FRESH-Thinking
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Fresh Thinking–Legal And Regulatory Issues

Presented By Health Care Reform

by Timothy Stoltzfus Jost

FRESH THINKING–LEGAL AND REGULATORY ISSUES PRESENTED BY HEALTH CARE REFORM

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I. Introduction

This session of the Fresh Thinking project, which addresses legal and regulatory reform, is the only session of the project dealing with law. As the audience of this project is not primarily engaged in thinking about law (freshly or otherwise), the paper will begin by considering what law is and the role it plays in health policy.[1] It will then proceed to examine four areas where changes in the law will be necessary to implement health care reform. These include the relationship between federal and state authority and responsibility in governing health care; the definition of health care entitlements, regulation of markets for health insurance, and regulation of the delivery of health care products and services. The paper will conclude with a brief discussion of medical malpractice.

II. What is Health Care Law?

The most relevant definition of law found in the American Heritage Dictionary is "the body of rules and principles governing the affairs of a community and enforced by a political authority . . . ." As such, law clearly includes statutes duly adopted by legislatures, regulations promulgated by administrative agencies; and binding precedents established by courts. But law, at least as it is understood by lawyers, also includes other authorities–guidances issued by administrative agencies that are in principle non-binding but are ignored at great peril; contracts that are crafted by private parties; even accreditation or certification standards that claim to be voluntary but that must be satisfied to participate in government programs. Our health care system is permeated by each of these forms of law.

Law performs several functions in a society–creating, reflecting, and establishing principles, institutions, policies, and procedures. First, law expresses the principles on which a society is founded and to which it aspires. Most obviously this is true in the United States of our Constitution, which enshrines principles such as due process, equal protection of the laws, and freedom of association. But basic principles are also reflected, for example, in the first two sections of Title XVIII of the Social Security Act, which commit the Medicare program to noninterference in the practice of medicine and to free choice of provider,[2] or in the Health Insurance Portability and Accountability Act Privacy Regulations, which proclaim a principle of protecting the confidentiality of individually-identifiable health information (subject to numerous exceptions).[3] The Employee Retirement Income Security Act of 1974 recognizes a basic principle that employers should be free to determine the scope of health benefits that they offer to their employees without state government interference. The bribe and kickback and the self-referral prohibitions are based on the principle that patient referrals should serve the medical interest of the patient rather than the financial interest of the provider. Principles enshrined in statutes rather than constitutions can, of course, be changed, but in fact are politically very potent and not lightly abandoned.

Second, law establishes institutions. Some of these are regulatory institutions, such as the Food and Drug Administration (FDA), the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS), or the insurance commissions of the several states. Others, such as the Center for Medicare and Medicaid Services (CMS) or the state Medicaid agencies, administer public programs. Some institutions, such as the Medicare Appeals Council, the courts, or private dispute-resolution services, settle disputes. Finally, ombudspersons and special complaint mechanisms are available under some programs to process informally concerns regarding program administration. Many legal institutions serve more than one of these functions: the Federal Trade Commission (FTC) both promulgates regulations and adjudicates disputes, for example.

Third, law establishes the procedures through which these institutions exercise their authority. These include, for example, procedures for enforcing regulatory requirements, for settling disputes, and for establishing eligibility for a benefit. Procedures include remedies, such as penalties that are imposed for violating regulatory requirements or damages for breaches of civil obligations. The importance of procedure cannot be overstated. If the procedures that a poor pregnant woman must navigate to gain access to Medicaid are impossibly complex, she will not be covered by Medicaid, regardless of the fact that the substantive law states that she is eligible. If the only remedy available to a regulatory agency is termination (of a license or of provider participation), the law will rarely be enforced and noncompliance is likely to be rife. Procedure, that is to say, often has substantive ramifications.

Fourth, law actualizes policy. The Medicare diagnosis-related group (DRG) prospective payment system and the Massachusetts Health Plan are both established by statutes, but the statutes merely articulate health policies designed by politicians, economists, or policy experts. Law reform is sometimes necessary because the existing law fails to realize policy effectively or because it attempts to articulate conflicting and inconsistent policies. But law reform is also needed when law effectuates ineffective or outdated policies, or fails altogether to address a particular problem. Thus law reform often depends on policy reform and is only possible when adequate political support coalesces to move forward on a particular policy initiative.

Law takes a variety of forms. When the general public thinks of law, it generally thinks of the criminal law, or perhaps of civil litigation or of Supreme Court decisions interpreting the United States Constitution. This is the content of the "law" sections of the CNN or Fox News websites. In health care, one very visible manifestation of law is medical malpractice litigation, which for a generation has been the focus of a highly politicized and publicized debate between organized medicine and trial lawyers.

When economists think of law, they generally think of regulation, indeed of traditional command and control regulation. It is through public regulation of private economic conduct that law has traditionally affected the economy most directly. It is not surprising that this section of the Fresh Thinking project is entitled "legal and regulatory" reform.

In fact, however, there are many forms of law. First, there is constitutional law, including state as well as federal constitutional law. As Professor Hall's commentary notes,

constitutional law imposes few constraints on health reform. It is important, however, to keep it in mind as reform proceeds, as it may limit certain approaches to reform. The federal government, for example, may encourage states to take certain actions through its expenditure of funds, but under the Tenth Amendment cannot order the states to take the same actions, or commandeer state governments to carry out its will.[4] The Due Process Clause may also limit the ability of government programs to exclude beneficiaries or providers without procedural protections.

Second, there is criminal law, or more generally, law that imposes obligations involving ethical censure, defining offenses that can be punished with personal confinement or fines. Some laws that impose civil remedies, like the civil suit provisions of the Racketeer Influenced and Corrupt Organizations (RICO) or the Civil False Claims Act carry virtually the same expression of public disapprobation as does the criminal law.

Third, traditional command and control regulation of private conduct continues to be very important in health care, as is demonstrated by Professor Noll's paper. Examples include aspects of state regulation of insurance, FDA regulation of drugs and medical devices, state professional regulation, and federal clinical laboratory regulation.

Too much attention can be paid, however, to traditional command and control regulation. In recent years, a great deal has been written about the "new governance." A major focus of the new governance project has been on creating new regulatory tools as alternatives to command and control regulation.[5] In health care, however, command and control regulation has never been the norm, and alternative approaches have been around for decades.

Most commonly, regulatory requirements in health care have been imposed as a condition of the receipt of some form of licensure or certification. Thus, regulatory requirements are imposed on nursing homes by the states as a condition of licensure. State medical licensure boards have general regulatory authority to prevent the unauthorized practice of medicine, but most of their regulatory activities are targeted at persons who have licenses or have applied for licenses. Similarly, the FDA has general authority to prevent the marketing of non-approved drugs and devices, but the focus of its regulatory operations are on processing applications for drug and device approval.

Rules governing coverage and payment for federal and state health care financing programs can be considered as another form of regulatory activity. The federal Medicare program and the federal and state Medicaid programs have a host of rules describing the populations, providers, products, and services covered by the programs and the conditions that must be met to establish eligibility and to obtain payment. In general, failure to comply with these rules or conditions simply results in denial of eligibility or payment. Knowingly submitting false claims or statements to obtain payment, however, can result in civil penalties, while intentional false claims are criminal.

In some instances, regulatory authority is exercised through private organizations. The most important of these might be the Joint Commission on Accreditation of Healthcare Organizations, which promulgates accreditation requirements for health care institutions and

accredits organizations that comply with these requirements. Although accreditation is nominally a private recognition of excellence, in fact Medicare certification and in some states licensure depends on accreditation status. Other examples of private exercise of regulatory authority abound in health care. Medicare contractors–usually private Blue Cross/Blue Shield plans, insurers, or claims processing companies–make local coverage determinations for Medicare; private Quality Improvement Organizations (QIOs) have the authority to impose sanctions for substandard medical care; and private Qualified Independent Contractors make Medicare redeterminations. In particular, private dispute resolution has become quite common in health care, including the use of arbitration to adjudicate coverage disputes and private external review entities.[6]

Another body of law important to health care is tax law. Federal and state income tax subsidies for employee health insurance benefits were estimated to amount to $208.6 billion in 2006, making this tax subsidy program our third largest public health insurance program.[7] Remarkably, this program operates with virtually no regulatory oversight. Federal and state tax laws also offer subsidies for nonprofit hospitals that claim to be "charitable." The program has also operated for decades with minimal regulatory oversight, although alleged abuse of these tax programs has led to more oversight recently (which to date has mainly taken the form of revisions of audit guidelines and reporting forms).

Law also includes judge-made common law, statutes, and even administrative regulations that govern relationships among private parties, as well as private agreements made pursuant to these laws. A prominent example of this body of law already mentioned is medical malpractice law. Malpractice law is tort law, which is largely common, i.e. judge-made, law. The other primary body of private civil law is contract law, which puts the civil courts at the disposal of private parties for the interpretation of their agreements and settlement of their disputes. Contracts are also often interpreted and enforced though private arbitration or dispute-resolution tribunals, whose decisions are often ultimately enforceable through the courts.

