



Advocacy

ADVISORY

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HOT TOPICS FOR ADVOCACY IN THIS ISSUE

THIS ISSUE of the Advocacy Advisory will focus on topics of current interest within the 110th Congress – including an examination of the outlook for health care issues. The CHRISTUS position is consistent that federal health care dollars must be preserved in programs such as Medicare and Medicaid, as both of these programs these serve a vital function as part of the health care safety net for the uninsured and underserved population. Also under scrutiny at the federal level at this time are funding for stem cell research and renewed examinations of the Medicare prescription drug plan.

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FDA PROPOSES NEW GUIDELINES FOR UMBILICAL STEM CELLS

The Food and Drug Administration proposed new standards this week meant to help companies and other organizations seek approval to sell stem cells from newborn's umbilical cord blood used to treat some cancers and other diseases. The FDA said it would allow cord blood banks that store the cells to submit research already available on use of the cells in an effort to streamline the approval process, rather than require them to

conduct their own clinical trials. Like companies selling other products, the banks must also meet other handling, storing and packaging requirements to win approval for the cells, the agency said.

Ellen Lazarus, an FDA medical officer in the division of human tissue, said use of the cells went so rapidly from research use to clinical use that the agency "didn't want to get in the way of development of the necessary medical technology," but did want to set clear guidelines for a bank to be approved.

Umbilical cord blood contains stem cells that can be used to treat bone marrow failure, immune system deficiencies and some cancers such as leukemia among other conditions in both children and adults. Researchers are also studying their use for other diseases, such as Alzheimer's and Parkinson's.

A mix of for-profit and not-for-profit companies collect cord blood donations for research and public use. Some companies offer private storage, including Celgene Corp.'s Lifebank USA and Viacell Inc.'s Viacord, although they may also sell some cells for public use. Both public and private banks already must meet FDA requirements for handling human cells, including facility inspections.

Mandatory approval for public banks would go into effect as soon as the standards are finalized following a 90-day comment period, the FDA said. Stephanie Simek, deputy director of the FDA's Office of Cellular, Tissue and Gene Therapies, said she hoped that could be completed within months.

Companies could apply for approval before the final guidelines are issued, Simek added.

The new standards would not apply to banks that manage cord cells for private use when parents pay to store their children's cells for possible future therapy. Those firms do not need licenses because they do not make cells widely available, an FDA spokeswoman said.

Source: Reuters News Service, 1/17/07.

BIPARTISAN PROPOSAL TO FUND STATE INITIATIVES FOR UNINSURED POPULATIONS

A bipartisan group of lawmakers this week introduced legislation in both chambers of Congress that would provide grants to individual states, groups of states and portions of states to test various health reform strategies. Grants could fund initiatives including tax credits, Medicaid or SCHIP expansions, and health savings accounts. Program proposals would be submitted to a bipartisan "State Health Innovation Commission," which then would present the proposals to Congress for review and funding. After five years, the commission would deliver a report to Congress on the effectiveness of the programs. Under the bill, states also would be able to "ask for relief from federal laws that they think complicate efforts to cover the uninsured, such as tax law or the 1974 Employee Retirement Income Security Act." Sen. George Voinovich (R-OH), a co-sponsor of the bill, said there is no specific funding level for the bill aside from \$3 million to \$4 million in start-up funds. Voinovich said that creating access to affordable, high-quality health care "is the greatest domestic challenge this nation faces," but he added that political pressures related to the 2008 presidential election make federal congressional reform "not realistic" at this time. Sen. Jeff Bingaman (D-N.M.), the bill's primary author, said that most health care reform efforts are occurring at the state level and that Congress should "give states greater latitude and resources with which to experiment to accomplish those objectives." Rep. Tammy Baldwin (D-WI), another co-sponsor, said, "Under our plan, states have a lot of freedom to think creatively and independently." Arthur Garson, dean of the University of Virginia School of Medicine and an adviser who helped Bingaman develop the bill, said, "The federal government has taken little substantive action, but the states have moved in impressive ways. This is a way to start moving, one state at a time, toward improving our health care system."

Coalition Also Set To Offer Proposal

In related news, a diverse group of business, consumer and health care organizations announced a closely guarded plan for covering more uninsured children and adults. The group -- called the Health Coverage Coalition for the Uninsured -- includes AARP, the American Medical Association, the American Hospital Association, America's Health Insurance Plans, Families USA, Pfizer and the U.S. Chamber of Commerce. The first phase of the coalition's plan reportedly dovetails on efforts to reauthorize SCHIP this year. The coalition also is expected to propose increases in tax credits to help the uninsured pay for coverage, as well as insurance pools to help people obtain coverage. The coalition's plan is notable because it represents a unified action plan by organizations with varied and often competing interests -- and because lawmakers and their staffers were excluded from negotiations.

