would deliver is an elemental building block to better clinical decision making.

Information Only, Please

Our nation has a long way to go to achieve true healthcare reform, but developing a comparative clinical effectiveness center is a critical step. The credible information that such a center can provide is truly needed if we are to learn how to spend smarter, a crucial part of overall healthcare reform. ●

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