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for National and Global Health Law

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LEGAL SOLUTIONS IN HEALTH REFORM PROJECT

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Legal Solutions in Health Reform: Project Overview and Emerging Themes

Elenora E. Connors* and Timothy M. Westmoreland**

I. Purpose of and Layout of Project

The American public has increasingly identified health care as a key issue of concern. In order to address the multiple problems relating to the access and affordability of health care, President Obama and federal lawmakers across the political spectrum continue to call for major health reform. In any debate on health reform, a predictable set of complex policy, management, economic, and legal issues is likely to be raised. Due to the diverse interests involved, these issues could lead to a series of high-stakes policy debates. Therefore, **it is critical that advocates of reform strategies anticipate such issues in order to decrease the likelihood that legally resolvable questions become barriers to substantive health reform**. In an effort to frame and study legal challenges and solutions in advance of the heat of political debate, the O'Neill Institute for National and Global Health Law at Georgetown University and the Robert Wood Johnson Foundation have crafted the "Legal Solutions in Health Reform" project.

This project is undertaken with the optimistic view that all legal problems addressed are either soluble or avoidable. Rather than setting up roadblocks, this project is a constructive activity, attempting to pave the road towards improved health for the nation. Consequently, it does not attempt to create consensus solutions for the identified problems nor does it attempt to provide a unified field theory of how to provide health insurance in America. Furthermore, this project does not seek to choose among the currently competing proposals or make recommendations among them. Instead, it is a comprehensive project written to provide policy makers, attorneys, and other key stakeholders with a concise analysis of the complex legal issues relating to health reform, and a clear articulation of the range of solutions available for resolving those questions.

The introduction to this project lays out the formulation of our project, why health reform is important, the pertinent legal questions applicable to federal health reform, and three themes that surface throughout the identified legal challenges: federalism and preemption; jurisdiction; and enforcement and remedies. After a discussion of the current state of health care in the United States, this introduction will cite brief examples and problems under each general theme. Additionally, it will point to some of the solutions and remedies discussed in detail in the papers.

II. Formulation and Definition of Key Legal Issues

Among the major issues in federal health reform, there are recurring questions that are policy-based and those that are legally-based. Of course, many times questions of policy and of law overlap and cannot be considered in isolation. For the purpose of this project, however, we draw the distinction between law and policy based on the presence of clear legal permission or prohibition. Under this distinction, policy issues include larger-scale questions such as what basic model of health reform to use, as well as more technical questions such as what thresholds to use for poverty-level subsides and cost-sharing for preventive services. In contrast, legal issues are those involving constitutional, statutory, or regulatory questions such as whether the Constitution allows a certain congressional action or whether particular laws run parallel or

conflict. Additional legal issues are based on the clarity of a statute and whether it contains omissions or ambiguities that require interpretation or allow flexibility.

Based on this dividing line of clear permission or prohibition, policy questions can be framed as those beginning with, "*Should we…?"* and legal questions can be framed as those beginning with, "*Can we…?"* The focus of this project will be the latter, broken into three particular issues to study: 1) "Under the Constitution, *can we ever…?*"; 2) "Under current statutes and regulations, *can we now…?"*; 3) " Under the current regulatory scheme, *how do we?"* (This final set of questions tends to be mixed questions of policy, law, and good legislative drafting.)

To clarify the distinction between questions of policy and of law, consider the difference between the policy implications of helping to pay for health insurance and a federal law requiring individuals to purchase health insurance (the "individual mandate"):

- The question of whether the federal government *should* subsidize such a purchase is a complex one of policy involving a calculus of need, likely take-up rates, and arguments about moral hazard. This question, however, presents almost no legal issues as to whether the federal government has authority to give money away if it chooses to do so.
- Alternatively, the question of whether the federal government *can* compel citizens to purchase health insurance is a legal question involving the absence of a general police power for the federal government, the definition of "interstate commerce", and the use of spending and taxing authorities.

Based on surveys of current health policy meetings and agendas, popular and professional press, and current health reform proposals, our team formulated legal issues relating to federal health reform. After much research, discussion, and expert advice and review, our initial list of over 50 legal issues was narrowed to ten. An initial framing paper was drafted which identified these ten legal issues, and briefly outlined the main components of each.[1] In May of 2008, a bipartisan consultation session was convened to provide concrete feedback on the choice and framing of the legal issues. The attendees of the consultation session included congressional staff, executive branch officials, advocates, attorneys, employers, and representatives of a wide range of interests affected by health reform. Feedback and analysis from this session further narrowed the ten issues to eight key legal issues that warranted in-depth analysis of the current law.

Eight nationally recognized experts were recruited to draft papers on each of these topics for dissemination early in 2009. In developing each paper, the authors consulted with experts and knowledgeable advisors representing a wide range of health-sector and political perspectives. These eight pertinent issues are truly legal in nature; they are questions that need to be resolved as part of formulating a health reform proposal to avoid needless debate or pitfalls as policy decisions are made. The main issues addressed in this project are those immediately necessary for a discussion of the implementation of a new federal policy. There are multiple other legal issues that will arise as the discussion evolves and, if a federal policy is adopted, as the system changes. In this project, however, we have targeted the issues essential for an immediate discussion of federal health reform.

1. The Constitutionality of Mandates to Purchase Health Insurance – Many health reform proposals include mandates requiring individuals and employers to purchase health insurance. An examination of whether such a requirement is within the powers of Congress to enact, and/or

whether it violates any constitutional provisions, can help in the design of a mandate that is most likely to withstand challenge.

2. Executive Authority to Reform Health: Options and Limitations – While much of health reform takes place through legislation, there are numerous regulatory and administrative tools, such as executive and administrative orders, which the President and federal agencies may use to reshape federal health programs. The legal questions following from these tools involve the extent and scope of this authority and where the authority is strongest under current law.

3. Health Insurance Exchanges: Legal Issues – Presidential candidates and policy makers have made comprehensive reform proposals that involve the creation of new market options through insurance exchanges (akin to Massachusetts' Connector). Any insurance exchange option, whether organized at the federal or state level or as a private entity, requires a constitutional and legal analysis to determine whether restrictions on individuals and insurance providers would withstand legal challenge.

