



## **Hart Health Strategy Legislative/ Regulatory Health Policy Brief: Dec 6-10, 2004**

### **Congress "Sine Die's" With Passage of Appropriations Omnibus and Intel Reform**

**Omnibus**--Last Wednesday President Bush signed the \$388 billion FY 2005 omnibus appropriations bill, HR 4818, that includes funds for HHS and other federal departments. The 658-page bill represents a near freeze on domestic appropriations for FY 2005. HHS funding is as follows: The total HHS budget for FY 2005 will increase by about 2.7% from FY 2004. The CDC budget will increase by about \$138 million, or 2%, from FY 2004, with \$27 million for nutrition and exercise programs and additional funds for a cancer registry, an environmental health laboratory and preparations for a flu pandemic. In addition, CDC will receive \$1.6 billion for antiterrorism efforts, although the budget for a grant program to help hospitals prepare for terrorist attacks will decrease by \$20 million. The NIH budget for FY 2005 will increase by \$575 million, or 2%, from \$28 billion in FY 2004. The NIAID will receive much of the additional funds to build a new biodefense research center. In addition, a separate public health emergency account administered by the HHS secretary will provide NIH with \$47 million to respond to radiological and chemical attacks. The FDA budget for FY 2005 will increase by \$76 million from FY 2004 to \$1.46 billion. The legislation also includes a provision under which federal, state or local agencies cannot force physicians, hospitals, health insurers, HMOs or other health care entities to provide abortion services or referrals. The bill did not include a provision to return unspent federal SCHIP funds from FY 2004 to states. Maternal and child programs will receive \$896 million, a 0.7% increase from FY 2004. Under the VA/HUD portion of the bill, health care programs for veterans will receive \$30.3 billion, a \$1.9 billion increase from FY 2004. The law also includes \$3 million in FY 2005 funds for the creation of a "working group" of citizens charged with studying health care policy issues. Sens. Orrin Hatch and Ron Wyden said in a press release they are pleased that appropriators provided funding for their initiative which was originally authorized under DIMA. Under this provision the GAO will appoint members to a "citizens' health care working group." The group will be charged with preparing a report on how health care dollars are spent. The working group will be charged with issuing a second report outlining health care policy recommendations. Sens. Wyden and Hatch plan for legislation to be offered in Congress based on their recommendations. Sen. Hatch said that the funding for the legislation would help to start a national discussion on the cost of medical care and health insurance, as well as how to reduce pharmaceutical costs and make health care services more widely available

**Intel Bill**—Last week the Senate also passed the intelligence overhaul legislation, 89-2, after the House approved the bill on Tuesday night on a 336-75 vote. The 9/11 Commission called for the legislation after it released its report in late July outlining numerous intelligence failures that allowed the Sept. 11, 2001, terrorist attacks to occur.

**Appropriations Subcommittee Revamp?**--The competition to replace outgoing House Appropriations Chairman Young, by Reps. Ralph Regula, Jerry Lewis, Harold Rogers, is caught up in Majority Leader DeLay's proposal to radically change the jurisdictions of Appropriations subcommittees and reduce their number from 13 to 10 which would wrest the gavels from three

of the panels' powerful cardinals. It was reported that Rep. DeLay's proposal was not getting a welcome reception from the Subcommittee chairs nor from Senate leaders.

**VA--** Last Thursday, President Bush appointed Jim Nicholson, U.S. ambassador to the Vatican, to replace Department of Veteran Affairs Secretary Anthony Principi, who submitted his resignation on November 16<sup>th</sup>.