Finally, as noted above, law also includes the jurisdictional, procedural, and remedial statutes and regulations that provide the ground rules for accessing and using legal institutions in order to enforce regulations, secure benefits, and decide disputes. As also noted, these procedural and remedial rules often have real substantive effects.

The remainder of this paper discusses the primary legal issues raised by health care financing and delivery reform and offers fresh proposals for approaching those issues.

III. The Role of the Federal and State Governments

The first issue that must be resolved if we are to comprehensively reform our health care delivery and financing system is the respective roles of the national and state law–the question of federalism. The current relationship between federal and state law is exceedingly complicated, inconsistent, and at times, simply odd.

The ultimate authority governing the relationship between federal and state law is the United States Constitution. The Constitution begins with the assumption that regulatory

authority resides with the states except insofar as it has been delegated explicitly to the federal government. Where authority has been delegated to the federal government, however, federal authority is, under the Supremacy Clause, preeminent. Although the Constitution allocates authority to the federal government in a number of areas, the primary sources of the federal government's authority in health care are the Commerce Clause and the Spending Clause. The Commerce Clause gives the national government broad authority to regulate the channels and instrumentalities of commerce and actions that substantially affect interstate commerce.[8] The Spending Clause authorizes the national government to raise taxes and to spend money to provide for the general welfare.[9] The antitrust laws and the Employee Income Security Act (ERISA) have been enacted under the Commerce Clause, while the Medicaid program and the Emergency Medical Treatment and Active Labor Act (EMTALA, which only applies to hospitals that participate in the Medicare program) find their authority in the Spending Clause.

Congress and the Supreme Court have long recognized the primacy of state police power for licensing professionals or health care institutions and for protecting the public health.[10] Although the scope of health care practice is increasingly interstate (and, indeed, international, through the use of telemedicine, for example), this tradition of state regulation continues largely intact, even though there is considerable cooperation among the states.[11]

The tradition of state regulation of the provision of healthcare, however, is subject to a few notable exceptions. One of these is the FDA's regulation of drugs and devices, which has long been recognized as an appropriate exercise of the interstate commerce power. A more recent example is the Health Insurance Portability and Accountability Act (HIPAA) which prohibits some health insurance underwriting practices and protects the confidentiality of individually-identifiable health information. HIPAA merely establishes a national floor, however. States that choose to impose further limits on insurance rating practices or protections of medical privacy are free to do so.

Congress has also acknowledged the primacy of state authority over health insurance regulation in the McCarran-Ferguson Act.[12] The Supreme Court had held in the nineteenth century that the sale of insurance was not interstate commerce and thus not subject to federal regulation, but the Court reversed itself in 1944,[13] holding that the federal antitrust laws applied to insurance. The following year, Congress adopted the McCarran-Ferguson act, recognizing authority in the federal government to regulate insurance, but further recognizing that federal laws that do not expressly purport to regulate the "business of insurance" do not preempt state laws and regulations that do. In general, states have total responsibility for regulating nongroup health insurance policies and retain considerable authority over health insurers generally.

The last half century, however, has seen a steady expansion of federal authority over health care finance. The Medicare program, established in 1965, is funded exclusively through the federal government and is administered by the federal government and its contractors. The states play only a marginal role, for example, certifying some providers (such as nursing homes) for program participation, applying federal certification standards.[14] State law that conflicts with Medicare program requirements–including state regulation of managed care organizations that participate in the Medicare program–is, subject to a few explicit exceptions, preempted by the federal law.[15]

The relationship between federal and state authority in the Medicaid program is far more complex. It can be argued that Medicaid, also established in 1965, was simply an effort to provide federal funding for state programs that provided medical assistance through vendor payments for certain categories of poor persons. From the beginning, however, the Medicaid statute recognized certain rights in Medicaid recipients, including the right to prompt determination of eligibility and provision of assistance and to a fair hearing where benefits were denied. In a series of cases decided in the 1970s and 1980s, the Supreme Court recognized that Social Security Act public welfare programs, including Medicaid, created federal entitlements in program recipients that could be enforced directly against the states by lawsuits brought in federal court.[16]

Over the past four decades, dozens, probably hundreds, of cases have been brought in federal courts against the states for violation of various provisions of the Medicaid statutes. Many of these cases have ended in consent decrees, which have in turn led to further litigation when states violated their terms. The ability of recipients (and providers) to bring this litigation, however, turns on arcane issues of federal court jurisdiction, and in particular on the reach respectively of 42 U.S.C. § 1983, a Reconstruction-era civil rights statutes that authorizes suits against the states for violation of rights "secured by the Constitution and laws" of the United States in federal court, and of the Eleventh Amendment to the Constitution which forbids federal suits against the states (but not against their officers) in federal court.

In the recent past, the federal entitlement to Medicaid has come under serious challenge. First, the Supreme Court has decided a series of cases that have increasingly narrowed the usefulness of § 1983 for enforcing federal laws, demanding increasingly specific evidence of congressional intent that a specific statutory provision afford federally protected rights.[17] The effect of this has been that the enforceability of the Medicaid statute varies from section to section, and even with respect to particular provisions, from one federal circuit to another. The second trend has been the increasing use of the Department of Health and Human Service's Demonstration Project Authority to waive provisions of the Medicaid statute with respect to particular projects in particular states. Under the pretense of authorizing research, HHS has waived core requirements of the Medicaid statute, including eligibility, coverage, and cost-sharing requirements. Finally, Congress itself in the Deficit Reduction Act of 2005 increased the discretion that states enjoy to deviate from the traditional eligibility, benefit coverage, and cost-sharing requirements of the Medicaid statute. In sum, the rights of recipients to Medicaid are increasingly defined by state rather than federal law.

The most complex issues of federalism arise under ERISA. ERISA was adopted in 1974 primarily to reform pension law, but it also regulated employee benefits. Section 514(a) of ERISA provides that ERISA "shall supersede any and all State laws" that "relate to any employee benefit plan."[18] The purpose of this provision seems to have been to permit employers to offer benefit plans on a national basis without having to adapt their plans to each state in which they operated. Section 514(a) preemption, however, is subject to a number of exceptions, one of which almost swallows the rule. Section 514(b)(2)(A) saves from preemption state laws that regulate insurers. States are thus free to impose regulatory requirements on health insurers

that insure employment-related benefit plans, including benefit mandates, "any-willing-provider" requirements, and external review provisions.[19]

The "savings clause," however, is also subject to an exception. Section 514(b)(2)(b) provides that states are not permitted to "deem" employee benefit plans themselves to be insurers. The courts have interpreted this provision to mean that states cannot require employers to offer any particular benefits and cannot impose any regulatory requirements at all on self-insured plans.[20] "Self-insurance" is defined to include almost any situation in which the employer bears some risk, even if the employer has a generous reinsurance plans. The vast majority of large employers are currently self-insured, while most small employers provide coverage through insured, and thus state-regulated, plans. The ERISA regulatory dichotomy creates two dilemmas for states: first, the states cannot directly impose coverage mandates on employers,[21] and second, if the states are too aggressive in requiring health insurers to offer expansive coverage, many employers will simply self-insure, thus escaping state regulation altogether.

Section 514 does not, moreover, fully define the scope of ERISA preemption The Supreme Court has read the remedial provisions of ERISA, § 502, to have their own independent preemptive authority. Indeed, the Court has interpreted § 502 to effect two kinds of preemption–jurisdictional and remedial preemption. First, the Court reads § 502 to allow any ERISA plan administrator sued in state court to remove the case into federal court. Second, the Court interprets § 502 to provide that the only remedy available against an ERISA plan for a denial of benefits or for an interpretation of an ERISA plan is a suit under ERISA. The remedies available under ERISA are very limited–effectively the recovery of the cost of an item or service covered under the plan for which payment is improperly denied. Nevertheless, state law suits for recovery of health care costs incurred by the negligent denial or limitation of health care services by a managed care plan are not permitted.[22]

The consequences of the interaction of the various ERISA preemption provisions and their exceptions can be quite bizarre. States can enact laws affecting benefit coverage as long as the effect is indirect rather than direct. They can, for example, enforce hospital rate regulations that require hospitals to charge self-insured health plans more than Blue Cross plans.[23] They may not, however, require employers to provide health insurance or to spend any particular amount on health coverage. States can impose virtually any mandate they wish on insured employee-benefit plans, but cannot impose any obligations at all on self-insured plans directly. ERISA itself imposes some procedural and disclosure requirements, but virtually no coverage mandates. Persons injured by managed care benefit denials–no matter how egregiously negligent and contrary of the terms of the benefit plan the denial may have been–are not permitted to sue in state court and can recover only, at most, the value of the benefit denied in federal court.[24]

The current American health care system, in which some Americans have rights to health care financing protected by federal law, others have rights protected by state law, and many have no rights at all; in which low-income Americans have federal rights under some sections of the Medicaid statute but not under others and rights that vary from one federal circuit to another; and where some employee benefit plans are largely regulated by state law and others largely

unregulated–makes no sense. But where should authority for regulation of health care delivery and finance reside–with the federal government, the state government, or with some mixture of both?