4. Insurance Discrimination on the Basis of Health Status: An Overview of Discrimination Practices, Federal Law, and Federal Reform Options – Underwriting in the insurance industry based on an individual's health status can occur at either the point of enrollment or in decisions regarding scope of coverage. Federal laws, in the form of civil rights laws, tax laws, labor laws, and laws funding state public health activities have focused on the former and have limited the ability of insurers to bar enrollment based on health status. However, questions persist about the coverage of, and interaction among, several federal statutes (*e.g.* Title VII; HIPAA; the Americans with Disabilities Act (ADA); the newly-passed Genetic Information Nondiscrimination Act (GINA); and the Mental Health Parity Act). These questions should be clarified for employers, insurers, and individual consumers alike.

5. Privacy and Health Information Technology – State and federal laws governing the privacy of personal information have left the legal landscape unclear as to who has access to personal health information, for what purposes, and under what circumstances. Any efforts to reform the nation's health systems and increase use of health information technology (IT) will need to address the legal concerns surrounding the privacy and security of personal health information and resolve issues with the Health Insurance Portability and Accountability Act (HIPAA) and other existing laws.

6. The Purchase of Insurance Across State Lines In the Individual Market – Recent proposals, such as "The Health Care Choice Act" (H.R. 4460), and Senator McCain's outlined plan, have called for revising current federal law to allow individuals to purchase insurance from a carrier domiciled in any state it chooses. Any federal proposal to allow the sale of insurance across state lines would need to be carefully drafted to ensure that it did not run afoul of the McCarran-Ferguson Act (designating states as the primary regulators of the business of insurance) or compel state officials to implement federal regulation (commandeering).

7. The Role of ERISA Preemption in Health Reform: Opportunities and Limits – The Employee Retirement Income Security Act (ERISA) is central to health reform efforts inasmuch as it encompasses a wide range of regulations and implicates both federal and state interests. ERISA regulates employer-sponsored health plans and, with some exceptions, generally bars states from enacting legislation interfering with the structure or administration of such health

plans. Some current proposals advocate legal flexibility to encourage state experimentation in health insurance regulation. However, the reach and legal status of these initiatives are largely uncertain because of the possibility of ERISA preemption. ERISA preemption places a burden on the federal government to act, either by amending ERISA to allow more state regulation or by enacting comprehensive national health reform.

8. Tax Credits for Health Insurance – Several recent proposals, including those by the Bush Administration and by Senators Ron Wyden (D-OR) and Robert Bennett (R-UT), have proposed changes to the tax code to promote the availability of individual health insurance and the types of insurance consumers choose. Changes include refundable tax credits, tax incentives, and other subsidies. While the law seems to allow variation in the tax code to support these proposals, policy questions remain regarding difficult administrative and implementation concerns.

Each of these eight legal issues will be organized with a brief introduction of the topic and the issue; the state of the current law; problems that may arise because of this law; any other considerations; and potential solutions to the problems. A few papers, such as "ERISA" and "Health Reform and the Tax Code" have evolved to be more discussions of policy than of law because the most salient issues are questions of whether the current system and laws should be changed rather than whether the legal authority exists to do so.

III. U.S. Health Statistics and Reform Proposals

An open dialogue about health reform is timely and necessary given the ever-growing population of uninsured and underinsured individuals, the escalating number of working-age adults with major chronic conditions, and the increasing costs of health care. While America has a combined system of private and public health insurance, individuals who are ineligible for public programs (*e.g.* Medicare and Medicaid) and do not receive insurance through their employer are left with very few affordable options for health insurance coverage. In 2007, an estimated 45.7 million United States residents were uninsured (15.3% of the population).[2] Among the 72% of the population continuously insured in 2007, 20% were considered underinsured (a 60% increase from 2003), equaling an estimated 25 million underinsured Americans.[3] Low income populations suffer the greatest proportion of absent or inadequate health insurance - 72% of adults below 200% of the poverty line are uninsured or underinsured contrasted to 27% of higher income adults.[4]

Being uninsured or underinsured dramatically affects the health and well-being of not only the individual without insurance, but also society at large. Without insurance, an individual has less access to and is less likely to seek out medical care, even for chronic conditions. The increasing number of uninsured and underinsured Americans is coinciding with increasing rates of chronic and sometimes preventable illnesses, such as obesity and Type II diabetes. The number of working-age adults reporting at least one of seven major chronic conditions grew to a total of almost 58 million people in 2008.[5] Aside from overall population growth, this increase indicates a rising rate of chronic disease among working adults. The nation's current system of health care does not emphasize primary and preventive care, which could improve illnesses and conditions that can be easily controlled. Many believe health reform should be comprehensive and include goals of high quality care, improved health outcomes, increased coverage, and cost containment.[6] Additionally, it is widely stated that the scope of benefits and key terms should be identified with each proposed change to avoid pitfalls and prevent unintended consequences.

The United States has an extremely expensive health care system. In 2007, national expenditures for health care exceeded $2.2 trillion[7] - more than three times the amount spent in 1990, and almost nine times the amount spent in 1980.[8] Employer-sponsored health insurance premiums have increased 87% since 2000.[9] Furthermore, while the United States spends twice as much per person for health care ($7,421),[10] it ranks lower than other industrialized nations on rates of mortality that are generally prevented with timely access to effective health care ("amenable mortality").[11]

Medical expenses can lead to extreme financial difficulties, and the current economic downturn has created serious financial problems associated with the cost of health care. Individual subscribers are particularly financially vulnerable due to changes in insurance benefits, such as high deductibles and restrictions on maximum coverage for conditions and physician visits.[12] From 2003-2007 an increased number of Americans reported difficulty accessing medical care, with both the insured and the uninsured reporting high rates of difficulty.[13] Furthermore, the rates of underinsurance in the middle-class have nearly tripled since 2003.[14] In 2008 election polls, 25% of adults surveyed cited paying for health care as a serious problem,[15] while 47% of the public reported someone in their family skipped necessary medical care within the past year due to costs.[16]

Of the 45.7 million uninsured Americans, only 18% come from households in which no one had a connection to the workforce.[17] 71% of the uninsured have at least one family member working full time.[18] However, many lower-income working adults are typically ineligible for public programs because they exceed the maximum income requirement.[19] Additionally, the waning economy has resulted in more unemployed Americans, which in turn means more uninsured Americans. Every one percent increase in the number of unemployed persons results in a projected increase of 1.1 million uninsured persons.[20]

A. Proposed Health Reform

Health reform is made especially timely by the current political climate and the new Congress and Administration. There are a multitude of critical legal issues involved in federal health reform: constitutional (federalism and individual rights); statutory and regulatory interpretation; enforcement (who carries it out); procedural (how it gets carried out); and financing (purchase and delivery). The President and federal lawmakers across the political spectrum have proposed health care plans that implicate the key legal issues addressed in this project.

