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Health Law & Policy (HLP) is a publication of American University's Washington College of Law (WCL) and the Health Law Project LL.M. Program on Law & Government.

Letter from the Editors

Dear *Health Law & Policy* Reader:

It is with great pride that we present to you the inaugural issue of *Health Law & Policy*. Health law has become one of the fastest growing practice areas in today's legal world, and we, at American University's Washington College of Law (WCL), are paying attention.

Health law gained prominence at WCL in 2004 with the founding of the Health Law Project, part of the LL.M. Program on Law & Government. As health law opportunities expanded at WCL, so did student interest. Students formed a health law organization and published *The Health Law Bulletin*, a short newsletter geared toward the WCL community. Last fall, the founding editors of *Health Law & Policy* saw the potential for a substantive publication designed to reach an audience outside of our law school. We envisioned a publication with compelling full-length articles written by attorney practitioners and students dedicated to the practice and study of health law. With the support of Professor Corrine Parver, our faculty advisor and the executive director of the Health Law Project, we recruited an amazing team of staff writers and editors and began working.

In the last five months, *Health Law & Policy* has progressed from an idea to the newsstand thanks to the countless hours of effort and hard work of thirteen dedicated staff members. It has been a pleasure to bring this first issue to life with such a committed group of people. We hope that you will enjoy reading *Health Law & Policy* as much as we enjoyed creating it. We look forward to bringing you innovative and informative articles on a diverse range of topics in future issues of *Health Law & Policy*.

Sincerely,

Georgiana Avramidis
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Where The Action Is: Innovative State Health Care Initiatives

This is a unique moment in the history of health care policy. Today, according to the latest statistics, there are some 47 million uninsured Americans; consumers spend $249.4 billion on out-of-pocket health care expenses;[1] and 30.9 percent of the Hispanic population does not have a regular source of health care compared with 14.6 percent of non-white Hispanics.[2] An infinite number of plans have been created to address these issues.

As officials work at the federal level to try to come to terms with these statistics, states are already taking action. In September, when we began to organize the February 13 Symposium, we could see changes on the horizon, but we did not realize just how different the health care landscape would look like today, seven months later.

From California to Massachusetts to Pennsylvania, states are proposing innovative programs to tackle some of the most difficult health care issues. Last April, Massachusetts passed legislation that requires all individuals to purchase health care insurance and uses state subsidies to assist low-income individuals to buy insurance. California has recently proposed similar legislation.[3] In Maryland, lawmakers have proposed adding a tax to cigarette sales to pay for health care for the uninsured.[4] Pennsylvania Governor Edward Rendell recently introduced a plan to reform health care in his state through a variety of new requirements, such as requiring insurers to offer plans that could provide coverage for dependent children up to age 30.

With these monumental changes taking place, I believe that it is an understatement to say that this is an exciting time in health care policy. In February, the symposium panelists shared a wealth of information on what is currently taking place at the state level. Some of them chose to turn their remarks into an article for this issue of *Health Law & Policy*. We hope you will find their articles thought provoking and informative. Enjoy reading.

Corrine Parver, Esq.

[1] *See Growth in U.S. Health Care Spending Slows*, Forbes, Jan. 9, 2007, *available at* http://www.forbes.com/forbeslife/health/feeds/hscout/2007/01/09/hscout600814.html (last visited Mar. 5, 2007).

[2] *See* Henry Kaiser Family Foundation, *Key Facts, Race, Ethnicity and Medical Care*, at 22, Fig. 26, *available at* http://www.kff.org/minorityhealth/6069.cfm (last visited Mar. 5, 2007).

[3] *See* Ezekiel J. Emanuel & Victor R. Fuchs, *Beyond Health-Care Band-Aids*, Wash. Post, Feb. 7, 2007, at A17.

[4] *See id.*

Where the Action Is: Innovative State Health Care Initiatives

*By Congressman John Sarbanes (D-MD)**

I am very pleased to be here to speak on a topic that is close to my heart, namely, what is happening at the state level in terms of health initiatives. I thought it made sense for me to give you a perspective on these state initiatives from the federal level. My perspective comes from having represented health care providers where one gets to see, up close and personal, the real breakdown of the health care system in all sorts of ways. I became convinced that the health care system in the United States, for all its wonderful attributes, particularly in terms of the very high quality of care that *some* can afford to get, is nevertheless fundamentally broken.

Today, we are moving past the question of whether we should have universal health care coverage in this country to where everyone, for the most part, is agreeing that this is what we need. If you keep your eye on the news, you know, for example, that not only are these statewide initiatives coming forward, but there are going to be marquee CEOs out of the business community and private industry stepping forward calling for universal health care. At the federal level, there are many in Congress who see this as a moment in time when we have to leap to that conclusion as well. So the debate is narrowing, and no longer whether, we should move toward universal health care. Those of us who have been in the health care field for years should take some comfort and satisfaction in that, and keep the energy moving forward.

Now, how do we get there? I will talk about two things in terms of the relationship between a federal initiative and what is happening at the state level. First, all of these proposals at the state level include an expectation of resources coming from the federal government. Most of them are premised on the notion of increasing Medicaid eligibility by raising the federal poverty level percentage that qualifies individuals for care. Of course, when that happens, it creates expectations that the federal government will provide more dollars at a time when the deficit is such that the current administration is looking for funds wherever it can get them, which sometimes includes from government health care spending. The federal government must be a full partner in these state-led health care initiatives if they are going to work.

The second potential source of friction between the federal government and state initiatives has to do with the regulatory framework. The Wal-Mart case [*Retail Industries Leaders Association v. Fielder*] in Maryland is a perfect example of this. The law requiring employers with more than 10,000 employees to provide the appropriate amount of health care in terms of the percentage of its payroll in this case was challenged and struck down because it interfered with the regulatory scheme under ERISA. Whether Congress will step in and be more flexible with federal impediments and allow these kinds of state proposals to come forward remains to be seen.

My perspective of what can be done at the federal level, and my vision, is to enhance and expand the federal health care reform model. From a political standpoint, if one comes in with a health care proposal that is too grand in its scope, there will be a group of people who support it and another group of constituencies who resist it. Hence, a proposal, such as the Clinton proposal, dies of its own weight. The question is: What can we bring forward that politically has a chance at viability and is still substantive that will solve the health care crisis?

In my view, there are three major components to the health care system that we have now: Medicare, Medicaid, and the employer-based coverage model that sits in the middle. If we can resource the Medicare system properly by making sure that the reimbursement formulas are adequate and are such that providers have the incentive to stay in the plan, and that the right kinds of care are rewarded so that they are tailored in the direction of preventive care, for example, then we can look at expanding the coverage that the Medicare system can offer. There are a number of ways to do this. One idea is to lower the age eligibility, which would tackle the group of persons who now fall between the end of employment, in terms of the health care coverage they have, and the beginning of Medicare coverage. In the same way that we took on the issue of uninsured children through the SCHIP program, we could identify this other population as one that is at risk and try to tackle that. At the same time, we need to look at the Medicaid program and what we can do to strengthen this program to expand

* This article is adapted from Congressman John Sarbanes' Keynote Address at American University's Washington College of Law Health Law Symposium on February 13, 2007.

the eligibility requirements and bring in millions of people who are uninsured. As advocates on behalf of those who are part of the Medicaid system, the states can become allies in this cause to tackle the health insurance crisis.

When left with the beast in the middle, the employer-based coverage system, it is fair to be as creative as we possibly can. I am always anxious of proposals that invite people to opt out of the system instead of encouraging them to opt in. Otherwise, at the end of the day, we will be creating a two-class health care system where healthy people with the means to opt out are able to do it, leaving a pool that is sicker and less well off to cover its cost and its risk. Instead, we should be creating a system that invites people in so that we can share the costs and share the burden and risk. The business community wants and needs most of all a healthy and educated workforce. For their benefit, we ought to be investing in health care and education so as to channel back into the economic vitality and competitiveness of the society. Thus it is in the interest of the business community and individuals to tackle this problem and to do it creatively. Applying a new structure will be very difficult to accomplish politically, but strengthening and expanding what the current models offer will soon create a system that covers everybody and reduces administrative overhead.

Finally, the goal is to create a health care system that has some sanity to it. In hospitals, people either receive care at the highest end of the system in emergency rooms of community hospitals or they do not have health insurance coverage. Many have waited so long that their condition has reached a point where the treatment required is more expensive than if it had been treated at the front end. Hence, you are treating a lot of people whose condition has progressed to a more costly point along the spectrum, at the point in the system that has the highest cost. We can move toward a system weighted in the direction of preventive care that covers everybody at the same time. The way we do that, and the states are taking the lead on this, is by designing a basic benefits package that has significant components of preventive and primary care built into it. By doing this, we can have a saner, more cost-efficient health care system and recover a lot of the costs that have been leaking out.

There is a universal desire in America for universal health care coverage. The question is, how do we do it? This is where we have to put our minds together and be as creative as we possibly can.

“As advocates on behalf of those who are part of the Medicaid system, the states can become allies in the cause to tackle the health insurance crisis.

State Initiatives on Health Care Access: Preserving the Fraying Safety Net

*By Richard A. Millstein, J.D. & Sarah M. Steverman, M.S.W.**

> Is health care a right or an entitlement or is it a commodity, a good, or a service?

I. Introduction

In his 2002 article in the *New England Journal of Medicine*, Victor Fuchs asks, "Should health insurance be organized on the same principles as automobile or homeowner's insurance?"[1] Is health care a right or an entitlement or is it a commodity, a good, or a service? These questions must be asked to begin to explain why the United States is the only industrialized nation that does not have a system of access to health care services for all of its citizens. Over 16 percent of Americans are uninsured, with attendant problems that include: lack of or inadequate access to utilization of health care services, especially preventive services; avoiding or delaying seeking care, often leading to worse medical outcomes; and problems in terms of quality and continuity of care.[2] With respect to children, despite a number of supportive programs, one child in eight lacks health coverage, including coverage offered by Medicaid and the State Children's Health Insurance Program (SCHIP).[3]

Further, for the two-thirds of Americans who rely on employer-based health insurance, businesses have employed cost-cutting measures at a time of globalization and increasing competitiveness. These measures include increasing the employee share of premiums; decreasing the benefit package; covering the employee but not family members; moving to defined contribution plans, medical savings accounts, and insurance coverage for catastrophic illness only; and cost shifting from employees who use little care to those who use more. These measures have resulted in declining numbers of people with access to employer-based health insurance. The problem really then is not just the uninsured but also those who are under- or inadequately insured.

According to Dubay and colleagues, in their 2006 article in *Health Affairs*, "[m]ore than half of the nation's uninsured residents are ineligible for public programs such as Medicaid but do not have enough resources to purchase coverage themselves."[4] Their conclusion is that there is a need for assistance to enable them to be covered.[5] At the federal level, attention to the increasing share of the budget devoted to Medicare and Medicaid is noted, bemoaned, and decried, but not truly addressed, at least not in a systematic fashion. However, increasingly, at the state level, responses to lack of insurance and under-insurance are being introduced and experiments implemented, both in terms of increasing the number of beneficiaries with at least some degree of health care coverage and in expanding the scope of covered services. These responses vary from comprehensive reform, to targeted initiatives, to legislatively mandated studies. Common to all, though, is an apparent recognition that the unaddressed health care needs of some state residents have effects on state coffers and on all state residents. These effects are due to such macro-level effects as increased state expenditures on emergency room visits, and higher hospital and other medical care charges made to individuals and private insurers to offset losses occasioned by caring for those who lack insurance.

This article will address state responses to increase access in health care. First, state Medicaid experiments are considered. Then state health insurance initiatives, whether for all populations or for children only, are reviewed. Concluding thoughts on health disparities, inequalities, and equity are then discussed.

II. Medicaid Experiments

Medicaid, a means-tested program tied to the Federal Poverty Level (FPL), provides a living laboratory for experimentation. This joint federal-state program includes both mandatory and optional beneficiaries as well as mandatory and optional services. For 2007, the FPL yearly income is $10,210 for an individual, with increments of $3,480 for each additional household member. Thus, for a family of four, the FPL is $20,650.[6] Keep in mind two other numbers, for purposes of context and comparison. The first is that, in 2005, per capita spending on health care exceeded $6,600. Second, it no longer is unusual for the annual cost of a health insurance policy for a family to reach or exceed $10,000.

Medicaid's income limits vary by eligibility category and by state. For example, one state may cover a service for those at the poverty level while a second may expand the reach by defining the beneficiaries as those earning up to 200 percent of the FPL.[7] While primary populations at the onset of the program in 1965 were single parents with dependent children, pregnant women, the aged, blind, and disabled, some

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states permit coverage for single adults other than those in these categories. Examples of optional services are prescription drugs, home health care services, and hospice care services.

The Congressional Budget Office displays the growing pressure on government spending.[8] At the federal level, projections for fiscal year 2007 show that outlays for Social Security will account for 21 percent of all spending, For Medicare, 16 percent, and for Medicaid, 7 percent. SCHIP, a conjoint federal and state program to provide health care access to children of non-Medicaid-qualifying "working poor" or "near poor," also is experiencing calls for increased growth.[9] At the state level, Medicaid accounted for 17 percent of spending. With growing pressures from other sources of governmental spending, particularly defense at the federal level and education at the state level, governments have been struggling to maintain an adequate level of benefits to as many people as possible.

For many years the states have been seeking greater control over how the Medicaid program is administered and under what rules. In 2005, the Federal Deficit Reduction Act accorded states greater flexibility in terms of program design, benefit structure, charges to Medicaid eligibles, and the role of private insurers. Specifically, state governments were permitted to impose higher health insurance deductibles and premiums and to institute co-payments. Already, different innovations have begun to be implemented in the various states. Despite these varying programs, there are common concerns, such as the tension between increasing the numbers of beneficiaries versus maintaining the level of services to existing beneficiaries. A general theme in state reform is to increase individual costs to some extent. A delicate balance must be struck: the costs imposed must not be so high as to be burdensome to eligibles, becoming disincentives to seeking health care services, yet be of a sufficient magnitude in the aggregate for the state to avoid eliminating categories of optional beneficiaries or optional services. Some ascribe to the philosophy that requiring some cost sharing makes the beneficiary of services a more active participant. Guiding some state innovations is the understanding that individuals who no longer qualify for Medicaid will be unable to receive needed and timely services and will later utilize emergency room and hospital services, at a higher cost to the health care system.

West Virginia, starting in July 2006, is asking beneficiaries to sign a member agreement.[10] In this agreement, they commit to keeping their doctor appointments, taking medicines as prescribed, and not using hospital emergency rooms for medical needs other than emergencies.[11] Those beneficiaries who do not sign the agreement or comport with the conditions will be eligible for lesser benefits.[12] The assumption is that by taking responsibility costs will be controlled.

Florida, as of September 2006, began to privatize the Medicaid system on a pilot basis in one large city and one large county in the state.[13] In these localities, eligible individuals have a choice of health plans, each offering a different menu of services. In addition, state health officials will evaluate the health status of every Medicaid eligible and reimburse only for the level of care consonant with these officials' estimates.

Arkansas, like Florida, is looking at privatization as a way of saving money. It has received permission from the federal Medicaid program to use its Medicaid dollars to subsidize small businesses with low wage uninsured workers if these companies offer employees a basic, no frills health insurance benefit package that includes six physician office visits, seven days of inpatient hospitalization, and two outpatient hospital procedures or emergency room visits per year, and two prescription drugs per month.[14]

Kentucky is creating four categories of Medicaid eligibles, based on health and age, with different benefits offered to each group.[15]

Iowa (IowaCares) also is among those states that have expanded Medicaid eligibility.[16]

In Rhode Island, the "RIte Share Health Insurance Premium Assistance Program" directs the state's Department of Human Services to assist families in which parents earn incomes up to 185 percent of the FPL.[17] The employee must enroll in the employer-based health insurance plan as a condition of state participation.[18]

Rhode Island also has adopted a Medicaid buy-in program that permits individuals with disabilities the option to purchase Medicaid coverage.[19] One of the stated legislative purposes is to "enable individuals with disabilities to enter and reenter the work force as soon as possible."[20]

III. Health Insurance Initiatives

With increasing recognition in recent years of the toll of inadequately or under-insured residents, a number of states have begun initiatives to expand services to populations previously not covered. These may be individuals who are employed but are not offered or who decline the offer of health insurance, and their families, or those who earn more than the FPL state cutoffs, yet still cannot afford to purchase insurance on their own. As some of these initiatives may be termed or referred to as universal health coverage, it is important to define this term. "Universal

With growing pressures from other sources of governmental spending, particularly defense at the federal level and education at the state level, governments have been struggling to maintain an adequate level of benefits to as many people as possible.

health coverage" does not necessitate that there has to be a single public payer. Instead, commonly there is reliance on multiple insurance plans from the private sector.