Much has been written on the topic of allocation of regulatory responsibility in federal systems, both in the United States and in other countries. It is not possible to review that literature here, but a few arguments on the topic can be noted. Disease and injury are more or less uniform in their presentation across the nation, and although there are significant regional differences in the use of medical resources, we do have more or less national standards for medical treatment. It makes little sense from a policy perspective that Americans should have better or worse access to medical care or protection from financial distress based on whether or not their employer offers health insurance and on the form of coverage chosen by the employer. It is also arguable that special interests have a harder time getting legislation adopted at the national than at the state level, and thus that federal mandates with respect to coverage would be more rational and limited.[25] It would also seem to be true that if the federal government is going to pay for expansion of health insurance through tax credits or other subsidies, it should have a major say in how the money is spent. Finally, as long as ERISA exempts self-insured plans from state regulation, only the federal government can regulate insurance coverage comprehensively. These factors argue for a uniform national approach to the regulation of health care delivery and finance.

On the other hand, health care is still delivered locally, and in most countries, at least some decisions respecting the allocation of health care resources are made at the local or regional level. There continues to be a belief in the United States that state governments are more flexible and innovative than the national government, as well as more responsive to the particular needs of their citizenry. The existence of a variety of mixes of regulation, taxation, and spending that varies from state to state also gives employers and residents considering relocating a range of choices as to the extent and form of health coverage that they prefer. These factors argue for greater state control over the regulation of health care delivery and financing.

There are, of course, a variety of possible combinations of federal and state regulation, ranging all the way from total federal control to total state or local control. One approach to insurance regulation raised by recent federal legislative proposals would be to retain state regulation, but to allow insurers to market policies nationally as long as they were licensed in at least one state.[26] It is difficult to believe that this would not cause a race to the bottom, as states vied to provide the most hospitable home for insurance companies. States that lost out in that race would lose all control over health insurance marketed in their states. At least with federal regulation, the states would still retain whatever power they may be able to bring to bear through their representatives at the national level.

The approach to be taken to federalism in health care reform will turn on the approach taken to reform. If political and policy gridlock continues at the national level and thus coverage expansion depends on state initiatives, it would make sense to give more power to the states and thus to weaken federal preemption. If, on the other hand, a national consensus emerges for universal coverage, individual states should not be allowed to stand in the way.

Recommendations:

I would favor a national approach to providing universal coverage, governed by federal law. I would hope that this law would provide a more robust and uniform entitlement than that currently offered by ERISA or Medicaid. States should not be permitted to offer less protection to their residents than that afforded by the federal law. States that want to offer more protection, however, should be allowed to do so, but only if certain conditions are met. The most important of these would be that at least three states would have to agree on a particular addition to the basic federal rules. A rough analogy here is the California auto emission standards which states can adopt as an alternative to the federal standards.[27] This approach would allow for regional variations in policy, but would reduce the burden of compliance faced by national employers and lessen the likelihood that a narrow interest group could drive coverage policy. I would favor the retention of state licensure of providers and institutions, as there is here more of an argument for special local expertise, but would accompany it with a general policy of free movement of providers who meet certain minimum standards, like that recognized in the European Union. It may also make sense to allow states that wish to do so to continue to bear responsibility for regulating insurers under contract with the federal government and applying federal standards, as is currently done with respect to certification of nursing homes for Medicare and Medicaid.

IV. Entitlement

Entitlement to health care coverage in the United States is, as was just noted, defined by either federal or state law or both. Title XVIII of the Social Security Act defines the Medicare entitlement. Medicare is clearly a legal entitlement–Title XVIII begins by stating that qualified beneficiaries are "entitled" to Part A and Part B services and uses the word "entitlement" repeatedly.[28] Procedurally, the Medicare entitlement is protected through a complex set of layers of appeals, all of which must be exhausted before judicial review is available. In many instances, however, judicial review is ultimately available if the amount of money at issue is high enough.[29]

As noted in the last section, the rights of Medicaid recipients may or may not be protected by the federal courts, depending on the section of the Medicaid statute at issue, and sometimes on the federal circuit in which the right is asserted. Recipients are in any event entitled to a state administrative fair hearing, at which their rights are ultimately determined by federal law.[30] Entitlement to eligibility or benefits under the State Children's Health Insurance Program (SCHIP) is not protected by federal law, and access to state court to define or protect eligibility or benefits is limited or uncertain in virtually all states with freestanding SCHIP programs.[31]

Entitlement to employee benefits is defined by federal law, and in many instances by state law as well. Ultimately, litigation to establish rights to benefits under ERISA plans or to interpret ERISA plans must be brought in federal court under § 502 of ERISA. When these cases get to court, the courts are usually highly deferential to plan determinations. Most issues involving ERISA contracts, however, are resolved through the procedures provided by ERISA plans or by state external review entities rather than through litigation. Under federal regulations, all ERISA plans must have in place internal procedures to allow reconsiderations

and appeals of benefit denials.[32] These are the only regulations governing self-insured employee benefit plans, but where plans are insured, the insurers are also subject to state regulation. State law will usually provide for internal review of plan decisions, but these laws will be preempted by the ERISA regulations insofar as they are inconsistent with the federal law. Forty-four states also provide external review procedures.[33] The Supreme Court has held that states can require that plans follow these external review procedures, although the federal ERISA regulations provide that beneficiaries need not apply for state external review before suing in federal court.[34]

Entitlements under nongroup health insurance policies or under group policies not governed by ERISA (such as association health plans that are not employment-related), are governed by state law. These laws vary from state to state, but generally include a right to external review and to state court interpretation and enforcement of rights to benefits. A member of a nongroup plan would be entitled to enforcement of the plan's terms in any event under state contract law, and might have rights under state consumer protection law as well. As Professor Hadfield's commentary reminds us, private contract litigation is in general a costly and inefficient approach to dispute resolution.

Employees covered by employee-benefit plans are entitled to federal tax subsidies, as are self-employed persons who purchase health insurance and persons who deposit money in health savings accounts. Rights to tax subsidies are defined by federal tax law, and are largely self-enforcing. The plan member (or the member's employer) or HSA account owner simply claims the exclusion or deduction on a federal tax reporting form, and except in rare instances when the claim is questioned, it is honored. Litigation dealing with federal health insurance tax subsidies is nearly nonexistent.[35]

Finally, a handful of other federal laws recognize federal rights to health care. The most important of these is the Emergency Medical Treatment and Active Labor Act, which requires hospitals that participate in Medicare and that have an emergency department to screen all persons who present at the hospital in an emergency and to stabilize that emergency condition before the person is discharged or transferred.[36] The law does not require health care facilities to provide emergency care for free, but does provide that they cannot insist on payment or proof of insured status before providing care.

Federal and state law determine not only the existence of entitlements to health coverage, but also the scope of that coverage–the benefits that public or private insurers must provide. Federal law defines the benefits covered by the Medicare program, although individual coverage decisions, as well as more general "local coverage determinations," are made by Medicare contractors. The federal Medicaid law provides a menu of benefits that the states may cover and a shorter list of benefits that they must provide, but the rights of individuals to particular benefits are determined by the states.[37]

Federal law provides a very short list of services that employment-related health insurance policies must cover, including hospital stays of at least 48 hours for vaginal deliveries and 96 hours for Cesarean sections; breast reconstruction following mastectomies (if the insurance policy covers mastectomies); and mental health care subject to annual and lifetime coverage limits as generous as those extended to medical or surgical benefits (if other

requirements are met).[38] Employment-related policies are also prohibited from treating maternity-related services differently from other medical and surgical services.[39] High deductible health plans must comply with minimum deductible and maximum out-of-pocket limits in order for the HSAs coupled with them to qualify for federal tax subsidies.[40] In general, however, federal policy has been to let employers and insurers define the scope of the coverage of their own plans. Federal law does not require insurance coverage, and lets those who offer it determine the scope of the coverage they offer. The principle grounding policy has been one of noninterference.

State law tends to be much more prescriptive. For the past two decades, states have steadily expanded the persons, providers, and benefits that insurers must cover under state law. These mandates, for example, require that insurers cover listed persons such as newborn or adopted children of members; specified providers such as chiropractors, psychologists, or nurse midwives; and certain products and services, such as bone density screening, bone marrow transplants, or cleft palate surgery.[41] By one count, seventeen states have forty or more mandated benefit laws, and only two have fewer than twenty.[42] States have been particularly prescriptive in regulating managed care coverage, specifying who must be included in managed care networks (and how a provider may be excluded); requiring direct access to certain specialists (e.g. gynecologists or pediatric specialists); specifying how utilization review may be conducted; and limiting the use or requiring the disclosure of certain provider incentive programs. A few states have even required insurers in the small group or nongroup market to offer a limited menu of standard benefit plans, thus assuring adequacy of benefits as well as making the market more transparent.