President Obama has outlined a health care plan that aims to ensure high quality, affordable universal coverage through private and expanded public insurance. The plan has three main approaches: 1) expand eligibility for Medicaid and the Children's Health Insurance Plan (CHIP); 2) require all children to have health insurance and require employers to offer health benefits privately or contribute to the cost of a new public program; and 3) create a national health insurance "exchange" to enable individuals and small businesses without coverage to enroll in approved private plans or in a new public plan.[21] Former presidential candidate Senator John McCain (R-AZ) proposed a health care plan focusing on increasing access to affordable care by paying only for quality care, having diverse and responsive insurance choices, and encouraging personal responsibility.[22] His overall approach was to provide individuals and families with direct, refundable tax credits to increase incentives for individual insurance coverage; to promote

insurance competition by allowing choice between issuers; and to contain costs through changes in provider reimbursement and tort reform.[23]

Another proposal, the Healthy Americans Act (HAA), is a bipartisan bill sponsored by Senator Ron Wyden (D-OR) and Senator Robert Bennett (R-UT). The bill strives to provide portable, affordable, high-quality, private health care for all Americans (equal to that of Members of Congress).[24] It focuses on cost-containment measures, discontinues the current tax treatment of employer-sponsored health insurance, and replaces it with individual tax credits. The HAA provides incentives for insurers and individuals to focus on primary and preventive care. The Wyden-Bennett bill blends certain traditionally conservative and liberal views on health care.

Multiple other health reform proposals continue to be released, emphasizing the multi-sector push for health reform. Shortly after the November 2008 election, Finance Committee Chairman Senator Max Baucus (D-MT) released a framework paper for health reform: "Call to Action."[25] Senator Baucus emphasizes increasing access to affordable coverage, improving value by reforming the delivery system, and financing a more efficient system. Health, Education, Labor & Pensions Committee Chairman Senator Edward Kennedy (D-MA) released a health plan in June 2009, as did the chairs of three House committees.[26]

B. Cross-cutting Themes

As part of health reform proposals involving federal action, there are several recurrent themes. Multiple health laws and regulations currently exist at both the state and federal level. A balance between the rights of the states and the power of the federal government must be considered, as well as the circumstances in which federal law overrules state laws. Therefore, federal health reform should take into account issues of *federalism and preemption*, the first theme of this project.

Additionally, when implementing any aspect of federal health reform, there will necessarily be a division of the government's authority over new or amended programs and regulations. Multiple committees in the House and Senate have jurisdiction to draft and oversee health legislation. Similarly, multiple agencies and sub-agencies have jurisdiction to regulate and promulgate rules over health programs. Therefore, the next theme is *committee and agency jurisdiction*, involving who has or would have jurisdiction over current and new health laws and programs.

New laws and programs create novel rights, obligations, protections, and powers. Consequently, the final theme encompasses questions of legal *enforcement and remedies*. The following sections of this introduction will address these overarching themes in more detail.

IV. Federalism and Preemption

Federalism, or the allocation of authority between the federal government and the states, has a long and complicated history. Since the founding of the nation and the adoption of the Constitution, the interplay of power between federal and state governments has been contested and established through constitutional and statutory law. Preemption, or the power of the federal government to trump state law, is derived from the Supremacy Clause of the Constitution, which states that the Constitution is the supreme law of the land.[27] Case law on the allocation of authority began in 1819, with a landmark case that established the implied Constitutional powers

of Congress and the limits of state authority.[28] Current case law illustrates the continuing importance of the federal government's preemption power: within the last year, the Supreme Court immunized manufacturers of medical devices from state tort liability if the device has pre-market approval from the Food and Drug Administration (FDA),[29] but also declined to find the same degree of preemptive power in other portions of the Food, Drug and Cosmetic Act.[30]

Although the protection of the public's health is traditionally a state and local government responsibility, the legal authority for public health powers exists at all levels of government.[31] The Tenth Amendment to the Constitution reserves to the states those powers not expressly delegated to federal government.[32] States have an inherent police power to ensure and regulate the health, safety, and well-being of the public, but the federal government does not. However, Congress does have broad authority to legislate on matters affecting interstate commerce, which covers many health-related issues. Therefore, pursuant to the Supremacy Clause,[33] any state law that conflicts or is inconsistent with the federal health and public health laws predicated on the Commerce Clause power will be preempted.

In the American health system, both state and federal laws affect public and private health insurance. Therefore, reform can implicate multiple problems regarding the allocation of authority and the interplay between federal and state law. Multiple federal laws affect the health system: the Medicare and Medicaid statutes, the Employee Retirement Income Security Act (ERISA), and the Health Insurance Portability and Accountability Act (HIPAA), among many others. The substantial preemption power granted to the federal government results in federal legislation overruling any conflicting state laws. Because federal preemption power is broad, states are often limited in options they can pursue for health reform. If Congress can constitutionally decide a specific issue and it has clearly expressed a desire to do so, federal law preempts state law.[34] Furthermore, when Congress does not explicitly state its intentions to preempt state law, there are two situations where a statute is considered to *implicitly* preempt state law: if the federal government has so comprehensively regulated the subject that it has "occupied the field"[35]; or if the state and federal law fundamentally conflict. Courts have leaned towards requiring clear statements of congressional intent to override state laws, as the two FDA-related opinions this term demonstrate.[36]