Massachusetts law enacted in April 2006 requires all uninsured adults to purchase a health insurance policy by July 1, 2007 or face a monetary penalty.[21] The Massachusetts plan builds on the model common to this country, namely, reliance on the employer for employee health coverage, but it goes beyond how employer-based programs traditionally have been structured. As noted by Patricia Barry, "[t]he state has become the first to adopt an idea promoted by the Heritage Foundation. . . . The law sets up a clearinghouse. . . intended to link uninsured individuals and companies having fewer than 50 employees to a choice of 'affordable' health plans designed by private insurers and regulated by the state. The [clearinghouse] aims to offer [employers and employees] the advantages that many people in large employer-sponsored groups now enjoy—deeper discounts, premiums paid out of pretax dollars and an opportunity to change plans every year."[22] The policy benefits include doctor's office visits, medications, and immunizations.[23] Another benefit is that the plan is portable, meaning that individuals can keep their insurance plan when they move, switch jobs, or experience life changes.[24]

Many details still need to be worked out, including the availability of new policies, their cost, employee premiums, and the amount of the co-payments. What is known is that uninsured adults who earn less than the FPL would pay no premium; the total cost of the premium would be subsidized by the Commonwealth of Massachusetts.[25] Individuals earning up to three times the FPL can buy partially subsidized policies.[26] There will be a sliding scale of premiums, based on earnings.[27] Businesses with more than 10 employees must offer their employees a health insurance plan.[28] If they do not, then they must provide the state with a per-employee monetary contribution to help defray the state's anticipated costs in picking up the costs of health services.[29]

In Vermont, effective October 2007, a new program will go into effect for uninsured persons.[30] Unlike the plan in Massachusetts, the Vermont plan is voluntary, not mandatory.[31] The state will provide the plan, offered by contracts with private insurers, for uninsured residents.[32] Those insured will be subject to a deductible, make co-payments for office visits and prescription medications, and pay coinsurance for services and tests.[33] There will be caps on out of pocket expenses: $800 per individual or $1,600 per family for use of in-network services.[34] The premium is expected to be about $300 per month for an individual, with subsidized premiums on a sliding scale offered to those with incomes less than 300 percent of the FPL.[35] Additional incentives are provided for enrollees with certain chronic conditions, such as chronic heart failure and diabetes.[36] These individuals may participate in a disease management program that will offer certain tests and services with no deductible and at no cost.[37] As in the Massachusetts legislation, businesses - defined in Vermont as those with nine or more employees - will pay the state for each uninsured employee.[38]

Of interest is the "base" upon which the Vermont plan will build. In Vermont, in 1989, a state financed program was initiated for women and their young children who did not qualify for Medicaid. This program was expanded in 1992 to include children up to age 18, living in families earning up to 300 percent of the FPL. Perhaps not surprisingly, Vermont leads the nation in terms of health care coverage for children, with only some 5 percent not covered.

An important caveat is that the Massachusetts law makes it a legal requirement that only uninsured *adults* must purchase health insurance. As Kowalczyk noted in the *Boston Globe*, "some advocates for the uninsured are worried that some of the state's 40,000 to 78,000 uninsured children will remain uncovered if parents cannot afford health plans that cover their entire family."[39] For those families that qualify for Medicaid, coverage of children is not considered to be a burden. However, for those families that receive a partial subsidy, namely, those whose income approaches three times the FPL, the premium for health insurance for children could be prohibitive. The Commonwealth's Secretary of Health and Human Services has sent to the Legislature so-called technical corrections to the law. One of these would expand the requirement to children.

The issue is particularly apposite as the number of uninsured children has been rising of late. Until recently this was not the case. In fact, even as the number of adults without health insurance has increased in recent years, the number of children without insurance was declining. Some experts posit that the recent increase for children may be attributable to a reduction in the number of employees who receive health insurance through their employer or who choose not to participate in employer-offered plans because of increased financial burden.

In 2004, the State of Illinois enacted the Health Care Justice Act. This legislation provides that "[i]t is a policy goal of the State of Illinois to ensure that all residents have access to quality health care at costs that are affordable."[40] According to the Campaign for Better Health Care, an Illinois advocacy group, the law "encourages [the state] to implement a health care plan that provides access to a full range of preventive, acute

and long-term health care services . . . . "[41] A concrete step in furtherance of this "policy goal" was the 2005 enactment of a proposal to subsidize health insurance for uninsured children who did not qualify for SCHIP.[42] The program covers children who live in families that earn up to twice the poverty level, or $40,000 for a family of four.[43] Now, a 2006 Illinois proposal would make eligible those children who live in families that earn between $40,000 and $59,000.[44] According to this proposal, premiums would be $40 per month for each child in a family, and $10 co-payments would be required for each visit to a doctor's office.[45] The justification for this program was provided by the director of the state Department of Healthcare and Family Services: "Who is falling through the cracks? The people at poverty levels are often covered, and the people who are making a relatively substantial income are covered through their employer or health insurance they have obtained."[46]

In Minnesota, the governor has established the "Smart Buy Alliance," through which the state government and private employers, working in tandem, increase their leverage to reduce costs while improving the quality of health care and the efficiency of health care delivery.[47]

Maryland tried a different approach to increasing health insurance coverage.[48] In 2006 it enacted a law that required all employers with more than 10,000 workers in the state to either provide health coverage to its employees or pay a penalty – the so-called "Wal-mart bill," as Wal-mart was the only large employer to be covered by the legislation.[49] In court action, a federal judge found the law unconstitutional.[50]

Montana is approaching the solution to the problem of insurance under-coverage in another way. It has established a health insurance pool that small businesses voluntarily may choose to join. The legislation provides for employer incentives such as tax credits for eligible small employers who provide health coverage for their employees.[51] Further, it is expected that a small-business bill will be introduced in several states in the 2007 legislative session, including Iowa.

Rhode Island has adopted a number of targeted provisions to expand the safety net. In addition to the Medicaid buy-in program for working people with disabilities which was described earlier, in the discussion on Medicaid, the state has adopted the "Rhode Island Health Care Affordability Act of 2006."[52] Among other enhancements, this act expands health coverage to dependent children through group health insurance coverage.[53] It also reduces the cost of health insurance for small businesses.[54]

For quite a number of years, Rhode Island has had a program of state community health centers that provide primary care services to under- and uninsured state residents. In addition, Rhode Island also has passed a law to establish, on a pilot basis, a state-subsidized, income-based primary health care program to provide health coverage for state residents who lack insurance.[55] However, although the program exists in statute, no funding has been identified and tied to it. In the future, state dollars, including state and matching federal Medicaid dollars, could be among the funding sources for this program.

Through legislative action, health care reform committees have been established in Colorado and in New York. In Colorado, the "Blue Ribbon Commission for Health Care Reform" was established "for the purpose of studying and establishing health care reform models to expand health care coverage and to decrease health care costs . . . . "[56] Of interest, funding for the "development of the three to five proposals" and other study costs are made by "reducing the fiscal year 2005-06 general fund appropriation to the department of health care policy and financing, indigent care program in the children's hospital, clinic based indigent care."[57] In New York, the "Commission on Health Care Facilities in the Twenty-First Century" was charged "with examining the system of general hospitals and nursing homes in New York State and recommending changes to that system…."[58] The New York Commission's report came out in the fall of 2006. The active response to its recommendations, particularly for large cutbacks in hospitals and hospital services, while not unexpected, served to highlight the accuracy of the legislative declaration in the Colorado Act: "Health care is the largest single industry in the United States, comprising multiple public and private interests, and these interests often have competing goals and values."[59]

IV. Disparities and Inequalities

Disparities exist for children, for women, and for the elderly. Disparities and inequalities also exist for another group – recent legal immigrants. In the 1996 Welfare Reform Act, Congress made most legal immigrants ineligible for federal programs and cash assistance during their first five years in this country.[60] More than twenty states restored health care coverage to at least some of these immigrants. These jurisdictions include Maryland, Virginia, and the District of Columbia.[61] However, the Maryland budget for the fiscal year beginning July 2005 withdrew health coverage for 4,000 pregnant women and their children who had been in permanent legal residence for less than five years.[62] Subsequently, the denial was mitigated somewhat when funds were restored for prenatal care for those pregnant women then receiving care.

Yet another disparity pertains to so-called mental health parity. The federal Mental Health Parity Act of 1996 attempted to regulate discriminatory industry practices limiting mental health coverage.[63] However, the Act is limited in scope. It does not require that health insurance plans cover mental health services. It pertains only to those employers who choose to offer mental health coverage in the plans they provide. The law provides no uniform definition, but covers "mental illness" as it is defined by individual plans. Alcohol and drug abuse services are excluded. Despite hearings and proposed bills in Congress in the decade since adoption, the content of the federal law has not been expanded. Indeed, as noted by the advocacy group Faces and Voices of Recovery, in the past three Congresses, from 2001 to 2006, ". . . the majority of U.S. representatives have tried to begin to address the discriminatory treatment of people seeking care for addiction. Despite bipartisan sponsorship by 230 members of the U.S. House of Representatives (in the last Congress), the House leadership has

> For those families that receive a partial subsidy, namely, those whose income approaches three times the FPL, the premium for health insurance for children could be prohibitive.

refused to let the Paul Wellstone Mental Health Equitable Treatment Act…come up for an up-or-down vote. They have not even allowed a hearing on the bill or a vote in committee." However, of note, the federal law does not preempt state mental health parity laws. Perhaps the states, then, can become the new venue for potential expansion of the reach of mental health parity. For example, while the State of Maryland exempts from its parity legislation Medicare and Medicaid beneficiaries, as well as federal and state employees, it provides benefits for treatment of mental illnesses, emotional disorders, and drug and alcohol abuse.[64] Different state experiments in incremental enhancements, such as those just enacted in New York and in Ohio at the very end of 2006, may offer a blueprint for turning the promise of parity into an actuality.[65]

The lack of political will, coupled with the reluctance to reallocate funding, have resulted in a shift of health care policy leadership and responsibility from the federal to the state level.

V. Concluding Thoughts

The lack of political will, coupled with the reluctance to reallocate funding, have resulted in a shift of health care policy leadership and responsibility from the federal to the state level. The states, through the multiple initiatives briefly noted in this article, as well as initiatives in other jurisdictions, including Maine, Oklahoma, Wisconsin, New Jersey, Oregon, Hawaii, and the City of San Francisco, are leading the way, and are doing this despite the limitation of mandated balanced budgets. It remains to be seen how these natural experiments will play out. Will states with more generous provisions experience a significant in-migration? What will be the effect on the millions of workers who reside in one state but are employed in another? What intended and unintended consequences will unfold? With the 2007 proposal by the governor of California, the most populous state, with an estimated 6.5 to 7 million uninsured persons, as well as the 2007 proposal by the governor of Pennsylvania, at least five states – Maine, Vermont, and Massachusetts, in addition to California and Pennsylvania – have enacted or proposed plans to cover the uninsured. As well, other states are covering uninsured children.

Will these 2007 developments prove to be decisive in tipping the scale? It is noteworthy that the President, in his 2007 State of the Union Address, spotlighted health insurance for the uninsured for federal legislative action. We soon will see whether there is a shift in political will or whether the underserved will continue to experience health care disparities and inequities.

Ultimately, as the late, eminent anthropologist Margaret Mead said, the measure of any society is how it treats the most vulnerable among them.[66] In terms of this discussion, access to health services, quality of health services, cost of health care services, reimbursement for health services, and equity are intertwined and interrelated issues that transcend health, policy, politics, and ethics. How we respond to these challenges will provide the measure by which our society will be judged.

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1 *See* Victor R. Fuchs, *What's Ahead for Health Insurance in the United States?*, 346 New Eng. J. Med. 1822, 1823 (2002).
2 *See* Lisa Dubay, John Holahan, & Allison Cook, *The Uninsured and the Affordability of Health Insurance Coverage*, 26 Health Affairs 22, 26 Ex. 1 (2006).
3 *See id*.
4 *See id*. at 22.
5 *See id*. at 28.
6 *See* The 2007 U.S. Dept. of Health and Human Services Poverty Guidelines, http://aspe.hhs.gov/poverty/07poverty.shtml (last visited Feb. 14, 2007).
7 *See* The Medicaid Institute: Eligibility and Enrollment, http://www.medicaidinstitute.org/eligibility/ (last visited Feb. 14, 2007).
8 *See* The Budget and Economic Outlook: Fiscal Years 2005 to 2014, Jan. 2004, http://cbo.gov/ftpdocs/49xx/doc4985/01-26-BudgetOutlook-EntireReport.pdf (last visited Feb. 19, 2007).
9 *See* Mark Booth, Chad Chirico, Barbara Edwards, & Kathy Gramp, Monthly Budget Review Fiscal Year 2005: A Congressional Budget Office Analysis (2005), http://www.cbo.gov/ftpdocs/60xx/doc6050/01-2005-MBR.pdf (last visited Feb. 12, 2007).
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16 *See* Iowa Code § 249J (2005).
17 *See* R.I. Gen. Laws §§ 40-8.4-12(1) (2004), *available at* http://www.rilin.state.ri.us/Statutes/TITLE40/40-8.4/40-8.4-12.HTM (last visited Jan. 29, 2007).
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19 *See* R.I. Gen. Laws § 40-8.7(3) (2004).
20 *See id.* at 40-8.7(1).
21 *See* 2006 Act of Apr. 12, 2006, ch. 58, 2006 Mass. Acts Ch. 111M §§ 2(a), 13(b)(iii), *available at* http://www.mass.gov/legis/laws/seslaw06/sl060058.htm (last visited Jan. 29, 2007).
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24 *See id*.
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26 *See id*. at Ch. 118H, § 3(a)(1).
27 *See id*. at Ch. 118H, § 2.
28 *See id*. at Ch. 118H, § 188(b)(i).
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31 *See id*. at § 1974(a).
32 *See id.* at § 702(c)(1)(A).
33 *See id*. § 4080f(c)(1)(A)-(D).
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36 *See id*. § 4080f(c)(1)(E).
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43 *See id*.
44 *See* Peter Slevin, *Illinois to Unveil Insurance Program*, Wash. Post, Oct. 6, 2006, at A03.
45 *See id.*
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47 *See* Minn. Stat. § 62T (2005).
48 *See* Md. Code Ann., Lab. & Empl. § 8.5-101 (2006).
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Legal and Policy Environment for State-Based Biomedical Research

*By Jack Schwartz, J.D.**

Support for biomedical research and protection of human subjects in that research are primarily federal responsibilities. However, primacy does not necessarily mean exclusivity. Although sometimes overlooked, state laws play an important role either by extending the reach of human subjects protection beyond that afforded under federal law, addressing issues left open by federal regulation, or determining which types of research to encourage or prohibit.

I. Augmenting Protection of Human Subjects

Under the Common Rule, federally funded or conducted research must comply with regulations aimed at protecting human subjects.[1] Similarly, researchers may submit research to the Food and Drug Administration (FDA) in support of an application for approval of a drug or device only if such research adhered to the protections for human subjects in FDA regulations.[2] These parallel regulatory schemes include the following essential elements: (1) voluntary informed consent; (2) the provision of information enabling intelligent choice by potential subjects, free of coercion or undue influence; (3) review by an institutional review board (IRB), a group independent of the researchers; and (4) an IRB determination that the benefits potentially derived from the research justify the risks to research subjects.

Important gaps and limitations characterize this federal regulatory regime. Specifically, core protections in the Common Rule and FDA regulations, including additional regulatory protections for prisoners and children, do not extend to privately funded and conducted research not used in an application to the FDA. Additionally, these regulations do not afford a remedy to individuals who may have been harmed as a result of their participation in research. Also, some of the protections are just plain vague (such as an IRB's duty to include "additional safeguards" for vulnerable subjects).[3] Other issues are left unaddressed (for example, circumstances under which an individual incapable of giving informed consent may nonetheless become a research subject).

Federal regulations are modest in recognizing that state law may serve to fill in these gaps. The Common Rule is explicitly non-preemptive: the regulations do not affect state laws that "provide additional protections for human subjects" or that "require additional information . . . for informed consent to be legally effective."[4] Similar language also appears in FDA regulations.[5] Accordingly, preserving a state's role in the protection of human subjects appropriately recognizes the state traditional police power.

Under the rubric of additional protections, four states - California, Maryland, New York, and Virginia - impose an informed consent requirement for *all* research, including privately funded research.[6] Three of these states - Maryland, New York, and Virginia - require IRB review for all research.[7] In addition, many state laws provide additional protections for vulnerable populations. At least five states prohibit using prison inmates for "medical, pharmaceutical, or cosmetic experiments," although these individuals may participate in research that is "medically appropriate for a specific inmate."[8] Also, to protect nursing home residents, states frequently grant residents an explicit right to refuse to participate in experimental research or require that informed consent be obtained prior to a resident's research participation.

II. Developing the Law of "Research Negligence"

State tort law potentially affords subjects a means of compensation for research harms. In comparison, federal regulations neither require compensation in the event of injury nor create a private right of action to seek compensation; they merely require disclosure about the extent of available compensation, which may be nothing. State common law fills this void by specifying a researcher's duty to subjects and the circumstances under which a breach of this duty occurs.

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In one respect, state research liability law is well-established, arising from ad hoc experimentation during the course of clinical care. As a New York court observed more than a century ago in *Carpenter v. Blake*, when standard therapy exists, "there should be no departure from it, unless the surgeon who does it is prepared to take the risk of establishing by his success the propriety and safety of his experiment."[9] Similar cases also highlighted this point: in the clinical setting, the patient is entitled to expect the skillful application of standard therapy.[10] Consequently, the use of experimental treatment that harms the patient

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gives rise to negligence claims, unless the patient properly consented to the procedure.

More recent cases often focus on alleged deficiencies in the informed consent process. In *Daum v. Spinecare Medical Group, Inc.*, the plaintiff alleged that his physicians failed to obtain his informed consent to implant an experimental, spinal-fixation device.[11] The California Court of Appeals held that the jury should have been allowed to consider all of the evidence, not just expert testimony, in deciding whether his physicians breached the standard of care.[12] In particular, the jury should have considered the effect of federal and California informed consent requirements.[13] Because the physician-investigators had agreed to comply with FDA regulations, the regulations themselves established the standard of care. The Court then held that the plaintiff had "presented sufficient evidence that his injury resulted from the kind of occurrence the statutes and regulations . . . were intended to prevent: participation in a clinical trial without the subject's fully informed consent in writing, with a copy for the subject and under circumstances permitting a free and deliberate choice."[14] Under this analysis, failure to adhere to regulatory standards for informed consent amount to the tort of "research negligence."