### **109th Congress Health Agenda Discussed**

At a forum sponsored by the Alliance for Health Reform and the Kaiser Family Foundation, congressional staff pointed to bipartisan support for steps to improve patient safety, advance health care information technology, link provider payments to quality, and revise Medicare's physician payment formula in the upcoming 109th Congress. However, they conceded that controversy will ensue in the months ahead as Congress looks for places to cut federal spending among Medicaid and Medicare accounts. It was stated that potential budget reconciliation instructions may include up to \$55 billion in Medicare cuts and \$27 billion in Medicaid cuts--a total of \$82 billion over five years. It was also indicated that a permanent fix for problems in the Medicare physician payment formula could cost \$25 billion over five years and \$90 billion over 10 years. In the Medicaid arena, staff indicated that states should not be able to divert federally provided Medicaid funds to areas outside of health care and that the program uses "one-size-fits-all" rules and has not been modernized since its creation. Efforts to lower Medicaid's long-term care costs, accounting for two-thirds of program spending, may include incentives for people to purchase long-term care insurance and steps to urge more home-based care. Staff noted that there is bipartisan support for finding a way to return to the states the \$1.1 billion in unspent State Children's Health Insurance Program funds that reverted to Treasury in September 2004. This, along with plans to reauthorize the Temporary Assistance for Needy Families program, would entail additional costs. Democrat staff said that many of the ideas for achieving savings in health care are controversial--block-granting Medicaid and reducing payments to hospitals and other providers, for example--and still do not yield sufficient savings. It was stated that while the House- and Senate-passed patient safety bills, H.R. 663 and S. 720, got hung up during the final days of the 108th Congress, there will be incentive to move the legislation early in the 109th Congress. The same was said of the legislation providing funding assistance to state-based health insurance high risk pools. With President Bush making it a priority, there will also be a push to pass legislation placing limits on medical lawsuits. Ideas are also being floated regarding tax related health initiatives, e.g. Senate Majority Leader Bill Frist's idea of phasing in a cap on the tax exclusion for employer-provided health insurance and allowing people who buy health insurance in the individual market to fully deduct the cost of their coverage. The health care debate might well be overshadowed, however, by President Bush's push to reform Social Security by allowing younger workers to contribute between 2-4% of their SS payroll taxes to individual accounts. Last week President Bush today served notice he will not accept increased payroll taxes to cover the huge costs of creating personal accounts as part of overhauling Social Security. "We will not raise payroll taxes to solve this problem," he said at the White House following a meeting with the Social Security trustees. The statement appeared to sink an option floated by Sen. Lindsey Graham who said Democrats could be enticed to back a Social Security proposal by increasing the amount of income subject to the payroll tax.

### **House E&C Subcommittee on Oversight and Investigations Targets "Inflated AWP's"**

States and the federal government are overpaying for prescription drugs because of states' excessive reimbursements under Average Wholesale Price (AWP), which pays Medicaid providers at an inflated rate according to panelists who appeared at the Subcommittee's hearing on December 7<sup>th</sup>. At the hearing, full committee Chairman Joe Barton announced that during the next session of Congress the committee will attempt to legislate to prevent the government paying too much for drugs. "Unfortunately, all too often AWP bears little or no resemblance to

what these providers really pay, particularly in the generic marketplace, where multiple manufacturers compete to sell identical drugs that are, for all intents and purposes, a commodity," Chairman Barton said during his opening statement. George Reeb, assistant inspector general for CMS, said that the Medicaid program—the largest national purchaser of prescription drugs—continues to pay too much for prescription drugs. He said in 2001 some \$86.7 million could have been saved if 42 states had reimbursed at the rate of the lowest paying state. He said that state savings on prescription drugs could be more substantial if they had better access to accurate pricing information.

### **Medicare/DIMA Corner**

**Prevention Focus**—CMS's regulatory implementation of the Medicare modernization act is focusing on enabling the revamped federal health care program to deliver personalized, high-quality care to beneficiaries, according to CMS Administrator Dr. Mark McClellan. He said last week that CMS's objectives are to deliver benefits and services tailored to meet individual medical needs and preferences, to use preventive medical procedures, and to rely on electronic capabilities to deliver, document, and reward the provision of high-quality care. Dr. McClellan is said to be one of the individuals on the short list of people who might replace Tommy Thompson as the next Secretary of Health and Human Services.

