

**Session Summaries from the
AcademyHealth & Health Affairs
2006 National Health Policy Conference**

February 6-7, 2006

*Debra Lipson
Erin Taylor
Myles Maxfield
Marsha Gold
Tara Krissik
Thomas Croghan*

These session summaries have not been reviewed by the presenters from the meeting or professionally edited.

Submitted by:
Mathematica Policy Research, Inc.
600 Maryland Ave. S.W., Suite 550
Washington, DC 20024-2512
Telephone: (202) 484-9220
Facsimile: (202) 863-1763

2006 NATIONAL HEALTH POLICY CONFERENCE

CONTENTS

	Page
DAY 1	1
THE ADMINISTRATION’S HEALTH POLICY AGENDA	1
Roy Ramthun, Special Assistant to the President for Economic Policy	1
Mark McClellan, Administrator, Centers for Medicare and Medicaid Services	2
Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration.....	3
Carolyn Clancy, Director, Agency for Healthcare Research and Quality	4
PAY FOR PERFORMANCE: A ROUNDTABLE DISCUSSION	7
Ron Bangasser, Beaver Medical Group	
R. Adams Dudley, University of California San Francisco	
Margaret Stanley, Puget Sound Health Alliance	
INNOVATIVE MEDICAID REFORMS	8
Alan Levine, Secretary, Florida Agency for Health Care Administration.....	9
Amy Lischko, Massachusetts Department of Public Health, Division of Health Care Finance and Policy	10
Matt Salo, Chief Health Lobbyist, National Governors Association.....	11
SOLUTIONS FOR REDUCING DISPARITIES IN HEALTH CARE	13
Bruce Siegel, George Washington University, Project Director, <i>Expecting Success: Excellence in Cardiac Care</i>	13
Marshall Chin, University of Chicago, Project Director, <i>Finding Answers: Research for Change</i>	14
Joseph Betancourt, Massachusetts General Hospital, Project Director, <i>Leading Change: Disparities Solutions Initiative</i>	14
Discussion	15
LUNCH SPEAKER: HEALTH SAVINGS ACCOUNTS	16
Uwe Reinhardt, Princeton University	16
IMPROVING SERVICES FOR MENTAL HEALTH AND SUBSTANCE ABUSE DISORDERS	18
Cynthia Wainscott, Chair, National Mental Health Association	18
Mark Trail, Chief, Georgia Department Of Medical Assistance	18
Craig Coenson, Senior Medical Director, CIGNA Behavioral Health	19

CONTENTS *(continued)*

	Page
APPLICATIONS OF DRUG SAFETY DATA.....	20
Gerald Dal Pan, Director, Office of Drug Safety, Food and Drug Administration.....	20
Elizabeth Andrews, Vice President, Pharmacoepidemiology and Risk Management, RTI Health Solutions.....	21
Tim Franson, Vice President, Global Regulatory Affairs, Eli Lilly and Company	21
MEDICARE MODERNIZATION ACT IMPLEMENTATION: REGISTERING LOW-INCOME BENEFICIARIES	22
Beatrice Disman, New York Regional Commissioner, Social Security Administration.....	22
Michael McMullan, Centers for Medicare and Medicaid Services	23
Cheryl Matheis, Director of Health Strategies Integration, AARP.....	23
Tom Hall, Chief Pharmacy Officer, Ovations	24
Discussion	25
POST-KATRINA: REBUILDING A HEALTH CARE SYSTEM.....	26
Fred Cerise, Secretary, Louisiana Department of Health and Hospitals.....	27
John Lumpkin, Senior Vice President, Robert Wood Johnson Foundation.....	28
ACADEMYHEALTH’S HEALTH SERVICES RESEARCH IMPACT AWARDS.....	29
DAY 2	30
CONGRESSIONAL HEALTH POLICY AGENDA	30
Recent developments.....	30
Recent federal legislation.....	31
Issues on 2006 Agenda.....	31
PREVENTING AND MANAGING CHRONIC ILLNESS IN CHILDREN.....	33
Debbie Chang, Nemours Health and Prevention Services.....	33
Tricia Leddy, Center for Child and Family Health, Rhode Island Department of Human Services	33
Charles Homer, National Initiatives for Children’s Healthcare Quality (NICHQ).....	34
Peggy McManus, Maternal and Child Policy Research Center.....	35
Question and Answer	35

CONTENTS *(continued)*

	Page
FEDERAL AND STATE EFFORTS TO IMPROVE PATIENT SAFETY	37
Vahe Kazandjian, Maryland Patient Safety Center.....	37
Alan Rabinowitz, Pennsylvania Patient Safety Authority	38
William Weeks, VA National Center for Patient Safety.....	39
Discussion	39
TECHNOLOGY, PRODUCTIVITY AND HEALTH CARE COSTS	39
Alan Rosenberg, Vice-President of Medical Policy, Technology Assessment and Credentialing, Wellpoint, Inc.	40
Robert Galvin, Director of Global Health Care, General Electric (GE)	40
Kim Williams, Nuclear Cardiologist, University of Chicago	41
Discussion	41
DECISION-BASED EVIDENCE MAKING.....	43
Mark Smith, California HealthCare Foundation	43
Discussion	43
PRIVATE SECTOR PERSPECTIVE: CORPORATE RESPONSIBILITY FOR AMERICA’S HEALTH CARE	44
David Blumenthal, Partners Health Care System	44
Michael Critelli, Pitney Bowes	45
Mark Paul, University of Pennsylvania.....	45
PUBLIC’S PERSPECTIVE ON HEALTH CARE.....	46
Robert Blendon, Harvard University	46
Discussion	48

DAY 1

THE ADMINISTRATION'S HEALTH POLICY AGENDA

Roy Ramthun, Special Assistant to the President for Economic Policy

Mr. Ramthun outlined President Bush's 2007 proposals to make health insurance more available and affordable, through changes in law designed to promote Health Savings Accounts (HSAs). As authorized in federal law two years ago, people can put money tax-free into such accounts if they also enroll in high-deductible health insurance plans, under which they pay at least the first \$1,050 of annual health costs. The Administration will propose three key changes to this law, which Ramthun said would go a long way toward giving HSA contributions by individuals the same tax advantage as those available to people who get health insurance through their employer.

First, the Administration proposes changes in tax policy to treat HSAs similar to other employer-sponsored health insurance. The President's 2007 budget proposes to allow all individuals who purchase a high-deductible health plan (HDHP) in conjunction with an HSA to deduct the amount of the health plan's premium from their income and payroll taxes. In addition, income tax deductible contributions to an individual's HSA would be exempt from payroll taxes. This would "level of the playing field" for people without employer-sponsored insurance. In response to a statement from an audience member that tax deductions are cheaper to high income than low-income people, Ramthun said it would be harder to take current tax benefits away from those receiving them now than to give tax benefits to others. The President's proposal, Ramthun explained, was not designed to fix everything that's wrong with the current tax treatment of employer-sponsored insurance.

Second, the Administration will propose increases to the amounts that can be contributed to HSAs. The maximum annual HSA contribution would be increased to the out-of-pocket limit for a participant's HDHP. Under current law, qualifying HDHPs must have a deductible in 2006 of at least \$1,050 for individuals and \$2,100 for families, with maximum out-of-pocket expenses of \$5,250 for individuals and \$10,500 for families. These would be increased. Third, the Administration's proposed 2007 budget proposes the creation of a refundable tax credit to offset employment taxes on HSA contributions not made by an employer. Refundable tax credits would also be available to lower income people for the purchase of HSA-eligible health coverage. The credit would cover up to 90 percent of the cost of a high deductible insurance premium up to \$1,000 for individuals and up to \$3,000 for families. He believed that the premium savings for high-deductible health plans would be more than sufficient to offset the higher deductible in some HSAs.

Additional changes will be proposed to make Health Reimbursement Accounts (HRAs) more portable to workers who switch jobs or move across state lines. For example, if an employee has an employer-sponsored HRA, he or she would be allowed to "cash out" the account when they leave that company and transfer the funds into their own HSA. To increase portability of health insurance across states, the Administration proposes to establish a federal

regulatory structure to oversee health insurance in all states. In response to a question, Ramthun said this would be similar to, or could build on, the U.S. Department of Labor's regulation of ERISA plans for self-funded employers. Some audience members asserted that improvements would be needed given past problems with ERISA oversight by DOL, and that the federal government would need to coordinate with existing state regulatory structures and rules governing health insurance.

Ramthun briefly discussed other initiatives to increase access to health insurance for people with high medical expenses. Under one proposal, employers that sponsor HSAs would be allowed to put more money into the accounts of chronically ill people or their dependents. The Administration's proposed 2007 budget also contains funds for Department of Health and Human Services (HHS) to award up to \$500 million in grants to up to 10 states to test innovative methods to make health insurance more affordable to people with chronic conditions. Ramthun outlined other changes to help consumers make more informed health care choices. For example, he said the President would like to see "list prices" for health care services widely available. Information on both the price and quality of care should be bundled and made as easily available as that for home and car repairs. The President will also challenge employers and insurers to be more involved in getting this information to consumers.

Mark McClellan, Administrator, Centers for Medicare and Medicaid Services

Dr. McClellan noted that the health care system is changing in fundamental ways and payment policy needs to adapt to those changes. For example, while medical advances permit treatment to be more personalized and tailored to individual characteristics, Medicare and Medicaid haven't been keeping up. Indeed, they should be driving these changes. His remarks summarized recent and proposed changes to Medicare and Medicaid designed to address this.

First, Medicare has updated its benefits coverage. Until the introduction of Medicare's Part D Prescription Drug Coverage, Medicare benefits lagged behind the reality of contemporary health care in which prescription drugs are essential to managing illness. One month into the new benefit, there are transition problems. But he said that drug plans are filling millions of prescriptions every day, over 3.6 million people enrolled in stand-alone Part D plans, and 300,000 are newly enrolled in Medicare Advantage plans. Millions of dual-eligible beneficiaries are using their Part D plans "just fine". Meanwhile, CMS is taking steps to ensure smoother transfers between plans, to share data across CMS, state agencies, and private Part D plans, and to shorten waiting times in customer and plan hotlines. CMS will require coverage of all mental health prescriptions and reimburse states that have assisted in the transition. Due to strong competition among prescription drug plans, costs would be lower than expected, he stated. Premiums are costing on average one-third less, and state "clawback" payments will be lower, than expected. Overall costs of the drug benefit are expected to be 20% less in 2006 and 10% less over the first five years than anticipated.

Second, Medicare payment policies are undergoing change to get better care at lower cost. At current rates of growth, spending on Medicare, Medicaid and Social Security are unsustainable. The President has called for a new Commission to examine the impact of the baby boomers on entitlement spending, and make recommendations for change to avoid

enormous tax deficits or massive cuts in other programs. For now, the President's budget proposals modestly affect growth in spending to avoid need for drastic action later.

CMS is evaluating proposals from the Medicare Payment Advisory Commission and other groups aimed at helping doctors and patients adopt behaviors that will save money and improve care, reduce duplicative care, and promote the adoption of effective practices. Paying more for better quality, and for evidence of higher quality care is a critical priority for Medicare. Medicare is conducting several pilot programs to pay higher rates for better results. Early evidence from the hospital pay-for-performance demonstration program with Premier Hospitals, said McClellan, shows that limited additional payments can drive across the board improvements. CMS will continue to expand these efforts with physicians.

Third, CMS will increase support for quality improvement and electronic health records. Part of this involves work with health care consumers, to help them become more informed about the quality and cost of coverage. HSA-type coverage will become part of Medicare over time, as people with HSAs age into Medicare and want to continue this coverage. The success of these and other types of consumer-directed health care, however, depends on patients having better information on cost and quality, including consumer satisfaction ratings and indicators of physician quality. CMS is also supporting the adoption of electronic health records, interoperable health information systems. Better ways of managing health information technology can also help consumers to have more control over their own health care information, he said.

With regard to Medicaid, the Administration has a more limited legislative agenda this year, as it awaits the report of a Medicaid commission later this year. But CMS is working with states and advocacy groups on several initiatives. To reduce the bias towards institutional long-term care, provisions in the Deficit Reduction Act provide strong financial incentives to states to give Medicaid recipients more control over who provides their care and where they get it. It includes \$1.7 billion for the "money follows the person" program, a new option for states to implement "cash and counseling" programs to manage their own care with support, and permits states to expand access to home and community-based services without requiring recipients to be so disabled as to need institutional level of care.

On the coverage side, the Deficit Reduction Act allows state waivers to allow state Medicaid programs to work with mainstream insurance coverage. The Administration included \$500 million in the FY 2007 proposed budget to expand coverage for chronically ill people with low-incomes. He concluded that health care policy is about more than how much to spend; he said the federal government needed to improve how it spends money, both to reinforce the use of evidence, and get more value for the dollars spent.

Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration

Dr. Woodcock stated that her remarks would focus on medical innovation, which is to some degree driving health care costs as well as improvements in healthcare delivery. She believes there are more opportunities for drug research and development to inform the debate on how to keep health care programs sustainable in the future. She spoke about three "translation" barriers

that prevent R & D from reaching the health care delivery system more quickly, or from being used to their greatest benefit: 1) from bench science discoveries to commercial availability; 2) from commercial availability to high-quality evidence-based care; and, 3) from evidence-based care to providing access and affordability. She said that new diagnostics identify people at risk for preemptive interventions, which today, are more often medications and medical products rather than hospitalization or surgery. This puts pressure on the R & D process to understand the likely uses of products during the development process.

Woodcock described FDA's Critical Path Initiative for Medical Product Development, which involves moving a newly discovered drug or medical product through the pre-clinical development process, clinical trials, the FDA approval process, and then bringing it to the market. Success in reaching the final stage depends increasingly on what Dr. Woodcock called the "evaluative sciences". This has three dimensions: 1) assessment of safety, 2) proof of efficacy, and 3) industrialization – that is, how to make sure that you can manufacture a product at commercial scale with consistently high quality and not have that product fail. She said that to improve health outcomes, FDA needed to improve the evaluative science that's applied to innovations within the medical product development environment.