In *Moore v. Regents of the University of California*, the California Supreme Court suggests that some courts view informed consent as requiring disclosure not only of the protocol-related information specified in the Common Rule but also of any material economic incentives that affect the researcher.[15] *Moore*, also arising in a clinical setting, held that a physician who used a patient's surgically removed spleen to create a patented cell line should have disclosed his research and economic interests to the patient prior to removing the spleen.[16]

A research negligence claim might also arise if research procedures are carried out in a different manner than described in the informed consent document.[17] In *Grimes v. Kennedy*, in controversial dicta, the Maryland Court of Appeals also laid the basis for claims that proxy consent (here, of a parent on behalf of a child), although permissible under the federal regulations, was deficient as a matter of state law and hence invalid.[18]

III. State Policy Decisions For or Against Research

If states deem that a particular type of research endeavor - human cloning, for example - is contrary to sound public policy, they are free to ban the research altogether. However, if a state's public policy favors embryonic stem-cell research, which some scientists seek to pursue using cloning techniques, a ban on cloning can be drafted to exclude those techniques from the ban. Indeed, several states have gone even further by using public funds to support the kind of embryonic stem-cell research denied federal funding under the policies of the Bush Administration. For example, California has established a state-funded Institute for Regenerative Medicine, which will support "open-ended, investigator-driven research related to stem cells" that is now hampered by "limited federal support."[19]

States may also facilitate research in more subtle ways. Laws protecting the confidentiality of medical records or mandating the reporting of certain diseases to a state registry, invariably allow access by researchers. Similarly, vital records laws typically have a broadly phrased research exception to their confidentiality requirements. For example, Illinois mandates the reporting of Reye's Syndrome cases which allows individually identifiable data available for "health-related research" to researchers who agree not to redisclose the data.[20] Also, public records laws, which always exempt individual health and other sensitive information from mandatory disclosure, usually allow researchers access to this information if they agree to protect the confidentiality of the records.

IV. Conclusion

In sum, current public policy on human subjects research is fractured. The federal regulatory scheme remains incomplete, and state laws vary significantly in their scope and content. This diversity, while an attractive aspect of federalism, has been criticized as inefficient and inconsistent with a research environment that increasingly involves multi-site collaborations. Nevertheless, in the absence of major federal initiatives, innovative public policy is more likely to originate from states.

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1 *See* 45 C.F.R. § 46.101(a) (2005).
2 *See* 21 C.F.R. §§ 50.1, 56.101 (2001).
3 *See* 45 C.F.R. § 46.111(b) (2005).
4 *See* 45 C.F.R. §§ 46.101(f), 46.116(e) (2005).
5 *See* 21 C.F.R. §§ 50.25(d), 56.103(c) (2001).
6 *See* Cal. Health & Safety Code § 24175(a) (2005); Md. Code Ann. Health-Gen. § 13-2002 (2006); N.Y. Pub. Health Law § 2442 (2001); Va. Code Ann. § 32.1-162.18 (2006).
7 *See* Md. Code Ann. Health-Gen. § 13-2002 (2006); NY Pub. Health Law § 2444 (2001); Va. Code Ann. § 32.1-162.19 (2006).
8 *See* 103 Mass. Code Regs. § 180.07 (2007).
9 *See* 60 Barb. 488, 523 (N.Y. Sup. Ct. 1871).
10 *See* Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 St. Louis U. L.J. 63, 70-72 (1993).
11 *See* 61 Cal.App.4th 1285, 1307-8 (Cal. Ct. App. 1997).
12 *See id.* at 1314-15.
13 *See id.* at 1317-18.
14 *See id.* at 1309.
15 *See* 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).
16 *See id.*
17 *See Grimes v. Kennedy Krieger Inst. Inc.*, 366 Md. 29, 41-43 (Md. 2001).
18 *See id.*
19 *See* Draft Scientific Strategic Plan (Oct. 2006), California Institute for Regenerative Medicine, http://www.cirm.ca.gov/meetings/pdf/2006/10/Strat_Plan_100406.pdf (last visited Nov. 2, 2006).
20 *See* Ill. Stat. Ch. 410, § 245/4(3) (1979).

Promoting Racial Equity in Health Care: Access and Quality Initiatives at the State Level

*By Daniel O'Brien, J.D.**

National studies demonstrate that a patient's race, ethnicity and socioeconomic status seriously impact when and if an individual can get into a doctor's office.

National studies demonstrate that a patient's race, ethnicity, and socioeconomic status seriously impact when and if an individual can get into a doctor's office. These factors also impact what happens once the door opens. States have a role in changing this situation. Unfortunately, it is not entirely clear what array of legislative, regulatory, and fiscal interventions can most effectively attack these problems.

The National Healthcare Disparities Report for 2005 documents the inequities that continue to plague our health care system. Minorities and the poor generally suffer higher mortality and morbidity rates that do whites. Minorities and the poor receive lower quality care. They are also less able to access the services that are available. For racial minorities, the "quality gap" is significant even though it has diminished slightly in recent years. For Hispanics, the disparity in health care quality continues to worsen. The same appears to be true of health care access measurements. African-Americans and other racial minorities report slightly better access in recent years; Hispanics report increasing barriers to the health care system.[1]

I. State Efforts to Promote Equity in the Health Care System

Two years ago, Maryland's General Assembly adopted legislation aimed at attacking these disparities.[2] This initiative gave rise to the "Maryland Plan to Eliminate Health Care Disparities," which offers a preliminary roadmap for coordinating policy efforts in the field. The Maryland Plan seeks to identify the nature and extent of existing disparities, understand their causes, and design interventions to eliminate these differences.[3]

Public health prevention is a sound investment.

At the state level, three factors will continue to influence the rise and fall of health disparity trends. First, will underserved communities have reasonable access to public health prevention programs? Second, to what extent will these communities be better able to access needed health care? Finally, at the individual practitioner level, will strategies emerge to eliminate unexplained deviations from accepted clinical norms?

Legal considerations are likely to influence each of these racial equity elements. Statutes, regulations, and grants will need to be drafted. Licenses, contracts, and certificates of need will be awarded. Licensing and disciplinary actions will be prosecuted. The law certainly will not solve this problem, but legal strategies can strengthen the movement to build a more equitable health care system.

II. Prevention as the First Order of Business

Public health prevention is a sound investment. This is especially true in the field of chronic disease prevention. The U.S. Department of Health and Human Services estimated in 2000 than 46.7 percent of all U.S. deaths were attributable to modifiable health behaviors such as smoking, poor diet, and alcohol use.[4] Chronic disease treatment is the primary driver of health care costs. Researchers believe that nearly 75 percent of health expenditures are related to preventable chronic disease treatments involving conditions such as diabetes, hypertension, and obesity.[5]

To the extent that racial and ethnic minorities shoulder a higher disease burden than other communities, preventive health programs can have a significant impact on individual health outcomes. The design and implementation of these prevention programs can be enhanced through the effective use of legal analyses and strategies.

Mandatory Vaccination Laws: In a series of legal reviews conducted for the Centers for Disease Control & Prevention (CDC), Professor Sara Rosenbaum highlighted significant differences in state immunization laws.[6] These studies demonstrate that the manner in which governing statutes reference clinical standards, define personal exemptions, and formulate due process protections can impact childhood immunization rates. A public health program that increases vaccinations for African-American and Hispanic children who previously lacked access to routine medical care clearly promotes a more equitable health care system.

Lead Paint Remediation Programs: For children, lead paint exposure may cause a range of adverse health consequences including reduced IQ, attention deficit disorders, impaired hearing, and kidney damage. At

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high levels of exposure, a child may become mentally retarded, fall into a coma, and even die from lead poisoning.[7] Like many states, Maryland adopted statutes designed to enhance lead paint remediation programs.[8] These programs also provide funding for community outreach and case management services.[9] Again, to the extent that a minority population suffers from increased exposure to adverse environmental conditions, prevention and abatement programs that reduce this exposure lower the overall disease burden and help reduce future health disparities caused by this exposure.

Tobacco Litigation and Prevention: Perhaps the most significant public health campaign over the last quarter century focused on the tobacco industry. Over time, individual damage actions gave rise to state Medicaid recovery claims. Subsequent settlement agreements imposed advertising restrictions on the industry and provided states with funding to support a range of health promotion efforts.[10] Maryland reserved some of these funds to support prevention programs in minority communities adversely affected by cigarette marketing strategies.[11] A properly framed litigation strategy can assist underserved populations in securing better access to needed care. For example, California's Public Health Trust has used class action and *cy pres* recoveries to support improvements in heath care services for a number of special populations.[12]

III. Access

At the heart of the health care access debate lies an unresolved policy question: Does this nation consider assuring access to a reasonable measure of health care services a personal right, an individual obligation, or a mere privilege to be meted out as finances permit? On balance, the nation continues to treat health care access as something of a privilege and not a right. Racial equity in the health care system cannot be achieved if large segments of the population lack the financial means to access medical services.

The debate concerning access to health care insurance is again taking center stage in many state legislatures. While this broad debate continues to play out, it is worth noting the ways in which incremental progress can still occur. At the national level, the Clinton Administration's effort to expand the Children's Health Insurance Program was a key incremental gain. Similar efforts are possible at the state level.

Expanded Access to Community Clinics: Recent Maryland legislation created a funding pool aimed at supporting the growth of local health care services.[13] The Commission administering these funds seeks to identify underserved areas and enhance the ability of underserved populations to access health care.

Increasing the Number of "Historic Providers:" As health care reform proceeds, licensed providers based in a minority community will face new economic challenges. Maryland addressed this problem in the context of moving its Medicaid population into a managed care program. State legislation encouraged newly created managed care organizations to include practitioners who "historically have served the community" in their provider panels.[14] While this helps preserve the limited physician practices that have historical roots in underserved communities, additional emphasis and funding is needed to make specialty services available to many minority communities. [15]

IV. State Efforts to Reduce Health Care Disparities

As noted in the National Healthcare Disparities Report for 2005, there is a statistically significant gap in the overall quality of healthcare services provided to racial minorities in America:

[D]isparities related to race, ethnicity, and socioeconomic status still pervade the American health care system. While varying in magnitude by condition and population, disparities are observed in almost all aspects of health care, including:

- Across all dimensions of quality of health care including effectiveness, patient safety, timeliness, and patient centeredness.
- Across all dimensions of access to care including facilitators and barriers to care and health care utilization.
- Across many levels and types of care including preventive care, treatment of acute conditions, and management of chronic disease.
- Across many clinical conditions including cancer, diabetes, end stage renal disease, heart disease, HIV disease, mental health and substance abuse, and respiratory diseases.
- Across many care settings including primary care, dental care, home health care, emergency departments, hospitals, and nursing homes.
- Within many subpopulations including women, children, elderly, residents of rural areas, and individuals with disabilities and other special health care needs.[16]

"Does this nation consider assuring access to a reasonable measure of health care services a personal right, an individual obligation, or a mere privilege to be meted out as finances permit?

These deficits cannot be explained by differences in age, sex, geography, lifestyles, diet, or a myriad of other factors.

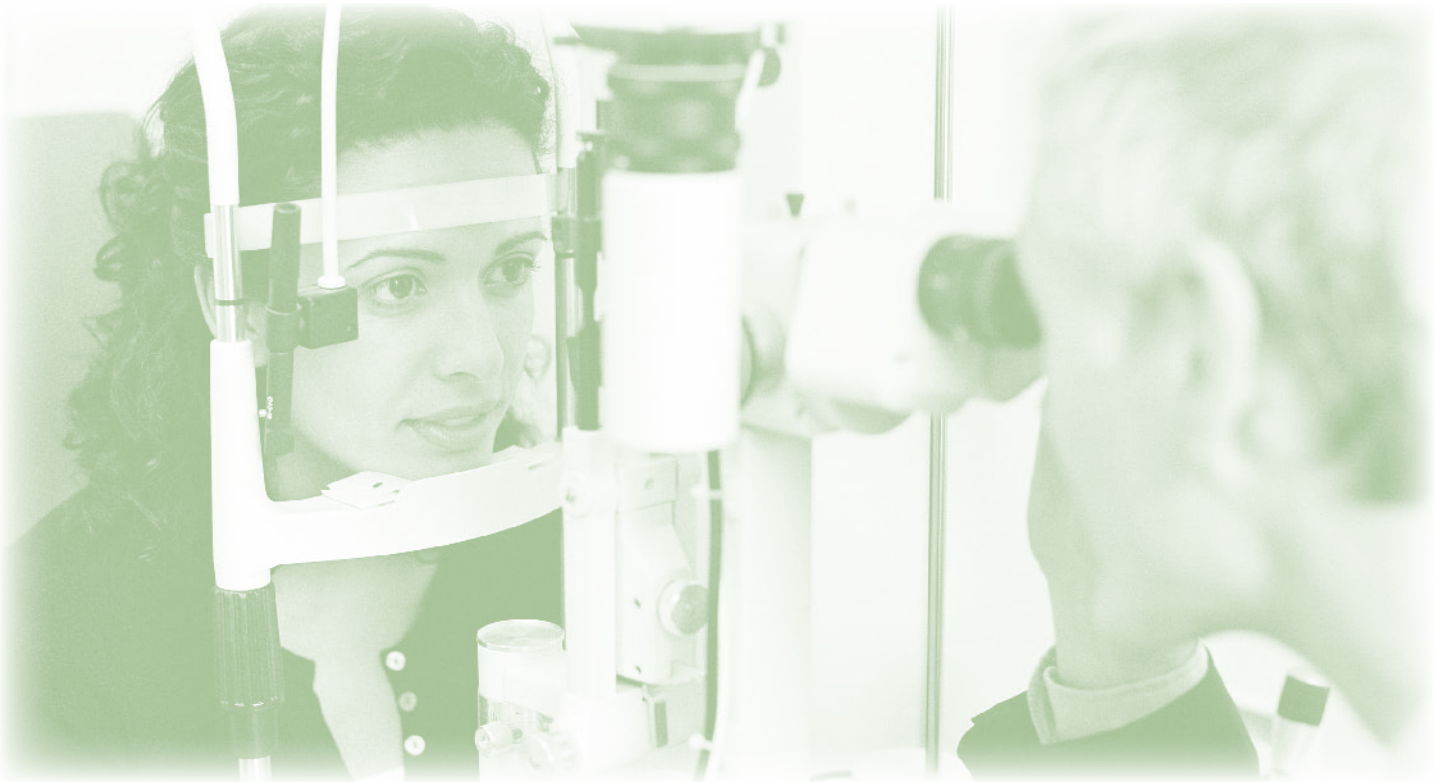
There is clearly an argument that expanding access to high quality health care services can remedy some portion of the racial and ethnic disparities problem, but there is also more to be done. The following types of initiatives may prove beneficial in bringing racial and ethnic equality to the health care system.

"There is clearly an argument that expanding access to high quality health care services can remedy some portion of the racial and ethnic disparities problem . . .

"Report Cards" and Quality Measurements: An important milestone in the effort to address health care disparities is creating an awareness that these differences exist. Knowledgeable patients may be able to advocate for more equitable treatment. As more disparities data becomes available, "report cards" can be used to alert consumers and payors about the comparative ability of different providers to achieve quality goals. The Maryland Medicaid Program now tracks certain quality indicators and has created financial incentives to improve provider performance.

Workforce Diversity and Cultural Competence: Minorities are seriously underrepresented in many of the health care professions. Under-representation in the provider ranks exacerbates access and cultural competency problems in the overall health care setting. Means exist to address these issues. Professional schools retain the ability to increase minority enrollment and to focus all students' attention on the prevalence of health care disparities. Later, health care licensing boards may impose continuing education requirements on licensees after graduation. All of these efforts could be combined with private sector initiatives to improve access to bilingual health care services such as those provided by CASA of Maryland, Inc.[17]

Economic Incentives to improve Health Care Quality and Consumer Participation: State health programs have begun to incorporate financial incentives into the design of health care programs for underserved populations. While not without controversy, West Virginia's Medicaid program has moved to condition a patient's continued receipt of certain Medicaid benefits on compliance with an established plan of care.[18] Overall, the impact of these incentives to secure long-term individual improvements in clinical outcomes is uncertain.[19] Nevertheless, efforts to eliminate disparities at the practitioner level are unlikely to be achieved solely through provider education and regulatory enforcement actions. The active involvement of the patient in achieving this goal is also important.



V. Conclusion

It is simple enough to assert that health care disparities exist. The more difficult question is determining which specific communities are affected and why. There has been some progress in answering these questions. A still more difficult task is to formulate strategies to eliminate these differences. States clearly have the epidemiological tools needed to frame the debate. They also have the regulatory and fiscal power to encourage providers, health insurers, and even patients to move the debate into forceful action.