**Formulary Rules**--Health plans participating in the new drug benefit will have to submit their proposed drug formularies to a committee for approval, CMS announced last Friday. CMS said it will compare the proposed formularies to industry standard lists to ensure that the proposals are in line with existing drug formularies offered by traditional health plans. CMS also said it will review the drug classifications and individual medications covered to ensure there is no discrimination against beneficiaries with conditions that require specific medications. CMS also said it will allow plans some "flexibility" in designing their formularies. CMS will issue final guidelines for the drug lists early next year

**Drug Regions**—Last Monday HHS Secretary Tommy Thompson announced that CMS has established 26 separate regions of the nation in which Medicare Advantage Preferred Provider Organizations will be offered and 34 separate regions in which the private drug coverage, or Prescription Drug Plans, will be offered. Each PPO and PDP would offer uniform benefits and premiums within a region, although benefits and premiums likely will vary from region to region. The Medicare law will allow state licensing regulations to be waived for up to three years for insurers looking to obtain a license to operate in additional states. In designating the regions, CMS drew the boundaries to maximize the number of participating insurers, according to Leslie Norwalk, acting deputy CMS administrator.

**Chronic Care Demo**—On December 8<sup>th</sup>, CMS named 10 applicants that will be part of a large-scale disease management project, intended to modernize Medicare. The Chronic Care Improvement Program, authorized by DIMA, will be operated by health care organizations that were chosen through a competitive selection process. The first program is expected to begin in spring of 2005 with others to follow. In Phase I of the three-year pilot program, the programs will be operated by Aetna Health Management in Chicago; American Healthways Inc. in the District of Columbia and Maryland; CIGNA HealthCare in Georgia; Health Dialog Services Corporation in Pennsylvania; Humana, Inc. in Central Florida; LifeMasters Supported SelfCare, Inc. in Oklahoma; McKesson Health Solutions in Mississippi; Visiting Nurse Service of New York, in partnership with United HealthCare Services, Inc.-Evercare in Queens and Brooklyn in New York City; and XLHealth in Tennessee. The programs will serve 150,000 to 300,000 beneficiaries in fee-for-service who have multiple chronic conditions, including congestive heart failure, complex diabetes, and chronic obstructive pulmonary disease. The areas to be served have high prevalence of diabetes and congestive heart failure among Medicare beneficiaries. They represent a mix of rural and urban areas and include ethnically and culturally diverse populations, CMS said.

**Price Controls Condemned--** If the Medicare program sets limits on drug prices, consumers would be paying 67.5% less for their medicines but drug companies would be investing less money in research and development, according to a report released by the Manhattan Institute December 7th. The consumer savings would come at a high cost in terms of forgone research, lost lives, and reduced life expectancy, according to the report. An estimated 277 million life years would be lost due to lack of new medicines and future research, the report said. Lost life years is a figure that describes the lives shortened or impaired due to early death or illness, according to the report. Under a price control system, spending on pharmaceutical research and development would decline nearly 40%, or \$372 billion over the life of the Medicare benefit, the report said. Under current law, CMS is barred from directly negotiating drug prices. However, some Democrats have advocated changing that provision to allow Medicare to limit drug prices.

**AMA Seeks Code Changes--**The American Medical Association House of Delegates approved a resolution December 6<sup>th</sup> calling on the AMA to advocate that CMS conduct pilot studies on the use of clinical examples to guide physicians in determining appropriate evaluation and management (E&M) code levels. In approving Resolution 819, they also called on the AMA to educate physicians and their coding staff on the use of Current Procedural Terminology (CPT) E&M codes including clinically appropriate documentation that supports quality care. The resolution also called on the AMA to work with the CMS Program Integrity Group and the Department of Health and Human Services Office of Inspector General to clarify and simplify the criteria that would trigger an audit under the Medicare program; establish and promulgate the rules, including the rights of physicians, by which such audits would be conducted; develop guidelines for setting penalties, beginning with physician education, for specified levels of audit discrepancies and Medicare billing errors; and disregard one-level differences in CPT E&M codes and not consider one-level differences an error for audit or error report purposes. The resolution also calls on the AMA to seek legislation and/or regulatory change, requiring CMS, the IG, and third-party carriers to conduct Medicare and Medicaid audits fairly, recognizing the imprecision of E&M code level assignment; and require that audits must consider coding patterns in the aggregate, including consideration of both assessments for up-coding as well as credits for down-coding. Finally, the resolution calls on the AMA to seek legislation and/or regulatory change that would limit CMS, the IG and third-party carriers from using "spurious" fraud claims and other excessive tactics that put physicians in compromised positions in which they are unable to obtain fair and just resolution of audit results.