An additional aspect to the interplay between federal and state government is the extent to which federal agencies can decide if their *regulations* preempt state statutes. After health legislation is codified, the federal agency with jurisdiction over the legislation usually issues rules and regulations interpreting how it will carry out the laws. Depending on how specific Congress outlines its intent when enacting the legislation, the agency may have strict guidelines for carrying out the legislation or it may have a broad grant of authority to interpret the legislation in its rules and regulations. Extensive debate has taken place to determine when it is appropriate for an agency itself to decide when federal law should displace state law and whether Congress or the agency should decide how expansive the interpretation should be. Aside from the express preemption power granted by Congress, it is not entirely clear how far an agency can go in interpreting the scope of its own preemption power. However, a significant case in 1984 established that the judiciary will give a high level of deference to an agency's interpretation of an ambiguous or silent law.[37] Under so-called "Chevron deference", courts will not overturn a regulation unless the regulation, when viewed as whole, is an arbitrary, capricious, or unreasonable interpretation of the law.[38] In other words, if a statute is ambiguous or silent on an issue, the agency's interpretation of the statute only needs to be reasonable for the court to defer

to the agency and allow the interpretation to stand. Deference to federal agency interpretation is addressed further in the paper on "Executive Authority".

Perhaps the most complex area of preemption in health law is the Employee Retirement Income Security Act (ERISA).[39] Enacted in 1974, it encompasses a wide range of regulations in employer-sponsored pension and welfare benefits, including health benefits, and is central to most health reform efforts.[40] ERISA is a prime example of federalism and of the allocation of authority underlying the discussion of federal health reform. It is also an example of problems that arise with the interplay of state and federal government, and is discussed in greater detail in the paper on "ERISA." Congress originally intended ERISA to provide a framework for the uniform provision of employee benefit plans by private employers in the United States. Consequently, Congress included a provision that generally preempts state laws that "relate to" private sector employer-sponsored benefit plans, which include health plans. The Supreme Court has altered its interpretation of the breadth of "relates to," and the application of that phrase is still frequently litigated.[41] While uniform regulations in health may be necessary, ERISA's preemption provision has been cited as a major barrier to health insurance reform at state and local levels.

A. Complex Issues Arising From Federalism

Federalism and jurisdiction are intertwined in many areas of the law. This, in part, contributes to questions about which laws apply when dealing with the health of the public, and which level of government may act in applying these laws. The interaction between ERISA and state laws is far from clear: sometimes the two coexist, other times ERISA preempts state law. For example, some of the new "pay-or-play" laws passed by state governments, which require employers to provide a minimum level of health benefits or make payments to the state, have been preempted by ERISA.[42] (This issue is further explored in the paper on "ERISA.")

Although the federal government has broad authority over employer-based health insurance plans, it has exercised limited authority over the regulation of private individual insurance. Another example of the interplay between state and federal authority in health care is the 1945 McCarran-Ferguson Act, which limits the federal government's regulation of state individual insurance.[43] This Act allows state law to have the primary role of regulating the business of insurance without the interference of the federal government.[44] The Act, however, is not an absolute bar to federal involvement. By enacting the McCarran-Ferguson Act, Congress in essence ceded some of its power under the Commerce Clause. But Congress retains its constitutional authority to reclaim portions of that power by enacting legislation that regulates the purchase and sale of insurance policies (*e.g.* the Health Insurance Portability and Accountability Act, HIPAA). To do so, Congress must make clear its intent to create an exception to the McCarran-Ferguson Act. (See Section B, *infra*.)

States regulate and license insurance companies that provide health insurance to citizens of the state. States set the standards for the financing, marketing, coverage and benefits of these individual plans. Because each state has the authority to develop its own standards, the laws vary dramatically from state to state. While this flexibility allows states to address the policies that they care most about, it may also promote inefficiencies and limit consumer choice of targeted benefits and lower price plans. Inconsistency in state laws can create legal complications among regulations not only from state to state, but also between federal and state

control. For example, the purchase and use of health insurance across state lines poses some distinct questions such as what law applies, when does it apply, and who has the authority to implement the applicable law? Should authority lie with the state where the insured individual resides or with the state where the insurance is purchased? Does the insurance commissioner from the first or the second state have authority and control? Members of Congress have proposed to allow insurance regulated and licensed in one state ("primary") to be sold to a customer in a different state ("secondary"). These proposals are further discussed in the papers addressing the "Purchase of Insurance Across State Lines" and "Insurance Exchanges."

Another example of the pervasive theme of federalism is the principle of "anti-commandeering," which limits the federal government's ability to control the way a state regulates private parties.[45] Under this principle, any federal proposal that regulates health insurance cannot compel states themselves to carry out specific functions to implement it. New legislation and proposals should be careful about assigning duties to current insurance regulators (*e.g.* state insurance commissioners) as they may be interpreted as federal commandeering. The degree to which the federal government can compel states to play a certain role remains unanswered.

B. Potential Resolutions To Complex Issues

Despite the myriad issues that arise, solutions exist for resolving conflicting state and federal laws. For example, the federal government is able to satisfy the requirements of the McCarran-Ferguson Act by enacting legislation that: 1) clearly states it is an intentional use of federal authority to regulate the business of insurance; 2) contains provisions that meet the Supreme Court test of "specifically relating to the business of insurance"; or 3) amends the McCarran-Ferguson Act itself. Alternatively, the federal government could provide states with subsidies to improve access and quality of care. In doing so, the federal government could use its well-established power of attaching conditions to the state spending of federal dollars. Even if states take the primary role in overhauling the health system, federal leadership and funding will still be necessary for health reform. One approach in pursuing health reform may be to combine the substantial resources, stability and uniformity of federal financing with a state's creative innovation in health reform.[46] Further potential solutions are discussed in the individual papers.