Despite the investment of hundreds of millions of dollars in drug development, FDA often lacks key information at the approval stage about performance of product. They know that the product is effective in some people, and they can describe common side effects. But, many people who are subsequently receive the drug or medical device will not get benefit from it and some of them will experience harm. "We have accepted this as the best we can do over the decades, but now we can do better," she asserted. FDA has the opportunity to take the scientific and technologic advances in recent decades and begin to develop a whole new set of "mechanistically linked biomarkers" to better target treatments. She said that the pharmaceutical industry could develop more informative clinical trial designs and use bioinformatics to produce rich information about individual patients.

As an example, pharmacogenomic markers can signal whether and how people will respond to a particular drug. The FDA recently approved the first pharmacogenomic test to assess drug metabolism polymorphisms – the different ways that people metabolize drugs. "The science of genomics will allow us to target treatment to patients in a way that was really unthinkable a decade ago," she said. Applying these sorts of tests will make it possible to avoid treating those with counter-indications, or at risk of adverse side effects. New publicly available quantitative disease models can model and simulate the effect of new interventions, which can improve evidence base for treatment. FDA's Critical Path Initiative is fostering public-private partnerships across sectors to stimulate the development of such techniques to improve health care outcomes by tailoring drugs to each individual's profile.

Carolyn Clancy, Director, Agency for Healthcare Research and Quality

Dr. Clancy spoke about AHRQ's recent initiatives in three priority areas: 1) expanding information to consumers to help them make informed health care decisions, 2) health information technology, and 3) implementing the recently enacted patient safety legislation.

As an example of the difficulty consumers face in getting clear information, she asked audience members to consider the health care decisions they have had to make in the last six months. Women with a suspicious mammogram result must decide whether to have an ultrasound, an MRI, or a biopsy; getting information to make that decision should be easy and straightforward with all the information on the Internet, in the media, etc. But it's not, because too much of the information is inconclusive or difficult for consumers to interpret. That's why she was pleased that the Medicare Modernization Act of 2003 Section 1013 authorized the Effective Health Care Program, which is designed to systematically assess comparative effectiveness of health care interventions.

The program began last year, when the HHS Secretary established 10 priority conditions affecting the Medicare population; other conditions were selected for the Medicaid and SCHIP population. For all of these conditions, AHRQ is commissioning comparative effectiveness reviews from its existing network of evidence-based practice centers. Each review will evaluate the effectiveness of different treatments, what is unclear, and what needs to happen to improve the value of existing treatments. The first review, Comparative Effectiveness of Management Strategies for Gastroesophageal Reflux Disease, or GIRD, was released in December. It showed that for the majority of patients with uncomplicated GIRD a class of drugs called proton pump inhibitors can be as effective as surgery in relieving the symptoms and improving quality of life. At the same time, although surgery is sometimes chosen with the goal of eliminating the need to take medications, the evidence is unclear as to whether a significant number of surgical patients eventually become free of the use of medications.

The Effective Health Care Program will continue to identify the most pressing needs through a transparent and inclusive process, and plans to make communicate the results quickly and clearly. AHRQ recognizes that interpretation of complex scientific findings is difficult. Weighing benefit and harm, high and low risk can be difficult. So, AHRQ recently created the Eisenberg Center for Communication and Clinical Decision Sciences to communicate the research results in plain English and to make the results usable to many different audiences. Clancy called the Effective Healthcare program "breathtaking" in scope and in its potential impact on the American health care system.

However, real advances are expected to come when evidence based medicine combines with health IT to deliver information to clinicians in real-time. AHRQ uses its "DECIDE" network to take advantage of rapid advances in health IT by harnessing de-identified patient data from electronic health records, pharmacies, laboratories, and other sources. DECIDE researchers have begun 15 new projects that address research gaps and test the methodological underpinning for using these new data sources. Researchers are preparing to analyze Medicare prescription drug data in early 2007 to detect adverse drug events in the Medicare population.

Overall, AHRQ's health IT program has more than 100 grants and contracts in 43 states. They aim to bring health IT to new settings, e.g. rural and underserved settings, in community health centers, to improve quality and safety. They seek to demonstrate how to harness IT to use it at the bedside. The health IT community is advising the HHS Secretary on how to develop interoperability of health care information. Four our workgroups -- consumer empowerment, chronic illness, bio-surveillance, and electronic health records -- are now developing

recommendations. Four pilot projects are testing electronic prescribing standards; administered by AHRQ and CMS, the projects will test their impact on reducing adverse effects.

Finally, Clancy commented on the landmark patient safety legislation passed last July. As AHRQ works to implement the law, they want to build on the work of states. Patient Safety Organizations will conduct after the fact assessments and identify threats, i.e. near misses, before patient are harmed. Providers are granted federal confidentiality protection if they work with PSOs, and the Act prohibits the use of privileged communications by PSOs in civil or criminal proceedings. No funding was allocated to the PSOs yet. AHRQ is discussing how it can be a “science partner” to the PSOs to widely share their lessons.

PAY FOR PERFORMANCE: A ROUNDTABLE DISCUSSION

Joanne Silberner, National Public Radio, chaired the session. Panel members included: **Ron Bangasser, Beaver Medical Group; R. Adams Dudley, University of California, San Francisco; Margaret Stanley, Puget Sound Health Alliance**

Bangasser began by describing the Institute for Healthcare Advancement's (IHA) pay-for-performance (P4P) initiative, started in 1999. It developed a set of 15 common measures for physicians, focusing on clinical process of care, but including some preventive care and chronic care measures. The IHA is currently working on care coordination, satisfaction, and information technology (IT) measures. The program currently covers 35,000 physicians and 6.2 million patients in 8 health plans. The measures are used for public reporting and for P4P, which resulted in \$37 million in payouts the first year of operation and \$60 million the second year. All measured domains improved. Payouts represented approximately 1.5 – 2 percent of physician compensation. The IHA has a goal of P4P reimbursements growing to eventually be 10 percent of compensation.

Bangasser noted the need for additional measures for overuse, measures for specialties other than primary care and chronic care, and efficiency measures. He indicated the need for more research on the return on investment (ROI) for quality programs and on how to design P4P programs for PPO settings in which attribution to a specific physician is more difficult to establish.

Stanley continued the discussion by noting that the Puget Sound Health Alliance (PSHA) is still designing its P4P program. It is developing measures for heart disease, diabetes, back pain, and depression. PSHA uses the metrics for public reporting, and tiering networks, and is now working on using the metrics for P4P. Challenges in developing its P4P program include that most physicians operate in a PPO rather than a managed care environment and that most of the physician groups are small. They plan extensive use of claims data, and are exploring a link to the Bridges to Excellence program and to the Institute for Healthcare Improvement's (IHI) 100,000 lives program.

Stanley also highlighted the distinction between process of care measures and outcome measures, noting that process measures must be correlated with outcome measures. One of the challenges for outcome measures is that patient compliance, which is largely out of the control of the physician, affects outcomes. She reported that PSHA analyzed the clinical processes associated with back pain, finding that many patients could be referred directly to a physical therapist, but that reimbursement rates for physical therapy often do not cover provider costs.

Dudley also works with the IHA program and outlined the major challenges to developing P4P programs. These include determining what is to be measured, risk adjusting appropriately, making a business case for each measure, and ensuring the ease of data collection to support the measure. Dudley also suggested that the technical specifications for the IHI 100,000 lives program and some of those published by the Centers for Disease Control and Prevention (CDC) are vague and open to alternative interpretations. He cited his recent study of the factors that form effective incentives for physicians. The study identified three factors: compensation,

reputation, and timesavings as effective for changing physician behavior. Small groups are most sensitive to money and timesavings, whereas larger groups are sensitive to all three factors.

Bangasser suggested that, with regard to physicians, P4P programs would result in redistributing current levels of compensation, as opposed to adding “new money” to the system. His experience suggests that P4P programs could overcome the challenges they face, including generating consensus among multiple stakeholders, computing an ROI, and reducing the need to risk adjust outcomes through patient compliance education. He suggested overcoming the attribution problem in PPO settings by allocating the P4P payment to multiple physicians in proportion to each physician’s billing for the episode of care. Both Bangasser and Stanley warned against requiring physicians to respond to multiple report cards, because the incentives generated by those report cards may conflict. Bangasser noted that IHA’s P4P program allocates some payments to lower performing physicians who improve, but he noted that this component of payment is time limited, i.e., lower performing physicians have a limited amount of time to achieve high scores.

Stanley suggested that the magnitude of the P4P payment should start out at a few percent of compensation and rise to about 10 percent of compensation. She further suggested that the payment be made to the individual physician, as opposed to the group practice. Dudley, on the other hand, suggested that P4P payments eventually should constitute 100 percent of compensation. Bangasser warned that making the P4P payment a large proportion of compensation may cause some physicians to avoid taking on the most seriously ill patients. He went on to suggest that physician compensation be composed of a base rate, a factor for volume of services provided, and a factor for quality of care.

INNOVATIVE MEDICAID REFORMS

John Colmers, of the Milbank Memorial Fund chaired the session. He opened the session by noting that since its inception, Medicaid has been the source of testy relations between the federal and state governments. Complicated changes in law add to previous intricate rules, creating confusion and uncertainty. Recent federal changes in the Medicare Modernization Act and the Deficit Reduction Act compound the complexity. Nonetheless, states continue to push the limits of the law’s license to innovate, as shown by the three states presenting today.

Kevin Concannon, Director, Iowa Department of Human Services (substituting for Iowa’s Medicaid Director Eugene Gessow)

Iowa has pursued two major streams of innovation, both by-products of a major fiscal crisis. He has seen other states’ innovations come from such crises, which create a climate for change. In Iowa, widespread dissatisfaction with Medicaid grew out of its cumbersome administration, whose functions were contracted out to different companies: claims processing, IT, medical oversight, utilization, revenue collection, etc. When the contracts were up for renewal, state officials proposed a different approach. Medicaid would pick “best of breed” for each function via separate RFPs and make the awards contingent on co-locating functions in one state building. They believed this would facilitate the detection of health care utilization and spending patterns.

The “Iowa Medicaid Enterprise” will take one year to transition, from its start June 30, 2005. Already, the state can respond more quickly, track patients, secure better prices from pharmaceutical manufacturers, and more clearly articulate their performance expectations.

Change in federal rules regarding intergovernmental transfers (IGTs) as a source of state Medicaid financing presented another major challenge to Iowa’s Medicaid program. Iowa would lose at least \$200 million due to the changes, unless it could preserve local funds as part of the state’s share of Medicaid match funds. In “financial plea-bargaining” with federal officials, Iowa sought a way to use the local funds for safety net hospital funding. The three-part agreement involved Iowa giving up its IGTs, creating a separate fund for indigent care, and using the funds to secure federal matching funds for a limited benefit/limited network program called Iowa Care to provide health coverage to childless couples between 22 and 64, not disabled, up to 200% FPL. People can be hospitalized at either of the state’s two largest medical center, and if necessary, one of the four state-operated psychiatric hospitals. So far, about 14,000 people have enrolled. It doesn’t cover medications or a full range of benefits, and individuals are charged premiums, but no co-pays, on a sliding scale based on income.

In the long-term care arena, Iowa has one of the oldest populations adjusted for age in US, and one of the highest rate of institutionalized residents per population. This is due in part from requirements that people receiving home and community based care be eligible for institutional level of care. Iowa has proposed to make the institutional rules more stringent, e.g. more need for help with activities of daily living, but make it easier to qualify for home and community-based services. Through this change, the state hopes to gradually shift more long-term care clients into home and community settings. One of the audience members questioned whether this would raise overall spending, given unmet need for long-term care. Concannon cited Oregon, where similar concerns were raised, but their experience was that the rate of growth in long-term care dropped after home and community-based services were expanded. While the cash and counseling program may add to costs in the short-term because it allows people to be paid for providing personal care to their relatives, in long-term he said costs could be controlled.

In other areas, Iowa created a Medicaid Health Transformation fund of \$32 million for a variety of needs: pharmaceutical assistance for drugs not covered by Medicare Part D, a nurses consultation hotline, electronic medical records program development, creating a “dental home” for all Medicaid children, tobacco cessation and weight loss programs in cooperation with the state’s Department of Health, and conducting complete medical assessment of all patients with developmental disabilities. Changes in the mental health system are also in store to reduce institutionalization.

Alan Levine, Secretary, Florida Agency for Health Care Administration

Mr. Levine outlined the forces driving reform of Florida’s Medicaid program. He noted that 50 percent of the state’s Medicaid population is ethnic minority, so Medicaid policies could be a tool to combat disparities in health care services. The more urgent impetus, however, was the looming fiscal crisis; Medicaid could consume 60 percent of the state’s budget in the future, if nothing changes. Moreover, many policymakers have grown tired of annual debates on provider reimbursement rate increases and have begun searching for structural reforms that would address

the underlying reasons for Medicaid cost growth, and the rising numbers of uninsured people that increasingly turn to Medicaid.

Florida's Medicaid reform initiative is grounded in the belief that consumers are not engaged enough in their own health care decisions, except for a few waiver programs, such as the cash and counseling program that allows elderly and disabled people to purchase their own personal care services. The waiver reforms reflects three key principles: 1) transparency in evaluating care. For example, 800,000 Medicaid recipients are now in HMOs, but there is little transparency in their performance, and greater effort is needed to ensure that children get well-child checkups and women get mammograms; 2) choice – giving consumers the option to choose among different health benefit plans. Initially, Levine expects plan benefits to conform to minimum state guidelines, but over time, they will evolve to adapt to the population they serve and he expects the plans to offer a “more robust benefit package”; and, 3) for those needing long-term care and the chronically ill, policies must be designed to keep them out of institutions by creating more incentives to provide home and community based services.

Levine believes that Medicaid needs to change from a “pay and chase” fee-for-service reimbursement system to a payment methodology that adjusts HMO premiums based on medical risk profiles, and provides incentives to deliver preventive care and manage chronic illness.

Amy Lischko, Massachusetts Department of Public Health, Division of Health Care Finance and Policy

Ms. Lischko noted that the proposed health care reforms currently under consideration by the state legislature had not yet been resolved. Her remarks therefore focused on what made reform possible, the principles and major components of all reform proposals, and the debates and issues under discussion. Massachusetts is uniquely positioned to improve health coverage; it has a low rate of uninsured (7 percent) and a high rate of employer-subsidized health insurance. It also has excellent access to health care, a long-standing uncompensated care pool and a strong health care safety net for the poor. The state spends over \$1 billion for the uninsured.