**GAO says "NO" to Oncologists--**The GAO dismissed as unfounded concerns that oncologists will lose money and patients will suffer once the 2005 Medicare reimbursement rates for chemotherapy services go into effect. The GAO report on the issue acknowledges that payment rates will drop compared with 2003, but that oncologists who provide chemotherapy will still make money on the services. The GAO concluded that oncologists will be reimbursed about 6%-above-cost for the drugs and paid in some cases 300% more for services involved in administering the drugs.

### **MedPac: MD Payment Increases, Pay-for Performance**

**Reimbursement Hikes--**The Medicare Payment Advisory Commission December 10<sup>th</sup> unveiled a preliminary recommendation for a 2.7% increase in physician reimbursements for 2006. According to staff, the current projected change for input prices is 3.5% and productivity growth is 0.8%. Recommendations for the payment update will be voted on by the commissioners in January 2005, in time for their March report.

**Pay-for Performance—**MedPac also issued a series of draft recommendations that, among other things, propose instituting a pay-for-performance system that could bring about an historic change in the way Medicare and potentially other insurers pay for health care. The recommendations, which are subject to revisions, will be voted on by MedPac members in January. Some of the draft proposals are as follows--Pay for Performance: The

recommendations call on Congress to establish quality incentives that take into account the severity of patients' illnesses in Medicare payment policy for hospitals, physicians and home health agencies. Under the proposals, CMS would earmark 1% to 2% of the entire pool of money paid annually to each of the three sectors involved in the proposed pay-for-performance system and use the funds to pay bonuses to providers that meet quality measures; DRG System Changes: MedPac also recommended changes intended to eliminate incentives in the DRG system that reward providers with higher payments for treating patients with particular conditions that are more profitable. The changes are targeted at physician-owned specialty hospitals and call for CMS to eliminate most profit-based incentives for patient selection by refining the definition of DRGs, weighting DRG payments based on a hospital's actual costs rather than its charges, implementing a "relative value method" to adjust hospital costs and reducing weights for hospitals that receive large outlier payments. Related recommendations aim to improve regulation of referrals to doctor-owned hospitals; Payment Freezes: Several MedPac draft recommendations call for freezing payments to home health agencies and skilled nursing facilities and a 2% payment update for outpatient dialysis services -- equal to the composite rate increase in the dialysis market basket index, minus an adjustment for productivity growth of 0.8% for 2006; Full Market Basket Updates for Inpatient and Outpatient Care: According to data presented to MedPac members, hospitals' profit margins for Medicare beneficiaries fell from 5% in 2001 to negative 1.9% in 2003, and that figure is projected to remain below negative 1.5% in 2005; MedPAC members thus recommended a full-market basket update for both inpatient and outpatient payments for 2006; Health Care Information Technology: Another draft recommendation calls on Congress to "authorize an appropriated loan fund" for community-based efforts to increase use of health IT systems. According to a MedPac analysis, a loan fund would raise short-term Medicare spending but ultimately would result in better quality of care and better-coordinated treatments. However, some commissioners expressed concerns that Congress would not support a loan fund because of concerns about the federal deficit. In related news, Sen. John Breaux, who is retiring at the end of the year, predicted that the next Congress will move toward tying future health care provider payment increases to health care quality improvements.

**Hospitals Losing Money**--Hospitals lost money on their Medicare business in 2003 and will continue to do so in 2005, in part because of their inability to restrain costs, MedPac reported December 9th. In light of this, the MedPac put forward a draft recommendation for Congress to give hospitals a full marketbasket payment update in fiscal 2006 for their inpatient and outpatient departments. The update would mirror current law. The recommendation will be voted on at the commission's January 2005 meeting.