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2 *See* Md. Health-Gen. Code Ann. § 20-1004 (2006).
3 *See* Maryland Plan to Eliminate Health Disparities, *available at* http://www.dhmh.state.md.us/hd/pdf/MDPlantoEliminateHealth Disparities Preliminary2006.pdf (last visited Feb. 11, 2007).
4 *See* Ali H. Mokdad et al., *Actual Causes of Death in the U.S.*, 291 JAMA 1238, 1238-41 (2004).
5 *See* National Business Group on Health, The Role of Clinical Preventable Services in Disease Prevention and Early Detection 26, *available at* http://www.businessgrouphealth.org/ prevention/purchasers/guide/part1.pdf (last visited Feb. 11, 2007).
6 *See* Sara Rosenbaum & Alexandra Stewart, George Washington University Medical Center, *Translating CDC Immunization Guidelines into Practice: State Laws Related to the Use of Standing Orders Covering Immunization Practice* (2006), *available at* http://cdc.confex.com/cdc/nic2006/techprogram/P10022.HTM (last visited Feb. 21, 2007).
7 *See* National Safety Council, Lead Poisoning (2004), http://www.nsc.org/library/facts/lead.htm (last visited Feb. 11, 2007).
8 *See* Md. Env't. Code Ann., §§ 6-801, 6-848 (2006).
9 *See id*. at § 6-848 (2) (2006).
10 *See* Md. Health-Gen. Code Ann. §§ 13-1101, 13-1119 (Supp. 2006).
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12 *See* Public Health Trust, Linking Settlement Funds to Community Needs, http://www.publichealthtrust.org/settlements/index.html (last visited Feb. 11, 2007).
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14 *See id*. at § 19-2111(b)(2) (Supp. 2006).
15 *See id*. at § 19-2111 (Supp. 2006).
16 *See* Disparities Rep., *supra* note 1, at 2.
17 *See* CASA of Maryland's Health Program- Bilingual Health Hotline, http://www.casademaryland.org/Health_md.htm (last visited Feb. 11, 2007).
18 *See* Gene Bishop and Amy C. Brodkey, *Personal Responsibility and Physician Responsibility – West Virginia's Medicaid Plan*, 355 New Eng. J. Med. 756, 756 (2006).
19 *See* Agency For Healthcare Research & Quality, No. 101, Economic Incentives For Preventative Care 3 (2004), *available at* http://www.ahrq.gov/clinic/epcsums/ecincsum.pdf (last visited Feb. 11, 2007).

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60 *See* Personal Responsibility, Work Opportunity and Medicaid Restructuring Act of 1996, Pub. L. No. 104-193, §§ 401-3, *available at* http://www.libertynet.org/edcivic/welfbill.html (last visited Jan. 29, 2007).
61 *See* Mary Otto, *State to Restore Some Coverage to Immigrants*, Wash. Post, Oct. 20, 2006, at B06; Wendy Zimmermann & Karen C. Tumlin, *Patchwork Policies: State Assistance for Immigrants Under Welfare Reform*, 64 Tbl. 8 (Urban Inst., Occasional Paper No. 24, 1999), *available at* http://www.urban.org/UploadedPDF/occ24.pdf (last visited Jan. 29, 2007); Karen C. Tumlin, Wendy Zimmermann & Jason Ost, *State Snapshots of Public Benefits for Immigrants: A Supplement Report to "Patchwork Policies,"* 17 (Urban Inst., Occasional Paper No. 24, 2004), http://www.urban.org/UploadedPDF/occa24_sup.pdf (last visited Jan. 29, 2007).
62 *See* Mary Otto, *State to Restore Some Coverage to Immigrants*, Wash. Post, Oct. 20, 2006, at B06.
63 *See* the Mental Health Parity Act of 1996, P.L. 104-204.
64 *See* Md. Code Ann., Ins. § 15-802 (1994).
65 *See* Timothy's Law (2006) New York Senate Bill 8482; Ohio Sen. Bill 116, 126th Gen. Assem. (2006), *available at* http://www.legislature.state.oh.us/bills.cfm?ID=126_SB_116 (last visited Jan. 29, 2007).
66 *See* Margaret Mead, The Changing Significance of Territoriality in Human Societies, Presentation at the National Institutes of Health (Oct. 17, 1973).

Federal Efforts to Impose Uniformity in Health Care Regulations: Peer Review

*By Edward J. Krill, J.D.**

The value of open communication among practicing physicians, without fear that their comments could be used to establish malpractice liability, is universally seen as essential for improvement of quality in the delivery of health care services by physicians.

Since the development of the Standards for Hospital Accreditation promulgated by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), hospitals have been required to maintain an organized medical staff.[1] Part of the duties and responsibilities of the medical staff is to credential physicians applying for hospital privileges and to enforce standards of quality care and adherence to the administrative requirements of the hospital. Current hospital peer review procedures are a direct result of the JCAHO's mandates in this regard. Additionally, all accredited hospitals have organized a committee process to evaluate new applicants for the medical staff, to determine the scope of their privileges, to evaluate the renewal of privileges based on their performance, and to address concerns regarding practice below the applicable standard of care by individual physicians.

The peer review process is remedial and corrective, not punitive. The value of open communication among practicing physicians, without fear that their comments could be used to establish malpractice liability, is universally seen as essential for improvement of quality in the delivery of health care services by physicians.

This process has been protected in the laws of District of Columbia[2] and elsewhere[3] as necessary to quality assurance, based on the belief that physicians are in the best position to evaluate and oversee the clinical performance of each other. The proceedings of these peer review committees have generally been immune from discovery in civil litigation and inadmissible in court proceedings such as a malpractice case against the subject physician.[4]

The rationale for this protection has been that if the minutes and records of peer review discussion and physician evaluation serve as evidence, they would have significant weight as expert opinion and their use would have "a chilling effect" on the entire review period. Physicians involved in the evaluation of their colleagues would not volunteer to sit on such committees, considering that their comments could end up being used against them in court, in the press as criticism of the subject physician, in the peer review process, and even in the hospital at which the patient care took place.

The rule in the District of Columbia has been that the underlying medical records are certainly discoverable by a plaintiff in a medical malpractice case,[5] but that peer review committee meeting minutes, where those same records could be evaluated, would be off limits to the plaintiff.[6] The practical effect is that plaintiffs are required to obtain their own expert evaluation and to present their own expert testimony and cannot "piggyback" on what a hospital peer review committee did or said about the particular case.

By differentiating between the underlying factual material, including the entire medical record, and the opinions, statements, and expressions of peer review committee members or special reviewers, the District of Columbia has joined virtually all jurisdictions in the United States in putting these mental impressions, work product, opinions, and recommendations of peer review committee use "off limits" to plaintiffs in medical malpractice cases. A recent survey of peer review statutes in the United States demonstrates this relative uniformity.[7]

The state Boards of Medicine are responsible for the licensing of physicians to practice in their respective jurisdictions. Part of this responsibility includes taking disciplinary actions against physicians who have demonstrated an inability to provide patient care that meets the applicable standards of the medical profession. Under the rules of the National Practitioner Data Bank, hospitals that take final adverse action against physicians, for any reason, must report that to the Data Bank when the action involves a suspension of hospital medical staff privileges for more than 30 days, termination of privileges, or other serious discipline.[8] Medical boards throughout the United States monitor the Data Bank and, as in the District of Columbia, are notified that such action has been taken against the physician and receive a brief summary of the grounds for that action.[9]

At this point, the Medical Board would normally proceed further to determine whether or not there was any basis for action beyond that taken by the hospital. Some examples of such actions include suspension of a physician license, remedial action, e.g., mentoring or actual termination of a license. The Board would then exercise its subpoena power to attempt to obtain

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all the information it could from the hospital that took the initial action and this is the point in time when these issues, which are the subject of this article, become joined. Query whether under the laws of each state the hospital can assert the peer review privilege and successfully seek to quash that subpoena.

Hospital medical staffs have a legitimate and well-recognized responsibility to perpetuate and protect the peer review process. Medical Boards have a similarly well-recognized duty to protect the public from physicians who are not capable of adhering to the standards of the profession.[10] The question is how a hospital's peer review organization can accommodate the needs of the Medical Board without compromising the immunity from discovery and protection from being used to prove a malpractice case.

It is understood that hospital medical staff activities are private in nature and that the Board of Medicine of the District of Columbia is a public body whose records are subject to Freedom of Information Act requests, and which holds public hearings and publishes the results of its decisions on its website.[11] Presumably, the entire transcript of a hearing before the Medical Board or before a hearing officer appointed by the Medical Board to gather evidence, including all oral testimony and exhibits, is available to members of the general public once a case has gone to a final decision.

In civil litigation, when one party is seeking documents that are viewed as privileged from discovery or confidential or highly sensitive, a process exists for balancing the rights of the parties requesting this information to support his case in litigation versus the rights of the persons and other parties mentioned in the records that may have a right of privacy or need for protection from public disclosure. An excellent example of what a court might deal with in this regard would be child abuse records where the names of innocent children are found in reports regarding an abuser. In this situation the party demanding production of the documents is typically told by the custodian of the records that they will not be produced and why. If the party requesting the records does not agree with the rationale for withholding the records or redacting the records to eliminate the names of individuals, this can be brought before a judge for resolution. After both sides are provided an opportunity to state why, on the one hand, the records should be produced and, on the other hand, why they should be either redacted or withheld entirely, courts typically issue the ruling which is usually described as a "protective order."

Hearings before judges on matters of discovery rights, privacy and privilege are commonplace, especially in medical malpractice cases, and take into account one party's need for the information as well as the other party's desire to protect individual privacy, trade secrets, business reputation, and so forth. This approach is recommended where a hospital review organization wishes to withhold basic documents from the Board of Medicine.

The utility of both parties appearing before a judge to sort out what should be produced and what might be withheld can be illustrated by looking at the kinds of documents that a peer review organization might have. In a matter involving serious discipline, there may have been a hearing before a panel of physicians specially appointed to hear the case. In that situation, the hearing would include the presentation of an evaluation of each case under review by, for example, the chairman of a particular department in the hospital. There might be follow-up testimony by an expert in the field retained for an independent review of the cases in question. The subject physician may have retained his or her own expert to rebut the findings of the hospital's peer review committee and especially retained independent expert. Witnesses to what occurred in various cases might not appear and testify as to what they saw, what was done, and so forth. Throughout, members of the peer review panel might ask questions of witnesses and might express their points or opinions for the record. Finally, the subject physician would testify in response to the criticisms on a case-by-case basis, additional witnesses might be called and the peer review committee would adjourn to discuss the appropriate action that it would recommend. Typically, this recommendation is provided to the subject physician and to the medical executive committee for final action, along with a summary of the testimony, selected exhibits, the opinions of the peer review panel, and its recommendations. This would then be discussed by the Medical Executive Committee, which typically has the authority to finalize a remedy or disposition of that action, unless appealed to a higher body. If this is provided for in the by-laws, then it would become the final action of the hospital staff and would then be reported to the Data Bank.

"The question is how a hospital's peer review organization can accommodate the needs of the Medical Board without compromising the immunity from discovery and protection from being used to prove a malpractice case.

One can easily see that this record provides a mix of substantially different kinds of information. In this situation, a judge looking at the entire proceedings might decide that the medical records that were the subject

of the hearing, the testimony of the subject physician, and the final decision of the Medical Executive Committee be turned over to the Medical Board, while the on-record discussions of the members of the peer review panel, the testimony of various experts, draft statement of facts, draft report to the Medical Executive Committee, and so forth, not be produced. This would put the Medical Board in the position of having just about all factual information that the peer review committee worked with, but none of the opinions of individual peer review members or the debates or discussions of the panel or the Medical Executive Committee. That should be sufficient for the Medical Board to conduct its own separate evaluation.

> Admitting a mistake is frequently seen as a strong indication of willingness to correct the problem.

One of the values to be protected regarding peer review is the opportunity for candor, frank statements, and discussions by all participants. If the subject of a peer review meeting or hearing knew that the licensure authorities could later use anything said in that context against him or her, the strategy might be to say nothing that could be seen as an admission of wrongdoing, poor quality, or a violation of hospital policy.

One of the purposes of peer review activities is to bring them to the attention of the subject physicians, identify problems, and ask for remedial action. If any part of that dialogue could support the suspension of a physician's license or other public disciplinary action, the subject would be extremely reluctant to admit anything. That could tend to discourage the formal peer review activity and to encourage dialogue "off the record" which can be very problematic in a situation where there are undocumented repeated problems. Admitting a mistake is frequently seen as a strong indication of willingness to correct the problem.

Disclosures of information by the hospital's peer review committees to the Medical Board should be sensitive to the problems that will arise if subject physicians believe they have to fight every allegation or criticism of their patient care to avoid admitting to grounds for licensure discipline. For this very important reason, unless a medical staff peer review matter proceeds to a formal hearing, a Board of Medicine should never attempt to obtain or provide records and documents from the preliminary stages of quality assurance, case evaluation, and discussion, nor the opinions of members of any peer review panel, hearing body or outside expert.

The encouragement for uniformity in peer review that the Health Care Quality Improvement Act sought to achieve is only partial. What remains to be assessed is whether some accommodation can be reached between hospital peer review bodies and licensure boards who are on notice of problems because of reporting to the National Practitioner Data Bank that maintains the protection necessary for voluntary peer view to continue.

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1 Accreditation materials available from the Joint Commission on Accreditation of Healthcare Organizations, One Renaissance Boulevard, Oakbrook Terrace, Illinois 60181.
2 *See* D.C. Code §§ 44-801-5 (2001).
3 *See* William Bremer, *Scope and Extent of Protection from Disclosure of Medical Peer Review Proceedings Relating to Claim in Medical Malpractice Action*, 69 A.L.R.5th 559 (1999).
4 *See* Jack Spalding Schroder, Jr., Peer Review Records: Keeping Them Privileged, Presentation to Hospitals & Health Systems Law Institute, American Health Lawyers Association (March 2-3, 2000) *available at* http://www.alston.com/articles/PeerReview.htm (last visited Feb. 28, 2007).
5 *See* D.C. Code §§ 44-801(7), 805(a)(1) (2006).
6 *See Jackson v. Scott*, 667 A.2d 1365 (D.C. App. 1995).
7 Unpublished survey on file with author, copies available upon request.
8 *See* 42 U.S.C. § 11101 (2007).
9 For a thoughtful criticism of this requirement, *see* Bryan G. Hall, *The Health Care Quality Improvement Act of 1986 and Physician Peer Reviews: Success or Failure?*, *available at* http://www.usd.edu/elderlaw/student_papers_f2003/health_care_quality_improvement_act.htm (last visited Feb. 28, 2007).
10 *See, e.g. Spinks v. Childrens National Medical Center*, 12 F.R.D. 9 (D.D.C. 1989) (holding that the minutes of a Mortality and Morbidity Committee were privileged peer review documents and that the statements of eye witnesses made to the Committee were outside the scope of discoverable information).
11 *See* Board of Medicine website, http://hpla.doh.dc.gov/hpla/cwp (last visited Feb. 28, 2007).

Federal Efforts to Impose Uniformity on State Health Information Privacy Laws

*By Joy L. Pritts, J.D.**

Over the last several years, there have been repeated federal efforts to impose uniformity on state health information privacy laws. This article discusses the historical background of state regulation of health information privacy, recent efforts to preempt state health privacy laws, and reasons these efforts are not likely to succeed.

I. Background

The power to regulate health primarily resides with the states. According to the National Governors Association, individual states have regulated the creation and management of medical records for over 150 years.[1] Towards the end of the 20th century, states began to adopt statutory provisions to regulate the confidentiality or privacy of health information, a matter which had previously been primarily addressed through professional ethics. Presently, every state has statutes and regulations governing the use and disclosure of health information.

Beginning in the 1970s, states began passing comprehensive health privacy laws intended to promote patients' full participation in the healthcare system by fostering trust between patients and healthcare providers.[2] These detailed statutes are based on established fair information practice principles. While the respective state statutes are somewhat similar in their core principles of notice, disclosure, secondary use, correction, and security, they often differ in the details, such as the required contents of consent authorization forms.

In response to health needs of their citizens, most states enacted laws to enhance privacy protections for information related to specific medical conditions that are associated with stigmas or discrimination, such as HIV/AIDS or mental health conditions. Generally, these statutes require specific, informed, and written patient authorization before information related to these "sensitive" medical conditions may be shared with others. These laws are intended to encourage individuals to pursue testing and treatment by providing patients with the assurance that their most sensitive health information will be treated with the highest degree of confidentiality. Additionally, most states developed common law whereby tort actions based on a theory of invasion of the right to privacy are used to redress wrongful disclosures of health information. However, levels of privacy protection continued to vary widely by state. By the 1990s, some states had broad, detailed privacy protections for health information while others offered few protections.[3]

II. The HIPAA Privacy Rule

As efforts to encourage the health care industry to adopt computer technology intensified, the need for federal standards to protect the privacy of health information became further apparent. In 1996, Congress addressed the issue of health information privacy within the context of the Health Insurance Portability and Accountability Act (HIPAA). The Administrative Simplification provisions of HIPAA were intended to encourage the development of an electronically based health care system. Congress gave itself a three-year deadline to enact comprehensive health privacy legislation designed to protect individuals' identifiable health information. As a fallback provision, if Congress failed to act within three years' time, the task of promulgating health privacy standards would shift to the U.S. Department of Health and Human Services (HHS). HIPAA expressly provides that if federal regulations are indeed promulgated, the federal mandates would not supersede a contrary provision of state law where the state standard is more stringent than that imposed by federal regulations.

Congress failed to pass comprehensive health privacy legislation within the self-imposed deadline. Some of the key stumbling blocks included hot-button privacy-related issues that continue to plague national policy debate, including reproductive rights and the treatment of minors' medical information, and tort reform issues of whether individuals should have the right to sue for wrongful disclosure of health information. When the 1999 deadline passed, in accord with HIPAA's requirements, the duty to craft federal health privacy protections passed to HHS.

In the waning days of President Clinton's second term, his administration issued the first version of the HIPAA Privacy Rule. The Bush administration allowed the rule to go into effect in 2003, only after making significant changes to the original rule. Under the current HIPAA Privacy Rule, with the exception of psychotherapy notes, all health information is handled in the same manner: it can be disclosed for treatment, payment, and

> Under the current HIPAA Privacy Rule, with the exception of psychotherapy notes, all health information is handled in the same manner: it can be disclosed for treatment, payment, and health care operation purposes without first obtaining the individual's permission.