But the state recognized several problems that signaled the need for significant reform. Health care and insurance costs are growing rapidly, and Medicaid spending was starting to crowd out state investments in other basic services. Cost shifting was estimated to be as high as \$1 billion annually. Policymakers are concerned that regulation limits insurer innovation, there is too little transparency about health care prices and quality, and that the uncompensated care pool provided bad incentives to deliver care in the most costly setting. Additional pressures for Medicaid financing reform came from the federal level; new policies regarding the use of disproportionate share hospital funds, intergovernmental transfers, waivers, and other factors led to the conclusion that the financial “games are up.”

Lischko said everyone shared a common vision: that all state residents should be able to obtain access to quality care, that health insurance was the best way to decrease barriers to care in most appropriate setting, and that subsidies are needed for those who cannot afford insurance. There is also wide agreement that state government must play a role in bringing health insurance to all. The major principles of the state's reform began to take shape over the last year, including:

strategies to address each segment of the uninsured differently, affordable health insurance products, subsidies for low-income people; insurance market reform, and creative financing. The state also wanted to use Medicaid funds to subsidize coverage for the uninsured to the extent possible.

Over the last year, Medicaid has improved its ability to enroll those who are eligible using an electronic system to assess eligibility among uncompensated care pool applicants. Over one million are now on Medicaid. For those with incomes above 300% FPL, the state has worked with actuaries to identify ways to make insurance more affordable, such as getting care in the appropriate setting, setting an annual deductible between \$250-\$1000 and co-pays for inpatient and office visits, except for preventive care, and additional pharmacy benefit management. Through such changes, the small group monthly premium average of \$350 can be reduced to \$200/month, she said. For people between 100-300% FPL, subsidies vary by income from 1.3% of income for those below 100% FPL to 5.8% for those at 300% FPL, not including cost sharing.

Regarding employer contributions to premiums, the Governor's bill did not include mandatory "pay or play" provision, although a House bill did. Data from the 2003 MEPS-IC survey indicates that 95% of employers already offer insurance; even for firms with 10-24 employees, 66% offer insurance. The smallest employers not offering health insurance are often excluded in pay or play proposals anyway. The uninsured are more likely to work part-time, short-term, and seasonally, and so are ineligible for insurance. To address the need for small employers to gain access to insurance, the state favors an "exchange/connector model", or a clearinghouse of products available to sole proprietors, small businesses, and employees not offered insurance. This would allow tax deductibility of premiums for working people, merging of the small and non-group markets, ability to reach part-time workers and people with multiple jobs, and eliminate rules in the small group market that raise costs, e.g. rate bands, mandatory offer, etc. The state plans to redirect funds from current spending on the free care pool and waiver programs to subsidies for health insurance.

Finally, she said that a mandate on individuals to purchase insurance was agreed upon, but the debate is over how to do this. The only model they have is auto insurance, which is not relevant to health insurance. Other activities, such as pay-for-performance, disease management programs, and other quality initiatives are part of the overall package of reforms.

Matt Salo, Chief Health Lobbyist, National Governors Association

His remarks were intended to put the state reforms into the larger context. Total Medicaid spending, including federal and state, exceeds Medicare. Medicaid covers more people than Medicare, he said, with caseload growing by 40 percent over the last five years, in part because employer sponsored health insurance is declining. From the state perspective, Medicaid budget growth is unsustainable. Last year for first time total Medicaid spending eclipsed total K-12 spending in the states. With continuing high level of growth in spending, it will crowd out other investment.

State officials must be nimble in responding to changing health care developments, he said. The difficulty of reforming Medicaid at federal level means states will continue to be the engines

of reform. The Deficit Reduction Act contains provisions allowing states to try new ways to expand coverage, and to reallocate resources to where they needed. States can do so through filing state plan amendments, rather than applying for waivers for some of these changes. For example, Medicaid can institute “rational and reasonable” cost sharing based on the S-CHIP model. He predicted that changes to make the average manufacturing price of prescription drug more transparent would save billions of dollars. Other savings will result from new provisions governing the treatment of assets for nursing home residents, designed to combat attorneys counseling them about how to hide their assets.

Still, no matter how much one tinkers with Medicaid, he believed that its growth is driven by factors beyond states’ ability to control. Initiatives addressing quality and patient safety, and health IT might help to contain cost growth, he said, although one of the audience members questioned whether quality initiatives would produce significant savings. The key to containing Medicaid costs, said Salo, is to make Medicaid less necessary as a safety net program by “getting employers back into the game,” and mandating insurance for individuals who can afford it.

SOLUTIONS FOR REDUCING DISPARITIES IN HEALTH CARE

Michael Painter, who leads the disparities team for the Robert Wood Johnson Foundation chaired the session. He began by describing why RWJF is working in this area. It's objective is to: reduce racial and ethnic disparities in the care of cardiovascular disease, diabetes, and depression by 2008. A joint RWJF-Harvard School of Public Health survey found that 65 percent of Americans believe that the federal government should do more to reduce disparities. The figure is substantially higher among Blacks and Hispanics. The RAND quality report card on health care showed that on average, patients get care consistent with the standard 55 percent of the time; the percentage is even lower for racial/ethnic minorities. Thus, different approaches are needed to provide culturally appropriate care that is evidenced based and patient centered. The foundation is also concerned with building sustainable improvements so innovations continue when grant money goes away. In addition to the three programs discussed today, RWJF also is funding a variety of other projects and aiming to link them into a "solutions network".

Bruce Siegel, George Washington University, Project Director, *Expecting Success: Excellence in Cardiac Care*

Dr. Siegel opened by noting that the program he runs is not a dating service despite its name. Rather it is focused on quality, measurement and disparities. *Expecting Success* is a multi-hospital learning collaborative to improve cardiac care for blacks and Latinos. The program aims to use quality improvement and evidence based practice to improve care for myocardial infarction and heart failure in inpatient and outpatient settings. CMS also has reporting requirements for these conditions, so clinical data already exist even if they have not disaggregated by racial group. Standardized orders, clinical pathways, etc. are being used to ensure hospital patients get all the care they should be. The program requires monthly standardized reporting of 23 performance measures by race, ethnicity and language and also includes surveys of patient experience at three points. The critical difference, compared to current practice, is that data are reported by race, ethnicity and language and those coding the data are trained to report in uniform fashion, possibly the first time this has been done so comprehensively. The patient surveys aim to "peel the onion" on patient experience.

The project is designed to move lessons in real-time to industry. By this spring, for example, they will have an electronic newsletter and will start to develop case studies. The program will have an external evaluation, with John Billings of NYU as the Principal Investigator. The ten hospitals picked to participate are a diverse group of institutions that are broadly representative of hospital types, e.g. not all are academic health centers, so that other hospitals could identify with them. Though diverse, they all have large minority populations.

Hospitals have submitted preliminary data to create baseline measures. For example, the AMI measure of ideal care (did the patient get all the recommended care they should have during hospitalization) was 66 percent and did not vary by race. However, the heart failure measure showed a huge opportunity for improvement, with 6 percent for blacks and 13 percent for whites. The data helped to target interventions and illustrates that they expect improvements for all patients and to reduce disparities. One hospital reporting on a measure for return visits to the emergency room within 7 days after a heart attack found a rate of 13 percent for blacks versus 3

percent for whites. The system wants to partner with organizations across the care continuum to address the gap. One of the hospitals reported no disparities, which the program intends to explore and understand.

There are many policy implications of this work. First, can we mandate and standardize the collection of race, ethnicity and language data? The project will offer ideas about the feasibility of this. Second, what are the implications for public reporting or for pay for performance? For example, it raises the question of whether we should address equity and look at measures by race. And third, can we craft legal “safe harbors” for providers to encourage work on disparities? More information on the program can be found at www.expectingsuccess.org

Marshall Chin, University of Chicago, Project Director, *Finding Answers: Research for Change*

RWJF seeks to demonstrate the links between quality improvement and disparities. They recognize that there is a continuum between discovery and translating research into practice. *Finding Answers* focuses on the beginning of the continuum—creating new knowledge. Their goal is to discover and evaluate practical solutions to reduce racial disparities in health care, i.e. which interventions work. The program has three main components: 1) a \$5 million, four-year grant program, 2) systematic reviews of the evidence in a special supplement to the journal *Medical Care Research and Review* and creation of a web-based database that can be searched for effective interventions, and 3) dissemination. The program hopes to produce a portfolio of 20-25 interventions that can be broadly disseminated. The call for proposals was just released and can be found at www.solvingdisparities.org.

Proposals must address one of three conditions: cardiovascular disease, depression, and diabetes. Applicants must be providers, plans, employers, or others such as academics or community groups as partners. The grants must support evaluations of interventions that are already under way to reduce racial and ethnic disparities in care; only about 20-25 percent of the money can be used for the intervention with the rest for evaluation. The program’s National Advisory Committee (NAC) is racially diverse and combines users (60 percent) and academics.

Various types of interventions and targets can be examined since the mechanisms that cause disparities are diverse. Examples of targets include: quality improvement organizations; providers and physicians (e.g. cultural competency training); patients (e.g. tailored disease management); policy (e.g. pay for performance); and community actors linked to the health system. Because other programs focus on communities, this program targets community organizations linked to the health system. The grants will be awarded to projects that combine scientific rigor and practicality; are replicable and sustainable; and provide evidence on outcomes and costs. They expect this program to have policy implications for multiple leverage points, and to produce knowledge that can influence real world practice.

Joseph Betancourt, Massachusetts General Hospital, Project Director, *Leading Change: Disparities Solutions Initiative*

This is the newest RWJF program; it was just approved for funding in December 2005 and it is the translation arm for the other two programs. Its task is to take disparities work and not just

disseminate it but also provide technical assistance to lead change. *Leading Change* will work with the other two programs to convert their findings into practical and useable forms that identify critical success factors. It will disseminate solutions to diverse stakeholders, create leaders and provide training and advice to implement solutions to disparities. It also will develop a clearinghouse of disparities solutions.

This is not a research program but one that is action and intervention-oriented. Activities include a Strategic Forum, annual national meetings, co-sponsored events, e-newsletters, a website, web seminars, and list serves. The Strategic Forum will convene a small group of around 25 people with diverse perspectives to generate synergy and new knowledge. The first national meeting will be in 2007. While they don't expect to have a lot of solutions then, they want to prepare the field to receive and implement solutions. At Massachusetts General Hospital, it took two years before an intervention was ready to implement. They had to create data, a disparities dashboard, expand hospital quality rounds include questions of disparities etc. So the program wants to prepare the field and create infrastructure to support work on disparities. The premier translation activity will involve an executive disparities institute, which will convene two to three people from about 40 institutions and bring them together a year later to discuss their experience and results. The website will highlight projects, feature a searchable database, include case studies, showcase new interventions, and contain literature searches.

Discussion

In response to a question about when untested interventions can be regarded as effective, the programs are still assessing the right level of rigor needed to qualify something as a solution. They are not necessarily looking for randomized controlled trials, although that would be welcomed. But it is hard to produce that level of evidence with complex interventions. In *Expecting Success*, they are putting evidence into practice, and are conducting a formal evaluation comparing the participating hospitals to comparison groups, to analyze their relative improvement. Many hospitals don't care too much about rigor and almost are too willing to accept potential solutions. *Finding Answers* is explicit in its call for proposals that a randomized controlled trial is good, but not always the best, e.g. there are tradeoffs on generalizability. Other possibilities include qualitative studies of implementation and cost studies.

A participant asked if the foundation will try to make a business case for reducing disparities on the basis of evidence from its programs. Changes in funding streams may be needed before one can make a business case. *Expecting Success* picked low cost interventions because they thought the business case may be more compelling. Dr. Siegel said the lack of a business case at this point shouldn't stop hospitals from doing right thing. People think reducing disparities costs more money but there could be things that reduce costs. For example, an interpreter could reduce the need for a costly and unnecessary test. Some health plans say they use disparities to gain the attention of employers in marketing. The issue also needs to be framed such that if organizations are not addressing disparities reduction, they are not committed to quality improvement, since the IOM listed equity as one of six key indicators.

LUNCH SPEAKER: HEALTH SAVINGS ACCOUNTS

Uwe Reinhardt PhD, Princeton University

Professor Reinhardt began by noting that the rate of growth in real per-capita healthcare spending has averaged 2.5 percentage points higher than the growth in non-health gross domestic product (GDP). While spending on healthcare measured as a percentage of GDP will continue to grow, the magnitude of GDP devoted to non-health goods and services will also continue to grow, suggesting that the nation can afford the projected growth in healthcare expenditures.

Reinhardt stated that health savings accounts (HSAs), as currently structured, would price low-income and lower middle class people out of the healthcare market. One in four workers in the U.S. earns \$18,800 or less annually, and one in three earns \$35,000 or less. Such people may have difficulty paying the high deductible associated with an HSA. Moreover, the rate of growth of wages in low-wage industries is projected to be lower than that of out-of-pocket costs for healthcare, resulting in this problem becoming worse in the future.

After recounting a brief history of the past several administrations' efforts to control inflation in the price of health care, Reinhardt commented that HSAs are based on the premise that consumers will be motivated by their financial stake in the efficiency of their healthcare to analyze their healthcare options and select the most cost-effective option. He highlighted the difficulty faced by consumers in gathering and analyzing the data necessary to select the most cost-effective option.

Reinhardt next stated that HSAs are neither necessary nor sufficient for consumer directed healthcare. Consumer directed healthcare requires that consumers have complete information on both quality and price by both treatment and provider. Since such information does not yet exist, consumer driven healthcare is not currently possible.

Based on a survey sponsored by the Kaiser Family Foundation, 2.3 percent of firms offered HSAs in 2005, covering 810,000 employees and about 1.6 million lives. The study estimated that the typical HSA participant with family coverage saves nearly \$3,000 in insurance costs relative to participating in a managed care plan, and faces a \$4,000 deductible. For low-wage employees, employer-sponsored HSAs appear to be more manageable than individual HSAs, which can have deductibles as high as \$10,000. An additional advantage of employer-sponsored HSAs is that the employer can provide information to assist the employee in making cost-effective choices. A recent GAO study of the Federal Employees Health Benefit Program found that beneficiaries who choose HSAs are younger and have higher salaries than those who do not.