### **FDA Advisory Committee to Review New Studies on Silicone Implants**

As reported last week, officials from California-based Inamed said that an FDA advisory committee in April will review new safety studies on silicone breast implants which the agency banned in 1992. The FDA in January rejected the recommendation of an advisory committee to allow market re-entry for implants manufactured by Inamed and said that the company must conduct new studies to prove the safety of the products. The FDA limited the availability of silicone breast implants in 1992 to consider safety concerns, such as the effects of implants with leaks or ruptures. Under current FDA rules, only women who seek breast enlargement or reconstruction surgery as part of clinical trials can receive silicone breast implants. It was reported that Inamed will present the FDA advisory committee with new studies that examine the causes of implant leaks and ruptures and the efficacy of new mechanical tests on the products.

### **Importation Update**

**HHS Report Delayed**—HHS Secretary Tommy Thompson said HHS missed a deadline to deliver to Congress a report on the safety of purchasing lower-cost prescription drugs from other

nations which was mandated under DIMA. The Secretary said he expected to receive the report Wednesday from a government panel established earlier this year to study the issue, adding that he would make it public after he returns next week from an official trip to Europe. He also said there was no intentional delay in the release of the report to keep it from coinciding with this week's announcement that the federal government will be purchasing additional doses of flu vaccine that were manufactured in Germany.

**AMA Endorses**—The AMA last Monday voted to endorse the purchase of lower-cost prescription drugs from Canada and other nations, provided that U.S. regulators can ensure the medications are safe. According to AMA, which voted on the issue during its annual meeting in Atlanta, importation should be allowed if the medications are FDA-approved and subject to reliable electronic tracking and if Congress provides the FDA with the resources and authority to ensure the supply is reliable.

**Canada Restrictions**--Canada's Manitoba Pharmaceutical Association said it will not renew the licenses of Internet pharmacies that "knowingly fill prescriptions that are issued contrary to known provincial medical standards of care." The move is designed to address cases in which physicians co-sign bulk U.S. prescription drug orders without evaluating patients. Several members of MPA said Internet pharmacies are creating a shortage of qualified pharmacists in Manitoba.

### **Down the FLU Comes Vaccines**

**German Flu Vaccine**—Outgoing HHS Secretary Tommy Thompson announced last Tuesday that the government will buy 1.2 million doses of the German flu vaccine Fluarix and that it will be available later this month. An additional 3 million doses from GlaxoSmithKline are expected to be available later. Fluarix, manufactured in Germany, has not been licensed for use in the U.S., but will be made available as an investigational new drug. Vaccine recipients will have to sign a consent form acknowledging that the vaccine is not licensed. It was reported that the FDA has inspected the Fluarix manufacturing facility in Germany and tested the vaccine's effectiveness for the dominant strain of flu expected in the U.S. HHS officials said they also checked to ensure that the vaccine was stored properly.

**Smallpox Vaccine to Global Stockpile**—Last week HHS Secretary Thompson thanked and congratulated the governments of Canada, France, Germany, and the United Kingdom for their pledges to the WHO Smallpox Vaccine Bank and pledged that the U.S. will add 20 million more doses to the stockpile. The United States donation is by far the largest contribution to date to the global stockpile. The 20 million doses of vaccine pledged by the United States will physically remain in the U.S. Strategic National Stockpile, but will be available for the WHO to use in the event of an emergency. The global stockpile will be used only if at least one case of smallpox is confirmed in the human population. At the announcement, Secretary Thompson said, "We have stockpiled more than enough smallpox vaccine for every man, woman, and child in America. But in this age of global interconnectedness, we need to take extra steps to be prepared for threats around the world."

### **Senator Grassley Plans to Introduce Mandatory Clinical Trial Database Bill**

Sen. Grassley was reported to be planning to introduce legislation in early 2005 that would require pharmaceutical companies to register drug trials and report findings in a public database. Reportedly, the legislation is expected to include some features from recent proposals by Democrats, including a requirement that makers of drugs and medical devices register all trials involving human subjects in a government database before the trials could proceed. Test results would be reported in the same database. In related news, Eli Lilly officials said last week that the company will unveil a Web site that contains results from clinical trials, a registry of ongoing trials, a list of trials recruiting participants and an education section. The site initially will contain results for tests of eight prescription drugs -- including schizophrenia medication

Zyprexa, antidepressant Cymbalta and attention deficit hyperactivity disorder treatment Strattera -- and company officials said they hope to have tests for all products on the Web site by mid-2005. Users will be able to search the site by medication or medical condition and find published and unpublished clinical trial results. Lilly officials said the site would contain information about all test results of Phase I trials after they begin.