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health care operation purposes without first obtaining the individual's permission.[4] Although patients have the right to file complaints with HHS for violations of the Rule, they have no private right of action against the individual HIPAA violators.

Throughout the rule-making process, HHS consistently reiterated that it was establishing minimum federal standards which would not disturb more protective state laws. HHS explained that the Privacy Rule was "a new federal floor" establishing a set of basic consumer protections that states could choose to broaden or expand upon.[5] In short, the Privacy Rule was built on the understanding that it would serve as a minimal floor of protection and that state laws affording higher protections would be preserved.

As a result, many state laws still remain in effect today. Such laws afford heightened protections for sensitive medical information, particularly with regard to information related to genetic testing, HIV/AIDS, or mental health. Typically, states upholding more stringent standards will require that an individual's authorization or consent be obtained before this information may be shared beyond the originating health care provider. States also continue to enforce their own health privacy laws and afford their citizens the right to sue for improper disclosures of their privacy or to obtain their medical records.

III. Renewed Efforts to Preempt State Law

In 2004, the Bush administration released its outline of a ten-year plan to build a nationwide electronic health information infrastructure in the United States.[6] As this plan has progressed, there has been a renewed interest in wholly preempting state health privacy laws through new federal legislation. In 2005, the Healthcare Leadership Council, a coalition primarily comprised of health researchers and health industry executives from pharmaceutical and insurance companies, urged Congress to fully preempt state health privacy laws and to make the HIPAA Privacy Rule the single national health privacy standard.[7] Shortly thereafter, Representative Nancy Johnson (R-CT) introduced the Health Information Technology Promotion Act of 2005 (H.R. 4157), which seemed to pave the way for federal preemption.[8] H.R. 4157 required HHS to conduct a study of existing federal and state health information privacy laws and report to Congress with recommendations on how to "harmonize" the array of standards. According to the bill, if Congress failed to enact legislation based on the study's results within three years, HHS would then have the authority to propose a single set of federal standards preempting state health privacy laws. Essentially, H.R. 4157 permitted the preemption of state law by default. Though this provision proved to be extremely contentious and was removed from the final version of the bill passed by the House in September 2006, the separate authorization of the HHS study of state health privacy laws did remain.[9]

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HHS's Agency for Healthcare Research and Quality has undertaken a nationwide project to assess and address the impact of organization-level business policies and state laws on security and privacy practices, and examine the degree to which they pose challenges to interoperable health information exchange.[10] Under the project, 33 states and one territory are to identify variations in state privacy practices and laws that represent "barriers" to health information exchange and then propose practical solutions to remedy the problems.[11] States were instructed that their recommendations could encompass changes in state and federal laws and regulations.[12] Privacy advocates have expressed concerns that the project could actually be used to encourage federal preemption of those state and local laws intended to protect the privacy of patients' medical records.[13] The established April 2007 deadline for states to issue their final reports summarizing the observed variations and proposed solutions is rapidly approaching.

IV. Future Prospects for Preemption

Even if current attempts to "harmonize" the diversity in state health privacy laws prove unsuccessful, efforts to fully preempt state health privacy laws are unlikely to subside any time in the near future. Many professionals in the health care industry have strong incentives to push for a single minimal federal health privacy standard. Allowing professionals to share all health information without first obtaining individual consent would undoubtedly be easier and less expensive than complying with current requirements.

However, it remains questionable whether one federal standard for protecting health information is appropriate. First, states *are* different both in the health status of their populations and in their approaches to furthering public

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health goals. The states have occupied the medical record/health information field for decades and continue to serve as laboratories for the development of this area of law. For example, California regulates online services that allow individuals to create their own personal health records. A number of states have begun requiring that notice be provided to affected individuals after a security breach of health information. Although the states have enacted legislation addressing these issues, currently there are no comparable federal statutes. Furthermore, some states are particularly strict with regard to the enforcement of privacy laws. For instance, a hospital in Oregon recently settled a state investigation into a large medical data breach by paying over $95,000 in costs and committing to spend millions more to provide one year of credit-protection services to all individuals whose records were stolen.[14] In contrast, at the federal level, HHS has not imposed a single dime in civil penalties to satisfy the more than 20,000 complaints of privacy infractions that have been reported to the agency.

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Politically, it may be extremely difficult for Congress to fully preempt state health privacy laws. Polls have consistently shown that the privacy of health information is a major concern for the majority of Americans. Thus, it is unlikely that politicians would take a stance on the preemption issue that would leave them vulnerable to allegations of stripping citizens' state-endorsed privacy rights. In order to fully preempt state health privacy laws, Congress would first be required to agree on controversial issues, such as access to minors' health information. Hot-button issues such as this remain at least as divisive today as they were ten years ago, if not more so. Former Representative Johnson's original bill essentially conceded this point and called for the default preemption as a fallback measure designed to circumvent the lack of political consensus on the controversial issues. Lawmakers have nonetheless been reluctant to delegate their power over high profile issues in the manner she proposed.

V. Potential Solutions

States may agree to harmonize their laws in some less-controversial areas yet retain their traditional powers. For instance, states may successfully adopt uniform laws specifying the requisite content for disclosure consents or authorizations. Though changes in these areas would help to facilitate the interstate exchange of data, variation will likely remain in more substantive provisions, such as the requirement for specific authorization to disclose health information related to HIV/AIDS,

Technology may prove useful in resolving some of the difficulties posed by the need for interstate compliance with various state health privacy laws. Canada plans to include an automated policy negotiation service as part of its nationwide health information network.[15] Under Canada's proposed service, each regional health information system will encode its respective privacy policies and laws. When a system receives a request for data from another region, the two systems will interact to determine automatically whether the privacy laws of their respective jurisdictions permit the interstate transfer of the requested health data. This type of technology may help alleviate the perceived need for federal preemption of state law by resolving differences between state health privacy laws through computerized automation.

VI. Conclusion

Federal efforts to preempt all state health privacy laws will likely be unsuccessful anytime in the foreseeable future. Rather, it would be more effective to focus energy and efforts on encouraging states to harmonize their own laws where appropriate and to develop technology to accommodate differences where they continue to exist.

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1 *See* John Pulley, Untying the Privacy Knot, Government Health It, Aug. 14, 2006, *available at* http://govhealthit.com/article95583-08-14-06-Print (last visited Feb. 12, 2007).

2 *See e.g.*, Mont. Code Ann. § 50-16-502 (2006).

3 *See* Joy Pritts, et. al, *Altered States: State Health Privacy Laws and the Impact of the Federal Health Privacy Rule*, 2 Yale J. Health Pol'y L. & Ethics 325, 327 (2002).

4 *See* Privacy of Individually Identifiable Health Information, 45 C.F.R. § 164.501 (Feb. 1, 2007) ("Psychotherapy notes" is narrowly defined as "notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record").

5 *See Preamble, Standards for Privacy of Individually Identifiable Health Information; Final Rule* (as modified), 67 Fed. Reg. 53, 212 (Aug. 14, 2002).

6 *See* Press Release, U.S. Dept. of Health and Human Services, Thompson Launches "Decade of Health Information Technology," (July 21, 2004), *available at* http://www.hhs.gov/news/press/2004pres/20040721a.html (last visited Feb. 12, 2007).

7 *See Health Information Technology*: *Hearing Before the H. Ways and Means Comm.,* 109th Cong. (2005) (statement of Mary R. Grealy, President, Healthcare Leadership Council), *available at* http://waysandmeans.house.gov/hearings.asp?formmode=view&id=2950 (last visited Feb. 12, 2007).

8 *See* Health Information Technology Promotion Act of 2005, H.R. 4157, 109th Cong. (2005-06).

9 *See generally Subcommittee on Health Report on H.R. 4157*, *The Health Information Technology Promotion Act of 2006* (June 13, 2006) (indicating that H.R. 4157 reported out of the Subcommittee on Health with the study on state laws intact, but without automatic preemption of state law if Congress failed to act). *But see* Chairman's Amendment in the Nature of a Substitute to H.R. 4157, The Health Information Technology Promotion Act of 2006, as reported by The Subcommittee on Health, *available at* http://waysandmeans.house.gov/Media/pdf/FC4157/4157SubcommitteeReport.pdf (last visited Feb. 12, 2007) *and* The Health Information Technology Promotion Act of 2006, H.R. 4157, 109th Cong. (June 13, 2006) (as reported by the Subcommittee on Health), *available at* http://waysandmeans.house.gov/Media/pdf/FC4157/HR4157asReported.pdf (last visited Feb. 12, 2007) (documenting that a variation of the provision was re-inserted in the Chairman's mark of the bill and was removed again before the bill ultimately was passed by the House).

10 *See Privacy and Security Solutions for Interoperable Health Information Exchange: Request for Proposals*, June 2005, Agency for Healthcare Research and Quality, Rockville, MD., http://www.ahrq.gov/fund/contarchive/rfp050015.htm (last visited Feb. 12, 2007).

11 *See id*. at 9.

12 *See* RTI International, *Transcript of Bidders' Conference Call,* Jan. 11, 2006 at 12. http://www.rti.org/files/Jan11BiddersCallTranscript.pdf (last visited Feb. 12, 2006).

13 *See Pulley*, *supra* note 1.

14 *See* Joe Rojas-Burke, *Providence Settles Data Breach*, The Oregonian, Sept. 27, 2006, at B1.

15 *See* Canada Health Infoway Inc., *Electronic Health Record Infostructure (EHRi) Privacy and Security Conceptual Architecture*, Version 1.1 (June 2005), *available at* http://knowledge.infoway-inforoute.ca/EHRSRA/doc/EHR-Privacy-Security.pdf (last visited Feb. 12, 2007).

Prescription Drug Importation and Reimportation

*By David M. Ermer**

> The interstate shipment of any prescription drug (including importation and exportation) that lacks required FDA approval is illegal.

The U.S. Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., creates a closed prescription drug manufacturing and distribution system in the United States to preserve a safe public drug supply, free from counterfeit and other adulterated medications.[1] The U.S. Food and Drug Administration (FDA), which is responsible for the safety of the nation's drug supply, must approve for marketing all prescription drugs distributed in the United States. Those prescription drugs must bear FDA approved labeling and packaging.[2] They also must be manufactured at a domestic or foreign facility registered with the FDA, which routinely inspects those plants, whether foreign or domestic, for good manufacturing practices.[3] Drug wholesalers and pharmacists must be state licensed.[4] The interstate shipment of any prescription drug (including importation and exportation) that lacks required FDA approval is illegal.[5]

Prescription drugs are often manufactured in the United States and then exported to foreign countries for sale there. Once exported, drugs may only be reimported to the original manufacturer in the United States.[6] While the United States generally does not regulate prescription drug prices, foreign countries may do so.[7] For example, in Canada, the Patented Medicine Prices Review Board (PMPRB) "limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive."[8] As a result of these price regulations and other factors, such as U.S. patent laws, prescription drugs tend to be priced lower in foreign countries than in the United States.[9]

The PMPRB reported that manufacturers' prices for patented drugs were 69 percent higher in the United States as compared to Canada in 2001.[10] A study published in the Annals of Internal Medicine concluded, "[b]rand name medications are often substantially less expensive when purchased from Canadian internet pharmacies instead of from major online U.S. drug chain pharmacies."[11]

State and local governments faced with rapidly increasing prescription drug costs for their Medicaid and employee benefit programs have considered controlling those costs for themselves and their citizens by reimporting U.S.-manufactured prescription drugs from Canada and other countries. For example, Illinois has created the I-SaveRx program.[12] Minnesota created the Minnesota RxConnect program earlier in this decade to help control prescription drug costs.[13] The FDA, however, opposed both programs on safety grounds.[14] Where other state and local governments challenged the FDA's position in court, the FDA has prevailed.[15] Nevertheless, the FDA has refrained from enforcement actions against similar state-run prescription drug programs.[16]

Congress entered the fray in 2000 when it passed the Medicine Equity and Drug Safety (MEDS) Act. The law permitted the reimportation of prescription drugs originally manufactured in the United States if the U.S. Department of Health and Human Services (HHS) Secretary determined that reimportation would be safe and would significantly reduce costs. However, both Donna Shalala, President Clinton's last HHS Secretary, and Tommy Thompson, President Bush's first HHS Secretary. declined to make those determinations.[17]

In 2003, Congress replaced the MEDS Act with a provision in the Medicare Prescription Drug and Modernization Act, which authorizes the HHS Secretary to:

1. Promulgate regulations permitting pharmacists and wholesalers to import drugs from Canada into the United States, [and]

2. Grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices under such circumstances as the Secretary determines to be appropriate.[18]

Similar to the MEDS Act, implementation of this law remained contingent on the HHS Secretary certifying to Congress that importation would be safe and cost-effective.[19] The Act also required HHS to prepare a study on the issue for Congress.[20]

Both Secretary Thompson and his successor, Michael Leavitt, have declined to issue this certification. In a 2004 report, the Congressional Budget Office agreed with HHS's position when it concluded that:

> Permitting the importation of foreign-distributed prescription drugs would produce at most a modest reduction in prescription drug spending in the United States. H.R. 2427, for example, which would have permitted importation from

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> a broad set of industrialized countries, was estimated to reduce total drug spending by $40 billion over 10 years, or by about 1 percent. Permitting importation only from Canada would produce a negligible reduction in drug spending.[21]

When Vermont challenged HHS's inaction under the federal Administrative Procedure Act, the federal district court sided with the HHS Secretary.[22] Currently, a stalemate exists between the federal government and the state governments that are operating drug importation programs without FDA approval. Although the FDA has criticized these programs, it has not taken any action to shut them down. In contrast, the FDA successfully used the courts in 2003 to shut down an American-based business, Rx Depot, which had been operating 85 storefronts in the United States to distribute prescription drugs purchased from a Canadian pharmacy.[23]

Will Congress take further action to resolve this stalemate? At the conclusion of its final session in October 2006, the 109th Congress did add a provision to the Homeland Security Fiscal Year 2007 appropriations law that permits individuals to import up to a 90-day supply of prescription drugs (excluding controlled substances and biological products) purchased in Canada.[24] This action did not directly affect American mail-order and internet purchases from Canadian pharmacies. However, also in October 2006, U.S. Customs and Border Protection announced that it would no longer seize prescription drugs that Canadian pharmacies send to U.S. residents.[25] The Senate in December 2006 approved the President's nomination of Dr. Andrew von Eschenbach as FDA Commissioner.[26] Senate action on that nomination stalled for several months due to the FDA's opposition to prescription drug importation, among other legislator concerns.[27]

Time will tell whether the Democrat-controlled 110th Congress will break the stalemate. On January 10, 2006, Senators Byron Dorgan (D-ND) and Olympia Snowe (R-ME) as well as Representatives Rahm Emmanuel (D-IL) and Jo Ann Emerson (R-MO) introduced bipartisan drug importation legislation.[28] If such legislation were to pass, the Administration's opposition to the plan could lead to a Presidential veto. In any event, the prescription drug manufacturers may hold the ultimate trump card because they control the drug supply upon which re-importation is dependent.

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1 *See* Testimony of R. Lutter on Pharmaceutical Supply Chain Safety before the House Criminal Justice, Drug Policy, and Human Resources Subcommittee (July 11, 2006), *available at* http://www.hhs.gov/asl/testify/t060711.html (last visited Feb. 11, 2007).

2 *See* 21 U.S.C.A. §§ 351(a), (d), 352, 355 (2006).

3 *See id.* at §§ 351 (a), (h), 360.

4 *See id.* § 353(c).

5 *See id.* § 331.

6 *See id.* at §§ 331(t), 381(d)(1). The Secretary of the U.S. Dept. of Health and Human Services may authorize an exception to this rule for emergency use of the reimportation drug.

7 *See* U.S. Govt. Accountability Office, Highlights: Prescription Drugs: An Overview of approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs, Rep. No. 07-358T (Jan. 12, 2006) *available at* http://www.gao.gov/highlights/d07358thigh.pdf (last visited Feb. 11, 2007).

8 *See* Frequently Asked Questions, Patented Medicine Prices Review Board, http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#1 (last visited Feb. 11, 2007).

9 *See* CRS Report for Congress, Importing Prescription Drugs: Objectives, Options, and Outlook, at 7-8 (Aug. 4, 2004), *available at* http://www.senate.gov/~hutchinson/RL32511.pdf (last visited Feb. 11, 2007).

10 *See* David Gross, *Prescription Drug Prices in Canada*, AARP Issue Brief (2003), *available at* http://www.aarp.org/research/health/drugs/aresearch-import-725-IB62.html (last visited Feb. 11, 2007).

11 *See* Bradley S. Quon, et al., *A Comparison of Brand Name Drug Prices between Canadian Internet Pharmacies and Major U.S. Chain Drug Pharmacies*, 143 Annals Int. Med. 397, 397 (2005).

12 *See* How I-SaveRx Works, I-Save Rx website, http://www.i-saverx.net/how_works.htm (last visited Feb. 11, 2007). I-SaveRx obtains its drugs from a Calgary, Alberta provider called Pegasus Health Services Ltd. According to the website, "Pegasus has established relationships with an extensive network of licensed pharmacies in Canada, United Kingdom, Australia, and New Zealand."

13 *See* Minnesota RxConnect website, http://www.state.mn.us/portal/mn/jsp/home.do?agency=Rx (last visited Feb. 11, 2007). Minnesota RxConnect provides a prescription drug pricing comparison service as well as access to several Canadian pharmacies, two of which have British affiliates.