To assess HSAs in the individual market, Reinhardt used a scenario of a single mother of three children earning \$25,000 from a full-time job in Texas. The children are covered by SCHIP but the mother is uninsured. Using www.ehealthinsurance.com, Reinhardt found a plan with a \$150 monthly premium, no co-insurance, and a \$10,000 deductible; a plan with a \$180 monthly premium, 20 percent co-insurance, \$5,000 deductible, and a maximum liability of \$10,000; and a plan with a \$600 monthly premium, \$3,200 deductible, 20 percent coinsurance, and a maximum liability of \$4,000. Even with the maximum tax credit of \$3,000, Reinhardt

expects that this woman would find it difficult to pay for the premium, co-insurance, and deductible.

Reinhardt returned to the theme that, since HSA benefits are pre-tax, the tax savings is greater for higher paid employees. As an example, a root canal procedure may have a price of \$1,000, which translates into a cost to a high-paid employee of \$550 and to a low-paid employee of \$880. He wondered whether such a program design was consistent with the American social ethic, and suggested that it was tantamount to rationing healthcare by income class. Further he cited a study by Joe Newhouse that indicated that high cost sharing led many people to forgo appropriate healthcare, resulting in worse health outcomes. Reinhardt suggested that the deductible and maximum out-of-pocket expense could be set lower for low-paid employees and higher for high-paid employees. As an illustration, he suggested that corporate executives should face a fee schedule that may be 400 times higher than the schedule that would apply to other people.

Reinhardt also pointed out that the current HSA design will shift the financial burden of covering the care of chronically ill individuals away from healthy individuals to those who are chronically ill. He cited a study by Ken Thorpe indicating that the most expensive 20 percent of individuals account for 78 percent of all healthcare spending. “Chronically healthy” people will not use up their HSA account, which will accumulate over time, whereas chronically ill individuals will always exhaust their HSA accounts. Reinhardt again questioned whether this was consistent with the American social ethic. He pointed out to health care professionals who favor HSAs in the hope that they will help them avoid managed care plans and government programs that, under HSAs, three quarters of healthcare will be paid by catastrophic insurance, which will be managed much as care is managed now.

IMPROVING SERVICES FOR MENTAL HEALTH AND SUBSTANCE ABUSE DISORDERS

Mary Jane England, M.D, President, Regis College, served as the moderator and began by focusing attention on the IOM report entitled, *Improving the Quality of Healthcare for Persons with Mental and Substance-Use Conditions: Quality Chasm Series*, released in November 2005. She highlighted the importance of co-occurring mental and substance use conditions, and the importance of providers specializing in mental and substance-use (M/SU) conditions to avoid treating each condition independently. She expanded this point by noting that other health care providers must take account of M/SU conditions. The stigma and discrimination encountered by people with M/SU conditions is a threat to patient centered care.

Cynthia Wainscott, Chair, National Mental Health Association

Ms. Wainscott stressed the importance of making healthcare for people with M/SU conditions patient-centered. The primary requirement for patient-centered care is ensuring that patients have control over their treatment choices. Challenges to patient choice include the lack of information comparing providers, the lack of multiple providers in rural areas, patient competency and health literacy. She cited research showing that, contrary to common stereotypes, half of institutionalized people mental conditions are competent to make choices among alternative treatment options.

Common stereotypes include that the consumer is unable to make appropriate decisions and may be dangerous to others or to him or herself. Some members of the public and some providers respond to such stereotypes by favoring coercive treatments. Unfortunately, sometimes the fact that many consumers are treated as incompetent may have the effect of convincing the consumer that they are in fact incompetent. Such stereotypes can be expressed in subtle ways, such as using the word ‘persistent’ to describe a long-lasting condition, where a similarly long-lasting medical condition would be called chronic. Stereotypes can also be expressed in less subtle ways such as legal rulings that require some people with M/SU conditions to relinquish custody of their children, whereas no other medical condition leads to a similar ruling. She cited other research indicating that people with mental illness are not more dangerous than the general public, whereas people with SU conditions may be more violent. The result of such stereotypes is that most treatment for people with SU conditions is coercive, and that most institutionalization for mental illness was coerced through the 1960s.

Methods to remedy such stereotypes include involving consumers in the design of treatments, providing consumers with comparative information and other decision support tools, encouraging the use of advance directives, supporting consumer self-management of his or her condition, and ensuring that treatment decision are transparent to the consumer.

Mark Trail, Chief, Georgia Department Of Medical Assistance

From a Medicaid program perspective, the appropriate focus is the effectiveness of care. Best practices are not widely disseminated among providers. The Georgia Department of

Medical Assistance is experimenting with using web casts and quality review organizations to disseminate best practices. Trail notes the importance of co-locating M/SU providers with other medical providers, for example in Federally Qualified Health Clinics. One of the challenges for disseminating best practices includes the fact that 60 percent of serotonin reuptake inhibitors (SSRI) prescriptions and 40 percent of anti-psychotic prescriptions are not written by providers specializing in mental health. He cited evidence that much of the inappropriate use of selective SSRI medications can be traced to prescriptions written by primary care physicians.

Trail noted the importance of developing a systematic approach to addressing the healthcare needs of the whole consumer. The Georgia Department of Medical Assistance uses an enhanced case management system to track consumers, views the primary care physician as the consumer's medical home, and uses disease management contractors to address all of the consumer's healthcare needs. Georgia has promoted patient-centered care by permitting Medicaid to reimburse peer counselors for people with M/SU conditions. The Department also provides education to the patient's family, advance directives, and assertive community treatment.

From a payer's perspective, it is also important for the treatment to be efficient. Trail has found that providing consumers with information and other supports for self-management can reduce the likelihood of relapse or decomposition. The Department has also found that it is easier to implement quality and efficiency standards in a managed care environment or with disease management contractors. The Department has implemented a procurement approach that allows contract awards to take into account quality in addition to cost.

Craig Coenson, Senior Medical Director, CIGNA Behavioral Health

CIGNA Behavioral Health has removed pre-authorization requirements and has begun providing consumers with educational packets and calls by nurses. CIGNA Behavioral Health's continued utilization review consists of examining claims data to identify deviations from practice patterns and inappropriate prescription patterns. When such a situation is identified, a case manager reviews the situation with the provider. CIGNA Behavioral Health uses claims-based performance metrics to assess network providers, and is planning to add consumer satisfaction metrics. It is also planning to add providers specializing in behavioral pediatrics to its network.

Other devices for improving care to those with M/SU conditions include the use of integrated rounds in which a M/SU professional makes rounds with medical staff. CIGNA Behavioral Health encourages consumers to use the employee assistance plan (EAP) provided by their employer. It also encourages disease management organizations to incorporate depression screening, provide information on depression to primary care physicians, and use claims data to identify persons at risk for depression. It encourages employers to adopt health lifestyle programs.

APPLICATIONS OF DRUG SAFETY DATA

Thomas Croghan of Mathematica Policy Research chaired the session. He began by reviewing the policy issues that have emerged as a result of concerns about Vioxx and antidepressant-related suicidality. These include structural issues such as whether to establish an independent safety office outside of the FDA, who should pay for, implement, and analyze drug safety studies, and who should be the ultimate arbiter of costs and benefits. Regulatory issues include the FDA's relationship with the pharmaceutical industry, whether some or all drugs should be subject to provisional approval, and establishing the necessary levers to enforce FDA requests for post-marketing studies. Legal issues include the role of product liability law.

Underlying these policy issues are many technical aspects of drug safety, including study designs, surveillance mechanisms, and statistical methods that can be applied or developed to improve detection of drug related adverse events. This session focused on some of these underlying technical aspects of drug safety.

Gerald Dal Pan, Director, Office of Drug Safety, Food and Drug Administration

Dr. Dal Pan reviewed the sources of risk from medical products, both drugs and devices, and the current methods the FDA uses to detect and assess potential adverse effects. Risks can come from known side effects, errors in use, and product defects. While some adverse events may be avoidable through improved design, better patient selection, and other methods, many are unavoidable consequences, such as infections associated with cancer chemotherapy. Unexpected adverse events, defined as those that are not included in the product's label, may result if they are rare, if they are related to unstudied uses of the product, and if they occur only in unstudied populations.

While Dr. Dal Pan focused his remarks on post-marketing assessment, he briefly reviewed the information in a new drug's pre-marketing safety database, including information from pre-clinical pharmacology and toxicology studies, clinical pharmacology studies, and data from controlled and open-label studies. Because of the small size of these studies, the information from them is very limited.

The FDA relies on three sources of data following approval and marketing: (1) spontaneous case reports, (2) computerized insurance and medical records, and (3) data collected during phase IV clinical trials designed to support new indications for the drug. The spontaneous reporting system is limited by its voluntary nature, but it has proven an effective means of identifying rare but very serious adverse events (e.g., aplastic anemia) associated with drug use. Electronic medical records and databases that include information regarding health care utilization are more useful for detecting potential adverse events that occur commonly in the population (e.g., heart attacks) or that may be associated with the disease that the product is intended to treat (e.g., sudden death associated with arrhythmias). Dr. Dal Pan provided several examples of the use of these types of data to detect adverse effects of drugs and noted that FDA has recently signed contracts with four organizations to provide data and analysis. The FDA is also working with CMS to develop an "active" surveillance system that will rely on Medicare data to prospectively look for potential adverse events.

Elizabeth Andrews, Vice President, Pharmacoepidemiology and Risk Management, RTI Health Solutions

Dr. Andrews began by presenting the notion of a “risk-management zone”, described as the difference between acceptable risks and benefits for some patients (e.g., those with very severe symptoms or disability) and the acceptable risk and benefit for all patients, even those with few symptoms and no disability. She then reviewed the strengths and weaknesses of large database studies as described by Dr. Dal Pan and the scientific basis for making value judgments regarding the costs and benefits of drugs. Large databases are useful in some circumstances, especially when an adverse event results in medical care and is reliably coded (e.g., heart attack). They can also provide information regarding effectiveness when the treatment results in reductions in improved compliance or reductions in hospitalization or emergency department use. However, many adverse events do not result in medical care, are unreliably coded (e.g., post-herpetic neuralgia, or have long latency (e.g., cancer). Moreover, large databases based on insurance claims do not contain information on symptoms, functional status, and many long-term outcomes.

Dr. Andrews also reviewed current methods used by pharmacoepidemiologists to weigh risks and benefits and to make value judgments. Although many stakeholders (e.g., physicians, make judgments regarding the trade-off between risks and benefits, risk preference of patients is theoretically the preferred method to define acceptable levels of risk. Revealed preferences are those that can be assessed by observing behaviors, such as use of seat belts and smoke alarms. Determining risk preferences is more difficult when there are not behavioral data. In this case, “stated” preferences can be determined, but even these have caveats such as when patients must be given large amounts of complex information. Dr. Andrews also noted that the manner in which this information is presented is critically important, and she provided an example of large differences in risk preference when risk related to use of hormone replacement therapy was presented as absolute vs. relative risk.

Tim Franson, Vice President, Global Regulatory Affairs, Eli Lilly and Company

Dr. Franson discussed some of the issues that he believes need to be introduced into any discussion of drug safety policy, beginning with common definitions. He drew a distinction between the notion of drug safety (being protected from harm) and risk (the probability and severity of a negative event), noting that the current discussion of “drug safety” leaves many with the impression that medications should be risk-free. Franson discussed current mechanisms to address drug risk, including the emerging elements of risk management procedures that rely on various tools (e.g., label restrictions, patient registries, education, and restricted distribution or advertising) to limit risk in certain circumstances.

Franson believes that current perceptions that the current drug safety system is “out-of-control” are not representative of the reality, but he also noted that all stakeholders have contributed to this impression and that there are many issues to be addressed. For example, he noted that there is no mechanism to audit the results of drug safety studies, that current risk communication practices appear to emphasize risk over benefits, and that calls for an independent drug safety office are at odds with current trends to integrate risk and benefit. Finally, Franson called for collaboration, communication, agreement on common standards, and commitment among all stakeholders as necessary elements to move forward.

MEDICARE MODERNIZATION ACT IMPLEMENTATION: REGISTERING LOW-INCOME BENEFICIARIES

Michael Hash, a principal at Health Policy Alternatives, Inc. chaired the session. He opened the session by reviewing some basic information about MMA's eligibility requirements for the low-income subsidy, and some indicators about enrollment to date. This session focused on how different organizations are finding and enrolling individuals eligible for LIS.

Beatrice Disman, New York Regional Commissioner, Social Security Administration

Under the MMA, the Social Security Administration was charged with defining and reaching out to the Medicare population with "limited resources and income." SSA chose those words carefully after talking to Medicare beneficiaries about how they viewed themselves. SSA's challenge is to find this population and help them file for "extra help" even as SSA tries to educate all other Medicare beneficiaries that prescription drug coverage is not just for those with limited income and resources. SSA is a trusted source in the community, which people are used to turning to enroll in Part B. For drug plan enrollment, SSA refers people to 1-800-MEDICARE or the drugs plans, because it is not SSA's role to do this, nor does SSA have experts who can advise beneficiaries about which plan to enroll in.

To reach the LIS population, SSA has used a multi-faceted approach that included mailings, follow-up calls, community events, and education to community-based organizations. SSA has contacted every Medicare beneficiaries at least three times, and some of them many times more. SSA included information about extra help for prescription drug costs in a mailing to 52 million Social Security beneficiaries on annual cost of living adjustments, which beneficiaries look for.

To identify potential LIS-eligibles with income less than 150 percent of the federal poverty level (FPL), SSA used its own database and those of other federal agencies. But these databases had no data on beneficiary resources or private pensions. They identified 19 million people that met the income limits and sent a letter to them in mid-May 2005. SSA hired a vendor to get beneficiary telephone numbers to remind people about the extra help, and find out who needed more help so SSA could follow up by phone. The vendor made nine million calls and sent another eight million applications. SSA made four million follow up calls and sent letters to those whose phone numbers could not be found. SSA's 1300 local offices began outreach and training in mid-April to over 400,000 state agencies, community-based organizations, and other groups about the extra help and how to assist in preparing applications. SSA staff has participated in 66,000 educational events around the country.

To make it as easy as possible, SSA offers several ways to apply for extra help: the Internet, which is meant mainly for caregivers and other third parties; scannable paper applications; on-line applications in 14 languages; the 1-800 number to take applications over the phone or make appointments in local SSA offices. SSA will verify income on LIS applications with the IRS; further contact is needed only if there are differences. Now that the focus has shifted to enrollment in Part D plans, SSA will retool their public information website to emphasize that extra help is still available.

