

Bill Introduced to Create Institute to Research “What Works” in Medicine

On August 1, Senate Finance Committee Chair Max Baucus (D-MT) and Senate Budget Committee Chair Kent Conrad (D-ND) announced their introduction of S. 3408, the *Comparative Effectiveness Research Act of 2008*. The bill would establish the Health Care Comparative Effectiveness Research Institute, a nonprofit corporation responsible for comparing the effectiveness of medical treatments. The Institute would be a “private entity,” Baucus said – adding, “But it would be governed by a public-private Board of Governors. It would not be an agency of the federal government.” According to advocates of comparative effectiveness research, it is important that such an entity be insulated from political pressures because federally funded programs to study the value of medical treatments in the past have been slashed when findings undercut a lucrative treatment.

Baucus also said that officials from both federal agencies and private corporations standing to benefit from the research would be among the 21 members of the board overseeing the new institute. Specifically, the board would include the Secretary of the Department of Health and Human Services, and the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health. The other 18 members would be appointed by the Comptroller General of the United States and are to include three individuals from each of the following groups: private payers; pharmaceutical, device, and technology companies; patients and health care consumers; doctors; and agencies administering public health programs.

As for funding, S. 3408 authorizes the institute to rely strictly on taxpayer funding from general revenues in its first three years, then to switch to an “all payer” system with money from both public and private sources. This arrangement would provide for a budget of \$5 million in 2009 rising to \$300 million by 2013. The bill also requires that, beginning in 2012, the institute’s funding include payments from private insurers of \$1 per insured person per year and from the Medicare trust funds of \$1 per beneficiary per year.

Currently, the federal government spends only \$15 million to compare the effectiveness of treatments, and Baucus said, “We should devote more than one-tenth of one percent of health spending to study how well health goods and services actually work.” In addition, Congressional Budget Office Director Peter Orszag has estimated that up to \$700 billion a year in health spending could be eliminated through research identifying treatments that do not produce the best medical outcomes.

The Advanced Medical Technology Association (AdvaMed) and the Pharmaceutical Research and Manufacturers of America (PhRMA) issued statements indicating support for comparative effectiveness research. AdvaMed CEO Stephen J. Ubl said that S. 3408 “reflects a number of AdvaMed principles on comparative effectiveness and we look forward to working with the bill sponsors as it continues through the legislative process.” He cautioned, however, that the “research should focus on comparative clinical effectiveness, and not on cost-effectiveness – which could lead to decision-making that may not be in the best interest of the patient.” Voicing similar views, PhRMA Senior Vice President Ken Johnson said the lobby “supports the development and use of high-quality evidence, including comparative clinical effectiveness (Cont’d page 2)

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CDC Reports on Increase in ED Visits

According to new health care statistics released August 6 by the Centers for Disease Control and Prevention (CDC), patients in the United States made 119.2 million visits to EDs in 2006, up from 115 million in 2005 and a 36% increase over 1996. Meanwhile, over that 10-year period, the number of EDs decreased by about 5%, from 4,019 to 3,833. The rise in ED visits also coincides with an increase in the number of medical visits in general – to physicians' offices, hospital outpatient services, and EDs combined – up by 26% to 1.1 billion visits in 2006 compared with a decade earlier, despite just an 11% growth in population. The data come from various components of CDC's National Center for Health Statistics National Health Care Survey featured in a series of new National Health Statistics Reports.

Other findings include:

- The ED served as the route of admission to hospital inpatient services for roughly 50% of non-obstetric hospital patients in 2006, up from 36% in 1996.
- Certain subgroups are more likely to visit the ED than others. Patients with Medicaid visited the ED at a higher rate (82 visits per 100 persons) than those with Medicare (48 visits per 100 persons), those with no insurance (48 visits per 100 persons), or those with private insurance (21 visits per 100 persons).
- Most ED visits occurred after business hours (defined as 8:00 a.m. to 5:00 p.m. on weekdays), when 63% of adults and 73% of children younger than age 15 arrived.
- While overall, the average waiting time to see a physician in the ED was nearly 56 minutes, half of the ED users had wait times of 31 minutes or less. Urban EDs with waits longer than an hour boosted the average.
- Infants younger than one year of age had the highest ED use of any age group (84.5 visits per 100 infants). People age 75 or older had the second highest ED use (60.2 visits per 100 people).