The insurance industry is adamantly opposed to insurance mandates. Mandates have also been broadly condemned by free-market advocacy organizations and scholars, indeed by economists generally. Mandates are criticized as paternalistic and as forcing insurers to offer and insureds to purchase benefits that are of little value to particular insureds and that they would not otherwise purchase. Mandates, it is claimed, drive up the cost of insurance, making it less affordable and thus increasing the number of the uninsured.[43] Mandates are also condemned as being provider-protection legislation, adopted by legislatures to assure access to insurance payment for particular providers or in response to politically-powerful disease lobbies. Finally, it is argued that some mandates have been adopted by legislatures in response anecdote-driven media frenzies that do not actually reflect real world problems.[44]

Those who support mandates contend that they are necessary because unregulated insurance markets do not necessarily provide the coverage that purchasers need . First, mandates respond to the possibility that insurers will use coverage design as a means to favorable risk selection, refusing to cover treatment for high cost/low incidence conditions as a means to excluding persons with those conditions.[45] This will in turn channel persons with those conditions to insurers who do cover those conditions, and whose policies will become ever less affordable as they are left with an increasingly expensive population. Second, persons at risk for some rare or costly conditions may fail to purchase adequate coverage in the absence of mandates because they may irrationally underestimate the likelihood of their contracting those conditions. Indeed, the "bounded rationality" of consumers may limit their ability to focus on the entire range of their needs and options and thus to purchase the coverage that they need in

ways that justify coverage regulation.[46] Third, the nature of the insurance transaction–in which insurers collect premiums in advance in exchange for a promise to pay out money in the future if the insurer unilaterally determines that certain conditions defined by lengthy adhesion contracts have been met–is a situation ripe for strategic behavior that may need to be regulated. Fourth, the way in which health insurance is provided in the United States raises agency problems. Insurance contracts are often negotiated by employers, who could use their bargaining power to assure that their employees get adequate coverage. On the other hand, the fact that the employer negotiating the contract may be more interested in how much the policy costs than in how well it will care for employees may exacerbate rather than solve the problem.[47]

Research shows that legislatures that adopt insurance mandates have often been genuinely concerned with consumer protection rather than simply responding to provider advocacy groups, although legislation is often based on anecdotes rather than sound research.[48] Legislatures also seem to be aware of the cost of coverage mandates, and a number of states have adopted sunset provisions or established mandate review commissions. Legislative interest in adopting new mandates seems to be receding, and very few have been adopted since the end of the 1990s. As already noted, few coverage mandates have also been adopted to date at the federal level.

Virtually all current health insurance policies include cost sharing, be it in the form of deductibles, coinsurance, copayments, or maximum payment limits for particular procedures or periods of time. State regulation of cost-sharing for commercial insurance policies is not common, although federal law establishes limits on cost-sharing for Medicare and Medicaid. Most states, moreover, have eliminated whatever restrictions they might have placed on deductibles in response to the Medicare Modernization Act, which only allows federal tax subsidies for health savings accounts in states that do not permit high deductible health plans. Nevertheless, there is growing evidence that high cost-sharing impedes access to necessary health care and causes financial distress for low and moderate income families.[49] Limits on cost-sharing, therefore, might be an appropriate subject for regulation.

Recommendations:

A key legal reform necessary to achieve universal coverage is the definition of the health care entitlement. If universal coverage is to be achieved through the expansion of a federal government program, this will be accomplished through federal law. If coverage is achieved alternatively through some form of tax credit-funded private insurance system, the entitlement should still be defined by federal law, subject to the possibility of a group of states mandating a more expansive entitlement (as described above). If the federal government proves incapable of reaching consensus on universal health care reform, entitlements will continue to be defined on a state by state basis.

A legally-established entitlement to health care items and services should be protected by a combination of internal review and external review procedures, with judicial review ultimately available. That is to say, a person denied services ought to be able initially to ask the plan to reconsider, then be able to appeal to an external entity, and ultimately have access to the courts. This is the approach currently taken to protecting coverage entitlements under the Medicare

program, as well as under state managed care protection laws and laws governing insured ERISA plans in most states. It makes sense to allow an insurer to have a second chance to reconsider a decision denying coverage and, in the event the insurer holds to its initial decision, to have the decision reviewed in the second instance by an impartial, independent, specialized review body. This body should review the insurer decision de novo and if necessary, accept additional evidence. External review could be provided, as it is now in some instances, by private dispute resolution entities. Legal representation should not be necessary at this stage, but should be permitted if the insured desires it. If the insured is still dissatisfied with the external review decision, access to judicial review should be available, at least for claims involving a significant amount of money. Judicial review should be similar to judicial review of administrative agency decisions, however, determining whether the external review decision is supported by substantial evidence and is not an abuse of discretion. Attorneys fees should normally be available to the successful claimant in such cases, as they are under ERISA. Expedited determinations should be allowed for urgent claims, and emergency care should be covered if it is provided in a situation where a prudent layperson would have sought care.

Insureds should also be allowed to sue insurers where intentional bad faith claims denials cause catastrophic consequential damages to the insured. If an insurer denies coverage for care that clearly should be covered and does so under circumstances that indicate an intent to evade legal responsibilities, there must be some consequence beyond the insurer merely having to pay eventually for the denied care. An insurer almost always faces a financial incentive to deny coverage, and some counterbalancing penalty may occasionally be necessary to deter bad faith. A regulatory body should also have the power to impose sanctions in such a circumstance. But damages, including reasonable punitive damages, should also be available to assure optimal deterrence. Cases where damages are necessary will, it is hoped, be rare, and the insured should have to prove bad faith by clear and convincing evidence.

Universal coverage is meaningless if there is no content to the coverage requirement. Health insurance policies are being sold today that are in fact largely illusory–that have such high cost sharing and offer such limited coverage that they are little better than self-insurance. On the other hand, mandates should be kept within reasonable limits, as they do affect the cost of coverage. The default assumption should be that consumers and their agents, such as employers, are capable of identifying and purchasing the coverage best suited to their needs, and that intervention in the market should be at the margins.

To begin, basic medical services and cost-effective alternatives should be afforded by universal coverage. All Americans should have access to most of the services covered by Medicare–medically necessary physician services; inpatient and outpatient hospital care; prescription drugs; cost-effective preventive care; radiology and laboratory tests; physical, occupational and speech therapy; mental health and substance abuse services; and durable medical equipment.[50]

Current state mandates, of course, do not usually require coverage of "physician services" or "hospital care" but apply to more specific or unconventional services. The question remains, therefore, as to which of these specific services should be covered by a universal insurance program. Assuming that we continue to have a system in which private insurers are

responsible for covering basic health care services but can continue to compete on the basis of coverage and price, insurers will need to have considerable discretion as to which items and services to cover. On the other hand, as long as insurers draft insurance policies and insureds are dependent on those policies to cover their health care needs, we will need some mechanism to assure that coverage is real, adequate, and transparent.

I would propose the creation of one or more institutions (or the adaptation of existing institutions) to perform three functions in this regard. The first of these functions would be to create, maintain, and continually update a catalogue of items and services that could potentially be covered by health insurance. This would resemble the Healthcare Common Procedure Coding System (HCPCS) but might need to be more comprehensive and would certainly have to be less specific. It would provide a common vocabulary for describing coverage.

Second, a federal commission should be created to determine which items and services insurers must cover. In part this task would be technical–the entity would commission and review technology assessments to determine which items and services were sufficiently effective and cost-effective to justify coverage. The Commission would also engage in policy-making, however, determining which items and services might prove particularly amenable to being used for risk selection, and thus for unfair competition among insurers. The entity should, insofar as possible, be shielded from political pressure.[51] Its members should be appointed by someone reasonably apolitical, like the Comptroller of the Currency, and serve for long terms. This Commission would review coverage of existing as well as new items and services, but it could not possibly review all possible candidates. Its agenda should rather be driven by requests from insurers, concerned about the cost implications of covering questionable technologies, or from patients or providers seeking services not generally covered by insurers.

The Commission should sort items and services into four categories. The first of these would be those that must be covered by all insurers, such as vaccinations for common diseases or emergency treatment for trauma victims. These would in all likelihood be relatively uncontroversial in most instances, and indeed the list could be quite short since most of these services will not come to the attention of the Commission. Second, there would be items and services that should not be covered by insurance policies subsidized by tax credits or other public funds because there is no credible evidence that they are effective or because they are even dangerous, like laetrile therapy for cancer. This list could be quite extensive, and could play a major role in controlling health care costs by limiting public payment for ineffective care. Insurers could cover the products and services found on this list, but not at public expense. Third, there would be items or services that insurers could cover or not cover at their option, like Lasik surgery for correcting refractive error. Finally, there should be a list of services that would be recommended for coverage but not required. Insurers would not have to cover these services, but would have to prominently disclose in their marketing literature that these items or services were recommended by the federal commission, but were not covered by the particular policy. This would allow insurers to compete on the basis of coverage and cost, but in an environment where consumers knew what they were giving up for the price they were paying.