SSA continues to look for new ways to reach beneficiaries. SSA is talking with tax preparers about informing those with earned income tax credits about their potential eligibility for LIS. They have encouraged rural electric companies that provide energy assistance to identify LIS-eligibles. Ms. Disman said SSA welcomed any ideas on how to better reach the LIS population that has not been automatically deemed eligible for a subsidy. It is willing to try almost anything that has promise because this group is hard to reach.

By early February 2006, over four million applications for extra help were received. About 700,000 beneficiaries didn't have to file because they were already deemed eligible for LIS. After duplicates were eliminated, 3.7 million applicants required a decision and SSA made a determination for 3.4 million of them. About 1.4 million were eligible for LIS (40 percent).

Michael McMullan, Centers for Medicare and Medicaid Services

Until the prescription drug discount card was adopted in 2003, Medicare had no income-based program. CMS learned through the discount card program that Medicare beneficiaries had trouble distinguishing between what is available for those with low income and what is available to everyone. People also are used to opting out of, not into Part B. The prescription drug benefit now makes them opt in, i.e. to make a decision to enroll. In addition, Medicare beneficiaries are passive information seekers. The 2006 Medicare and You handbook, sent every year to beneficiaries, CMS included on the front, "Important Information—You Need To Make A Decision" in large letters, because beneficiaries otherwise might file it without reading it.

An important part of CMS's strategy for enrollment is to leverage relationships with people who can reach the LIS population, both in the community such as the Access to Benefits Coalition groups, area agencies on aging, and thousands of local providers, as well as different parts of government. CMS also working with SSA to make sure beneficiaries know there are two steps, the LIS application, and the drug plan enrollment. CMS finds that some beneficiaries wait until their LIS is approved to enroll in a drug plan, but they encourage people to file an application for both at the same time. CMS also is using national and local media to get out the word. CMS has done consumer research to find out which messages work. CMS is also exploring techniques that the commercial market uses for similar purposes.

The response to the LIS subsidy is not as high as CMS hoped it would be, even though the LIS is a significant benefit. CMA has learned that people need multiple exposures to the information. Still, some point people will refuse to follow-up. Like SSA, CMS welcomes ideas and assistance.

Cheryl Matheis, Director of Health Strategies Integration, AARP

AARP works closely with SSA and CMS on outreach to low-income beneficiaries, but has a different role and perspective. At the national level, AARP has 11 staff working full-time on Medicare outreach and education, which it has found to be inadequate to the job. Despite having 53 state offices, most have only a few staff with many other responsibilities, and a limited number of volunteers. So AARP uses its core competencies to target its resources. With a strong

communications group, AARP produced a *Parade* magazine article and has placed ads elsewhere. AARP also produced its own publications, which are simpler because AARP is not subject to the restrictions placed on government agencies. AARP prepared a special booklet on the low-income subsidy, and is about to publish a step-by-step guide to using CMS's on line tool on how to select a drug plan. Because the SSA application for LIS is still hard for many to fill out, AARP developed a screening tool for its partners to identify good candidates for the full application process.

At the state level, AARP finds differences across states and communities about what works, reinforcing the need for one-on-one work to get people enrolled. Seven months into an intensive outreach and education campaign, only 1.4 million people have qualified for LIS out of the 8 million people estimated to be eligible. There are just three and a half months before the end of the first enrollment period to find the rest. Sixty percent of applications are rejected because individuals' income or assets exceed the thresholds. But it would help to have a breakdown on the reasons for disqualification, as they have different implications. Most applicants clearly think they have limited incomes; their assets are not so high that they generate much income, making many believe that the assets test is thwarting people from qualifying for the LIS program. For that reason, AARP has recommended that Congress revisit the assets test.

AARP also believes SSA needs to produce information about applicants and potential LIS-eligibles by zip code, to identify areas with high concentrations of low-income elderly that have not resulted in proportionately high numbers of LIS applications. Also, while federal poverty guidelines were reissued just recently, some report that local SSA offices are not using them to screen people. That makes it harder to find those who were wrongly rejected and persuade them to re-apply. The bottom line is that everyone needs to do better to reach the estimated target for LIS enrollment. Some solutions are legislative but some can be done administratively.

Tom Hall, Chief Pharmacy Officer, Ovations (United Health Group subsidiary)

He identified a common theme in the presentations so far. His experience and others' indicates that enrolling in LIS/Part D is a very personal decision so it requires direct outreach and contact with those making these decisions. To begin with, people must understand the value of the benefit. Ovations already offered a pharmacy card for AARP members and a Medicare discount card as well. It was amazing to them how many dollars were "left on the table" by those who could have qualified for the drug discount card. Ovations has educated caregiver groups, community organizations, state agencies, and others. But they believe that pharmacies play a key role and have the most awareness of who can benefit from drug program, and who might qualify for the low-income subsidy. Ovations has partnered with retail pharmacies to do outreach and education and has been very successful with the chain drugstores. Greater work is needed with independent and community pharmacies that are most prevalent in rural areas.

Ovations talks with 100,000 to 400,000 people per day about Part D, giving it the ability to make personal contact. Agents tell them about the LIS and how to complete application forms. However, application procedures are challenging, he said. Some people think an application for the LIS program also takes care of drug plan enrollment, making it important to explain that it is a two-step process. Ovations is considering modifying its drug plan application to find out if

applicants are dual eligibles, have applied for LIS, etc. There is great confusion on the diverse subsidy programs available and how to use them together. For example, Medicaid will still cover some drugs and Ovarians has to track drug manufacturers' patient assistance programs.

Discussion

It is not yet known about how many Medicare beneficiaries enrolled in the LIS program did not have previous drug coverage; one of the panelists said that in the program as a whole, about one million did not have pharmacy coverage before, and an unknown number had prior coverage that was probably limited. United Healthcare used information on members enrolled in the drug discount program to convert virtually all of them to a Part D plan, and informed them about the extra help available. In the absence of such a list, it is harder to reach LIS-eligible people.

One audience member wondered if more LIS-eligibles could really be enrolled without a legislative fix, given all the efforts described by panelists. AARP responded by saying that more can be done to enroll more people into LIS, but it will probably take legislative change to achieve big numbers. Maybe SSA needs more resources than it has received. Some questions on the LIS application deter people from filling it out, e.g. the face value of life insurance, which individuals often don't know. However, SSA noted that a lot of the people coming into the SSA offices were not seeking extra help; instead they needed help with general Part D questions, which SSA hasn't got the resources to address. Disman noted that the life insurance information is required by the MMA law and is counted towards the assets threshold, as is any property other than the house you live in. Household goods or cars do not count as assets because they cannot be converted to cash in 20 days.

In some cases, the number of applications is influenced by other programs' requirements. For example, seven states require applicants for state pharmaceutical assistance programs (SPAP) to submit LIS applications to determine if they should enroll in the SPAP or in the LIS program. Some drug manufacturers also require a denial letter from SSA to continue to receive donated drugs. For deemed LIS-eligibles (those who automatically qualify for LIS by virtue of being eligible for the Medicare Savings programs such as QMB, SLMB, QI) who do not enroll in a drug plan by May 15th, CMS plans to "facilitate enrollment" in a drug plan by June 1st by random assignment. After that, CMS will facilitate enrollment of deemed LIS eligibles as they enroll in Medicare Savings Programs.

POST-KATRINA: REBUILDING A HEALTH CARE SYSTEM

Diane Rowland, Executive Director of the Kaiser Commission on Medicaid and the Uninsured chaired the session, which focused on the task of rebuilding the health care system and the health care safety net in particular in the Gulf Coast region, after the Katrina and Rita hurricanes wrought massive destruction and loss of human life. As background to the two presentations, she offered a profile of the region's economic and health situation before the hurricanes. It is among poorest regions of country; one in five people live below the poverty line and nearly one in three children live in poverty. It has a high proportion of African-Americans, and a higher proportion of people enrolled Medicaid, although fewer low-income uninsured than the national average due to the higher rate of Medicaid coverage.

The region's population had high rates of chronic disease, including high blood pressure, diabetes, and physical disabilities. Survivors in Baton Rouge, Houston, and New Orleans have unmet mental health needs, but face a severe shortage of inpatient psychiatric care and gaps in prescription drugs for those who had been receiving them. Those who used to know where to go for care have no idea where to go today. They are under severe stress as housing remains inadequate. Promises of Medicaid coverage for evacuees have gone unmet. In short, she said, desperate conditions remain five months post-Katrina.

Donald Smithburg, Executive VP CEO, Louisiana State University Health Care System

He began by acknowledging that although Katrina destroyed the ability to provide decent health care, LSU Healthcare System staff displayed heroism in their attempt. The catastrophe holds lessons for future emergency preparedness, but his remarks focused on issues involved in restoring the health care system in New Orleans, and in reviving health professional training programs.

Most hospitals were badly damaged in the storm and will not reopen. But Charity Hospital was not just another hospital – it was the lynchpin of the health care safety net in Louisiana. Before Katrina, Louisiana State University's health system had 11 hospitals throughout the state and 150 clinics; state residents could get care at any location. Those with income below twice the federal poverty level paid nominal amounts, either on a sliding fee scale or at no cost. Charity Hospital provided over 90 percent of uncompensated care in the state and was a referral hub for most other hospitals. Most health professionals in the state trained at Charity; there were 800 medical residents at Charity or LSU hospitals, and Charity was the only Level 1 trauma center in southern Louisiana.

After Katrina, 500 hospital beds are out of service in New Orleans. The state lacks a multi-specialty clinic to provide care to the uninsured. A tent hospital at the Convention Center does not yet qualify for Medicare or Medicaid reimbursement. Four community hospitals in New Orleans are seeing emergency room patients, but their survival is under threat. Even if the city's population is smaller, that is inadequate to meet the need. The closest Level 1 trauma service to the city is in Houston or Shreveport. Other LSU hospitals in the state have had to care for more patients from New Orleans. Reconstruction of hospital and clinics is badly needed. Charity

Hospital had serious infrastructure problems before the storm. FEMA has argued that it can be rebuilt for \$23 M, far less than has been estimated by independent contractors.

In the meantime, the state is trying to lease unused, relatively undamaged hospitals. They hope to open a trauma center and University Hospital downtown soon. After the storm, 3600 staff or 90 percent of the workforce were let go and only 300 remain. They expected help from the federal government, but dealing with FEMA has become an extended and adversarial process. The amount of aid they can count on is still unknown. Louisiana's public hospitals were excluded from disaster aid and loan programs. Meanwhile, the federal VA hospital system was immediately funded to plan for its recovery. The state cut \$200 million from the system's budget allocations due to its fiscal crisis. LSU's hospital in Baton Rouge has doubled in census since Katrina, but it has not received any FEMA funds. Pfizer donated a mobile medical unit, the National Association of Public Hospitals sent many donations, and Saudi Arabia made a major contribution.

The storm and its aftermath represent a catalyst for planning the role of safety net hospitals in the state's health care system. Employer sponsored health insurance is likely to erode further after the storm, producing a higher percentage of uninsured. There were approximately 900,000 uninsured residents pre-Katrina; Blue Cross Blue Shield of Louisiana estimates at least another 200,000 will be uninsured because of business failures. Smithburg does not expect any sweeping changes to induce private doctors and hospitals to take over the public sector role. The crisis in mental health services is almost too large to tackle. The state budget will not be able address their needs or those of the uninsured. Medicaid waivers are worthy of pursuit, but unlikely to be sufficient to address the need.

He closed by saying that Louisiana needs an integrated safety net of primary and tertiary care services, built on disease management, information technology, and other improvements identified before Katrina and Rita destroyed lives, homes and the economy. But with 95% of all businesses in the state employing fewer than 50 employees, and few of them able to afford health insurance, the public health care system needs to be rebuilt to subsidize their existence. In absence of insurance coverage, the need for a strong health care safety net is greater than ever.

Fred Cerise, Secretary, Louisiana Department of Health and Hospitals

Mr. Cerise began by expressing gratitude for the outpouring of support and help from many organizations around the country. His remarks provided an overview of health care system before and after Katrina, and needed actions in the short, medium and long-term.

Pre-Katrina, Louisiana had high rates of uninsured and poverty, a shortage of health care professionals, and inadequate mental health system capacity. The Medicaid budget spent over \$5 billion, but produced low value for the dollars spent. Louisiana has the highest cost per patient and the lowest quality indicators among all states in the Medicare program. The state had made some strides in covering children under SCHIP, due to targeted outreach to eligible families. The state's top priorities pre-Katrina were to expand access to health care for the uninsured through use of a Medicaid waiver that would allow the state to match disproportionate share hospital (DSH) funds with local funds. They also intended to improve and restructure long-term

care, improve quality and IT applications, disease management, pay for performance, immunizations rates, and fluoridation.

Post Katrina, they estimate that over 100,000 will lose employer-sponsored insurance and the unemployment rate has doubled. The shortage of health professionals has worsened. The Medicaid shortfall is now projected at \$648 million, due to reduction in state revenue. Provider rate cuts were implemented January 1st. In the short-term, they are focused on creating special needs shelters, vaccine distribution, assuring access to prescription drugs, and providing preventive and routine health services, such as tetanus and flu shots, and immunizations of kids in shelters. The storm provided impetus to speed up health IT projects; for example, one week after the storm, the national committee on Health IT gathered information from chain drug stores, insurers, and others, in order to give physicians access to patients' prescription drug history for last six months. It was assembled in just 10 days. They also received federal approval to designate 60 new health professional shortage areas to help recruit providers.

In the medium and long-term, they must provide stopgap funding to sustain primary care, behavioral health and hospital services, and realign financial and regulatory incentives to reward quality and support systems of care. Katrina 1115 waivers and memoranda of understanding were signed to enroll Louisiana Medicaid eligibles into other states' programs, with Louisiana picking up the states' share of the match (with help from federal government), but this does not include funds for uncompensated care. The federal reconciliation bill allows Louisiana to use social services block grant and other funds in ways not usually allowed. For example, of the \$2 billion allocated to Gulf Coast states, some funds can be used as 100% FMAP for Medicaid.