Families USA Executive Director Ron Pollack said, "We felt that for us to really achieve the consensus breakthrough that we were looking for that we should meet quietly and confidentially and without members of Congress participating. Now that we've concluded the process, we are very actively talking to members in both houses and on both sides of the aisle" about legislation to adopt the recommendations. AHIP President Karen Ignagni said, "We wanted to craft something that appeals to Democrats, Republicans, conservatives and liberals, and has a balanced public-private approach. We think there's a moment in time now that various groups coming together can make a material difference." AFL-CIO, SEIU and the National Association of Manufacturers initially were part of the coalition but apparently left the group over disagreements about the final proposal.

Association Health Plans

In other congressional news, Sen. Ben Nelson (D-NE) on Wednesday of this week said that he and Sen. Michael Enzi (R-WY) are looking for ways to win approval for a bill to allow small businesses to join together across state lines to form association health plans. Legislation was approved in the House during the last Congress but was rejected in the Senate. The bill faced fierce opposition from Democrats and several Republicans, who expressed concern that allowing small businesses to form insurance pools would permit them to bypass too many state regulations. Possibilities for compromise might still exist in terms of pooled health insurance plans within a regulated government framework, according to some sources Nelson said, "There is a middle ground being discussed," adding, "Sen. Enzi and I have talked about possible changes." Enzi last week told reporters that he is "making progress" in negotiations with colleagues. Separately, Sens. Susan Collins (R-ME) and Mary Landrieu (D-LA) have also introduced a bill that includes health tax credits for small businesses and federal grants for states to help businesses set up group purchasing cooperatives.

Source: Kaiser Daily Health Policy Reports, 1/18/07.

CONGRESS TO BEGIN LOOK AT SCHIP FUNDING

The debate over whether additional funds are available to sustain state SCHIP programs will begin next month after President Bush unveils the administration budget. The program, which has six million beneficiaries nationwide, is financed with a \$5 billion annual allocation. Government estimates indicate that maintaining the current funding level could result in at least 1.5 million children losing coverage by 2012. Addressing the funding gap could cost an additional \$13 billion to \$15 billion over five years. Former CMS Administrator Mark McClellan said he believes Congress will approve legislation to "provide full funding for the program's current obligations," adding, "This has proven to be a very popular program with strong bipartisan support, and a very cost-effective way to cover kids." According to some White House sources, it seems likely that Bush will propose funding to close the gap, but he also might propose funding reductions for other health care programs to offset the spending increase for SCHIP. Democrats likely would oppose such a proposal. Democratic Senate leaders have said they want to vote on a bill before summer. However, the confrontation over the children's program is likely to pit Democrats against Democrats. Liberal Democrats will support reauthorizing the program to provide health coverage for all uninsured children. However, conservative Democrats will likely support strengthening the current program but are not ready to take the leap to cover all children. Drew Altman, president and CEO of the Kaiser Family Foundation, said, "Many people who are interested in broadening coverage see this as the train to ride for the next big step on health reform," adding, "But the desire to go beyond the renewal of the law is going to run straight into the desire to balance the budget."

Source: The Associated Press, 1/16/07.