14 *See* Letter from Lester M. Crawford, Acting Commissioner of Food and Drugs, to Rod Blagojevich, Governor of Illinois (June 3, 2004) *available at* http://www.fda.gov/oc/opacom/hottopics/importdrugs/GovB63.pdf; *see also* Letter from William K. Hubbard, Acting Commissioner for Policy and Planning, to Tim Pawlenty, Governor of Minnesota (Feb. 23, 2004) *available at* http://www.fda.gov/oc/opacom/hottopics/importdrugs/pawlenty022304.html (last visited Feb. 11, 2007).

15 *E.g., Montgomery County v. Leavitt*, 445 F. Supp. 2d 505 (D. Md. 2006); *Vt. v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005).

16 *See* 21 U.S.C. § 384 (Supp. 2001).

17 *See* Letter from Tommy Thompson, U.S. Dept. of Health and Human Services Secretary, to James Jeffords, U.S. Senator (July 9, 2001) *available at* http://www.fda.gov/oc/po/thompson/medsact.html (last visited Feb. 11, 2007).

18 *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 108-173, § 1121(a), codified at 21 U.S.C.A. § 384 (2006).

19 *See id.* at § 384(1).

20 *See* The U.S. Dept. of Health and Human Services Task Force website, http://www.hhs.gov/importtaskforce/ (last visited Feb. 11, 2007).

21 *See* Cong. Budget Office, Economic and Budget Issue Brief: Would Prescription Drug Importation Reduce U.S. Drug Spending?, *available at* http://www.cbo.gov/showdoc.cfm?index=5406&sequence=0 (last visited Feb. 11, 2007).

22 *See Vermont v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005).

23 *See United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238 (N.D. Okla. 2003). The Court subsequently entered a permanent injunction against Rx Depot.

24 *See* Dept. of Homeland Security Appropriations Act of 2007, 120 Stat. 1355, Pub. L. No. 109-295, § 535 (2006).

25 *See U.S. Customs Offers Stop Seizing Mailed Prescription Drugs Purchased from Canada, available at* http://www.medicalnewstoday.com/medicalnews.php?newsid=53411 (Oct. 6, 2006) (last visited Feb. 11, 2007).

26 *See* 152 Cong. Rec. S11404-29, 11447-51 (Dec. 7, 2006).

27 *See* Christopher Lee, *Senate Approves FDA Chief*, Wash. Post, Dec. 8, 2006, A37, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2006/12/07/AR2006120701706.html (last visited Feb. 11, 2007).

28 *See* S. 242, 110th Cong. (2007) (introduced in the House), *available at* http://dorgan.senate.gov/documents/newsroom/drugimportation.pdf (last visited Feb. 11, 2007); *see also* Press Release, Significant Bipartisan Drug Importation Legislation Introduced in the Senate (Jan. 10, 2007) *available at* http://www.house.gov/apps/list/press/il05_emanuel/RX_Jan1107.html (last visited Feb. 11, 2007).

Health Care Litigation: Overcoming Language Barriers to Reduce Liability

*By Vashti Mercado**

> Further litigation could ensue unless health insurers communicate with applicants and policyholders in appropriate languages . . .

In September 2006, the U.S. Census Bureau listed Hispanics as the nation's largest ethnic group, comprising 14 percent of the American population.[1] Although many Hispanics primarily communicate in English, or are bilingual, a significant number are still acquiring English as a second language. Consequently, these Spanish-only speakers face significant challenges when communicating in medical settings. Language barriers often preclude Hispanics, and other non-English speakers, from receiving quality health care. Courts are increasingly placing the burden on health care providers to overcome language barriers by providing language assistance programs.

Health care providers' failure to provide language assistance to non-English-speaking patients opens the door to a world of litigation. For example, a Spanish-speaking couple in California recently sued their health insurer, alleging that the company reneged on its promise to provide coverage.[2] When the couple first spoke to a bilingual representative of the insurance company by phone, they responded to the agent's questions in their native language. However, when the couple received the agent's pre-completed insurance contracts in the mail, the documents were written in English.[3] Though the couple could not read the contracts, they signed them, assuming that the documents accurately reflected the terms the parties had previously agreed to over the telephone.[4] The couple later submitted a claim for $130,000, which the insurance company subsequently denied, stating that the couple had inaccurately reported preexisting conditions on their signed applications.[5] If the insurer had made a Spanish-written contract available from the onset, the need for litigation possibly could have been avoided. Further litigation could ensue unless health insurers communicate with applicants and policyholders in appropriate languages which all parties understand.

Another example of language-barrier litigation played out in Florida during 2006. In *Northwest Medical Center, Inc. v. Ortiz*, the Court of Appeals of Florida held that a Spanish-speaking obstetrical patient did not receive reasonable notice from her hospital regarding her participation in Florida's Birth-Related Neurological Injury Compensation Plan (NICA).[6] According to Florida statutes, once a patient consents to participate in the Plan, NICA provides the exclusive remedy for birth-related neurological injury claims, and impedes the signatory's ability to file a malpractice suit against a physician covered under the plan.[7] Although the patient signed an NICA consent form prior to giving birth to her child, the consent form was not written in Spanish, and the hospital failed to provide her with Spanish-language brochures explaining the stipulations of the NICA plan.[8] The Court held that since the patient neither received information about NICA during her pre-registration months nor during the actual in-patient stay, the hospital failed to provide adequate notice to make an informed decision about her participation in the NICA plan.[9] Specifically, the hospital should have provided such information in her primary language, or in some manner that would have enabled her to make an informed decision about her medical care.

Even if patients receive information in their primary languages, courts may render such information ineffective if the information is conveyed in a manner that the patient cannot comprehend. In *Quintanilla v. Dunkelman*, though the hospital provided a Spanish-speaking patient with Spanish-language consent forms, the patient was illiterate and was thus unable to read or understand the forms prior to signing.[10] The Court of Appeal of California reasoned that the "conclusive presumption" of the California Evidence Code Section 622, which provides that the facts "in a written instrument are conclusively presumed to be true," is inapplicable where substantial evidence exists that the patient "did not receive a real opportunity to read" or "was not able to read the language" of the consent form, and did not understand what procedures were going to be performed upon her.[11] Since the hospital failed to present evidence that the consent forms were interpreted for her, or that she received adequate information regarding the procedures, the Court held that the physicians were liable for failing to obtain her informed consent.[12]

In addition to traditional medical settings, courts have required effective language-appropriate communication for patients receiving medical care in correctional institutions. In *Gutierrez v. Dubois*, a class of primarily Spanish-speaking inmates sued the Massachusetts Department of Corrections, alleging, among other complaints, that the lack of interpreters in medical visits

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posed a risk to their health.[13] Specifically, they claimed that they could not adequately explain their conditions or symptoms to the English-speaking medical staff and consequently would receive improper medical treatment as a result of the language barriers.[14] While the Superior Court of Massachusetts granted summary judgment on the other counts, the court remanded the issue of whether the lack of regular interpreters endangered the inmates' health for further factual finding.[15]

The need to provide language assistance in this country is not limited to non-English languages. In 2005, hearing-impaired, English-speaking patients brought suit in *Gillespie v. Dimensions Health Corp.* when the hospital denied their requests for sign-language interpreters to facilitate their communications with hospital personnel.[16] Rather than providing interpreters, both doctors and nurses unsuccessfully attempted to communicate by reading lips and writing notes. Ultimately, the doctor encouraged the patients to seek treatment at another hospital.[17] The U.S. District Court for the District of Maryland granted the hospital's motion to dismiss two claims on jurisdictional grounds but denied its remaining motions for most of the plaintiffs.[18] The message is clear that efforts to improve communications in health care settings must include substantial changes to address the language needs of the American population as a whole. Accordingly, effective communication in health care is no longer a mere courtesy for the patient, but rather, an essential strategy for increasing quality health care while decreasing provider liability.

Taking a lead on this issue, the California State Department of Managed Health Care has proposed the implementation of Language Assistance Programs.[19] These programs provide enrollees with language assistance, including translation and interpretation services.[20] Although the proposed regulations remained under comment and revisions as of late 2006, if effectuated, the programs may ultimately require language assistance services at hospitals and doctors' offices throughout the state. Notably, the programs may require health care providers to provide beneficiaries with materials translated to their primary languages. Such measures can increase health care quality and access, while decreasing language barrier litigation.

In summary, courts nationwide are taking note of language barriers that non-English speakers face within the health care system. Specifically, there is an evolving recognition that languages need not be barriers to health care. As litigation stemming from language barrier problems increases, courts will continue to be increasingly adamant about requiring *true* informed consent and effective communication to patients in a language-sensitive manner. Solutions do exist and litigation can possibly be avoided. Effective communication that improves health care and decreases medical liability represents a winning strategy in any language.

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1 *See* Press Release, U.S. Census Bureau, Facts for Features, CB 06-FF.14 (Sept. 2006) (on file with author).
2 *See* Lisa Girion, *Language Becoming an Issue for Health Insurers,* L.A. Times, Mar. 20, 2006, at C1.
3 *See id.*
4 *See id.*
5 *See id.*
6 *See* 920 So. 2d 781, 786 (Fl. Dist. Ct. App. 2006).
7 *See id.*
8 *See id.* at 783.
9 *See id.* at 785-86.
10 *See* 133 Cal. App. 4th 95, 105 (2005).
11 *See id*. at 116-17.
12 *See id.* at 119.
13 *See* No. 97-3695-A, 2002 Mass. Super. LEXIS 292, at *3 (Mass. L. Rep., July 16, 2002).
14 *See id.* at *5
15 *See id*. at *26.
16 *See* 369 F.Supp. 2d 636, 637 (D. Md. 2005).
17 *See id.* at 637-38.
18 *See id.* at 646.
19 *See* Cal. Code Regs. tit. 28, § 1300.67.04 (proposed Dec. 23, 2005).
20 *See id.*

[E]ffective communication in health care is no longer a mere courtesy for the patient, but rather, an essential strategy for increasing quality health care while decreasing provider liability.

A New "Catch 22" for Managed Care:

ERISA's Failure to Preempt Any Willing Provider and Vicarious Liability Laws Creates a Serious Problem for Managed Care

*By Kathryn Leaman**

I. Introduction

In response to the crisis of increasing health care costs in the 1970s, Congress passed the Health Maintenance Organization Act,[1] sparking a health care revolution in which managed care organizations (MCOs) became and remain the dominant form of health insurance in the United States.[2] As MCOs gained dominance, physicians realized that they were a prime target in the MCOs' cost containment strategy.[3] Physicians responded by lobbying their state legislatures to enact "any willing provider" (AWP) statutes, which generally require that MCOs allow any physician who meets the MCOs' set requirements and agrees to the payment system, to join the MCOs' provider network.[4] MCOs with plans that fell under the Employee Retirement Income Security Act (ERISA)[5] fought back, arguing that ERISA preempted AWP laws, and therefore these MCOs did not have to accept "any willing provider" into their network.[6] Importantly, the Supreme Court unanimously held that AWP laws are subject to ERISA's saving clause, meaning AWP laws are excepted from ERISA preemption and ERISA MCOs must abide by AWP laws.[7]

Recent circuit court decisions have held that state vicarious liability laws are also not preempted by ERISA, posing an even greater problem for MCOs because they can now be found liable for negligent network physicians even if the MCO did not invite the physician into its network.[8]

> MCOs...can now be found liable for negligent network physicians even if the physician did not invite the physician into its network.

This article first assesses how the lack of ERISA preemption for state AWP and vicarious liability laws affect an MCO's ability to control costs, and then argues that subjecting MCOs to both AWP and vicarious liability laws places a huge burden on MCOs because they have to accept "any willing provider" and, at the same time, be ready to bear liability for that provider. Part II discusses how MCOs, AWP laws, and vicarious liability laws generally operate. Part III examines courts' analysis of ERISA preemption for AWP and vicarious liability laws. Part IV explores the flawed policy MCOs must deal with when subjected to both state AWP and vicarious liability laws. Part V concludes that the lack of ERISA preemption for both state AWP and vicarious liability laws places an undue burden on an MCO's ability to control health care costs, undercutting the very reason for their existence. Finally, this article recommends that Congress amend ERISA's preemption provision in order to protect MCOs from vicarious liability suits in states that force MCOs to take any willing provider.

II. Three's Company: Managed Care, Any Willing Provider, and Vicarious Liability

A. Managed Care

In general, an MCO is a health insurance company that provides a set of health care benefits for a negotiated price. An MCO's main goal is to provide patients with quality health care while containing costs. MCOs achieve this in various ways, illustrated by the MCO models that have developed over the years, including health maintenance organizations (HMOs) and preferred provider organizations.

i. Health Maintenance Organizations

HMOs are responsible for financing and delivering health care services to an enrolled population. HMOs may refuse to pay for services provided by a non-HMO physician, unless the HMO authorized the treatment before it occurred or in cases of an emergency.[9] This policy encourages, if not de facto requires, that all HMO members receive their health care services from HMO physicians.[10] HMOs use this arrangement in order to negotiate more advantageous financial terms between the HMO and the physician, usually resulting in capitation payment.

Capitation payment is when the HMO pays the physician a set fee per month, based on the characteristics of the HMO's enrollees, rather than the amount of medical services a physician performs during the month.[11] Therefore, HMOs that are able to contract with a select number of physicians to provide services for the HMOs'

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beneficiaries are able to negotiate a lower per member per month (PMPM) capitation payment, because physicians are guaranteed payment for a large number patients, many of whom will not seek services every month.[12] If an HMO is unable to limit the number of physicians in its network, it is less able to negotiate a low PMPM payment because each physician will have fewer patients, meaning lower PMPM payments and a greater risk of patients utilizing health care services each month.[13]

HMO members must choose a primary care physician, also known as the "gatekeeper." Health care providers control 70 percent of health care spending by providing treatment, ordering tests, and referring patients to health care specialists.[14] Upon realizing this, HMOs sought to minimize the amount of unnecessary services[15] by providing financial incentives to the gatekeeper physician through capitation, capitation withholds, and capitation pools.[16] HMOs reasoned that these financial incentives would be balanced by a physician's risk of medical malpractice to ensure that a physician provides quality care without any unnecessary spending.[17]

ii. Preferred Provider Organizations (PPOs)

PPOs contract with a select network of physicians to provide health care services for their members. PPOs differ from HMOs in three main ways. First, members of PPOs can choose to receive health care services from a non-network physician. PPOs try to discourage members from seeking health care outside the network by requiring that the member pay a higher deductible than if the member chooses a network physician. While PPOs provide patients with greater access to physicians than HMOs, PPOs still want to maintain a select group of network physicians in order to control costs. The second major difference is that PPOs do not require members to have a primary care (gatekeeper) physician. Finally, physicians in PPOs do not accept capitation risk; rather, the financial risk of paying out more money for medical expenses than the total amount of money initially taken in remains with the insurance company. Since PPOs retain this financial risk, it is even more imperative that they select network physicians wisely because PPO physicians lack financial incentives to provide the highest quality of care at the lowest possible cost.

B. Any Willing Provider Laws

Health care laws are typically made at the state level and not by the federal government. After significant lobbying to prevent MCOs from limiting the number of network physicians, some state legislatures enacted any willing provider laws.[23] Currently, 22 states have AWP laws.[24] In general, AWP laws require that an MCO permit "any willing provider" who satisfies the MCO's hiring requirements, accepts the MCO's reimbursement rate, and agrees to the MCO's utilization guidelines, to join the MCO's network.[25] AWP laws fit into three categories. First, "freedom of choice" laws require that an MCO reimburse any non-network provider that accepts the MCO's fee rate for the service rendered.[26] Second, "mandatory admittance" laws require MCOs to accept into its network any health care provider who agrees to the MCOs' network contract terms.[27] Third, "due process" statutes require that MCOs abide by certain administrative procedures when admitting and terminating a network provider.[28] Regardless of the type, all AWP laws prohibit MCOs from limiting the number of network providers and thus directly contradict MCOs' cost containment strategies.

C. The Doctrine of Vicarious Liability

All employers risk liability under the doctrine of *respondeat superior*, which holds the employer liable for an employee's tortious actions that occur within the scope of employment.[29] The rationales for imposing liability under this doctrine include: (1) a business is best able to balance the benefits and risks of its operations; (2) the employer can anticipate the risk, buy insurance, and pass costs on to consumers; (3) it provides a strong incentive for the employer to control its employees' actions; and (4) the employer typically has the financial capacity to properly compensate the injured party.[30]

These policy considerations also extend vicarious liability for independent contractors.[31] Under the apparent agency doctrine, an employer can be held liable for an independent contractor's tortious actions if the injured party reasonably, but mistakenly, believed that the independent contractor was a direct employee of the employer.[32]

Because MCOs typically hire health care providers as independent contractors, rather than employees, *respondeat superior* is rarely applied to MCOs.[33] However, recently, courts found MCOs liable for their health care providers' negligent actions through the doctrine of apparent agency.[34] In order to establish an apparent agency claim, the plaintiff generally must show: (1) the MCO held itself out as the health care provider without informing the patient that the provider is an independent contractor; and (2) the plaintiff justifiably relied upon the MCO's actions by looking to the MCO, rather than the physician, to provide health care services.[35]

With the lack of clear guidance on how MCOs should adequately inform its members of a health care provider's employment status and the courts' reluctance to leave a wrongly injured plaintiff without

compensation, it is even more imperative that MCOs carefully select their network physicians in order to reduce the risk of liability and maintain cost-effective business operations.