Finally, some control should be imposed on cost-sharing to assure that policies are of real value and that health care needs do not result in financial ruin. Presumably, if coverage is to be

provided through private insurers with premiums funded by a tax credit or voucher, some sort of evaluation of the income of insureds will have to take place before the value of credits is determined. The information yielded by this evaluation should also be used to determine the level of cost sharing to which insureds should be exposed. Persons at or below the poverty level should be excused from anything more than purely nominal cost sharing, as has been the case with the Medicaid program. Cost-sharing could be introduced gradually above this level (initially in the form of copayments), but there should be a limit to the health care cost exposure of any one family, not exceeding 5% of total income for a family at 200% of the poverty level gradually increasing to 10% of total income at 400% of the poverty level. Universal coverage must mean that no one should have to worry that obtaining medical care will result in bankruptcy.

V. Regulation of Health Insurance Markets

Legal regulation has also been actively engaged with a third aspect of health care organization and finance–the structure of the market for health insurance. It is a well known fact that health care expenses in any given year are highly concentrated–one percent of the population accounts for over one quarter of health care costs, ten percent of the population for almost seventy percent of costs.[52] Thus, the optimal market strategy for a private health insurer is quite clear–attract as many low risk individuals as possible, avoid high risk individuals, make certain that if you insure high risk individuals your premiums are high enough to cover the risk, and, when possible, insure groups that are large enough to provide a large number of low risk individuals to absorb losses attributed to high risk individuals in the group. Insurers also use contract provisions such as pre-existing conditions clauses or waiting periods to limit their exposure to high risks. This approach to the sale of insurance is not problematic unless private insurers are expected to provide health insurance for all comers, healthy and unhealthy, regardless of the premium paid–that is, to function effectively as social insurers. Insurance underwriting and rating practices have in fact come to be quite tightly regulated in many markets in the United States. Health care financing reform in the United States will, therefore, require a review and reform of health insurance market regulation.

This is another area where the state regulation is currently more of an issue than federal regulation. The federal government, however, has been quite active, playing a more important regulatory role than it has with respect to benefit structure. The most important initiative of the federal government is one that has been around for some time: income tax subsidies for employment-related group health insurance. Although tax subsidies are not the only reason why employment-related group health insurance has become common in the United States, and perhaps not even the most important reason, they have played a major role in encouraging group health insurance.[53] Employment-related group health insurance has, in turn, allowed less healthy employees and employees who have dependents with serious medical needs to obtain private insurance that would otherwise been unaffordable. It has also (although this issue is contested) probably made high quality health insurance more accessible to employees who receive lower compensation.[54]

In recent years the federal government has gone further in regulating insurance markets. First, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) permits several

categories of "qualified beneficiaries" who lose employment-related insurance through specified "qualifying events" (such as termination of employment or reduction of hours, divorce, or cessation of dependent status) to extend their coverage, in most instances for a period of 18 to 36 months, by paying 102 percent of the premium or cost of the insurance.[55] Because there seems to be heavy adverse selection against COBRA coverage, this turns out to be an important benefit for some formerly-covered persons, but imposes a significant cost on employers.

Second, the Health Insurance Portability and Accountability Act (HIPAA) limits the ability of insurers to engage in certain risk selection practices. It prohibits employment-related group plans from discriminating in the determination of eligibility for enrollment or premiums based on health status.[56] It effectively requires community rating within groups. HIPAA also imposes three limits on the use of pre-existing conditions clauses in employment-related group policies–it imposes a reasonably narrow definition of pre-existing condition, it limits the look-back period for determining whether a pre-existing condition exists to six months, and in most instances it only permits the preexisting conditions clause to operate for a maximum of twelve months.[57] Insurers must reduce this twelve month period by the length of immediately preceding time periods during which the insured had "creditable coverage," i.e. another form of insurance, which in many instances will completely eliminate pre-existing conditions clauses. HIPAA further requires insurers operating in the small group market to guarantee issue and renewability to small employer groups, although it does not govern the price at which policies must be offered.[58] Finally, HIPAA requires insurers that operate in the individual market to offer (and subsequently to renew) nongroup coverage to persons who lose prior "creditable coverage" under certain circumstances.[59] This final provision only applies in states that do not make alternative provision for covering uninsured individuals. Most states do offer an alternative, usually a high-risk pool, as discussed below.

Other federal laws can also affect insurance coverage practices. The Age Discrimination in Employment Act, requires employers in general to offer the same coverage or coverage of the same value to their employees regardless of age,[60] while the Americans with Disabilities Act (ADA) prohibits at least intentional discrimination against the disabled in insurance underwriting, although as a practical matter it permits insurers to take health status into account as long as they do so rationally.[61]

The states have been much more active than the federal government in regulating insurance markets. For the purpose of regulation, states divide insurance markets into three segments–the large group (usually over 50 members), small group (under 50), and nongroup (individuals and families) markets. States rarely regulate the large group market, which functions reasonably well because of the market power of employers and in, any event, is largely exempt from state regulation under ERISA because of the prevalence of self-insurance in large groups. States have been most active in regulating the small group market, the market-segment, which accounts for most of the country's uninsured.

States have taken a variety of approaches to expanding coverage in the small group market, in addition to imposing the federally required mandates of guaranteed issue and renewal.[62] About a dozen require insurers to community rate premiums charged to small groups, or at least to not take into account health status and claims experience in setting their premiums.[63]

Many more states require insurers to remain within rating bands, allowing insurers only to charge premiums to their most expensive groups within a particular category that are no greater than twice those they charge their most favored groups, for example.[64] Some states also impose tighter restrictions on the use of preexisting conditions clauses than those permitted by federal law. Finally, about half the states have also established risk pools and either require or permit insurers to pool their risks with other insurers. New York offers state-funded reinsurance for high risk individuals in some groups.[65]

States regulate insurance underwriting and rating not only in the small group, but also in the nongroup market. Here too some states require community rating or modified community rating (allowing variation based on age, for example) while others limit premium variation within rating bands.[66] Because the risk that insurers face from adverse selection is greater in the nongroup market than in the group market, and because there is always the danger that young and healthy applicants will be priced out of the market if they are pooled with higher risk applicants (potentially causing an insurance death spiral as the pool of insureds that remains becomes ever more risky), states tend to be more reticent about restricting the underwriting practices of insurers in this market. A few states have used voluntary or mandatory reinsurance pools to assist insurers who draw the worst risks in the nongroup market.[67] The most common response of the states, however, has been state operated high risk pools which insure individuals denied nongroup coverage, and which are financed by a combination of premiums, state funds, and assessments against insurers.[68] Although high risk pools tend to cap premiums at 150 to 200 percent of the cost of a standard nongroup insurance policy, they are still unaffordable to many of the uninsured.

All of these regulatory interventions attempt to make health insurance accessible to those who would otherwise be excluded from it, and thus to expand the scope of the risk pool. An alternative public policy approach is to encourage individuals to save for their own health care needs, pooling only catastrophic risk. The Medicare Modernization Act offers tax subsidies to individuals (and their employers) who contribute to health savings accounts (HSAs) to cover their own future health care needs and who pool only catastrophic risk through high deductible health policies.[69] Virtually all states that have an income tax offer corresponding state tax subsidies and have removed any regulatory barriers to conforming high deductible policies.[70] Over 4.5 million Americans currently have HSA-compatible, high deductible policies, although many of these do not have significant savings invested in an HSA. It is unclear what effect this strategy will have on risk pooling generally–that is, whether it will expand pooling of catastrophic risk or facilitate the healthy and wealthy in opting out of broader risk pooling.[71]

Attempts to expand insurance coverage through regulation and tax subsidies will no doubt be evaluated in other Fresh Thinking papers. This is basically a matter of policy rather than principle. Suffice it to say here that it is difficult to use government regulation to force a private insurer to behave like a social insurer. Attempts to do so tend to resemble a game of whack-a-mole. Insurers become more and more sophisticated in their attempts to risk select, while regulatory interventions become more and more draconian in the attempt to force insurers to cover those whom they do not want to cover.[72]

Recommendations:

The obvious solution to this problem is to move to public insurance. In virtually all countries with public health insurance, private insurance remains available but plays a more marginal role, covering persons not included in the mandatory pool, as in Germany; or items and services not covered by public insurance, as in Canada; or cost-sharing obligations, as in France; or facilitating queue jumping, as in England.[73] In most instances, supplemental or complementary private insurance is regulated much more lightly because it is not responsible for covering essential services.