In the long-term, the state may revise a HIFA waiver proposal submitted before the hurricane, to allow the state to use DSH funds for primary and preventive care and for health insurance coverage. It would include performance accountability measures. He welcomed HHS Secretary Leavitt's commitment to work with Louisiana officials on the redesign of the Medicaid program. He concluded that state health officials face numerous challenges including producing data on population estimates, reconstituting disrupted systems of care, filling health workforce shortages, and meeting immediate needs while building a system for the future.

John Lumpkin, Senior Vice President, Robert Wood Johnson Foundation

In the wake of the storm' devastating damage, Dr. Lumpkin said the foundation made significant donations to Red Cross, Salvation Army, and to CDC to provide direct assistance to local public health departments to deal with urgent needs. Now that rebuilding lies ahead, the question is what philanthropy can and ought to do next. He believed it should not just replace what was lost, but bring about meaningful social change for residents of the Gulf Coast. Since municipalities lack the resources to do the job on their own, philanthropy must step into the breach. We can't just rebuild to the way it was, he said; rather, we must demand a better future and use our collective expertise to lift the region up to where it should be.

Lumpkin said that foundation resources pale in comparison with needs but it has much to offer besides money. They can link knowledge about what works with communities. They can train and nurture homegrown leaders. And, while many other organizations have stopped making

donations, foundations can take a long-term view. Over next few years, RWJF plans to focus its grants on four areas: 1) serve the most vulnerable populations, including those with mental health and substance abuse problems, and seniors who are most likely to be overlooked; 2) rebuild the health care and public health infrastructure in the Gulf Coast, especially at the local health department level, which have struggled to provide safety net care as well as prevention and public health services; 3) promote healthy living through neighborhood development and healthier communities; 4) help providers build interoperable health information systems, by building on Connecting for Health lessons to make electronic health records a reality. In closing, he said that the resilience of the people he met on his visits to the Gulf Coast make him convinced that people who are committed to rebuilding their lives and communities are the key to the future.

ACADEMYHEALTH'S HEALTH SERVICES RESEARCH IMPACT AWARDS

On behalf of AcademyHealth, Liz Fowler awarded the first HSR Impact Awards to two groups of researchers, one led by Dr. Paul Ginsburg, Director of the Center for Studying Health System Change, and the other by Dr. Jack Needleman of the University of California, Los Angeles and Dr. Peter Buerhaus of Vanderbilt University. The award recognizes research that has had a significant impact on health and health care. For further information, visit <http://www.academyhealth.org/awards/hsrimpacts.htm>. In accepting their awards, both honorees spoke to issues they saw as important in making their work policy relevant.

Ginsburg, who won the award for the Center's analyses of the proliferation of specialty hospitals, noted that health services research that informs policy debates without advocating for a particular policy solution is at the heart of the Center for Studying Health System Change, and was pleased to be honored for such research. He recounted the origins of the research, which grew out of a trend detected during a series of site visits for the Center's Community Tracking Study. In placing the analysis and dissemination of findings on a fast track, the Center was able to bring it to policymakers' attention.

Needleman, who together with Buerhaus won the award for an analysis of a business case for increased hospital nurse staffing to prevent adverse patient outcomes, noted that his team's ability to do the work rapidly benefited from its access to timely and relevant data available through public use data files. He encouraged greater support for ongoing data collection activities to permit similar analysis. When they started their research, it wasn't clear that people regarded nurses very highly. He believed that their study changed that. He noted that a focus on discrete and easily measured quality improvement techniques risked overlooking less tangible but critical inputs into patient safety and quality. Researchers need to consider how complex systems work together to produce quality.

DAY 2

CONGRESSIONAL HEALTH POLICY AGENDA

Mark Hayes, Senate Finance Committee (majority)

Steve Northup, Senate Health, Education, Labor, & Pensions Committee (majority)

Chuck Clapton, Chief Counsel, House Health, Energy & Commerce Committee (majority)

Cybele Bjorklund, House Ways and Means Subcommittee on Health (minority)

David Helms introduced this session and panelists. He explained that the panel gives congressional staff the opportunity to share their thoughts about what is likely to happen this year on Capitol Hill, the issues on the agendas of key health committees, prospects for the President's proposed budget, and other issues affecting the Administration's goals in health policy. Because some panelists offered their comments off the record, the notes below do not identify the speakers. For the web cast, visit: www.academyhealth.org/conferences/nhpc.htm

Recent developments

President Bush's budget came out yesterday (February 6, 2006). One speaker stated that the President's budget includes substantial funding related to health savings accounts (HSAs); yet there is little information on how many uninsured people will become newly insured as a result of HSAs. The speaker compared HSAs to 401Ks, noting that 401Ks were originally introduced as a supplement to defined benefit pensions. Now pensions are almost a thing of the past. HSAs could erode employee benefits in a similar fashion. Moreover, HSAs are likely to attract healthier and wealthier people rather than low-income uninsured people with health conditions. One speaker noted that the President's budget ignored MedPAC's recommendation to reduce payments to Medicare Advantage plans, which are now paid an average of 115 percent of the FFS rate.

Launch of the Medicare Part D benefit began January 1 and has received a lot of attention. A recent meeting of the Senate Finance Committee discussed issues that have arisen in the first 30-35 days of implementation. The Senate was scheduled to hold a hearing on February 8, 2006 to discuss Part D. CMS Administrator Mark McClellan would testify before the committee, along with some plans and pharmacists. DHHS Secretary Leavitt and CMS Administrator Mark McClellan are also expected to testify on Part D in the House of Representatives in late February or early March. One speaker noted that there were quite a few problems with the roll out of Medicare in the 1960s, but things were resolved quickly; he expects history to repeat itself with Part D. Medicare prescription drug plan premiums are 20 percent lower than expected, according to one staff. Another speaker said Part D generally provides prices that are no better than Costco or drugstore.com, and therefore really is not a "good deal" for some. One speaker noted that the Senate did not wish to include dually eligible beneficiaries under Part D; it was contained in the House bill and accepted by Senate conferees.

Recent federal legislation

Congress recently passed the Deficit Reduction Act (DRA), which the President signed. The DRA includes the Family Opportunity Act, which is projected to cover around 115,000 new disabled children and 120,000 people are projected to receive new or additional home and community-based services. The “money follows the person” program was also slated to receive one of the largest expansions for the disabled in the history of Medicaid, according to one speaker, and should help about 100,000 persons leave institutional long-term care settings.

One speaker said that DRA provisions would reduce Medicaid prescription drug costs through increased use of generics, higher rebates, and lower amount that states pay individual pharmacists. Congress has also protected states from SCHIP shortfalls for another year, by authorizing additional funding, though this issue will be on the agenda again next year, as states will continue to face shortfalls. The DRA also included provisions that would reduce Medicaid spending by allowing states to reduce benefits and impose additional cost-sharing requirements and premiums on certain enrollees. Governors from across the country supported these changes in testimony before Congress last June, believing that such flexibility would increase states’ ability to save and perhaps even allow for expansions.

The Patient Safety and Quality Improvement Act of 2005 passed, which represents a major step in how medical errors are reported. It allows for the creation of patient safety organizations and will provide a protected legal environment for discussion of medical errors by health care professionals. While legal action can still be taken when errors occur, the law creates “a parallel universe of information so people can... communicate about system errors without worrying about lawsuits,” according to one speaker.

In other areas, legislation was adopted to test the use of health navigators by people with chronic illness and to provide federal support for states’ high-risk pool programs. One speaker indicated that all states that have such pools operate them at a loss, so this legislation provides some funding to them.

Issues on 2006 Agenda

- HSAs and other coverage options -- According to a few staffers, HSAs can help small employers struggling to provide coverage to their workers. According to one speaker, in 2000, small employers spent \$4,000 per covered person; by 2006, the rate has increased to \$8,000. A few staffers believed legislation would be introduced to provide new and more affordable options to small employers. One speaker said purchasers should provide consumers with better access to price and quality information, and need to improve transparency. The speaker noted that the average manufacturer price on prescriptions becomes public information in summer 2006. Another speaker noted that 37 percent of people who buy HSAs were previously uninsured.
- During question and answer period, a representative from a state regulatory agency noted that association health plans are touted as vehicles for small business to gain access to affordable coverage, but by being exempt from state insurance laws and

mandates, don't have adequate benefits. She cited plans that did not cover childhood immunizations or mammograms.

- Medicare physician payment – The Deficit Reduction Act only includes a one-year fix, so Congress will need to revisit this issue. One speaker noted some talk about pay for performance as a solution to the physician payment problem.
- Ryan White Care Act – Reauthorization of this act is a presidential priority discussed in the President's most recent State of the Union address.
- Congress may take a new look at Medicaid Section 1115 waivers, given the flexibility allowed under Medicaid per the reconciliation bill. One staff noted that there is a bipartisan effort to make the 1115 waiver review process more transparent and more accountable, especially with regard to the budget neutrality requirements, as well as more examination on the lessons learned in those demonstrations. The intent is to return the program to the demonstration program that it was intended to be.
- Information technology – One speaker suggested the health system needs to be pushed along to develop electronic health record systems, which can help promote safety and quality. Another noted that legislation would promote inter-operability.
- The Bioterrorism Act of 2002 has to be reauthorized this year. Congress will revisit it and one speaker noted that the public health emergency response to Hurricane Katrina may have some bearing on the details of its reauthorization.
- One speaker suggested that the National Institutes of Health (NIH) would continue to be a major priority. The NIH has been unauthorized since 1993, though its budget has increased over time. Given the way funding is currently structured, the NIH director little ability to manage the various NIH institutes. The speaker noted that Dr. Zerhouni, the NIH Director, has been trying to shift resources at the NIH to maximize the return on investment.
- Although not necessarily an issue on the Congressional agenda, one speaker noted that the groundwork for an “automatic hatchet” was laid in the Medicare Modernization Act of 2003. This provision put in place a “warning system” to tell Congress when 45 percent of Medicare's total spending will be subsidized by general revenues within seven years. After two consecutive warnings, it is supposed to prompt presidential action, or failing that a mandatory cap on spending goes into effect. Some believe that it was designed to make Medicare a capped entitlement, but others dispute that interpretation. In response to an audience question about the “automatic hatchet” during Q&A, another speaker said the provision is not intended to break the system.

PREVENTING AND MANAGING CHRONIC ILLNESS IN CHILDREN

Debbie Chang, Nemours Health and Prevention Services

Debbie Chang, chair of the session, summarized the problem of chronic conditions in children and then offered solutions. Chronic conditions, particularly asthma and obesity, are increasingly prevalent in children and caring for such conditions is expensive. Of the \$200 billion in health care costs consumed by children in 2003, the top 20 percent of the sickest children accounted for over 80 percent of the costs. Although prevention and health promotion constitutes only five percent of annual health care costs, Chang said it is a promising approach to children's health.

Nemours' approach moves beyond the traditional primary care office setting to the whole child, the family, and the community. To achieve lasting improvements in child health, Nemours aims to foster a cultural shift to an environment that supports behavioral changes in children, such as healthier lifestyles, as well as systems change, in which the community supports these choices. Target sectors for change include childcare, primary care, schools, and the community.

Chang described Nemours' community-based health promotion program in Delaware to prevent obesity in children, involving initiatives to support changes in policy, programs, and practices. The core components of the initiative include: (1) coalition building and strategic partnerships, (2) dissemination of knowledge and best practices, and (3) social marketing. Nemours has set goals for child health outcomes in 2015 and will use specific measures to track progress over time in reducing obesity in children.

Tricia Leddy, Center for Child and Family Health, Rhode Island Department of Human Services

Leddy described Rhode Island's "public health approach" to Medicaid in relation to the children with special health care needs (CSHCN) population. Rhode Island goes beyond the traditional Medicaid approach of tracking utilization data and the cost of services by also assessing the problem, planning, implementing change, and evaluating. Leddy summarized four initiatives Rhode Island Medicaid has implemented for CSHCN:

1. A needs assessment survey of CSHCN parents that provides the state with more information on this population than MMIS utilization data because parents reveal their child's health condition, their health status/severity, and their unmet needs.
2. Statewide CEDARR Family Centers (Comprehensive, Evaluation, Diagnosis, Assessment, Referral, and Re-evaluation) that provide services and support to CSHCN families. The family-centered centers resulted from planning by parents, providers, and stakeholders.
3. KIDS CONNECT initiative that provides therapeutic services and supports in child and youth care settings for CSHCN and offers an alternative to private duty nursing services.

4. Voluntary enrollment in one managed care plan to provide an integrated coordinated system of care for CSHCN. Since 2004, 68 percent of eligible children have enrolled in the plan.

Leddy also commented on steps that Rhode Island has taken to improve care for Medicaid children with lead poisoning including the creation of lead centers that provide case management and other services. The state will also try to improve access to dental care by enrolling Medicaid children in a managed care program for dental services beginning in May 2006.

In addition to anecdotal evidence from families about the success of their initiatives, Rhode Island relies on data and evaluation. The state has performance-based contracts with its health plans using HEDIS and other performance measures and uses HEDIS and SLAITS (State and Local Area Integrated Telephone Survey) data to measure changes in outcomes for CSHCN.

Charles Homer, National Initiatives for Children's Healthcare Quality (NICHQ)

Homer described NICHQ's approach to improving the quality of services for CSHCN by conducting learning collaboratives to help states implement the medical home concept, which has been slow to spread. The medical home links the practitioner to the community, improves access for children, is family-centered, and for states, fosters a relationship between the Title V program and the primary care community.

NICHQ's strategy for implementing the medical home concept in states involves tapping into state-based resources such as health departments, Medicaid agencies, and MCOs. Over 20 states have participated in the two Medical Home Learning Collaboratives that NICHQ has conducted. Although similar to the IHI Breakthrough Series, the collaboratives were structured a bit differently so that states could participate. Homer said they recruited state Title V programs and the states then had to recruit three primary care practices to participate. The collaboratives lasted 10 to 12 months.

NICHQ modified Ed Wagner's chronic care model for the collaboratives to encompass children's health. Participants used measures such as ED visits, care experience, and a pre- and post-medical home index to track progress. Homer said results have demonstrated that the collaboratives contributed to improvements in care for CSHCN and states now have the support and infrastructure for a medical home. However, it has been challenging for states to spread the initiative beyond the three practices. NICHQ did develop a planning tool for states during the second collaborative for assistance in reaching additional practices.