IV. How the Courts Decided that State AWP and Vicarious Liability Laws Were Not Preempted

Congress enacted ERISA in 1974 in order to establish a national standard for employer-sponsored pension and benefit plans, thereby making it easier for large companies to provide benefits to their employees because the plans are no longer subject to 50 different state's regulations.[36] ERISA accomplishes this simplification with administrative ease by preempting any state law that relates to a self-insured employee benefit plan, including health insurance. ERISA's preemption analysis begins with whether the state law in question "relates to" an employee benefit plan.[37] The Supreme Court held that "relates to" should be understood in a broad commonsense way.[38] A state law "relates to" an ERISA plan, "if it has a connection with or reference to a welfare benefit plan."[39]

Secondly, the court determines whether the state law falls under ERISA's savings clause and is thus saved from preemption.[40] Congress added the savings clause in order to harmonize ERISA with the McCarran-Ferguson Act of 1945.[41] In essence, a state law that regulates the business of insurance is "saved" from ERISA preemption and thus an ERISA MCO is subject to state insurance laws. If, however, a state law does not regulate the business of insurance, then it falls outside the limited scope of ERISA's savings clause and remains preempted.[42] To determine whether a state law regulates the business of insurance, the Supreme Court recently repudiated a test of McCarran-Ferguson factors and announced two requirements, the state law must: (1) be "specifically directed toward" insurance entities; and (2) "substantially affect the risk pooling arrangement between the insurer and insured."[43]

> The Supreme Court reasoned that AWP laws affect risk pooling arrangements because they expand the number of potential providers and restrict the scope of legal contacts between insurers and insured....

The final step of ERISA preemption analysis requires courts to decide whether a state law "deems" that an employer providing a self-insured employee benefit plan to employees is an insurer.[44] ERISA's deemer clause is an exception to the savings clause, thus, even if the state law regulates the business of insurance, it can still be preempted by ERISA.[45] In general, the deemer clause ensures that employers who self-insure are exempted from state insurance regulations. ERISA's complicated preemption analysis establishes a heavy burden on plaintiffs seeking to avoid ERISA preemption and bring state law claims against an ERISA MCO, but recent decisions show the courts' willingness to chip away at ERISA's broad preemption power.[46]

A. ERISA Fails to Preempt State AWP Laws

The increasing prominence of state AWP laws and confusion among the circuit courts as to whether ERISA preempted these laws led the Supreme Court to settle the issue in *Kentucky Association of Health Plans Inc. v. Miller*.[47] In this case, several Kentucky HMOs sued Kentucky's Commissioner of Insurance, Mr. Miller, claiming that ERISA preempted Kentucky's AWP laws and therefore these laws did not govern the HMOs.[48] The HMOs believed Kentucky's AWP laws related to the plan because they impaired the HMOs' ability to limit the number of providers in their network, thereby reducing their ability to assure in-network physicians high patient volume in exchange for discounted service rates, leading to higher health care costs for patients.[49]

The Supreme Court did not address the first prong of ERISA preemption analysis, letting stand the Sixth Circuit's affirmation of the District Court's analysis that Kentucky's AWP laws "relate to" ERISA employee welfare plans.[50] The District Court reasoned that since Kentucky's AWP laws defined "health benefit plans" to include, among other things, "a self-insured plan or plan provided by a multiple employer welfare arrangement, to the extent permitted by ERISA," that the AWP laws "refer to" and thus "relate to" an ERISA plan.[51]

The Supreme Court began its ERISA preemption analysis with the savings clause.[52] The HMOs had argued that Kentucky's AWP laws fell outside ERISA's saving clause because the laws were not directed at the insurance industry and did not regulate an insurance practice.[53] The Supreme Court found neither argument persuasive, noting that Kentucky's AWP laws only come into effect when a health insurer or a health benefit plan excludes a provider from its network, and thus Kentucky's AWP laws are directed toward the insurance industry.[54] Furthermore, the fact that the Kentucky AWP laws prohibit health insurance plans from discriminating against any willing provider imposes conditions upon the business of insurance, and, therefore, regulates the business of insurance.[55]

The Court then looked to whether the state law substantially affected the risk pooling arrangement between the insurer and insured. The Supreme Court reasoned that AWP laws

affect risk pooling arrangements because they expand the number of potential providers and restrict the scope of legal contracts between insurers and insured because Kentucky patients can no longer seek health care from closed network HMOs in exchange for a lower premium.[56] For these reasons, the Supreme Court concluded that ERISA did not preempt Kentucky's AWP laws and that the HMOs were subject to their requirements.[57]

B. Circuit Courts Hold ERISA Fails to Preempt State Vicarious Liability Laws

i. United States Court of Appeals, Tenth Circuit

The Tenth Circuit was one of the first circuits to hold that ERISA fails to preempt state vicarious liability claims. In *Pacificare of Okahoma v. Burrage,* Ms. Schachter brought suit against Pacificare, an HMO, on behalf of Ms. Davidson's surviving children alleging that it was vicariously liable for the physician's negligent care when he released Ms. Davidson from the hospital while she was still bleeding internally; and she later bled to death at home. [58] The Tenth Circuit found that issues of the physician's negligence and the HMO's apparent agency could be assessed without referencing the plan and therefore did not "relate to" an ERISA plan.[59] Additionally, the vicarious liability claim did not involve a claim for benefits, a claim to enforce rights under the benefit plan, or a challenge to the administration of the plan, and thus the malpractice action was too remote to find that it relates to an ERISA plan.[60] The Tenth Circuit further noted that "just as ERISA does not preempt the malpractice claim against the doctor, it should not preempt the vicarious liability claim against the HMO if the HMO held out the doctor as its agent."[61]

ii. United States Court of Appeals, Third Circuit

The Third Circuit has held that ERISA fails to preempt state vicarious liability claims when the complaint concerns the quality, rather than the quantity, of the benefits provided by the ERISA HMO.[62] In *Lazorko v. Pennsylvania Hospital*, Mr. Lazorko alleged that the HMO was vicariously liable for its physician who negligently refused to re-hospitalize Mrs. Lazorko, at her request, after her suicidal thoughts returned.[63] Mrs. Lazorko later committed suicide.[64] The Third Circuit concluded that Mr. Lazorko's vicarious liability claims failed to "relate to" an ERISA plan because the financial incentives placed on the physician by the HMO affected the quality of care provided, rather than the type or quantity of benefits provided.[65] Because Mr. Lazorko's allegations concern the propriety of care, rather than the administration of care, the vicarious liability claim was not preempted.[66]

iii. United States Court of Appeals, Seventh Circuit

The Seventh Circuit took a more circuitous route in finding no ERISA preemption when, in *Rice v. Panchal*, the court found ERISA failed to preempt the plaintiff's vicarious liability claim against the plan after the plaintiff became seriously handicapped due to alleged physician negligence.[67] In this case, the court began its analysis with the well-pleaded complaint rule, and found that the plaintiff's *respondeat superior* claims did not rest on the ERISA plan because: (1) the plaintiff never asserted that he failed to receive benefits due to him under the plan; (2) the plaintiff did not argue that the ERISA plan guaranteed malpractice-free services; and (3) the plaintiff failed to claim that the plan was negligent in selecting its in-network physicians.[68]

In finding that the ERISA HMO was liable under *respondeat superior*, the court did not find the need to utilize ERISA, thereby preventing preemption of the *respondeat superior* claim.[69] In order to determine whether the ERISA plan held the physicians out as its agents, the court must to look to the plan as evidence of the agency relationship.[70] However, the alleged apparent agency did not "rise and fall" with the plan, since the plaintiff could present other evidence of apparent agency without solely relying on the plans' representations.[71] The plaintiff's *respondeat superior* claim was remanded back to state court for further proceedings.[72]

IV. Caught Between a Rock and a Hard Place: MCOs Cannot Choose Their Doctors, but They Can Be Liable for Any Doctor's Negligence

In granting ERISA broad preemption power, Congress intended to subject national health plans to a single body of law rather than 50 variations. However, it appears that courts are becoming more reluctant to apply broad preemption power.[73] Not only are ERISA plans now subject to 22 AWP laws, they are increasingly subject to an individual state's vicarious liability laws. The irony of these legal impositions becomes clear only after examining the policy reasons behind vicarious liability.

First, the idea of enterprise liability links the benefits and risks of running a business.[74] However, health care is unlike any other business in that it concerns people's lives. It is difficult to make purely economic or business decisions because one cannot ignore the fact that denying, delaying, or encouraging more cost-efficient medical care could cause that person to die, leading to anger, resentment, and, in some cases, a lawsuit.[75]

Second, the employer can anticipate the risk, buy insurance, and pass costs on to consumers.[76] In a closed provider network, the health plan can choose physicians who present the least amount of risk for the plan.[77] However, AWP laws require health plans to take

any willing provider, regardless of the risk the provider poses to the plan, undermining this rationale of apparent agency. While it is true that many AWP laws allow a health plan to establish criteria that a physician must meet in order to be a "willing provider," such as board certification or having no prior medical malpractice lawsuits, these are poor indicators of whether a physician is likely to be sued.[78] Many physicians settle malpractice claims because the costs of successfully defending against the lawsuit often may not be worth it.[79] Moreover, most physicians carry malpractice insurance and thus are better equipped to assess the risk they pose to their own patients.[80] If MCOs continue to be held liable for negligent physicians that must be allowed into their networks, health care costs will inevitably rise, undermining the entire cost-saving purpose of MCOs.

Third, vicarious liability provides a strong incentive for the employer to control employees' actions.[81] While this is especially true for MCOs, as they are put in the position of needing to exert more control over providers in order to contain costs, physicians are pushing back, demanding that MCOs exert less control.[82] Therefore, vicarious liability laws further strain the MCO-physician relationship and undermine the primary goal of providing quality health care at a low cost.

Finally, the employer typically has the financial capacity to properly compensate the injured party.[83] As mentioned, physicians typically are able to compensate an injured patient through their own malpractice insurance.[84] In addition, an insurance company can more accurately assess and underwrite the risk of individual physicians than it can assess and underwrite the risk of an entire network of providers.[85]

V. Conclusion

While courts need to follow the law, they must also realize that the law does not operate in a vacuum. Congress expressly desired ERISA plans to be subject to a single body of federal law, not 50 various state laws, in order to ease administration and control the costs of health care. However, as courts chip away at the broad power of ERISA preemption, they are creating an unrealistic environment for MCOs to operate in. What other industry is required by law to accept any supposedly qualified employee and then be held liable when that employee, who the employer never wanted to employ in the first place, acts in a negligent manner? MCOs have two options: (1) cut the number of benefits covered; or (2) raise the premiums rates for each patient. In the end, both solutions place the financial burden on the patient, completely contradicting the reason for establishing MCOs in the first place.

In order to avoid this, Congress should amend ERISA expressly to preempt state vicarious liability laws in states with AWP laws. This proposal strikes a delicate balance by allowing patients to hold MCOs liable for a negligent physician selected by the MCO, while not forcing liability on MCOs for negligent network physicians who were allowed into the network only by virtue of an AWP law.

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1 *See* 42 U.S.C. § 300(e) (2006).
2 *See* Robert F. Rich & Christopher T. Erb, *The Two Faces of Managed Care Regulation & Policymaking*, 16 Stan. L. & Pol'y Rev. 233, 234 (2005) (noting that in 2003, MCO enrollment totaled more than 184 million Americans).
3 *See* James W. Childs, Jr., *You May Be Willing, But Are You Able?: A Critical Analysis of "Any Willing Provider" Legislation*, 27 Cumb. L. Rev. 199, 204 (1996-97) (discussing how MCOs realized long-term cost savings could only be achieved if provider networks were limited to physicians who practiced cost-effective medicine).
4 *See, e.g.*, Idaho Code Ann. § 41-3927 (2006) (mandating that any MCO be "ready and willing" to contract with all "qualified providers" so long as the provider is qualified, desires to become part of the MCO network, meets the MCO's hiring requirements, and practices within the MCO's geographical region).
5 *See* 29 U.S.C.S. §§ 1001-1461 (2006).
6 *See Ky. Ass'n of Health Plans v. Miller*, 538 U.S. 329, 333-34 (2003) (rejecting petitioner's claims that AWP laws were not specifically directed toward the insurance and did not regulate the insurance industry).
7 *See id.* at 342.
8 *See, e.g., Lazorko v. Pa. Hosp.*, 237 F.3d 242, 249 (3d Cir. 2000) (holding that plaintiff's state vicarious liability claims against her HMO were not pre-empted by ERISA and therefore the HMO could be held liable for the negligent acts of its network physician).
9 *See* Peter R. Kongstvedt, Essentials of Managed Health Care 7 (4th ed. 2003).
10 *See* Malcolm Gladwell, *The Moral-Hazard Myth*, The New Yorker, Aug. 29, 2005 at 44 (citing that the number one cause of bankruptcy in America is unpaid medical bills).
11 *See* Kongstvedt, *supra* note 9, at 106-08 (explaining that the capitation payment for each member per month (PMPM) depends on the age and sex of each member, and the actual PMPM payment to a physician may vary from month to month as the age and gender demographics of the enrolled population change).
12 *See id.*
13 *See id.*
14 *See* William J. Bahr, *Comment: Although Offering More Freedom to Choose, "Any Willing Provider" Legislation is the Wrong Choice*, 45 U. Kan. L. Rev. 557, 564 (1997).
15 *See id.* at 565.
16 *See* Kongstvedt, *supra* note 9, at 110-11 (explaining how capitation works as an incentive for physicians to make fewer referrals or provide fewer institutional services).

17 *See id.*
18 *See id.* at 20.
19 *See id.* at 110-11
20 *See id.* at 21 (noting that PPOs typically contract with select providers based on his/her cost-efficient practices, community reputation, and scope of services).
21 *See id.* at 7-8.
22 *See id.* at 7.
23 *See* Sharon Reece, *Puncturing the Funnel – Saving the "Any Willing Provider" Statutes from ERISA Preemption*, 27 U. Ark. Little Rock L. Rev. 407, 412 (2005) (citing that providers argued that MCOs' restrictions on provider selection resulted in patients having limited choices, long travel times to see a provider, and restrained competition among).
24 *See* Rich & Erb, *supra* note 2, at 261.
25 *See* Bahr, *supra* note 14, at 568-69.
26 *See id.* at 569.
27 *See id.*
28 *See id.* at 570.
29 *See* Restatement (Second) of Agency § 219 (2006).
30 *See generally,* Daniel S. Kleinberger, Agency, Partnerships, & LLC's 86-87 (2d ed. 2002).
31 *See* Restatement (Second) of Agency § 220 (2006) (distinguishing a servant from an independent contractor based upon the employer's ability to control the servants physical conduct in the performance of the employer's services).
32 *See id.* at § 267.
33 *See id.* at § 219 (requiring that the employee be a servant rather than an independent contractor in order for liability to attach).
34 *See, e.g., Petrovich v. Share Health Plan of Ill. Inc.*, 719 N.E.2d 756, 766 (Ill. 1999) (holding an HMO may be held liable for its independent contractor's negligent actions).
35 *See id.*
36 *See* Aaron S. Kesselheim & Troyen A Brennan, *The Swinging Pendulum: The Supreme Court Reverses Course on ERISA and Managed Care*, 5 Yale J. Health Pol'y L. & Ethics 451, 454 (2005).
37 *See* 29 U.S.C.S. § 1144(c)(1) (2006).
38 *See Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990).
39 *See Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96-97 (1983).
40 *See* 29 U.S.C.S. § 1144(b)(2)(A) (2006) (explaining that "nothing in this title shall be construed to exempt or relieve any person from any law of any State which regulates insurance").
41 *See* 15 U.S.C. §§ 1011-1015 (2006) (providing that state insurance laws would only be preempted by federal laws if they specifically related to the business of insurance).
42 *See* Reece, *supra* note 23, at 415.
43 *See Ky. Ass'n of Health Plans v. Miller*, 538 U.S. 329, 341-42 (2003).
44 *See* 29 U.S.C.S. § 1144(b)(2)(B) (2006) (explaining that "[n]either an employee benefit plan . . . nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies").
45 *See* Bahr, *supra* note 14, at 573.
46 *See, e.g.*, *Miller*, 538 U.S. at 342 (holding that ERISA failed to preempt Kentucky's AWP law); *Lazorko v. Pa. Hosp.*, 237 F.3d at 249-51 (finding that ERISA failed to preempt the state vicarious liability claims).
47 538 U.S. 329.
48 *See id.* at 332-33.
49 *See id.*
50 *See Ky. Ass'n of Health Plans Inc. v. Nichols*, 227 F.3d 352, 359 (6th Cir. 2000), *aff'd Miller,* 538 U.S. at 332.
51 *See id* at 227 F.3d at 359.
52 *See Miller* at 334.
53 *See id.*
54 *See id.* at 335.
55 *See id.* at 338 (emphasizing that ERISA's savings clause is not concerned with how to characterize insurance conduct, but how to characterize state law with respect to what they regulate).
56 *See id.* at 338-39, 342.
57 *See id.* at 342.
58 *See* 59 F.3d 151, 155 (10th Cir. 1995).
59 *See id.* at 154 (noting that to determine if the physician was negligent the relevant evidence is what transpired between the patient and physician and whether the physician's actions breached the standard of care).
60 *See id.*
61 *See id.* at 155.
62 *See In re U.S. Healthcare Inc.*, 193 F.3d 151, 162-63 (3d Cir. 1999).
63 *See* 237 F.3d at 245-46.
64 *See id.*
65 *See id.* at 249-50.
66 *See id.* at 250.
67 *See* 65 F.3d 637, 638-39 (7th Cir. 1995).
68 *See id.* at 642.
69 *See id.* at 645.
70 *See* Lawrence E. Smarr, Tort Reform, Presentation for Physician Insurers Association of America (Feb. 23, 2005) (noting that the mean settlement amount was just less than half the mean cost of a physician successfully defending himself/herself against suit).
71 *See id*.
72 *See id.* at 646.
73 *Compare* Kesselheim & Brennan, *supra* note 36, at 454, *with Petrovich*, 719 N.E.2d at 766.
74 *See generally,* Kleinberger, *supra* note 30 at 86.
75 *See* David A. Hyman & Charles Silver, *You Get What You Pay for: Result Based Compensation For Health Care*, 58 Wash. & Lee L. Rev. 1427, 1472 (2001).
76 *See generally,* Kleinberger, *supra* note 30, at 87.
77 *See* Edward B. Hirshfield, et al., *Structuring Provider-Sponsored Organizations: The Legal and Regulatory Hurdles,* 20 J. Legal Med. 297, 348 (1999).
78 *See* Steven Lubet, *Like a Surgeon*, 88 Cornell L. Rev. 1178, 1189-90 (2003) (noting that a surgeon's book argued that physicians are sued in a bell curve fashion, generally not indicative of how "good" or "bad" the physician is).
79 *See* Lawrence E. Smarr*, Tort Reform Presentation,* Physician Insurers Association of America, Feb. 23, 2005 (noting that the mean settlement amount was just less than half the mean cost of a physician successfully defending himself/herself against suit).
80 *See id.*
81 *See generally,* Kleinberger, *supra* note 30, at 87.
82 *See* Carl F. Ameringer, *Devolution and Distrust: Managed Care and the Resurgence of Physician Power and Authority*, 5 DePaul J. Health Care L. 187, 203 (2002) (explaining that the best physicians are beginning to leave managed care to start their own concierge services for those who can afford it).
83 *See generally,* Kleinberger, *supra* note 30, at 87.
84 *See* Smarr*, supra* note 79.
85 *See* Lubet*, supra* note 78.