HOUSE PASSES BILL THAT WOULD REQUIRE PRICE NEGOTIATIONS FOR MEDICARE DRUG BENEFIT

The House of Representatives voted 255-170 last Friday to approve a bill that would require the HHS secretary to negotiate prices directly with pharmaceutical companies under the Medicare prescription drug benefit and report to Congress in six months. All House Democrats and 24 House Republicans voted in favor of the bill, which Democrats had pledged to pass in the first 100 hours of the 110th Congress. The bill states that the HHS secretary "shall negotiate with pharmaceutical manufacturers the prices that may be charged" to private Medicare prescription drug plans. The bill would allow insurers that sponsor Medicare drug plans to negotiate lower prices than those obtained by the government. The 2003 Medicare law prohibits the government from negotiating with pharmaceutical companies under the drug benefit. House Republicans introduced one motion that would have prohibited restrictions on access to medications and forbidden price negotiations to result in an increase in prescription drug prices under Medicare or the Department of Veterans Affairs' drug program. That motion failed 196-229. Supporters of the House bill project that it would save \$96 billion over 10 years. However, the Congressional Budget Office (CBO) last week released a report stating that the bill "would have a negligible effect on federal spending because we anticipate that the secretary would be unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by the prescription drug plans." Many observers believe that the bill is unlikely to become law in its current form. White House Press Secretary Tony Snow said on Friday, "If this bill is presented to the president, he will veto it." Prospects for the bill in the Senate are "murkier" than in the House, according to Hill observers, who note that there has yet to be a companion bill introduced in that chamber. A potential compromise bill introduced last week by Sens. Olympia Snowe (R-ME) and Ron Wyden (D-OR) would require HHS to help negotiate prices for drugs that were developed with substantial funding from the federal government, and it also would require negotiations when a brand-name drug is available from only one manufacturer and no "therapeutic equivalent" or substitute is on the market. Senate Finance Committee Chair Max Baucus (D-MT) has said he would consider supporting negotiations legislation in the Senate if it were to "include some kind of instruction" to the HHS secretary on how to negotiate.

House Energy and Commerce Committee Chair John Dingell (D-MI), the chief sponsor of the House bill, said Medicare "pays more than the VA pays for the same prescription pharmaceuticals," adding, "The reason is no one is able to negotiate on behalf of the citizens." Dingell said, "Those who insist that the sky will fall if drug companies negotiate lower prescription prices are arguing that those companies should continue to skin a fat hog at the expense of taxpayers and beneficiaries." Dingell also said, "Forty-three million people can have the purchasing power to perhaps encourage these drug houses to give the government and the American retirees a better price." House Speaker Nancy Pelosi (D-CA) said, "As pharmaceutical companies reap record profits, it is clear that the president's flawed prescription drug plan is benefiting drug companies more than American seniors."

Medicare Advantage

In related news, some House Democrats are pushing to reduce government subsidies paid to Medicare Advantage plans under the prescription drug benefit. Some Democrats maintain that lowering payments to MA plans could help offset increases in spending on other health programs, such as SCHIP or reimbursements to physicians under Medicare, the *Journal* reports. Rep. Pete Stark (D-CA) said, "There are precious few areas where we can save money. Medicare Advantage is a prime target to pick up a few dollars."

Source: The Associated Press, Kaiser Daily Health Policy Report, 1/16/07.

CMS ISSUES FINAL RULE ON USE OF RESTRAINTS AND SECLUSION IN HOSPITAL SETTINGS

Prior to the close of 2006, CMS issued a long-awaited final rule concerning the proper use of restraints and seclusion in hospital settings. The Final Rule comes seven years after publication of CMS's interim final rule, published in July 1999, regarding the use of restraints and seclusion in various patient care settings. The

Final Rule, published in December 2006, took effect on January 8, 2007 and addresses the more than 4,200 comments to the 1999 interim rule. The Final Rule identifies the intent of CMS to apply the standards to all patients when the use of restraint or seclusion becomes necessary. As such, the Final Rule consolidates provisions formerly found in two separate sections of the former rule which differentiated the application of restraints or seclusion based upon patient setting. A significant change in the Final Rule is the adoption of the definition of “restraint,” taken from the Children’s Health Act of 2000. This definition attempts to respond to several comments critical of the use of restraints to prevent patients from falling out of bed or for other instances in which patients may cause harm to themselves. CMS also clarified in the Final Rule that although there is no express prohibition on the use of restraints or seclusion, it is prohibited as a substitute for adequate staffing, monitoring, assessment or investigations of the reasons behind the patient behavior that led to such use in the first place. The Final Rule further clarifies that such use may never be a standing order and sets limits with respect to the length of time for a restraint or seclusion to managed violent or self-destructive behavior. The rule also establishes new training standards for medical personnel requiring that staff be trained and able to demonstrate competency prior to applying or implementing such measures.

Source: Baker Hostetler Health Law Update, 1/10/07.

Of Physician Interest

NATION’S LEADING PHYSICIAN GROUPS UNITE TO PUSH FOR UNINSURED CARE

Ten of the nation's leading physician associations recently spoke with one voice to release principles to reform the U.S. health care system. This unity among physician groups is intended to help provide the impetus for bipartisan Congressional action to cover the uninsured. Recognizing that many newly elected Members of Congress campaigned on fixing the health care system, the Principles serve as a guide for Congress to improve both individual health and the collective health care system in the U.S.