Homer concluded by listing four steps for practices to implement a medical home: (1) engage parents, (2) identify, categorize, and create a CSHCN registry, (3) use planned encounters, and (4) care coordination. He stated that the medical home concept requires state leadership to make it a priority, the engagement of consumers, a technical component in the health care delivery system, and an alignment of the financial base (both public and private).

Peggy McManus, Maternal and Child Policy Research Center

McManus' presentation focused on the pediatric subspecialty workforce shortage and promising approaches to improving the interface between primary and specialty care in pediatrics. There are 30 pediatric subspecialties and nearly all are facing current and projected shortages as well as increased demand for services. McManus described the evidence that demand exceeds supply, including the small number of specialists relative to the growing population and significant recruitment and retention problems.

In response to the pediatric subspecialty capacity problem, the Maternal and Child Health Bureau formed a work group in 2004. The group identified necessary improvements in three areas: (1) referrals, (2) consultation, and (3) collaborative management. McManus then discussed promising practices in each of these areas:

- Approaches to improve referrals include adhering to guidelines such as those offered by the Madigan Army Medical Center; pre-appointment management of referrals; referral management for special populations; and, pre-visit contacts.
- Promising consultation approaches include child psychiatry consultation and liaison, which allows child psychiatrists and other care workers to work with PCPs; Title V pediatric subspecialty consultation such as a program in Illinois for which pediatric subspecialties are available for PCP phone consultation; and, family practice pediatric consultation for which family practices receive support from pediatric subspecialists.
- A successful collaborative management approach involves service agreements to develop partnerships between PCPs and pediatric subspecialists. Other successful practices are co-management and multidisciplinary approaches that involve a partnership to care for medically fragile children needing multiple specialties.

Question and Answer

Chang asked panelists to comment on key factors critical to the success of their initiatives. McManus said it is important to identify improvements in the delivery system rather than just focusing on one particular child. Homer and Leddy both said that involving the family is critical. Leddy added that it is important to make data-driven decisions and to evaluate the impact of changes. Chang noted the importance of identifying and working with community partners.

A question was asked about how to coordinate the various guidelines and measures used in pay for performance initiatives, e.g. Bridges to Excellence because practitioners are confused. Homer suggested that the recent IOM recommendation to establish a new organization for such coordination might be effective. McManus emphasized the importance of paying providers at appropriate levels. Unlike with Medicare, there has not been much payment reform in Medicaid and it's needed, she said. Leddy thought the key was integrating delivery and financing. She would like to see more family and child-centered measures for CSHCN. Homer added that CMS is driving the Medicare side on pay for performance and measures, but has not done so for Medicaid. CMS might need to take the lead on coordinating a Medicaid measure set.

An audience member asked Leddy about Rhode Island's financing for their CSHCN model. Leddy said the Rhode Island plan is paid on an ASO basis and the program was implemented without a waiver because it is a voluntary program and only mandatory programs required waivers. The session concluded with panelist comments on early identification of children's health problems. Homer noted that most children do get their traditional medical needs identified, but we continue to fall short with the identification of mental health needs and developmental issues. Leddy added that data show excellent identification at the newborn level, but mental health and developmental issues are often not apparent at the newborn level so these problems are not being identified in many children. McManus commented that the time spent doing evaluations for children costs money and the services are not well reimbursed. Physicians need to be paid better to do a better job with screenings.

FEDERAL AND STATE EFFORTS TO IMPROVE PATIENT SAFETY

Alan Weil, with the National Academy of State Health Policy, served as moderator and began the session with some background on the issue of medical errors and patient safety. Weil referenced the IOM report *To Err is Human*, noting that between 44,000 and 98,000 hospital patients die each year in the U.S. because of errors. The IOM report suggested that a systemic approach was necessary to promote a culture of safety and improve outcomes. IOM recommendations include identifying and learning from medical errors and setting standards.

Federal responses to the issue of medical errors include the Patient Safety and Quality Improvement Act of 2005, which, among other things, promotes the creation of patient safety organizations; AHRQ's work in this area; the VA's National Center for Patient Safety; and CMS' Hospital Compare. States also have a major role in patient safety given that they license health care facilities and are large purchasers of health care. State responses include the creation of patient safety centers in seven states through state legislation; quality reporting efforts; patient safety coalitions; and improving purchasing to promote safety. As of December 2005, 25 states had authorized adverse event reporting programs. NAHSP recently completed a project, funded by the Commonwealth Fund, on maximizing the use of state adverse event data and has created a toolbox for states. For more information, see www.pstoolbox.org

Vahe Kazandjian, Maryland Patient Safety Center

Kazandjian noted that Maryland has worked on health care quality and safety issues for 25 years and has been preparing quality indicators for 20 years. While the state realized that errors were contributing to variation in outcomes across facilities, the IOM report really helped crystallize the issue as being one of patient safety. Maryland sees safety and quality as the same thing, though others talk about them as different issues.

The Maryland Patient Safety Center began two and half years ago. According to Kazandjian, the Maryland Health Care Commission (MHCC) sought organizations that might be interested in being the designated patient safety center. The Center is now housed within the LogicQual Research Institute, a non-profit research organization, in collaboration with the Maryland Hospital Association, Delmarva, the regional QIO, and Maryland hospitals and nursing homes. The Center has three full-time staff, and draws on the expertise of staff from collaborating organizations. The Center also has formal links with the University of Maryland and the Johns Hopkins School of Medicine and Public Health. The Center received the Eisenberg Award for innovation this year out of about 140 applicants.

Kazandjian identified 3 "pillars" of the Center: (1) Maryland's track record on quality improvement, (2) three decades of trust developed with providers and the community, and (3) a promise to look at safety as part of quality. The Center has four functions: to sponsor collaboratives building on Delmarva's expertise with IHI-type groups; to provide education using the Maryland Hospital Association's training resources; to conduct data collection and analysis; and to conduct research. These functions are interactive and dynamic. What is learned from one function, e.g. research is used in others, such as education.

Kazandjian indicated that facility participation in the Center is voluntary. All data are protected by legislative act and are non-identifiable, which helps promote trust. The Maryland Patient Safety Center did not start data collection until its second year. It first wanted to develop a better sense of the issues and problems before collecting data. The Center also wanted to emphasize collecting information on the *potential* for error, rather than just collecting information on adverse events. Kazandjian noted that accountability comes from the French word for “to count”; accountability without measurement doesn’t go anywhere.

Alan Rabinowitz, Pennsylvania Patient Safety Authority

Rabinowitz explained that Pennsylvania’s Patient Safety Authority differs from Maryland’s on several dimensions. Pennsylvania’s is a mandatory reporting system and is “generously” funded by the state. Moreover, while Maryland had time to study the issue before collecting data, the Authority was required to begin data collection within months of its creation.

The impetus for the Patient Safety Authority, according to Rabinowitz, was escalating malpractice insurance premiums, the alleged physician exodus from the state, and the threatened closure of certain specialties, like obstetrics, in some hospitals. The state legislature’s Act 13 of 2002 was a multifaceted bill that included the creation of a patient safety agency, with an 11-member board of directors.

Rabinowitz said the state’s Patient Safety Authority is a non-punitive learning program that examines both adverse events and “near misses” in hospitals, ambulatory surgery centers, and birthing centers in the state. There are now 451 facilities in the database, and all information is reported by facilities— rather than providers or consumers— using a web-based reporting tool that includes 21 core questions, with sophisticated skip patterns depending on the type of event. The data are confidential and non-discoverable for legal cases. The Authority’s database now has about 250,000 reports, 95 percent of which represent near misses rather than adverse events.

According to Rabinowitz, the Patient Safety Authority has a generous funding stream of up to \$5 million annually from an assessment on medical facilities. The Pennsylvania Hospital Association was willing to cover the costs. He said the Authority provides “real time” feedback to facilities, and is beginning to focus more on education and outreach. While a facility can see its own data online, as well as a statewide average, it cannot see information on other facilities.

Rabinowitz gave an example of the problem of color-coded wristbands in hospitals. The state had one case in which a nurse worked in two different hospitals. A yellow wristband in one of those hospitals indicated that no IV should be administered in that arm of the patient, whereas it meant “do not resuscitate” (DNR) in the other hospital. A near miss occurred when the nurse believed the patient had a DNR order; fortunately, another nurse was there and averted the problem. The Authority prepared an advisory and released it to hospitals in the state.

William Weeks, VA National Center for Patient Safety

Weeks provided some background information on the VA. It serves about 5.2 million patients, most of whom are poor, old, and male. About \$30 billion of the VA's \$33 billion annual budget is spent on health care services. A mass transformation of the VA occurred around 1995. Before then, the VA care was generally considered low quality, but after Ken Kizer assumed leadership and initiated major changes, the VA now has an outpatient focus, improved quality and efficiency, and high patient satisfaction scores.

The VA's National Center for Patient Safety was established in 1998. It is responsible for policy development and oversight in the area of safety, and has put many patient safety managers and officers in place across the system. Weeks stated that the Center's goals are to identify and mitigate system vulnerabilities, conduct root cause analyses, evaluate the severity and frequency of safety problems, implement corrective actions, and share results.

Information on patient safety incidents is collected through computerized entry forms; 74,000 reports were collected in the last fiscal year. Incident reports are reviewed at the local level, and often undergo regional and national review as well. The Center provides support to VA facilities through training, calls, toolkits, alerts, etc. Weeks suggested that while the Center has focused mostly on process measures to date, such as facility participation in reporting and the quality of data reported, it will be moving to outcome measures in the future.

Discussion

In response to a question about patient safety in nursing homes, Kazandjian indicated that Maryland is working with nursing homes, but noted the differences between hospitals and nursing homes in terms of setting and staffing/turnover. Rabinowitz (Pennsylvania) said nursing homes are not currently covered under their mandate. Another audience member asked whether the centers had approached patients about medical errors. The panelists indicated they had not, though the VA does conduct a patient survey and is considering adding a few questions related to safety. Kazandjian (Maryland) suggested that patient safety activities are geared towards improving the system, so facility reporting is likely most appropriate.

TECHNOLOGY, PRODUCTIVITY AND HEALTH CARE COSTS

Joseph Newhouse, Professor of Health Policy and Management at Harvard University, chaired the session. He offered some introductory comments to put the presentations in context. He said the U.S. is an outlier among developed countries in health care costs per capita, but not in the rate of growth in health care costs over the 40-plus year period from 1960 to 2003, expressed as the annual increase in real personal spending per person. He stated that medical advances and technology represents most of the cost increase; societal aging, he asserted, does not contribute much to the factors driving costs. "At the society level it was worth it," he said, in terms of increased life expectancy, which rose 6.6 years in the U.S. from 1970 to 2000, with much of the improvement owing to better treatment of people with cardiovascular disease. The main challenges ahead are how to pay for care for lower income groups and how to reduce waste

and poor quality in the health care systems of all countries, without removing valuable services and without decreasing future innovation.

Alan Rosenberg, Vice-President of Medical Policy, Technology Assessment and Credentialing, Wellpoint, Inc.

Dr. Rosenberg spoke to the issue of medical technology assessment from the perspective of someone responsible for deciding on health benefit coverage policy for a large health insurer that covers 34 million lives nationwide. Wellpoint's overall goal is improve members' health while maintaining affordability of health care coverage. Health benefit coverage decisions are constrained to some degree by legal frameworks reflected in benefit plan documents, practitioner/provider contracts, and court settlement agreements that have defined medical necessity in various situations. Insurance regulatory frameworks of the 50 states influence benefits. And, there are claims and utilization management frameworks that make it difficult to know which technology is being used to perform specific procedures covered by the insurer.

Wellpoint does not directly determine which technology should be used to perform a procedure. However, it does issue guidelines through a process involving review of the evidence for effectiveness, input from medical professionals and societies, and review by Wellpoint network physicians about whether new technologies meet medical necessity criteria. The guidelines are published on the organization's websites as "medical policies". While the FDA requires proof of safety and efficacy for new drugs and medical devices, it does not require such proof for new medical procedures, so FDA approval is only required for coverage of drugs and devices. He pointed to low-dose MRI as an example of how the process works. The use of this procedure has been carefully examined in 4 controlled trials, but none of them address whether low-dose MRI is as effective as high-dose MRI. However, the addition of this new technology will increase overall health spending. Wellpoint has limited means to address this source of cost growth and must therefore leave it to public policymakers to place any constraints on its use.

Robert Galvin, Director of Global Health Care, General Electric (GE)

Dr. Galvin's views represented that of a large employer and major health care payer. About ten percent of GE's business now includes health care related goods or services, but he is not involved in that part of the firm, other than to provide his perspective as a health care payer. He asserted that the rapid growth in health care technology brings out all the faults in the US health care system. We need to embrace technological advances in health care, since innovation is a core value of this country and its health care system. But, we also need to assess how to pay for it. Current technology assessment and adoption does not work well, he asserted. Great innovations are not used soon enough, some with minimal benefit are overused, and there is no accountability in the current system. "Personalized medicine" will add to the technology burden.

This situation derives in great part from the "cycle of unaccountability". Pharmaceutical and device manufacturers say it's not them, but rather physicians who control the use of drugs and medical devices. Physicians say they are only trying to do their best to help every patient, or if they don't use the latest technology or procedure, they could be sued. Patients say they want the

latest and best, but don't ask me to pay too much. The FDA says that their job is to assure safety, not to control costs. And payers have too little data to judge whether it is effective or cost-effective to cover new drugs and technologies and fear that if they don't cover new technologies, they will jeopardize relationships with patients and physicians.

To break this cycle will require reconsideration of how evidence is produced, payment policy, and who takes a leadership role. For evidence, registries need to be established to gather evidence on effectiveness as technology comes into use and payers begin to cover it. Payers need to stop paying for ineffective or less effective technology in order to keep health care affordable. And payers need to take more proactive leadership in developing more useful evidence. For their part, suppliers of technology need to be willing to work with payers to meet their needs by taking on "head-to-head" trials to assess relative improvement.

Kim Williams, Nuclear Cardiologist, University of Chicago

Dr. Williams addressed the dilemmas surrounding the use of new technology from a practicing physician's perspective. It is because of technological advances in cardiology treatment, he claimed, that cardiology deaths have dropped by three percent each of the last ten years. He pointed to the trade-off between cost and access; reduced reimbursement for outpatient imaging leads to increased waiting times for at-risk patients. New technologies enable earlier diagnosis, which help to decrease morbidity and mortality, makes him concerned about the consequences of attempts to cut reimbursement. In the quest for cost control, he urged that payers and policymakers not forget about patients, and to allocate resources for prevention initiatives that will reduce the need for expensive imaging technologies in the long run.