Some comprehensive reform proposals build on the current employer-sponsored system by adding market options – also called "insurance exchanges" – for people without access to coverage and for small businesses. In order for exchanges to be viable, they must be composed of a broad cross-section of the population, not just people with serious medical conditions. Thus, these proposals often propose individual mandates for insurance. Individual mandates raise many of the legal issues arising out of the interplay between state and federal government authority, and are discussed in greater detail in the paper on "Individual Mandates." At the state level, individual mandates are not legally problematic. Massachusetts, for example, has already enacted such mandates. However, it is worth examining whether the federal government can constitutionally implement individual mandates. The Due Process Clause and the Takings Clause of the Fifth Amendment restrict the government's ability to seize private property for public use without just compensation and due process.[47] While states could enforce an individual mandate by relying on their inherent police powers (or plenary powers) to protect the health of the public, the federal government does not have this kind of inherent power. As a result, some might argue that an individual mandate for insurance on the federal level violates constitutional limits on the government's authority to seize property (here, by forcing the expenditure to buy

insurance). However, the paper on "Individual Mandates" concludes that challenges on this basis are unlikely to succeed.

V. Committee and Agency Jurisdiction

Crafting health legislation often involves amending existing laws, thus necessitating negotiations among multiple congressional committees. For example, when the Health Insurance Portability and Accountability Act (HIPAA) was enacted, it required simultaneous amendments of the tax code, ERISA, and the Public Health Service Act (PHSA). Therefore, the three House Committees with jurisdiction over these laws – Ways and Means, Energy and Commerce, and Education and Labor – needed to negotiate in order to pass HIPAA. Similarly, in the Senate there are multiple committees with jurisdiction over health: the Finance Committee and the Health, Education, Labor & Pensions Committee are delegated the majority of authority. Additionally, Appropriations Committees in both the House and the Senate are involved in the complex web of jurisdiction since some authority is dependant on spending allocations. Just as many committees oversee health legislation, multiple federal agencies are involved such as those within the Department of Health and Human Services, the Department of Labor, and the Internal Revenue Service.

The multiple jurisdictional issues involved will, in part, drive the policy positions of participants, policy makers, and interest groups. Key decisions must be made as to where the regulation should occur. For example, it must be decided whether primary authority is more appropriately delegated under the Internal Revenue Code or the Public Health Service Act or a new, freestanding law. Positions can be influenced and options favored or opposed based on these jurisdictional imperatives. Some debates that appear to be policy-based may, in fact, be jurisdictional power struggles. Each committee – whether dealing with tax, public health, or labor – tends to favor options in legislation that give it jurisdiction in both development and oversight of the relevant program. Similarly, each agency favors options that provide it with long-term jurisdiction over key program elements. Interest groups tend to favor options for reform that are within the jurisdiction of committees and agencies they work with most closely and that will reflect their interests in the long run.

A. Congressional Committee Jurisdiction*:*

Multiple committees in the House of Representatives and the Senate have jurisdiction over health legislation. Generally, after a member of the House or Senate introduces a bill, it is referred to the appropriate standing committee: the House has twenty standing committees while the Senate has sixteen.[48] Bill referral, while formally assigned to the Speaker of the House and the presiding officer of the Senate, is generally performed by the parliamentarians in each chamber. [49] If subject jurisdiction is clear, the parliamentarian assigns jurisdiction based on the appropriate House or Senate rules; most committees have ten to fifteen subject areas listed under their jurisdiction. If jurisdiction is ambiguous or overlapping, the parliamentarian can review past bill referrals for guidance ("common law jurisdiction"),[50] or can apportion a bill to several committees ("multiple referrals"). While the House makes use of multiple referrals, or allocating authority to more than one committee, the Senate rarely does. Because committee jurisdiction is generally divided by subject matter and placement in the U.S. Code, drafters pay particular attention to the wording of legislation if they intend to influence referral to a specific committee.

While this committee jurisdiction system allows for efficiency in lawmaking and specialization across a wide range of legislative areas, it can also create conflict among committees because of the potential influence committee referral has on proposed legislation.[51] For example, in 1993, with the advent of the Clinton Health Plan, the already politicized nature of health reform was exacerbated by "turf wars" involving which committee had jurisdiction over what parts of the legislation. At least sixteen congressional committees claimed jurisdiction over parts of the plan, which had an end goal of universal coverage.[52] While the Senate Finance Committee drafted a compromise bill focusing on incremental reform, the Senate Labor and Human Resources Committee substantially changed the bill. The House Ways and Means Committee approved a separate bill establishing a new "Medicare Part C" to cover the uninsured.[53] The House Education and Labor Committee expanded the benefits package in a bill similar to the President's proposal while the House Energy and Commerce Committee debated Clinton's proposed employer mandates.[54] Consensus was never reached among committee chairs who supported large-scale reform and those who did not.[55]

1. House Committees

Jurisdiction over heath and health insurance in the House of Representatives is generally dictated by the type of revenue for the program. Most health programs fall under the jurisdiction of the Energy and Commerce Committee or the Ways and Means Committee.[56] If the program's budget is funded by general revenues – such as parts of Medicare, all of Medicaid, the Children's Health Insurance Program, and all public health programs – jurisdiction falls under the House Energy and Commerce Committee.[57] If the money for the program comes from payroll deductions and addresses health issues – most notably Medicare Part A – jurisdiction falls under the House Ways and Means Committee.[58] If money is authorized to be appropriated from general revenues for a specific and discrete population – such as veterans' hospitals, medical care, and treatment – jurisdiction falls under the specific committee, in this case the Veterans Affairs Committee. The Armed Services Committee oversees military health care. Additionally, the Education and Labor Committee has jurisdiction over access to employee benefits for working families, including ERISA and its health programs.

2. Senate Committees

Jurisdiction over health in the Senate is based on statutory authority and generally falls under the authority of the Finance Committee or the Health, Education, Labor & Pensions Committee (HELP Committee).[59] The Finance Committee has jurisdiction over all general revenue measures, including tax policy related to health. Additionally, jurisdiction over all health programs under the Social Security Act – including Medicaid and Medicare, and those dealing with maternal and child health fall under Finance Committee jurisdiction.

The HELP Committee has jurisdiction over public health programs and any other free-standing laws not included in the Social Security Act or within the the International Revenue Code. Public health, biomedical research, employee health and safety, and ERISA fall under the jurisdiction of the HELP Committee. Similarly to the House, specialized services fall under specific committees: the Armed Services Committee oversees military health care while the Veteran's Affairs Committee has jurisdiction over veterans' hospitals, medical care, and treatment.