The Principles for Reform of the U.S. Health Care System released today call for the following actions:

1. Health care coverage for all is needed to ensure quality of care and to improve the health status of Americans. The health care system in the U.S. must provide appropriate health care to all people within the U.S. borders, without unreasonable financial barriers to care.
2. Individuals and families must have catastrophic health coverage to provide protection from financial ruin.
3. Improvement of health care quality and safety must be the goal of all health interventions, so that we can assure optimal outcomes for the resources expended.
4. In reforming the health care system, we as a society must respect the ethical imperative of providing health care to individuals, responsible stewardship of community resources, and the importance of personal health responsibility.
5. Access to and financing for appropriate health services must be a shared public/private cooperative effort, and a system which will allow individuals/employers to purchase additional services or insurance.
6. Cost management by all stakeholders, consistent with achieving quality health care, is critical to attaining a workable, affordable and sustainable health care system.
7. Less complicated administrative systems are essential to reduce costs, create a more efficient health care system, and maximize funding for health care services.
8. Sufficient funds must be available for research (basic, clinical, translational and health services), medical education, and comprehensive health information technology infrastructure and implementation.
9. Sufficient funds must be available for public health and other essential medical services to include, but not be limited to, preventive services, trauma care and mental health services.
10. Comprehensive medical liability reform is essential to ensure access to quality health care.

Source: The American Medical Association 1/11/07.

Of Regional Interest

LOUISIANA

Legislator Files Fix for Health Care. A state legislator this week unveiled a Louisiana health-care restructuring proposal that he wants the state to adopt with or without the federal government's blessing. "I'm trying to be proactive," Senate Health and Welfare Committee chairman Joe McPherson said. "I'm trying to get health-care reform." McPherson pre-filed Senate Bill 1 that he wants considered in the 2007 Legislature, saying he is tired of waiting on federal government's response to a proposal submitted in October. U.S. Health and Human Services Secretary Michael Leavitt pushed a universal health insurance plan on the state that could cost the state an extra \$500 million for the New Orleans area alone. That plan is contingent on federal approval. McPherson's legislation does not rely on the insurance component or federal approval. The state would oversee managed care networks that public and private health-care providers would put together. Under McPherson's proposal, formal networks of physicians, specialists and hospitals would see to the health needs of the poor and uninsured. Primary care physicians would act as the gatekeepers and refer patients to specialists, hospitals and others in their networks as needed, he said. In order to participate, the physicians and other providers would have to agree to meet certain standards of medical care that have proven track records of improving patient health and lowering health-care costs, said McPherson, D-Woodworth. In addition, the managed care groups would also have to agree to participate in an electronic medical records system where information could be shared among providers, he said. DHH Secretary Dr. Fred Cerise said McPherson has been keeping him in the loop as he developed the legislation. "I think the purpose is to direct us to implement the stuff we have been talking about," Cerise said.

The nine-page bill provides a broad outline and would require DHH to present fleshed-out plans to state legislative health-care and budget committees before being implemented. McPherson calls his plan "Louisiana Health First." The Legislature is scheduled to convene April 30.

McPherson said the state already was moving toward restructuring its health-care delivery system when the federal government stepped in "and put us on hold" in the wake of Hurricane Katrina. The state had several requests for Medicaid changes, including one to allow more physicians to be reimbursed for treating the uninsured, he said. Federal rules preclude that today.

But the state pulled back when Leavitt offered help in developing a plan for the New Orleans area that could be used as a model and offered federal help, McPherson said. Now, the state is waiting on federal officials who missed an end-of-year deadline for response.

"We are going to do it one way or the other," McPherson said.

Source: The Advocate, 1/18/07.

TEXAS

Spending Limit to Pose Challenge for Legislative Session. Despite a record budget surplus, Texas lawmakers adopted a state spending limit that will limit their access to money to pay for property tax relief, teacher pay raises or 80,000 new students expected to enroll in public schools over the next two years. The Legislative Budget Board, led by Lt. Gov. David Dewhurst and House Speaker Tom Craddick, is required to adopt a spending limit every two years that parallels the predicted growth of the state economy. They agreed on a limit based on 13.1 percent over the last two-year budget. About \$14 billion in property tax relief, passed last year under court order, will cause total state spending to surge, surpassing the spending limit by about \$4 billion. That means that unless lawmakers find a way to exceed the constitutional cap, they'll have to cut \$4 billion from last year's spending levels and scrap any new spending on school enrollment growth, Medicaid caseload growth and money that was promised last year for teacher pay raises and other new school initiatives. "We're always looking at ways to cut government, but that's a large number," Dewhurst said. He said he's also committed to saving about \$6 billion to pay for the property tax relief again in two years. Lawmakers could choose to exceed the cap with a majority vote, or propose a constitutional amendment with a two-thirds vote. A constitutional amendment would still need

a public vote. The vote will be tough for fiscal conservatives as lawmakers are forced to choose between abiding by the spending constraints and voting to surpass the cap.