### **Departing HHS Secretary Announces Launch of National Action Plan for Diabetes**

HHS Secretary Tommy Thompson last Tuesday announced the launch of "Diabetes: A National Plan for Action," a "step-by-step guide" to help individuals, businesses, local governments and community groups fight the disease. According to the guide, individuals should reduce their consumption of fat, use stairs rather than elevators and undergo tests for diabetes to help reduce their risk for the disease, which affects 18 million U.S. residents. The guide recommends that businesses stock vending machines and cafeterias with healthy foods and convert empty office space into exercise areas. In addition, the guide recommends that community groups place distance markers on sidewalks to encourage walking and establish community gardens to encourage exercise. The guide also recommends that local governments adopt "evidence-based strategies" to address diabetes. When the Secretary announced his resignation, he said he was "freed from the constraints of administration policy," and expressed "grave concern" about the risks of an avian flu pandemic and a terrorist attack on the U.S. food supply.

### **Health Spending Increased by Lowest Amount in Five Years**

A recent study shows that the rate of increase in the cost of health care increased by the lowest amount in five years. The study, conducted by the Center for Studying Health System Change and the Employee Benefit Research Institute, also suggests that health costs may continue to increase. According to the report, spending on health care commonly covered by insurance, including hospital care, physician services and prescription drugs, rose at an annualized 7.5% in the first half of 2004, the same rate as in 2003. The 7.5% rate on health-care spending is much higher than the 1% to 2% growth rates of the mid-1990s. At 7.5%, health-care spending is rising at a considerably faster rate than workers' income, an indicator that the number of uninsured Americans could continue to rise. Hospitals have contributed to the spending increase. While admissions and actual use of hospital services have risen less than 1% since 2003, prices climbed at an annualized 7.7% in the first six months of 2004, nearly as much as the 8% increase in 2003. One factor cited in the high hospital costs is the nursing shortage, which helped drive up hospital wages by 4.5%. Prescription drug prices have begun to moderate, though. In the first half of 2004, they climbed an annualized 8.8%, slowing from the 9.6% rate of the second half of 2003. The study's authors suggest that the growing popularity of tiered drug copayments, which force consumers to spend more if they opt for expensive brand-name drugs, may have held down drug prices.

### **CDC Study Overestimated the Number of Obesity Deaths**

The CDC announced that a widely quoted agency study published in the Journal of the American Medical Association inflated the number of deaths related to obesity by tens of thousands because of statistical errors. A CDC internal review identified that certain mathematical mistakes, such as using a total mortality number from the wrong year, might have incorrectly added 80,000 to the total estimated 400,000 obesity-related deaths. Such a mistake could have increased the growth rate of obesity mortality by 23 percentage points. The agency plans to reduce its estimated death total by a yet-to-be-determined number.

## **Health Legislation Introduced in Lame-Duck**

**H.R. 5429 (MEDICAL MARIJUANA)**, to require the National Institute on Drug Abuse to develop a meta-analysis of the available scientific data regarding the safety and health risks of smoking marijuana and the clinically-proven effectiveness of smoking marijuana for medicinal purposes, and to require the Food and Drug Administration to promptly disseminate the meta-analysis; SOUDER; to the Committee on Energy and Commerce, Dec. 6.

### Public Laws

**H.R. 3936**, to amend Title 38, United States Code, to increase the authorization of appropriations for grants to benefit homeless veterans, to improve programs for management and administration of veterans' facilities and health care programs (Pub. L. 108-422).

**H.R. 5213**, to expand research information regarding multidisciplinary research projects and epidemiological studies (Pub. L. 108-427).