Cloned Animals For Dinner

The U.S. Food and Drug Administration (FDA) announced that meat and milk from cloned animals and their offspring are safe for human consumption and may be sold without special labeling. This includes clones of cattle, pigs, and goats, but not sheep, which may reach grocery stores by late 2007. The FDA will assess public comments to its draft assessment and then issue a final ruling.

Controversy over States Mandating HPV Vaccine

In early February 2007, Texas Governor Rick Perry issued an executive order making Texas the first state to require vaccination against Human Papilloma Virus (HPV). The order calls for all girls entering the sixth grade to be vaccinated as a requirement for school enrollment. For this order to go into effect, however, it will have to survive efforts by the Texas legislature to rescind the order through legislation and lawsuits filed by parents alleging that the order is illegal. In this same month, Virginia's legislature became the first to pass a bill that would mandate the HPV vaccine for all girls entering the sixth grade. Virginia Governor Tim Kaine has said he will sign the bill into law. Twenty states have introduced legislation to make the vaccine mandatory, but several have already bowed to protests by conservatives and parents. Clinical trials have shown that the vaccine (called Gardasil) is nearly 100 percent effective in preventing the HPV strains known to cause 70 percent of cervical cancers and 90 percent of genital warts. While there is disagreement on whether the vaccine should be mandatory, there is general consensus that it could significantly reduce cervical cancer rates if young people are vaccinated.

Caretakers Convicted For Infecting Libyan Children with HIV

On December 19, 2006, a lower Libyan Court convicted and sentenced to death five Bulgarian nurses and a Palestinian doctor for intentionally infecting hundreds of Libyan children with HIV. The six medical workers were previously sentenced to death in May 2004 for allegedly infecting 426 children through contaminated blood products at Al Fateh Children's Hospital in Benghazi, Libya, and were ordered to pay a total of $1 million to the families of these HIV-positive children. In a December 2005 decision, the Libyan Supreme Court overturned the medical workers' convictions and ordered a retrial in a lower court. The health workers maintained their innocence , and claimed that they were forced to confess under torturous conditions by Libyan officials during interrogations. New genetic evidence recently published in the journal *Nature* revealed that the HIV outbreak at the hospital began as many as three years before the medical workers arrived at the facility. The evidence also showed that the children were infected with a strain of HIV that is common in West Africa, which could mean that the children were infected by another source. Bulgarian officials expressed that the ruling had no merits and was unfair, and appealed to the international community to respond. Other European countries and the United States have shown support for the medics' case, and have appealed to the Libyan government for their release. In response, Libyan leader Colonel Muammar el-Qaddafi stressed the impartiality of the Libyan judicial system and rejected what he called "Western intervention and pressure in this affair." Defense attorneys for the nurses and doctor have stated that the medics will file an appeal against the new verdict with the Libyan Supreme Court, and many analysts believe that it will be many months before the case is resolved as Libya attempts to use the workers to negotiate a financial settlement.

NIH Scientist Pleads Guilty To Charges

Federal prosecutors alleged that Trey Sunderland, the former chief of the geriatric psychiatry branch at the National Institute of Mental Health (NIMH), a division of National Institutes of Health (NIH), accepted $285,000 in consulting fees and other payments from Pfizer and failed to disclose this agreement to the appropriate federal authorities. According to prosecutors, between 1997 and 2004, Pfizer paid Sunderland $285,000 in consulting fees for a project that studied biomarkers potentially linked with Alzheimer's disease. Prosecutors alleged that Sunderland improperly entered into an agreement with Pfizer to advise the company on the study of biomarkers in spinal fluid samples provided by NIH. NIMH and Pfizer entered into a comparable agreement to study biomarkers, and Sunderland entered into a second agreement under which he received payments from the company. Prosecutors alleged Sunderland violated NIH rules that require disclosure of income received from outside activities and of reimbursement by outside sources for travel expenses. Furthermore, the prosecutors claimed that Sunderland

failed to disclose to his NIH supervisors the nature of his outside activities. Under the plea agreement, Sunderland would have to forfeit $300,000 in payments and reimbursements and perform 400 hours of community service. Sunderland would receive probation for two years and would have to pay a fine. The case is believed to be the first conflict-of-interest prosecution against a federal scientist since 1992, when NIH researcher Prem Sarin was convicted of embezzling a drug company payment to NIH that was intended to help with AIDS research.

Pharmaceutical Patent Right Negotiations Between the United States and Asian Nations

The United States has been negotiating bilateral free trade agreements (FTAs) with many Asian countries, including Thailand, Malaysia, Taiwan, and South Korea. These FTAs will greatly impact the intellectual property regimes of each country and affect pharmaceutical patent right negotiations between Asia and the United States. Additionally, the FTAs will harmonize the patent laws of participating nations, thereby eliminating barriers to trade by promoting fair competition and providing protection and enforcement of intellectual property rights. By creating a level of predictability and stability in intellectual property rights, the agreement provides the participating countries with the opportunity for increased investment from pharmaceutical firms worldwide. The FTAs are an example of the desire of Asian countries to provide the proper incentives for development of a highly research-intensive pharmaceutical industry. Further, the agreements create a level playing field upon which to develop, test, and market drugs, which will ultimately lead to a better understanding of diseases and more effective medicines with which to treat them.

New Congress Tackles SCHIP

Democrats are placing priority on health insurance for the 8.3 million children currently uninsured in the United States by focusing on the State Children's Health Insurance Program (SCHIP). Though the move is intended to be a step toward universal coverage for all, some argue that it is a small step rifed with problems and potential setbacks including a lack of funding for a need that could reach into the billions for a program that has already spent $40 billion in federal grants since 1997. SCHIP targets children from families who earn an amount twice the federal poverty level so that children who do not qualify for Medicaid may receive coverage when their families are unable to afford private insurance. SCHIP sets out guidelines within which a state may fashion its own program. Putting children's health at the forefront of this political debate may prove a prudent move by Congress, as several states have already begun expansion on their SCHIP programs.

Lawsuits To Follow Nicaragua's Abortion Ban

In October 2006, Nicaragua's legislature voted to ban all abortions, including those previously allowed in cases of rape, fetal malformations, and to save the mother's health or life. Although abortion had been illegal in Nicaragua for more than a century, the penal code allowed exceptions for "therapeutic abortions" if three doctors deemed it necessary. Religious representatives in Nicaragua argue that the principles of therapeutic abortions were commonly abused to allow any woman who did not want her child to abort it. No major medical society in Nicaragua advocates in favor of the ban, and some of the medical associations are preparing petitions declaring the ban unconstitutional. If the petitions to Nicaragua's highest court fails, activists are prepared to escalate their advocacy to the U.N. Human Rights Committee or the Inter-American Commission on Human Rights.

New Policy for Down Syndrome Testing

The American College of Obstetrics and Gynecology now urges all pregnant women, even those under age 35, to undergo Down syndrome testing. The traditional amniocentesis testing for women age 35 and older has given way to less invasive screening methods. For instance, the new nuchal translucency test combines blood testing with a simple ultrasound exam and is more than 80 percent accurate. Since infants with Down syndrome often need specialized care at delivery, the increased prenatal diagnosis that these tests offer will enable mothers to make informed decisions regarding where to give birth so as to receive optimal health care for their newborns.

D.C. Smoking Regulation In Effect

Citing the health of area residents, the D.C. Council passed a ban on smoking in bars, nightclubs, and restaurants, effective January 2, 2007. A partial smoking ban was in place since April 2006, prohibiting smoking in restaurant dining areas. The regulation successfully passed in part due to efforts by anti-smoking advocates and local council members who campaigned for the ban in 2004. The smoking ban is similar to a recently enacted regulation in New York City, where a recent government study showed that restaurants and bars continued to thrive despite the ban. The regulation contains exemptions for establishments that stand to suffer excessive economic hardship, such as hookah bars and other businesses that show a 10 percent decrease in sales. The Council hopes that the D.C. smoking regulation will have a positive effect on hospital care and costs, as has been the case in other U.S. cities that enacted similar smoking bans.

Georgiana Avramidis, David HyungHo Kim, Vashti Mercado, Eduardo Pezo, and Emily K. Strunk contributed to this column.

Washington Update: News from Our Nation's Capital

Preparedness in the Event of a National Disaster

Following recent catastrophic events, such as September 11th and Hurricane Katrina, and in response to threats of future national disasters, government, public and private organizations have worked to devise response plans to be implemented in the event of an emergency.

As of May 25, 2006, the Department of Homeland Security established an all-hazards approach to improve the ability of the United States to handle domestic incidents. The plan incorporates many disciplines into a unified structure and includes homeland security, emergency management, law enforcement, firefighting, public works, public health, responder and recovery worker health and safety, emergency medical services, and the private sector. Further, it establishes protocols to help protect the country from terrorist attacks and other national disasters in order to protect public health, safety, property, and the environment, save lives, and reduce post-traumatic consequences of such events.

In addition, over the past three years, Health Systems Research, Inc., in collaboration with the Health Resources and Services Administration and the Centers for Disease Control and Prevention, has assisted the Agency of Healthcare Research and Quality to share information and tools to help public health officials, health system decision makers, and providers detect and respond to acts of bioterrorism. It has designed and conducted a series of Web conferences on bioterrorism and health systems preparedness.

Finally, the National Bioterrorism Hospital Preparedness program has worked to improve state, local, and hospital preparedness and response to bioterrorism and other public health emergencies. The mission of the program is to prepare hospitals and health care systems to deliver coordinated and effective care to disaster victims.

For more information about these initiatives and trainings visit www.hsrnet.com, www.dhs.gov, and www.hrsa.gov

DTC Advertising: Does the FDA Have the Resources it Needs to Effectively Regulate?

A recent report on the Food and Drug Administration's (FDA) review of direct-to-consumer (DTC) advertisements by pharmaceutical companies has prompted a discussion about whether increased funding is needed to allow the FDA to better regulate the industry's marketing efforts. The report, *Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising, Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising* was released by the Government Accountability Office (GAO) in December 2006. Among the findings was GAO's conclusion that the FDA reviews only a "small portion" of the DTC materials it receives. The GAO also raised questions about the effectiveness of the regulatory letters the FDA sends to companies when DTC advertisements are "violative."

Senator Herb Kohl (D-WI) met with FDA Commissioner Dr. Andrew von Eschenbach on January 10, 2007 to discuss the regulation of DTC ads. Senator Kohl is the Chairman of the Agriculture Subcommittee of the Senate Appropriations Committee panel, which has jurisdiction over the FDA budget. Senator Kohl also sent a letter to President Bush seeking additional funding in the Fiscal Year 2008 budget request to allow the FDA "to effectively review and regulate" DTC advertising of prescription drugs. Senator Kohl expressed concern that "staff and funding levels [at the FDA] have not kept up with the increase in advertisements." According to the GAO, drug company spending on DTC advertising increased dramatically between 1997 and 2005, but the budget for the FDA's DTC review group has increased only slightly since its inception in 2002.

Currently, the FDA has oversight of DTC ads, but there is no requirement that companies have their ads approved or screened prior to airing. If the FDA identifies a violation of laws or regulations in DTC advertising material, the agency may issue a regulatory letter asking the drug company to take specific actions. However, the GAO report also questioned the effectiveness of the regulatory letters issued by the agency. According to the report, the FDA has issued fewer letters per year since 2002, when legal review of

all draft regulatory letters was first required. The report also concludes that the agency has had only "limited" success in halting the dissemination of violative DTC materials. The 19 regulatory letters issued by the FDA in 2004 and 2005 were, on-average, issued 8 months after the materials were first disseminated. The report notes that "by the time the FDA issued these letters, companies had already discontinued use of more than half of the violative materials." Further, the GAO says that receipt of regulatory letters from the FDA did not always prevent drug companies from later disseminating similar violative materials for the same drugs.

The GAO report recommends that the FDA document the criteria it will use for prioritizing DTC materials for review by systematically applying that criteria to the materials it receives and tracking which materials it reviews. However, the report also states that the U.S. Department of Health and Human Services "disagreed with the recommendations, stating that they would require vastly increased staff."

Meanwhile, the pharmaceutical industry is making an effort to increase self-regulation of DTC ads. In 2005, the Pharmaceutical Research & Manufacturers of America (PhRMA) released 15 "Guiding Principles" on DTC advertising that were intended to help companies in the industry self-regulate their marketing efforts. The Guiding Principles addressed issues such as compelling pharmaceutical companies to submit their ads to the FDA for review prior to being aired, including information about other options for treatment (such as diet and lifestyle), and holding conversations with physicians prior to the launch of a new DTC campaign.

Congress Reconsiders Stem Cell Research Legislation

Research involving human embryonic stem cells has stirred much debate in the United States in the past several years. Opponents of such research liken the harvesting of stem cells to abortion because embryos are destroyed in the process, and argue that it is wrong to destroy human life. Supporters, however, emphasize the important medical breakthroughs that such research may afford, such as a cure for Alzheimer's and Parkinson's disease.

In 2001, President Bush announced that federal funding could be awarded for stem cell research, but only under certain conditions. First, researchers must have harvested the cells prior to August 9, 2001. Second, researchers could only harvest cells from embryos that were created, but not ultimately used, for reproductive purposes. Finally, embryo donors must provide their consent, and may not receive any financial inducements for their donation.

In 2005, Congress tried to expand the scope of President Bush's federal policy, with the passage of H.R. 810, the Stem Cell Research Enhancement Act (the Act). The bill would have allowed for research on embryonic stem cells regardless of the date researchers harvested them. In 2006, President Bush vetoed the bill.

With the Democrats in control of Congress, and Senator Edward Kennedy's (D-MA) appointment as Chairman of the U.S. Senate Committee on Health, Education, Labor, and Pensions, the House reintroduced the Act as H.R. 3. Although the House passed the bill, it did not achieve the necessary two-thirds margin to overturn the President's likely veto. The Senate has placed the bill on its calendar for discussion.

Recent polls and scientific studies may shape the future of stem cell legislation. Polls indicate that most Americans support stem cell research. Furthermore, a scientific study published in January 2007 indicated that researchers may not need to destroy embryos in order to obtain viable stem cells; rather, amniotic fluid may also yield stem cells suitable for research. Opponents of the Act may use this study to argue that the harvesting of embryonic cells is now entirely unnecessary in order to conduct stem cell research. Supporters of the bill, however, note that cells harvested from amniotic fluid may not provide the same research potential as cells harvested from embryos.

At Last: Senate Approval of FDA Commissioner

On December 13, 2006, Dr. Andrew von Eschenbach was sworn in as Commissioner of the Food and Drug Administration (FDA) following the Senate's confirmation by a vote of 80 to 11 six days earlier. Although Dr. von Eschenbach's nomination occurred in March 2006, his confirmation had been on hold since September. Members of both parties protested the confirmation, largely because of political controversy surrounding the FDA approval of Plan B, the emergency contraception pill, for sale to adults without a prescription. As Acting Commissioner, Dr. von Eschenbach's approval of over-the-counter Plan B sales in August quieted many Democrats' objections to his confirmation. A vocal minority of Republicans continued to protest Dr. von Eschenbach's confirmation over concerns surrounding drug importation and the investigation of Ketek, an FDA-approved antibiotic

which has since been linked to liver disorders and deaths.

The confirmation provides stability for the FDA as the Democrat-controlled Congress is expected to issue new regulations for the FDA. Pending legislation on drug safety, generic medicine issues, and funding for FDA drug and device centers could substantially affect the agency's regular operations.

In the last decade, no FDA commissioner has held the position for longer than two years. Of the last five years, the FDA has been without a confirmed commissioner for all but 18 months. Dr. von Eschenbach, an oncologist and surgeon, previously served as director of the National Cancer Institute and as a chief academic officer to the M. D. Anderson Cancer Center.

Bridget Behling, Meryl Eschen Mills, Jessica Smith, and Rebecca Wolf contributed to this column.

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