Discussion

Questions were raised about the truth and accuracy of pharmaceutical and device manufacturers studies of safety, citing fraudulent research and incomplete literature searches. Speakers acknowledged this would always be a problem when sales are dependent on positive results. At the same time, doctors are too easily influenced by drug manufacturer marketing. It is also hard to get good outcome studies on the most appropriate diagnostic applications, or comparisons of new versus old treatments, since this can vary by patient and stage of disease. Rosenberg noted the three key questions for which insufficient evidence exists regarding the value of new diagnostic devices, drugs and procedures: Is the test more effective than others? Will it lead to changes in medical practice? And will changes in treatment lead to better health outcomes or fewer complications?

Some discussion centered on how to get consumers and payers to be more involved in the accountability process. One speaker suggested that instead of asking them whether or not consumers they want the new technology, they should be asked which benefits or services they would give up to keep health care premiums affordable. At the same time, speakers admitted that it is difficult to determine how much of total premiums can be attributed to technology. Appropriate distribution of technology remains an issue of concern; more doctors have sophisticated equipment and technology in their offices, but do they all need to have it? Do all

hospitals need an MRI? Payers say they face opposition when they try to impose limits. Perhaps, offered one audience member, payers should adjust payment levels when technology is used in outpatient settings. Medicare may need to take the lead to encourage other payers to adopt such practice. Payers are best positioned to get doctors' attention, Galvin concluded.

DECISION-BASED EVIDENCE MAKING

Mark Smith, California HealthCare Foundation

Mark Smith explained the title of his talk “decision-based evidence making”, as a phrase coined by Sean Tunis, which means that rather than creating evidence and getting people to use it, one should figure out what decisions are needed and then build the evidence to inform them. Smith contrasted the principles of the Oakland A’s’ success with the principles of health services research (HSR): the A’s are fast, cheap, fanatically devoted to practical research and development, and cunning while HSR is slow, expensive, devoted to uncontaminated experiments, and a “field of dreams” (if you publish it, they will come). HSR needs an overhaul to have meaningful definitions when framing research questions, to have a quick turnaround, and to have questions driven by stakeholder priorities.

Smith commented on other issues facing HSR, including factors that drive the selection of topics and methods: money, researcher interest and skills, researcher incentives, the data available, and the potential for publishing findings. He noted that researchers often feel more comfortable observing problems than fixing them and tend to build a separate platform for their research with little interaction with the care system that they’re researching. Further, the data that researchers typically collect on patients (e.g., age, sex, race) are not important for pressing issues such as health savings accounts. More meaningful attributes include risk aversion and income elasticity.

Smith discussed the idea of health care IT as the new silver bullet. Even more valuable than the promise of cost savings that IT offers is the fact that it provides the opportunity to measure and report quality and the outcomes of policy decisions speedily and economically. In conclusion, Smith described what HSR needs: relevance, i.e., ask the users; tie research to the efforts of decision makers; speed; “good enough” precision, i.e., balancing needs with information that is good enough to use in the real world; different analytical attributes and skills, i.e., questions such as how people react to co-payments cannot be solved by using traditional attributes like race and income; and, integrated care/research with IT as the platform.

Discussion

The session chair commented that some of Smith’s suggestions are ideas have been around for a while. For example, AHRQ’s User Liaison Program asks users about their policy issues and questions to inform their research agenda, and lately both AHRQ and CMS leadership are engaged in producing research results in “real time.” Smith agreed that his ideas are not new to people, but there are institutional obstacles to getting there – “the weight of people’s incentives pushes you back.” Besides, the “near-death” experience that AHRQ encounters every few years suggests they aren’t making their case to Congressional decision makers.

Smith was asked about health IT legislation that may pass this year. Smith noted the emphasis on interoperability and said although it is important for systems to communicate with each other, there is no “single banker” to ensure interoperability in banking, so a careful balance must be struck. In response to another question about how solo practitioners or rural physicians

could ever afford the data systems that are being envisioned, Smith said that eventually, the push towards IT may persuade such doctors to join larger medical groups, or find other administrative arrangements, to be able to respond to market and policy demand for accountability.

Smith advised all health services researchers, and young people starting out in particular, to pay attention to the audience and the policy relevance of their research from the beginning. Find people who have real decisions to make in the real world, he said, and they will be more likely to fund your research. An audience member questioned whether this was realistic, when most funders' have their own priorities and interests, and private sector organizations are not necessarily interested in funding the research that would inform public policy. Smith replied that health services researchers and state policymakers must persuade Governors to advocate on their behalf, to ensure that AHRQ and other public organizations that fund HSR respond to their needs.

PRIVATE SECTOR PERSPECTIVE: CORPORATE RESPONSIBILITY FOR AMERICA'S HEALTH CARE

Robert Gavin, from General Electric, served as moderator of the session, noted that employer-based health care has had low ratings; that is, employer-based coverage often is associated with high costs and low quality, and employer-based coverage rates are declining. But Gavin noted that there is some innovation coming from the private sector in the form of managed care, disease management programs, and pay for performance. Employer-based coverage has been around for as long as Social Security, and is not likely to go away anytime soon. Gavin also noted that former Senator Thomas Daschle thinks forces are building for reform of the employer-based health coverage system.

David Blumenthal, Partners Health Care System

Blumenthal has recently examined employer-sponsored insurance (ESI), looking specifically at how it has evolved over time, and how it might change in the future. Blumenthal began with a brief history of ESI, stating that it began in the 1940s in a rather accidental way but it's now a very powerful institution. In 1934, when Social Security was adopted, it did not include health insurance. In the 1940s, during War World II, wage controls were in place but employers were allowed to expand other employee benefits and began to offer health coverage. In 1954, employer payments on premiums were made non-taxable. In 1971, ERISA law allowed large self-insured firms to withdraw from insurance pools and exempted them from state regulation. Beginning in 1992, FASB regulation began requiring that retiree medical expenses be included on employers' balance sheet.

Blumenthal noted that, in recent years, employers underestimated the market power of providers in the health system; when employers tried to push them to contain costs, providers were able to organize to counter the pressure. Employers have also largely exempted employees from their efforts, though this may be changing with the advent of new options like consumer-directed health plans. Blumenthal said that 2-4 percent of firms are now offering HRAs, HSAs, or high-deductible health plans (HDHPs), but that figure is rapidly increasing.

Blumenthal suggested that some employers are pursuing their own kind of health care reform: consumer-directed plans represent an “information treatment” for consumers to make more informed decisions. Relatively new employer strategies include disease management, and wellness and health promotion programs. Broader reform efforts, he said, include local health care coalitions to shape local markets. The best examples are the efforts of the Pacific Business Group on Health (PBGH) in California and the Buyers’ Health Care Action Group (BHCAG) in Minnesota. National efforts include Leapfrog and the National Business Group on Health.

Blumenthal suggested that employers are now deciding between two strategies when it comes to ESI: 1) staying and fighting, which large sophisticated companies are likely to do, and 2) “running for the hills”, as in the case of small employers. Blumenthal predicted that both trends would persist but ESI would become a less important part of the system over time.

Michael Critelli, Pitney Bowes

Critelli made five main points. First, the key to success for employers is a fact-based system that looks at current year costs as well as downstream costs into the future. For example, Pitney Bowes reduced the copay on maintenance drugs because the company felt it would reduce emergency room and hospital costs in the longer run. Second, Critelli said that investing in employee health is a good use of shareholder money. Health coverage helps to reduce costs through reduced absenteeism, and increased “presenteeism”, as well as greater productivity.

Third, investments in disease management or injury prevention are good investments, according to Critelli. This includes programs promoting nutrition, healthy lifestyles, and wellness and subsidized gym memberships. Critelli noted that Pitney Bowes became a smoke-free company in 1990 and provides free smoking cessation programs for its employees. Moreover, smokers who work at the company pay more for their premiums than non-smokers, at least in states where such tiers are permitted.

Fourth, employers need to apply the total quality management process to health care just as they apply it to other business processes, and need to measure performance and outcomes. Critelli said that Pitney Bowes participates in Bridges to Excellence, the pay for performance program, and provides incentives to employees to choose better providers.

Fifth, Critelli stated that employers and the broader society need to make decisions about what we will and won’t cover through health insurance. Critelli said that employers need to think seriously about whether to cover quality-of-life treatments like fertility treatments, cosmetic surgery, and knee replacement, and also decide about experimental treatments.

Mark Paul, University of Pennsylvania

The focus of Pauly’s talk was what profit-maximizing firms should do to promote worker health and provide health insurance. Pauly said at the onset that his comments referred to non-unionized firms in competitive markets. Pauly posited three hypotheses: 1) employers will

observe laws about worker health and create and maintain a safe workplace, 2) employers will invest in health care—directly or indirectly—to the extent that improves worker productivity, and 3) employers divide employees’ total compensation between wages and health benefits in ways that workers prefer.

Pauly discussed the idea of “impaired presenteeism,” or the idea of workers not being very productive at work. If workers work in teams, absenteeism or impaired presenteeism affects more than just one person’s productivity. In extreme cases, employers may cancel their employer-sponsored coverage. According to Pauly, the consequences of dropping coverage is either that the employer won’t be able to hire the quality and quantity of workers it wants, or the employer has to pay employees more money if its benefits are lousy. In contrast, employers can theoretically gain an advantage over competitors by being clever in its benefits package and creating a package that looks better than those of other employers in the market.

Pauly noted that the percentage of costs paid out-of-pocket by employees has fallen over time. In addition, while the absolute dollar figure has clearly risen, the percentage of the health care coverage premium paid by employees has remained more or less constant at 20 percent. Employer offer of coverage has fallen a little. Pauly stated that the number of high-deductible health plans (HDHPs) is still low but is growing very rapidly and predicted that 15 percent of employees will be in HSAs 20 years from now.

According to Pauly, the benefits of employer-sponsored insurance include lower administrative costs, relative to the individual market, and the tax break associated with it. The main disadvantages are that the individual has no control over their group insurance and ESI is not portable. While COBRA allows for temporary portability, those who use it are shocked by its high costs. Pauly concluded that responsible employers should: (1) pierce the veil, or level with employees about health insurance benefits and its effect on wages, (2) scare employees into taking coverage, (3) fight mandates on employers to pay a minimum amount for health insurance only if workers do not want to sacrifice five years of wage increases, and (4) design policies that lower wage workers can afford.

PUBLIC’S PERSPECTIVE ON HEALTH CARE

Robert Blendon, Harvard University

Blendon focused his presentation on results from public opinion pools conducted in collaboration with the Kaiser Family Foundation. Blendon began by stating he did not believe health care will play a large role in the 2006 elections; rather, the major issues will likely be the Iraq war, gas prices, Hurricane Katrina, and possibly the recent federal government scandals but only if indictments come before the election. He felt that Medicare would not be an issue as long as the problems of Part D implementation are resolved by May. Blendon also noted that health care was barely mentioned in President Bush’s recent State of the Union address.

A recent poll found that only 37 percent approved of the Administration’s handling of health care and 60 percent disapproved; health care was the lowest rated of all nine items inquired

about. Moreover, only 9 percent of the public felt that the country's health care system would be better at the end of Bush's second term.

Blendon explained that there is a "principle-policy gap" in health care. Polls show support for principles of change; for example, polls show support for fundamental change in the health system, government guaranteeing health insurance for all, and government helping the uninsured. A Pew Center survey in July 2005 indicated that 64 percent of respondents favored government guarantees of health insurance for all citizens.

Despite such responses regarding principles, people and especially those in the middle class don't like the trade-offs associated with putting those principles into policy. More specifically, the public will oppose policies--despite how they answer questions on principles-- if the trade-offs include: major worsening in care arrangements or premiums; a substantial tax increase; or substantial harm to the economy. The public generally doesn't understand the magnitude of trade-offs and is confused about health policy proposals.

Blendon harkened back to the Truman health plan of 1949, noting the parallels to the Clinton health plan of the 1990s. While The Truman health plan -- which basically proposed that Social Security would also pay medical bills -- began with high support (68 percent approval in 1949), once people realized it would involve more taxation, support dropped off rapidly (61 percent opposition in 1950). Poll results on the Clinton plan followed a similar pattern. Similarly, when polls present respondents with initial information on a particular policy scenario, and then provide more details, approval typically falls.

The middle class in the U.S. is risk averse, according to Blendon. Most of the middle class, and the majority of voters, however, are insured. To the extent they become worried about losing their health insurance, they may begin to support certain health policies. According to Blendon, the media/expert role is critical to health care reform. It is crucial to communicate how much a policy will cost each individual personally since most don't understand aggregate figures on a program's costs, and what the impact will be in simple terms, i.e., whether it will help them, hurt them, or result in no difference. Americans don't like rationing in health care and are most concerned about prices, rather than, say, how many prescriptions people take on average.

Although the U.S. spends 16 percent of GDP on health care, Blendon stated that the majority of Americans (77 percent) say that the country spends too little on health care. They attribute rising costs, in this order, to: (1) high profits of insurers and pharmaceutical companies, (2) the large number of malpractice lawsuits and not the size of the awards, (3) greed and waste in the system, and (4) use of high tech equipment and drugs, among other factors.

No more than 30 percent of the public understands health proposals, according to Blendon. Those who don't understand look to "influentials" to form their opinions. More specifically, strong Republicans and Democrats look to their party leaders; others cue off of experts on TV that they respect. If people can't get a simple answer from one of these sources, they will rely on political advertising.

Discussion

One audience member asked whether the country will get to a tipping point where the middle class feels threatened enough by the possibility of uninsurance. Blendon responded that voters do not respond to the slow erosion of a problem. Rather, there would have to be a precipitating event—such as GM and Ford announcing they’ll no longer provide their employees health insurance—to scare the middle class into supporting a policy.

Another audience member asked if HSAs are likely to gain support among the general public. Blendon responded that HSAs are a choice, and the public is not against choice. As long as it’s voluntary, Blendon believes there will not be a backlash. Most don’t really understand the tax implications and other details of HSAs.