Universal public insurance, of course, brings its own problems and, in any event, may not be politically feasible in the United States. In the absence of universal public insurance, universal coverage will probably require both an individual insurance purchase mandate and generous subsidies for the purchase of private insurance. An individual mandate, like those found in Massachusetts, the Netherlands, and Switzerland, solves the problem of adverse selection against the insurance market, but does nothing to protect particular insurers from adverse selection by applicants or insurance applicants from favorable selection by insurers. Generous subsidies (probably in the form of tax credits) would make private insurance more accessible to low income households. If these subsidies were risk adjusted (as they are in the Medicare Part C and D programs), higher risk applicants would be more attractive to private insurers, although insurers may still avoid high risk applicants if they do not trust the government's risk adjustment mechanism or if risk adjustments are not adequate. The creation of a public insurer to compete in the private market, as is done in Australia, might force private insurers to be more efficient, and might provide coverage to persons who private insurers might not reach, such as those who live in rural areas. Finally, public reinsurance of high cost insureds, as is done in New York, or some form of mandatory risk pooling among insurers (as is found in Germany, the Netherlands, and some American states), might further reduce the incentives that insurers face to cherry pick.

How to accomplish universal coverage is, of course, the overriding theme of this project, and this one paper cannot solve the problem. Suffice it to say that doing so will require reform of insurance markets, and this will require selecting a particular combination of regulations and subsidies and repealing legislation and regulations requiring or encouraging inconsistent approaches. As noted earlier in this paper, I would support a federal approach to this regulation that would preempt inconsistent state regulation. I would also favor, insofar as it is possible, the use of incentives to encourage insurers to take on high risk applicants rather than regulation to force them to do so, in particular through reinsurance of catastrophic costs. The simple use of regulation to force insurers to accept high-risk individuals without appropriate incentives is probably an exercise doomed to failure, as Professor Noll points out. Finally, I would support regulations to limit preexisting conditions clauses, waiting periods, and post-claims underwriting, to ensure that those who obtain insurance policies are in fact covered for the conditions for which they have purchased insurance.

VI. Regulation of the Health Care Delivery System

Law governs not only markets for health insurance but also regulates markets for the delivery of health care products and service. As Professor Sage and Representative Cooper's comments illustrate, the current regulatory system is often counterproductive.

Law governs markets for delivery of health care in a number of ways. First, federal and state laws govern the entry of professionals, providers, and products into health care markets. State professional licensure laws determine the qualifications that must be met by persons who want to practice particular professions, as well as the scope of practice of those professions. While these laws assure that those who practice professions meet basic standards of competence, they also can limit professionals other than physicians from using the full scope of their training, and thus may be inefficient.[74] The state corporate practice of medicine doctrine limits the ability of firms to employ health care professionals in many states.[75] Institutional licensure laws (and accreditation standards) also ensure that institutions meet basic structural quality standards, but may discourage innovative approaches to health care delivery. Finally, federal Food and Drug Administration marketing approval of drugs, devices, and biologics are intended to assure the safety and effectiveness of those products, but have been criticized for slowing innovation (and, more recently, for being ineffective).

States also regulate the structure of health care delivery through certificate of need laws. Thirty-six states currently have a certificate-of-need (CON) program.[76] Most state adopted their CON laws in response to the National Health Planning and Resources Development Act of 1974 (NHPRDA), which required the states to adopt CON programs, although the CON laws of some states antedated the federal law.[77] The NHPRDA established a federal policy of health planning, based in part on the theory that the best way to supply the use of health care was to constrain supply. The federal requirement was repealed in 1986, but CON survives in the states. States with CON laws generally have health plans to direct the development of new facilities, and require applicants to show that their proposed new facility, beds, or equipment are "needed" under the plan. In general, CON programs have the effect of protecting existing institutions from competition. They also, however, restrain capital investment in health care facilities, which in turn means that payers do not need to cover the operating costs that would have been incurred had a facility existed.

Federal law also affects the structure of the health care industry. First the Sherman antitrust statute prohibits "combinations, conspiracies, and contracts" in restraint of trade, as well as monopolization.[78] Only since 1975 has the Supreme Court recognized that the antitrust laws apply to professionals,[79] but in the years that have followed, the antitrust laws have been used to loosen up professional ethical restrictions that had limited competition among health care professionals.[80] Indeed, in 1982, the Supreme Court held that an agreement among physicians to offer insurers agreed maximum prices was a per se antitrust violation.[81]

Antitrust enforcement guidelines issued jointly by the Federal Trade Commission and Department of Justice in 1996 address a range of topics from hospital mergers to collective provision of information to purchasers by providers, to physician network joint ventures.[82] These guidelines are taken into consideration by health care professionals and providers who are contemplating health care transactions. However, enforcement challenges to hospital mergers in recent years have by and large failed, and while enforcement actions against collective

bargaining by physicians has enjoyed somewhat more success, it does not seem to have succeeded in discouraging such activities.[83] Antitrust litigation challenging hospital staff privileging actions have been largely blocked by the Health Care Quality Improvement Act, and, in any event rarely succeeded even without that law.[84] If the United States were to adopt an approach to health care reform that would depend on independent physicians combining together to negotiate with managed care organizations or with the government, a change would be needed in the antitrust laws. Otherwise, it is unlikely that antitrust law as they are presently enforced would prove a major impediment to restructuring the health care industry in health care reform.

The laws that probably have the greatest impact on the structure of the delivery of health care in the United States are a set of federal laws that govern relationships among health care professionals and providers–the self-referral, bribe and kickback, and inducement to reduce services prohibitions. The self-referral law prohibits physicians who have (or whose immediate family members have) a "financial relationship" with a provider from referring Medicare or Medicaid patients to that provider for "designated health services."[85] "Financial arrangement" is broadly defined to include both "ownership and investment interests" and "compensation arrangements."[86] "Designated health services," include a list of eleven items and services, including laboratory tests, radiology services, durable medical equipment, outpatient drugs, home health services, and inpatient and outpatient hospital services.[87] No payment can be made by Medicare and Medicaid for services provided in violation of the prohibition, and knowingly billing or failing to refund payments under these circumstances exposes a provider to a civil penalty and exclusion from federal health care programs.

On its face, the self-referral statute seems to ban any situation where physician referrals flow in one direction and "remuneration" in the other. If a physician admits patients to a hospital, for example, and receives any benefits in any form at any time from the hospital, the hospital cannot bill Medicare for the services provided to the patient. In fact, however, the prohibition is subject to myriad exceptions. First, the prohibition is subject to about seventeen statutory exceptions, covering, for example, bona fide employment arrangements and investments in large corporations.[88] Moreover, the statute authorizes HHS to make regulatory exceptions where a financial relationship "does not pose a risk of program or patient abuse,"[89] and HHS has issued several rounds of voluminous regulations (the most recent of which was issued in September of 2007) recognizing such exceptions. In combination, the statutory and regulatory exceptions define in great detail, for example, benefits that hospitals may provide to physicians or the structure of physician groups.[90]

The bribe and kickback law similarly prohibits professionals, providers, or suppliers from "knowingly and willfully" paying or receiving, offering or soliciting "remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in return for referring a patient or for arranging or furnishing a service paid for by a federal health care program.[91] Violation of the bribe and kickback prohibition is a felony. The bribe and kickback law is, like the self-referral statute, subject to a number of statutory exceptions. The Office of Inspector General of the Department of Health and Human Services also has authority to promulgate "safe-harbor regulations" determining conduct to be permissible even though it would seem to be proscribed by the statute.[92]

Like the self-referral statute, the bribe and kickback prohibition limits the ability of a physician group, hospital, or other health care entity to remunerate health care professionals who are referring patients to the group or to other members of the group, hospital, or other health care entity. The statutory exceptions and regulatory "safe harbors" to the bribe and kickback statue are fewer in number and less comprehensive than those that implement the self-referral statute. Violation of the bribe and kickback statute also requires intent, however, and thus a health care professional or provider can argue that remuneration was not in exchange for referrals. But court decisions establish that if remuneration for referrals played any role in a transaction or relationship, the prohibition applies, even if obtaining the remuneration was not the primary purpose of the referral.[93] Relationships between health care professionals and providers have to be carefully scrutinized, therefore, to assure that the prohibition is not violated.

The bribe and kickback and self-referral statutes present endless conundrums given the complex relationships found in the health care industry. If a hospital offers a recruitment package to lure a new doctor to the hospital, is it paying the doctor to subsequently admit patients to the hospital? If a hospital purchases a physician's practice and thereafter employs the doctor to treat patients, is either the purchase price or the subsequent salary remuneration for referrals? Does a doctor within a group practice violate the prohibitions when she refers patients for tests at the group's own lab? Does a doctor who prescribes medication manufactured by a publicly-traded company in which the doctor owns stock violate the provisions? Does a radiologist who leases imaging equipment to or from a hospital violate the prohibitions if she also admits patients to the hospital? These laws affect virtually all business relationships that exist among professionals and providers.