The reports also indicate that, although the number of uninsured U.S. residents increased by more than five million since 1996 to about 47 million, the growing uninsured population did not account for higher ED use. Nor did the overall growth in population account for the trend. Instead, the reports attribute the increase in ED and general medical visits to an aging population, which raises concerns about the possibility of catastrophic ED overcrowding in a few years.

The CDC series of health care reports is available at <http://www.cdc.gov/nchs/pressroom/08newsreleases/visitstodoctor.htm>.

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evidence, for healthcare decision making.” He added, “PhRMA will continue to review the details of the bill, and look forward to working with both Chairmen and other members of Congress on this important issue.”

Despite the fees for insurance companies, they also expressed enthusiastic support for S. 3408. “We very much support this notion of a public-private independent organization,” Karen Ignagni, President of American’s Health Insurance Plans, said. She added, “The senators should receive kudos for this and we believe it’s the cornerstone of the health reform agenda and should be enacted this year.” Another statement supporting the legislation came from Blue Cross and Blue Shield Association President Scott P. Serota, who said the Blues “have long advocated for such an entity.” Serota added that by “promoting comparative effectiveness research – not just in America, but worldwide – we can improve quality, value and expand coverage for all.”

It is not clear whether the Bush Administration will support the bill or when lawmakers will take up the measure. A Baucus spokesperson said, “We will work to move the bill this year, but obviously time is very limited.”

Pandemic Vaccination Plan Released

In a recent document providing guidance on allocating and targeting pandemic influenza vaccine, the Departments of Health and Human Services (HHS) and Homeland Security (DHS) released long-awaited details on who would get vaccinated if and when a pandemic emerged. In essence, the plan puts a million essential health care workers, such as ED health care workers, as the first to be immunized, with 700,000 military and “mission critical” personnel to follow. After that, 300,000 public health workers, 3.2 million inpatient health care providers, 2.5 million outpatient doctors, nurses, and other professionals, and 1.6 million long-term care workers would be the next to get the vaccine. All of these play a “critical role in providing care for the sickest persons; highest risk of exposure and occupational infection,” the plan reads. Emergency services, law enforcement, makers of pandemic vaccines and drugs, pregnant women, babies, and toddlers are also in the first designated group.

Despite this seemingly inclusive list, Mike Osterholm, an infectious disease expert at the University of Minnesota’s Centers for Infectious Disease Research and Policy and an advisor to the government on the guidelines, said the plan did not do enough to protect critical workers. While Osterholm acknowledged that the plan designates people involved in making vaccines and drugs for flu, he pointed out that it does not account for other drugs such as insulin and antibiotics. He added, “It does nothing to help support the manufacturing and transportation system for moving these drugs from offshore to the United States.”

In the press release on the plan, HHS Secretary Mike Leavitt concentrated on the guidance’s development process and its goals and objectives. Leavitt said, “This guidance is the result of a deliberative democratic process. All interested parties took part in the dialogue; we are confident that this document represents the best of shared responsibility and decision-making.”

A severe pandemic has the potential to disrupt our everyday way of life. This guidance was developed to ensure that our nation’s critical infrastructure remains up and running and we address the needs of all of our citizens, enabling the country to recover from a pandemic more quickly.

– Jeffrey Runge
Then DHS Assistant for
Health Affairs and Chief Medical Officer

As part of developing the guidance, HHS held daylong public engagement and stakeholder meetings throughout the country, and received more than 200 written public comments on the goals and objectives of pandemic vaccination. In all the meetings, participants identified the same four vaccination program objectives as the most important: (1) protect persons critical to the pandemic response and who provide care for persons with pandemic illness; (2) protect persons who provide essential community services; (3) protect persons who are at high risk of infection because of their occupation; and (4) protect children. In line with these objectives, the guidance’s vaccination structure defines four broad target groups: (1) people who maintain homeland and national security; (2) people who provide health care and community support services; (3) people who maintain critical infrastructure; and (4) people who are in the general population. Everyone in the United States is included in at least one vaccination target group. People not included in any occupational group would be vaccinated as part of the general population based on their age and health status.