B. Agency Jurisdiction

Determining which federal agency should enforce and have oversight over new and expanded laws raises multiple challenging questions. Should a single agency or multiple agencies regulate a new system of federal health reform? Because health care involves the health of the public, is the Department of Health and Human Services the agency best equipped to regulate? If health reform is imposed through a federal tax, would the Internal Revenue Service gain oversight and control? As discussed above in the section on "Federalism," federal agencies are afforded a high level of deference in interpreting legislation over which they have jurisdiction.[60] Consequently, the designation of agency jurisdiction can be expected to have far-reaching implications for any new health activities.

1. Department of Health and Human Services

Jurisdiction over health falls mainly to the Department of Health and Human Services (HHS). This section will briefly introduce the numerous agencies within HHS involved in health, and some of the most recent budget requests for the 2009 fiscal year.

- The Centers for Medicare and Medicaid (CMS) oversee three public health insurance program: Medicare, Medicaid and the Children's Health Insurance Program (CHIP). Medicare covers people age 65 or older, people under 65 who are totally disabled, and those with End-Stage Renal Disease.[61] Medicaid is a joint federal/state program that covers certain low-income individuals and families; specific eligibility standards vary from state to state.[62] In 2007, Medicare covered 41.3 million people and Medicaid covered 39.5 million.[63] The budget requests for 2009 were $408 billion and $217 respectively.[64] CHIP, another federal and state partnership, provides insurance coverage for children whose families exceed the income requirement for Medicaid but who do not have private insurance. In 2006, CHIP covered about 6.6 million children, and the 2009 budget request was $6 billion.[65]
- The Indian Health Service (IHS) provides health care to approximately 1.5 million American Indians and Alaska Natives. Most services are provided directly by IHS or tribal organizations through health programs on reservations, but some funding is reserved for native people in urban areas.[66]
- The Centers for Disease Control and Prevention (CDC) oversee programs aimed at supporting public health protection and emergency preparedness, such as pandemic influenza, immunizations and vaccinations against emerging infectious diseases, health data surveillance, and bioterrorism preparedness.[67]
- The Food and Drug Administration (FDA) provides services to protect the nation's food supply and approves pharmaceuticals as safe and effective.
- The Health Resources and Services Administration (HRSA) increases access to essential health care, supports community health centers that provide primary care to 17.1 million low-income patients, recruits health care professionals for underserved communities, and provides funding for HIV/AIDS treatment services.[68]
- Finally, the Substance Abuse and Mental Health Services Administration (SAMHSA) promotes state and local behavioral health programs.

2. Additional Agencies

While HHS has jurisdiction over the majority of health programs, additional federal agencies are also involved.

- The Office of Personnel Management (OPM) oversees the Federal Employee Health Benefits Program (FEHBP). The FEHBP, open to all currently employed and retired federal employees and their dependents, is the largest civilian employer-sponsored health insurance program in the country. Depending on the plan involved, the federal government pays between 72% and 75% of the premium.[69]
- The Department of Labor's (DOL) Employee Benefits Security Administration (EBSA) is responsible for regulating and overseeing employer sponsored health plans under the Employee Retirement Income Security Act (ERISA).[70]
- The Department of Defense oversees TRICARE, the military health care system. In 2007, there were 9.1 million people enrolled in TRICARE.[71]
- Similarly, the Veterans Health Administration (VHA) operates an extensive health care system for over 5 million eligible veterans and their families, based on prior active military service. [72] The Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) is a health care program where the VA shares the cost of covered health care services with spouses or children of veterans not otherwise eligible for TRICARE.[73]

VI. Remedies/Enforcement

Federal health reform will create new rights for individuals, providers, and caregivers. New rights produce obligations, protections, duties, and powers, which in turn create legal questions regarding the remedies that will be used to maintain these rights and to enforce obligations. With the implementation of a new or restructured health system, it is necessary to consider what relevant enforcement will best uphold the remedies and solutions proposed. The scope of federal regulatory oversight over health care depends, in part, on the extent to which health care is public or private.[74] Mechanisms of oversight and accountability should be put in place to maintain compliance and quality. In a new health system, it will be even more necessary to determine standards of compliance, assessment, and quality assurance. The private sector has created associations that monitor some aspects of quality assurance, such as the National Commission on Quality Assurance, and public sector review has also been undertaken.[75]

This section discusses potential remedies for failure to comply with laws or regulations. The key legal issues in this project involve remedies regarding individuals, institutions, and government. Based on the scope of enforcement, remedies can be divided into civil, criminal, and private remedies.

A. Civil Enforcement

Under the Social Security Act, the Secretary of HHS is authorized to seek civil monetary penalties for multiple types of conduct related to health care. Using the authority of the Civil Monetary Penalties Law (CMPL)[76], the Secretary has delegated much of this enforcement to the Office of the Inspector General (OIG). CMPL authorizes civil penalties on organizations, agencies, and entities that knowingly file fraudulent or improper claims with the federal

government, including those defrauding Medicare and Medicaid.[77] Depending on the type of violation, the OIG may seek differing amounts of civil money penalties. Among other acts, individuals can be penalized for filing fraudulent claims or for offering/receiving kickbacks in return for business referrals under federal health care programs.[78] Similarly, the False Claims Act (sometimes referred to as the "Lincoln Law" because of its Civil-War-era origins)[79], imposes liability on persons who submit a claim or record that he or she knows is false. Additionally, the False Claims Act allows private parties to bring an action on behalf of the federal government and, if successful, receive a percentage of the damages recovered.[80]

Enhanced civil enforcement could be achieved by amending the Public Health Service Act in order to grant the Secretary authority to impose money penalties on insurance issuers[81]; or by amending the Internal Revenue Code to grant the Secretary of the Treasury the ability to impose an excise tax for violations.[82] New legislation could model protections after existing procedures - such as the OIG's appeal structure for exclusions, civil money penalties and assessments - which includes the ability to request an administrative hearing.[83]

Injunctions, an enforcement measure in which the court orders a party to refrain from an offending activity, are used when monetary penalties are ineffective to deter the activity or when waiting for judicial proceedings would result in irreparable harm. Injunctions are employed in health law as well, such as for the denial of health benefits under ERISA or for violations of privacy concerning a patient's personal health information.