Finally, another federal statute, prohibits hospitals from knowingly paying and physicians from knowingly receiving payments "as an inducement to reduce or limit services" to Medicare or Medicaid beneficiaries.[94] This statute, together with the antikickback statute, has driven the concern that the HHS OIG has had with "gainsharing" arrangements, under which hospitals reward physicians for reducing hospital costs by giving the physicians a share in cost reductions. Gainsharing arrangements also raise concern under the bribe and kickback statutes because these arrangements can potentially be used to reward physicians for patient referrals. The OIG has approved a number of gainsharing arrangements, and Congress in 2006 adopted a statute establishing a gainsharing demonstration project. The OIG has insisted on transparency, controls to assure quality, and safeguards to make certain that arrangements are not disguised bribes or kickbacks in gainsharing arrangements it has blessed.[95]

Recommendations:

A restructured health care delivery system should focus on coordinated and efficient delivery of care. The question of whether current interpretations of the antitrust laws are adequate to deter inefficient concentrations of economic power while permitting efficient coordination in the health care industry is one I will leave to economists, although I do feel that the current enforcement guidelines for physician networks probably are useful in encouraging integration of the delivery of health care services, and that courts have probably gone too far in permitting hospital mergers.

The bribe and kickback and self-referral laws, however, clearly need reform. They are based on a sound principle–that professionals should refer their patients to the provider that can best serve the patient's medical needs rather than the professional's economic interests–but the laws and regulations implementing this principle have become bizarrely complicated. The principle behind the incentives to reduce services–that professionals should not face too stark choices between their patients' interests and their own financial interests–is also commendable. Greater flexibility in the application of both principles, however, makes sense.[96] I would favor replacing the bribe and kickback and self-referral laws with a single law that would prohibit the knowing referral of patients where the referring professional stands to receive remuneration (including compensation or a return on an investment) from the referral. The prohibition should be subject to a short list of reasonably clear statutory exceptions, such as for investments in large, publicly-traded corporations or for situations in which the referrer is at risk for the cost of the referred service. The statute should also provide, however, that where an arrangement between a professional and a provider is not subject to an explicit statutory exception, but is intended to serve a justifiable purpose other than to secure referrals, the provider or professional would be permitted to file with the OIG a description of the arrangement and explanation of its justification. If the OIG did not object to the arrangement in a reasonable period of time (90 days for example), the arrangement could go forward. If the OIG, or any other party adversely affected by the arrangement, objected, the parties engaged in the arrangement would have to prove that the arrangement was justifiable to an administrative tribunal (subject to judicial review). If professionals or providers entered into transactions that violated the statute without submitting a justification or persisted in an unjustified transaction, they would be subject to civil fines. Intentional violations could result in criminal sanctions.

Gainsharing arrangements should be permitted that are transparent to patients, include quality assurance oversight, otherwise comply with the bribe and kickback laws, and also share some of the gain with patients.[97] Opaque gainsharing arrangements, or those that are simply payments for referrals, should not be.

Finally, state laws should be reformed to abolish the corporate practice of medicine doctrine where it still exists, and to revise licensure and scope of practice laws to assure that any professional competent to provide a medical service is allowed to do so.

VII. Postscript on Medical Malpractice

I know of little hard evidence that medical malpractice litigation is a major factor driving the high cost of health care in the United States or limiting access to it. The direct costs of malpractice account for a percent or two of health care costs, and claims that defensive medicine are a major factor in health care costs have not been substantiated. Nevertheless, it is clear that physicians find malpractice litigation to be an outrage, and their sense of justified grievance influences their attitude toward reform generally. Indeed, every discussion I have with physicians about health care reform gets around eventually to how indignant they are about medical malpractice and how much they had to pay for medical school.

There is some evidence that the solutions physicians advance for the malpractice problem–caps on noneconomic damages and procedural barriers to successful litigation–have

had a minor effect on costs and perhaps even access, but there is also evidence that these "reforms" disproportionately affect women, the elderly, and the poor, who are more likely to suffer predominantly from noneconomic losses, such as the loss of reproductive capacity or the death of a child. On the other hand, it seems obvious that our current approach to medical negligence litigation is deeply dysfunctional, imposing high administrative costs, denying justice to most people injured by medical negligence, and doing little to encourage quality. Indeed, the system seems to benefit no one except trial lawyers (on both sides of the litigation), malpractice insurers who collect high premiums, a few patients who suffer devastating injuries, and politicians (on both sides of the aisle).

The menu of solutions to the malpractice conundrum that emerges most commonly include no-fault administrative schemes, enterprise liability, contractual limits on liability, and health courts. All proposals have costs and distributional consequences. If a solution could be found to this problem that would salve the grievances doctors feel, it might also affect their willingness to cooperate with health care reforms that might otherwise affect their interests. Health care reform would be well-advised, therefore, to address this issue as well. It is, however, neither an issue as to which I claim expertise, nor the primary legal issue presented by health care reform.

VIII. Conclusion

Health care reform will require reform of health care law. This will require, first and foremost, rethinking of the relationship between the federal and state governments with respect to health care. It will also require redefinition of legal entitlements to health care. Finally, it will require revision of laws regulating health insurance and health care markets. This paper will, it is hoped, contribute to this project of law reform, and thus ultimately of health care reform.

ENDNOTES

[1] Because this paper is directed at a nonlegal audience, because it is a "think-piece" rather than an academic research paper, and also because of space constraints, it contains dramatically fewer and less comprehensive references than would customary be found in legal scholarship. In particular, it does not fully acknowledge its debt to a vast body of scholarly literature on the topics it addresses. I do, however, shamelessly cite books and articles that I have written on various topics, and in these further references can be found. I am also very willing to provide further references to anyone who desires to inquire further into a particular topic the paper addresses. I can be reached at jostt@wlu.edu.

[2] 42 U.S.C. §§ 1395, 1395a.

[3] 45 C.F.R. Parts 160 & 164.

[4] Prinz v. United States, 521 U.S. 898 (1997)

[5] See Lester Salamon, The Tools of Government: A Guide to the New Governance (Oxford U. Press 2002).

[6] See Eleanor DeArman Kinney, Protecting American Health Care Consumers (Duke University Press 2002), 128-33.

[7] Thomas M. Selden & Bradley M. Gray, Tax Subsidies for Employment-Related Health Insurance: Estimates for 2006, 25(6) Health Affairs 1568-1579 (2006)

[8] U.S. Constitution, Art. 1, § 8, cl. 3. See United States v. Lopez, 514 U.S. 549, 558 (1995).

[9] U.S. Constitution, Art. 1, § 8, cl. 1.

[10] See, e.g. New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654-662 (1995).

[11] This cooperation is facilitated through coordinating entities like the National Association of Insurance Commissioners (NAIC) or the National Conference of State Legislatures.

[12] 15 U.S.C. § 20

[13] U.S. v. South-Eastern Underwriters, 322 U.S. 523 (1944).

[14] 42 U.S.C. § 1395aa.

[15] 42 U.S.C. § 1395w-26(b)(3). This preemption gets complicated at the margins. The Medicare statute, for example, explicitly allows state licensing and regulation of managed care plan solvency, while several cases have held that state law may address issues not addressed by federal law, such as tort liability of managed care plans for the acts of their agents. Hofler v. Aetna Healthcare of Calif., 296 F.3d 764 (9th Cir 2002).

[16] See, tracing this history, Timothy S. Jost, Disentitlement: The Threats Facing Our Public Health Care Programs and a Rights-Based Response, 87-89, 91-96 (Oxford Univ. Press 2003).

[17] See, e.g. Gonzaga University v. Doe, 536 U.S. 273 (2002).

[18] 42 U.S.C. § 1144(a). ERISA does not govern government or church-sponsored plans.

[19] See, e.g. Kentucky Association of Health Plans v. Miller, 538 U.S. 329 (2003); Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355 (2002).

[20] FMC Corp. v. Holliday, 498 U.S. 52 (1990).

[21] See, e.g. Retail Industry Leaders Ass' v. Fielder, 475 F.3d 180 (4th Cir . 2007) (holding that Maryland is prohibited by ERISA from requiring Walmart to spend 8% of its payroll on health benefits).

[22] Aetna Health Inc. v. Davila, 542 U.S. 200 (2004).

[23] New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654-662 (1995).

[24] See DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442 (3rd Cir. 2003).

[25] At least to date, federal coverage mandates have been few and state mandates many. See below, section IV.

[26] See The Health Care Choice Act of 2005 (H.R. 2355).

[27] See 42 U.S.C.§ 7543.

[28] See 42 U.S.C. §§ 426, 1395c, 1395d, 1395k, Jost, supra note 16, at 30-32. Part D also creates federally-defined legal rights in those who enroll in and pay premiums for prescription drug coverage, while Part C enrollees have rights defined by the federal statute and regulation.

[29] See 42 U.S.C. § 1395ff.

[30] 42 U.S.C. § 1396a(a)(3).

[31] 42 U.S.C. § 1397bb(b)(4); Sara Rosenbaum & Barbara Smith, Policy Brief # 1: State SCHIP Design and the Right to Coverage (George Washington University Center for Health Services Research and Policy, 2001).

[32] 20 C.F.R. § 2560.503-1.