The ultimate goal of the pandemic vaccination program is to vaccinate every person in the United States who wants to be vaccinated. But, since pandemic vaccine cannot be made fast enough for everyone to be vaccinated at once, the guidance designates who should get the first doses, thereby helping governments (federal, state, local, and tribal), communities, and the private sector to allocate vaccine to best use.

While many public health experts agree that some sort of influenza pandemic is inevitable, it is impossible to predict when it might come and how severe it may be. It is also impossible to predict the strain of flu that might cause a pandemic, although H5N1 avian influenza is the main suspect now. That strain has become entrenched in birds in Asia, Europe, the Middle East, and possibly Africa. Since 2003, just 385 people have been infected (Cont’d page 4)

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and 243 have died, but experts fear H5N1 could acquire the ability to spread easily from human to human, setting off a pandemic that could kill hundreds of millions of people. It is, therefore, important to note that the vaccination plan can be modified to meet the characteristics of any real pandemic.

In addition, while vaccines clearly will be an important resource in a pandemic, vaccination will be only one of several tools to fight the spread of influenza. Other tools include antiviral medications, face masks and respirators, washing hands, covering coughs and sneezes, and community public health measures such as closing schools and limiting public gatherings. A copy of the CDC Pandemic Vaccination Plan can be found at <http://www.pandemicflu.gov/vaccine/allocationguidance.pdf>.

From the States . . .

Illinois' Medical Malpractice Law on Trial

A lawsuit testing the constitutionality of Illinois' medical malpractice reforms is expected to come before the state's Supreme Court this fall. State Sen. Bill Haine (D-Alton) – one of the leaders in a long bipartisan effort to draft the legislation – said that if the law is thrown out by the courts, the issue would wind up back in the State Legislature and, depending on how the court rules, new efforts to solve the problems might be even tougher to achieve than in the past.

The state law shaped by Haine and other legislators was enacted in 2005. It limits medical malpractice awards for non-economic damages to \$500,000 for doctors and \$1 million for hospitals. The law does not, however, limit compensation for economic damages. At the time the law was enacted, Illinois was wracked by a medical malpractice crisis. Doctors, worried about lawsuits and by soaring malpractice insurance premiums, were retiring early or moving to other states where insurance was less costly. Now the exodus of doctors has stopped and has, to some extent, been reversed. ISMIE Mutual, which insures a majority of Illinois doctors, announced recently it will hold premiums steady for the second year in a row due to a "stabilizing legal environment."

Dr. Harold Jensen, chairman of ISMIE Mutual, said filings of medical malpractice lawsuits are down about 25% and that the company has seen significant improvement in loss experience under the new law. He said the company lowered premiums an average 5.2% in 2006 and has returned dividends to policyholders two years in a row. According to Jensen, the thought of returning to the previous state of affairs is frightening.

Of course, opinions differ on reasons for the recent crisis and on the impact of the law. Philip Corboy Jr., president of the Illinois Trial Lawyers Association, said it was an insurance crisis rather than a litigation crisis. Corboy said filings of medical malpractice lawsuits had been declining for several years before the new law. He said ISMIE needed higher rates to compensate for bad investments.

Michael McRaith, Director - Illinois Division of Insurance, said he thinks other reforms in the law were more important than damage caps in bringing down rates. For example, the law allows state regulators to gather and make public the actuarial data used by medical malpractice insurers and also requires public hearings for proposed rate increases that exceed 6%. "The prospect of a hearing is a deterrent in itself," McRaith said.

The case that could overturn the law originated in Cook County. It was filed by Frances LeBron, whose daughter Abigaile was seriously injured at birth in October 2005. The lawsuit states that the girl suffers mental impairment and cerebral palsy and will need round-the-clock care for the rest of her life. In November, Cook County Circuit Judge Diane Larsen sided with plaintiffs and declared the law unconstitutional and invalid in its entirety. She said the statutory limits on awards interfered with juries' authority to award appropriate compensation for injuries.

At least twice before and most recently in 1997, the Illinois Supreme Court has declared laws that limit personal injury awards to be unconstitutional, partly on grounds they violate the separation of judicial and legislative powers. There is a very real possibility that the law will be nixed.