B. Criminal Enforcement

If a violation of federal health legislation is especially harmful and civil remedies are ineffective or inappropriate, criminal enforcement may be appropriate. When criminal sanctions are involved, the accused must be entitled to a fair hearing before an impartial administrative law judge.[84] The OIG frequently collaborates with the Department of Justice (DOJ) to investigate and prosecute situations involving health care fraud.

C. Litigation

The federal government enforces federal law through administrative and court actions by multiple entities (*e.g.* OIG, DOJ, and the Office of Civil Rights (OCR)). Another enforcement mechanism would be the creation of a private right of action in federal law to allow individuals to file suit in federal court to enforce terms in the health legislation. Private individuals could be authorized to enforce the legislation directly, instead of relying on the government to pursue their interests after they file a complaint. For instance, the Emergency Medical Treatment and Labor Act (EMTALA)[85] allows a private right of action through which individuals who suffer harm resulting from a hospital's violation of the Act can obtain damages and relief by filing a civil suit.[86] Recent Supreme Court cases have limited the interpretation of statutes to find an implied private right of action and suggest that any health reform legislation that relies on this tool must be explicit.[87]

Conclusion

With health reform more pertinent than ever, an open dialogue is necessary to determine the best way to tackle the increasing difficulty of finding available, affordable, quality care; the increasing occurrence of chronic disease; and the increasing costs of care. In federal health reform, a number of recurrent themes emerge: federalism/preemption, agency and committee jurisdiction, and remedies/enforcement. Under these broad overarching themes, there are legal issues that could pose challenges to implementing any federal health reform. This project was undertaken with the view that these legal challenges are either soluble or avoidable, and thus should be addressed ahead of any political debates.

After the papers were written and expert consultation received, we found that in most circumstances, the key legal issues targeted were, in fact, not insurmountable barriers to federal health reform. While overarching themes tie all eight papers together, each paper is written on a discrete legal issue and by a different author. Consequently, the tone may differ based on the experiences and background of the author. But all papers take a non-partisan approach and have been reviewed by experts with a wide range of political views. We hope that after reading one or all of the papers, the reader comes away with some solutions to tackle the legal problems that may be raised when attempting to create or implement federal health reform. Fundamentally we believe that the reader will recognize that the legal challenges – while sometimes complicated – are not impossible to resolve. We hope this project will provide a useful analysis of the legal issues relating to health reform, and a clear articulation of the range of solutions available for resolving those questions.

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[1] T. Westmoreland, et. al, The Law of Health Reform: Ten Legal Issues, O'Neill Institute for National and Global Health Law (May 30, 2008), *available at* http://www.law.georgetown.edu/oneillinstitute/documents/reform_top10.pdf (last visited Dec. 31, 2008).
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[3] C. Schoen et. al., "How Many are Underinsured? Trends Among U.S. Adults, 2003 and 2007," *Health Affairs Web Exclusive*, 27, no. 4 (2008): 298-309, at 299, *available at* http://www.commonwealthfund.org/publications/publications_show.htm?doc_id=688615 (last visited Dec. 31, 2008). Note: to qualify as "underinsured" an individual had to be insured throughout the year and experience one of three "indicators of financial exposure relative to income: 1) out-of-pocket medical expenses for care amounted to 10 percent of income or more; 2) among low-income adults (below 200 percent of the federal poverty level), medical expenses amounted to at least 5 percent of income, or 3) deductibles equaled or exceeded 5 percent of income".
[4] *Id.* at 300.