[33] Susan S. Laudicina, Joan M. Gardner, & Angela M. Crawford, State Legislative Health Care and Insurance Issues: 2006 Survey of Plans, 72 (Blue Cross and Blue Shield Ass'n, 2006).

[34] Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355 (2002); 20 C.F.R. § 2510.503-1(k).

[35] See Jost, supra note 16, at 33.

[36] 42 U.S.C. § 1396dd.

[37] 42 U.S.C. §§ 1396a(a)(10); 1396d(a).

[38] 42 U.S.C. §§ 1185,1185a, 1185b.

[39] 42 U.S. C. §§ 2000e(k), 2000e-2(a)(1)

[40] I.R.C. § 223(c)(2)(A).

[41] Laudicina, Gardner, & Crawford, supra note 33, at 73-78.

[42] Id. at 73.

[43] See Christopher J. Conover, Distributional Considerations in the Overregulation of Health Professionals, Health Facilities, and Health Plans, 69 Law and Contemporary Problems Symposium Issue: Who Pays? Who Benefits?181-193 (2006); Gail A. Jensen & Michael A. Morrisey, Employer-Sponsored Health Insurance and Mandated Benefit Laws, 77(4) Milbank Quarterly 425-59 (1999).

[44] David Hyman, Regulating Managed Care: What's Wrong With a Patient Bill of Rights, 73 S.Cal.L. Rev. 221 (2000).

[45] Amy Monahan, Federalism, Federal Regulation, or Free Market? An Examination of Mandated Benefit Reform, 2007 U. Ill. L. Rev. 1361.

[46] Russell Korobkin, The Efficiency of Managed Care "Patient Protection" Laws: Incomplete Contracts, Bounded Rationality, and Market Failures, 85 Cornell L. Rev. 1 (1999).

[47] The employee, of course, is also interested, at least ex ante, in the cost of the policy, since the employee ultimately pays for it through reduced wages. Employers and employees tend to believe, however, that employers are primarily responsible for the cost of insurance, and in the short run they often are. Once an injury or disease occurs, moreover, the employee is immediately interested in coverage, while the employer will only be concerned about coverage to the extent that the employee can enlist the employer in his or her cause. See, examining the economic rationales offered for managed care regulation, as well as the enforcement of those laws, Mark Hall & Frank Sloan, Market Failures and the Evolution of State Managed Care, 65 Law & Contemporary Problems 169 (2002).

[48] See Mark Hall, Managed Care Patient Protection or Provider Protection? A Qualitative Assessment, 117 American Journal of Medicine 932 (2004)

[49] See, e.g. Paul Fronstin & Susan Collins, Early Experience With High-Deductible and Consumer-Driven Health Plans, EBRI Issue Brief, 2006; Karen Davis, Michelle M. Doty, & Alice Ho, How High is Too High? Implications of High-Deductible Health Plans (The Commonwealth Fund 2005).

[50] This list does not include nursing facility services, home health care, and hospice care, which are currently covered by the Medicaid program and to some extent by the Medicare program, but not by most private insurance policies. I would support the creation of a separate social insurance program to cover these services, as in the Dutch system. These services are very costly and predominantly affect the elderly and disabled. Trying to cover them through private insurance policies could make those policies unaffordable to younger individuals and families. These services are already paid for predominantly by Medicare and Medicaid, and thus it might be politically feasible to cover these services publicly in a reformed health care system.

[51] See, examining the role that politics plays in health care coverage decisions, Timothy S. Jost, ed., Health Care Coverage Determinations: An International Comparative Study (Open University Press 2005).

[52] Marc L. Berk & Alan C. Monheit, The Concentration of Health Care Expenditures Revisited 20(2) Health Affairs 9, 12 (2001).

[53] See Timothy S. Jost, Health Care at Risk: A Critique of the Consumer-Driven Movement, 54-64 (Duke University Press 2007).

[54] Compare Clark C. Havighurst, Distributive Injustice(s) in American Health Care, 69 Law and Contemporary Problems 7 (2006) and Mark Pauly, The Tax Subsidy to Employment-Based Health Insurance and the Distribution of Well-Being, 69 Law and Contemporary Problems 83 (2006).

[55] 29 U.S.C. §§ 1161-1168.

[56] 29 U.S.C. § 1182(a) & (b), 42 U.S.C. § 300gg-1.

[57] 29 U.S.C. § 1181, 42 U.S.C. § 300gg

[58] 42 U.S.C. §§ 300gg-11, 300gg-12

[59] 42 U.S.C. §§ 300gg-42, 300gg-42

[60] 29 U.S.C. § 623(f)(2)(B)(i).

[61] An exception to the ADA's prohibition against disability discrimination permits insurance underwriting that is not in violation of state law or a "subterfuge" for violation of the law. 42 U.S.C. § 12201(c).

[62] See Mark A. Hall, Reforming Private Insurance (American Enterprise Institute 1994)

[63] Laudicina, Gardner & Crawford, supra note 33, at 57.

[64] Thirty-seven states had rating limits in 2006. Id.

[65] See Kathryn Swartz, Reinsuring Health: Why More Middle-Class People Are Uninsured and What Government Can Do (Russell Sage Foundation 2006); John Jacobi, Government Reinsurance Programs and Consumer-Driven Care, 53 Buffalo Law Review 537 (2005).

[66] Laudicina, Gardner, & Crawford, supra note 33, at 59.

[67] Id.

[68] Thirty-four states had high risk pools in 2006. Id at 68.

[69] I. R.C. § 223.

[70] See Timothy S. Jost and Mark A. Hall, The Role of State Regulation in Consumer-Driven Health Care, 31 American Journal of Law & Medicine 395-418 (2005).

[71] See Timothy S. Jost, supra note 53 at 119-49 (reviewing the evidence for and against the consumer-driven approach).

[72] See Timothy S. Jost, Public and Private Approaches to Insuring the Uninsured, 76 New York University Law Review 419-92 (2001); Mark A. Hall, The Competitive Impact of Small Group Health Insurance Reform Laws, 32 U. Mich. J.L. Reform 685, 722 (1999)

[73] See Jost, supra note 72.

[74] See Timothy S. Jost, Oversight of the Quality of Medical Care: Regulation, Management, or the Market? 37 Ariz. L. Rev. 825 (1995).

[75] **Error! Main Document Only.** See D. Cameron Dobbins, Survey of State Laws Relating to the Corporate Practice of Medicine, 5 Health Law 18 (1997); Jeffrey F. Chase-Lubitz, The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry, 40 Vand. L. Rev. 445 (1987).

[76] National Conference of State Legislatures, Certificate of Need: State Health Laws and Programs (2007), http://www.ncsl.org/programs/health/cert-need.htm.

[77] See Evan M. Melhado, Health Planning in the United States and the Decline of Public-Interest Policymaking, 84(2) The Milbank Quarterly 359 (2006).

[78] 15 U.S.C. §§ 1, 2.

[79] Goldfarb v. Virginia State Bar , 421 US 773 (1975).

[80] FTC v. Indiana Federation of Dentists, 476 US 447 (1986).

[81] Arizona v. Maricopa County Medical Soc., 457 US. 332 (1982).

[82] Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm

[83] See Thomas Greaney, Thirty Years of Solicitude: Antitrust Law and Physician Cartels, 7 Houston Journal of Health Law and Policy (forthcoming 2007); Thomas Greaney, Whither Antitrust? The Uncertain Future of Competition Policy in Health Care, 21 Health Affairs, Mar./Apr. 2002 at 185. .

[84] 42 U.S.C. §§ 11101-11152 (1995) ; Peter J. Hammer & William M. Sage, Antitrust, Health Care Quality, and the Courts, 102 Columbia Law Review. 545 (2002).

[85] 42 U.S.C. § 1395nn(a).

[86] 42 U.S.C. § 1395nn(a)(2), (h)

[87] 42 U.S.C. § 1395nn(h)(6).

[88] 42 U.S.C. § 1395nn(b), (c), (d), and (e).

[89] 42 U.S.C. § 1395nn(b)(4).

[90] Benefits provided by tax-exempt hospitals to medical staff members may also raise concerns because of the prohibitions under tax-exempt organization law against inurement, private benefit, and excess benefits to disqualified persons. See Furrow, et al, Health Law, 961-73 (WestGroup 5th ed. 2004)

[91] 42 U.S.C. § 1320a-7b.

[92] 42 C.F.R. § 1001.952.

[93] United States v. Greber, 760 F2d. 68 (3rd Cir. 1985).

[94] 42 U.S.C. § 1320a-7a(b)(1) & (2).

[95] Testimony of Lewis Morris, Chief Counsel, Office of Inspector General, http://oig.hhs.gov/testimony/docs/2005/Gainsharing10-07-05.pdf

[96] See James F. Blumstein, Of Doctors and Hospitals: Setting the Analytical Framework for Managing and Regulating the Relationship, 4 Indiana Health Law Review (forthcoming).

[97] Richard S. Saver, Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives, 98 Northwestern Law Review 145 (2003).