Source: *The Associated Press*, 1/16/07.

Key Issues for the 2007 Texas Legislature. From tax and spending bills to healthcare and education overhauls, Texas lawmakers have a full plate of proposals to consider:

Border and Immigration Issues: Gov. Rick Perry will ask lawmakers to spend \$100 million more to fight crime and drug trafficking on the border. Is an immigration crackdown imminent? Some want to cut off state services to the children of illegal immigrants, abolish in-state college tuition rates for them and require citizenship proof for any kind of state license.

Healthcare and reproductive issues: Social conservatives are pushing bills to restrict state funding for stem cell research and to outlaw abortion in case the U.S. Supreme Court overturns *Roe v. Wade*.

Some lawmakers are pushing bills to increase the number of participants in the Children's Health Insurance Program for poor kids.

CHRISTUS will be closely following and tracking the legislation of the Texas session and CHRISTUS advocates will play an integral leading role in helping to shape health care policy that will affect the state.

Source: *Associated Press*, 1/4/07, 1/11/07.

UTAH

Governor Uses State Address to Express Concerns about Health Care. Gov. Jon Huntsman used his recent State of the State address to announce he will no longer allow executive branch employees to receive gifts from lobbyists and to call on businesses and community advocates to work together to find a way to provide affordable health care. Huntsman's call came on the same day that a proposed constitutional amendment guaranteeing every resident the right to have basic, affordable health care stalled in a Senate committee. The Utah Department of Health estimates that 11.6 percent of residents, or more than 200,000 people, lacked health insurance in 2005, up from 2004. Healthy working males were about 30 percent of the uninsured, ages 18 to 64. While Huntsman acknowledged that uninsured residents are a "growing crisis," he provided few details on how to address the problem. "We are fortunate in Utah to have some of the finest doctors, nurses, technicians and hospitals in the world. Let us work together to craft a solution for the uninsured which is equally impressive," Huntsman said. In December, Huntsman announced that he's recommending spending \$4.2 million to expand the Children's Health Insurance Program, which will help about 14,000 more children in families that lack insurance. But that doesn't address uninsured adults, which Huntsman said are driving up costs for everyone. "We must stop kidding ourselves that those who are uninsured are simply not receiving health care. They are receiving care, but they are receiving too little, too late -- and typically in settings such as emergency rooms where the care is much more expensive," he said. "And who is paying for this care? ... In the overwhelming number of cases it is government -- which of course, means taxpayers." Huntsman gave his third State of the State address at the Salt Lake City Air Base to honor Utah soldiers while the Capitol is undergoing its last year of renovation. This was the first time the governor used his constitutionally required speech to address health care.

Source: *Salt Lake City Tribune*, 1/17/07.

ARKANSAS

Less Than 1% of Arkansans Pre-Enroll in Drug Program. Less than 1% of an estimated 400,000 Arkansas residents eligible for a state prescription drug discount program participated in the pre-enrollment period. Under the *Arkansas Rx* program, the state will negotiate discounted prices with drug manufacturers. Individuals younger than age 65 and families who have annual incomes lower than 350% of the federal poverty level and who do not have prescription drug coverage are eligible for the program. There are no income requirements for residents ages

65 and older. The state Legislature allocated \$2 million to develop and administer the program through the end of fiscal year 2007. Each beneficiary will pay \$25 annually to offset program costs. According to state sources, 2,200 eligible state residents enrolled during a "pre-enrollment" campaign that ran from Aug. 15, 2006, through Dec. 15, 2006. The campaign was intended to gauge interest in the program because enrollment numbers will help determine the discounts the state will be able to obtain from drug manufacturers. Julie Munsell, communications director of the Arkansas Department of Health and Human Services, said the department is concerned that the low number of residents who pre-enrolled will not give the state much leverage in negotiating discounts. She said the state is considering joining with other states to form a larger pool with which to negotiate. Arkansas plans to meet with drug manufacturers within the next 90 days to negotiate prices, according to Arkansas Medicaid Director Roy Jeffus. The state health department hopes actual enrollment will begin sometime this year.

Source: Arkansas Democrat-Gazette, 1/6/07.

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