[5] C. Hoffman and K. Schwartz, "Eroding Access Among Nonelderly U.S. Adults With Chronic Conditions: Ten Years of Change," *Health Affairs Web Exclusive*, 27, no. 5 (2008): 340-348, at 342, abstract *available at* http://content.healthaffairs.org/cgi/content/abstract/27/5/w340 (last visited Dec. 31, 2008).
[6] See Schoen, *supra* note 3.
[7] Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditure Data, Historical NHE, including Sponsor Analysis, 2007, *available at* http://www.cms.hhs.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp#TopOfPage (last visited Jan. 9, 2009) [Hereinafter cited as CMS NHE].
[8] M. Hartman et. al, "National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998," *Health Affairs*, 28, no. 1 (2009): 246-261, abstract *available at* http://content.healthaffairs.org/cgi/content/abstract/28/1/246 (last visited Jan. 9, 2009).
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[11] 2002/2003 data shows the United States ranks last among 19 industrialized nations for amenable mortality. See E. Nolte and C.M. McKee, "Measuring the Health of Nations: Updating an Earlier Analysis," *Health Affairs*, 27, no.1, (2008): 58-71; See also The Commonwealth Fund Comm'n on a High Performance Health System, The Commonwealth Fund, Why Not the Best? Results from the National Scorecard on U.S. Health System Performance, 2008 (July 2008), *available at* http://www.commonwealthfund.org/usr_doc/Why_Not_the_Best_national_scorecard_2008.pdf?section=4039.
[12] See Schoen, *supra* note 3.
[13] P.J. Cunningham and L.E. Felland, Falling Behind: American's Access to Medical Care Deteriorates, 2003-2007, Center for Studying Health System Change Tracking Report, no. 19 (June 2008), *available at* http://www.rwjf.org/files/research/3319.32191.trackingreport.pdf
[14] See Schoen, *supra* note 3, at "Exhibit 1", 301. Note: "middle-class" was defined as adults with incomes above 200 percent of the federal poverty level, about $40,000 per family.
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[18] ***Id.***
[19] Schoen, *supra* note 3 at 298.
[20] Kaiser Commission on Medicaid and the Uninsured, Kaiser Family Foundation, New Analysis Shows Effect of Rising Unemployment on Health Coverage, Medicaid and SCHIP Spending and Enrollment, (April 28, 2008); see chart "Impact of Unemployment Growth on Medicaid and SCHIP and the Number of Uninsured", *available at* http://www.kff.org/medicaid/kcmu042808pkg.cfm.
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http://edlabor.house.gov/documents/111/pdf/publications/DraftHealthCareReform-BillText.pdf (last visited June 23, 2009).
[27] U.S. Const. art. VI, cl. 2 (Supremacy Clause).
[28] See generally *McCullough v. Maryland*, 17 U.S. 316 (1819).
[29] See generally *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).
[30] *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).
[31] H. Markel, et. al, "Extensively drug-resistant Tuberculosis: an isolation order, public health powers, and a global crisis," *JAMA*, 298, no. 1 (July 4, 2007).
[32] U.S. Const. amend. X.
[33] See Supremacy Clause, *supra* note 27.
[34] For an example of express preemption, see *Boggs v. Boggs*, 520 U.S. 833, 841 (1997).
[35] This concept, termed "field preemption", exists when the federal government has so thoroughly regulated an area of law, there is no room for the states to interpret that law or if the federal interest in the field is so dominant it precludes enforcement of state laws. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *citing*
Pa. Railroad Co. v. Public Service Comm'n of the Commonwealth of Pa., 250 U.S. 566, 569 (1919).
[36] See generally *Riegel v. Medtronic, inc.* and *Wyeth v. Levine*, *supra* notes 29 and 30.
[37] See generally *Chevron U.S.A., Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837 (1984).
[38] *Id.*
[39] Employee Benefit Research Institutef, *available at* http://www.ebri.org/ (last visited December 4, 2008).
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[41] *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645 (1995).
[42] Note: pay or play acts preempted; Maryland Act preempted; New York Suffolk County Fair Share for Health Care Act (aimed primarily at Wal-Mart) preempted; San Francisco City and County – 9th circuit found Ordinance not preempted by ERISA.
[43] 15 U.S.C. §§ 1011–1015. (2008)
[44] "This act was in response to a 1944 Supreme Court decision which classified insurers conducting substantial business over state lines as interstate commerce and therefore subject to federal antitrust laws. Congress enacted this act in response to concerns of state authority over private insurance." See Claxton, *supra* note 40.
[45]See *Printz v. United States*, 521 U.S. 898 (1997).
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[47] U.S. Const. amend. V.
[48] See House Rule X, Government Printing Office: House Rules and Manual, 110th Congress, *available at* http://www.gpoaccess.gov/hrm/index.html; See Senate Rule XXV, Government Printing Office: Senate Manual, 110th Congress, *available at* http://www.gpoaccess.gov/smanual/index.html.
[49] See House Rule XII, Government Printing Office: House Rules and Manual, 110th Congress, *available at* http://www.gpoaccess.gov/hrm/index.html; See Senate Rule XVII, Government Printing Office: Senate Manual, 110th Congress, *available at* http://www.gpoaccess.gov/smanual/index.html.
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[52] J.W. Hardin, "An In-depth Look at Congressional Committee Jurisdictions Surrounding Health Issues," *Journal of Health Politics, Policy and Law*, 23(3) (1998): 517-550, at 517.
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[54] *Id.*
[55] See S. Waldman and B. Cohn, "How Clinton Blew It," *Newsweek*, June 27, 1994.

[56] See House Rule X, *supra* note 48; See Hardin, *supra* note 52, at 529. A study conducted by John W. Hardin found that the Energy and Commerce Committee received 53% of health bill referrals while Ways and Means received 35% of such bills.
[57] See House Rule X, *supra* note 48.
[58] *Id.*
[59] See Hardin, *supra* note 52, at 529. The Hardin Study found that 55% of health bill referrals went to the Finance Committee while the Labor and Human Resources Committee received 39% of such bills.
[60] See *Chevron*, *supra* note 37.
[61] Centers for Medicare and Medicaid Services, Department of Health and Human Services, Medicare Program: General Information Overview, *available at* http://www.cms.hhs.gov/MedicareGenInfo/ (last visited Dec. 26, 2008).
[62] *Id.*
[63] *Id.*
[64] United States Department of Health and Human Services, Budget in Brief: Fiscal Year 2009, *available at* http://www.hhs.gov/budget/09budget/2009BudgetInBrief.pdf (last visited Dec. 26, 2008) [hereinafter cited as HHS Budget].
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[66] Indian Health Service, U.S. Department of Health and Human Services: A Quick Look, *available at* http://info.ihs.gov/QuickLook.asp (last visited Nov. 29, 2008).
[67] See HHS Budget, *supra* note 64.
[68] *Id.*
[69] Testimony of John E. Dicken, Director, Health Care before the Subcommittee on Oversight of Government Management, U.S. Senate, United States Government Accountability Office, *Federal Employees Health Benefits Program: Premiums Continue to Rise, but Rate of Growth Has Recently Slowed*, GAO-07-873T (May 18, 2007), *available at* http://www.gao.gov/new.items/d07873t.pdf.
[70] U.S. Department of Labor, Health Plans and Benefits, *available at* http://www.dol.gov/dol/topic/health-plans/index.htm (last visited Dec. 28, 2008).
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[74] Furthermore, if more individuals switch to private insurance, the federal budget for public insurance programs would decrease accordingly.
[75] R.A. Goodman, et.al., eds., *Law in Public Health Practice, Second Ed*, (Oxford: Oxford University Press, 2007): at chapter 3.
[76] 42 U.S.C. §§ 1320a-7a (2008).
[77] *Id.*
[78] *Id.*
[79] 31 U.S.C. §§ 3729-3733 (2008).
[80] 31 U.S.C. § 3730 (b) (2009).
[81] P. Borzi and S. Rosenbaum, Pending Patient Protection Legislation: A Comparative Analysis of Key Provisions of the House and Senate Versions of H.R. 2990, prepared for the Kaiser Family Foundation, (March 2000).
[82] *Id.*
[83] 42 C.F.R. §§ 1005.1-1005.23 (2009)
[84] See Goodman, *supra* note 75.
[85] *Supra* note 76.
[86] *Id.* at 1395dd (d)(2)(A) (2008).
[87] See *U.S. v. Sandoval*, 532 U.S. 275 (2001).