

HIPAA as a Regulatory Model: How Much Weight Can This “Federal Floor” Carry?

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July 31, 2001

For the past four years, Congress has been debating what is popularly known as the “patients’ bill of rights” legislation. Deliberation over the substance of various consumer protection proposals has been accompanied by parallel discussions over how broadly such standards might apply across the population as well as which level of government will have primary responsibility for setting consumer protection standards and enforcing them.

As the debate has evolved, congressional proposals have taken a variety of approaches to how various arms of the federal government and states could determine and enforce consumer protections. One of the principal templates for how the new consumer protections might be enforced is the regulatory model Congress developed in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In essence, HIPAA was designed to help people in employer–sponsored health plans (and the plans themselves) gain access to health insurance regardless of their health status and to keep it once they changed jobs or found themselves unemployed and having to buy insurance as individuals. By amending three federal laws and inviting states to enforce many of its provisions, HIPAA attempted to apply uniform minimum consumer protections across most employment–based group health plans in the country. (For a summary of HIPAA’s main provisions, see Appendix A.)

HIPAA’s Origins

Viewed one way, HIPAA was a fairly straightforward expansion of federal standards governing employee health benefit plans. Viewed another, HIPAA represented a compromise in which states lost some turf but benefited from Congress bringing self–insured, private–sector employee health plans outside their regulatory reach under regulations similar to those for state–regulated insured plans, at least in a few substantive areas. In order to set federal minimum standards, Congress ratcheted back state autonomy over regulating health insurance; in return, it applied new standards to self–insured group plans governed by the Employee Retirement Income Security Act of 1974 (ERISA) as well as other group health plans.

A Federal/State Compromise

Under current law, the federal and state governments split responsibility for regulating employee health plans and health insurance in a variety of ways. ERISA, which governs private–sector employee health plans providing coverage for about 129 million Americans, creates an uneven playing field in several regulatory arenas.¹ Because ERISA preempts the application of state laws to private–sector employee benefits plans but allows states to regulate insurance, states generally can regulate the health benefits of people in fully insured plans (about 60 percent of ERISA plan participants) but not self–insured plans (about 40 percent).²

In some matters, state law is entirely preempted across all ERISA plans including those that are fully insured; for example, the Supreme Court has ruled that ERISA plan participants do not have access to state law remedies because ERISA’s legal remedies were intended to be their

exclusive means of resolving benefit disputes in court.³ States, however, generally can regulate the solvency, benefit content, and many other features of insured products sold to ERISA–governed plans. In part because the extent of state jurisdiction is very dependent on court decisions, there are many gray areas. For example, in some federal circuits it has been unclear whether and to what degree state can apply consumer protections to ERISA plan participants enrolled in HMOs (which some courts have declared are not in the business of insurance). It is also unclear whether external review requirements, which have been enacted by many states and are under consideration in many more, would be preempted for both self insured and fully insured ERISA plans.

Congress enacted ERISA in 1974 after years of deliberation following several highly publicized private–sector pension plans bankruptcies. To prevent employees from being left without their pensions in the future, ERISA established uniform national standards for funding and vesting in private–sector defined benefit pension plans and created a guarantee corporation that could compensate pension plan participants in the event of a plan insolvency. ERISA also covered employee “welfare benefit plans” – including health plans, and it pre–empted the application of state laws to these plans just it did to pension plans. At the time, almost all employee health plans were fully insured. In contrast to its treatment of pension plans, ERISA contains no plan solvency standards, other than its general standard that requires plan fiduciaries to act prudently and in the sole interests of participants. As they do today, states actively regulated the solvency of health insurers. At the time of ERISA’s passage, almost all employee health plans were indirectly subject to state regulation. Very few were self–insured.

In the years after ERISA’s passage, aided by a series of court decisions interpreting ERISA’s preemption of state law, most of the larger ERISA health plans opted to “self insure,” thereby unilaterally deregulating a large part of the market. Administrators of employee health plans moved away from fully insured products for a variety of reasons. Besides improving cash flow, they could segregate their plans from state–regulated risk pools and various state–imposed subsidies that might be built into insurance rates. They also could escape state regulations, such as reserve requirements, benefit mandates, and contributions to guarantee associations. By the end of the 1980s, most large employers had self–insured plans. Small employers offering health benefits generally cannot shoulder the risk of self–insuring and most stayed in the state–regulated insurance market.

Table 1
Percent of private–sector establishments offering health insurance that self–insure at least one plan (by firm size): 1998

<i>Less than 100 employees</i>	<i>100–499 employees</i>	<i>500 or more employees</i>	<i>Less than 50 employees</i>	<i>50 or more employees</i>
11.9%	29.9%	67%	11.2%	52.3%

Source: Agency for Healthcare Research and Quality, Center for Cost and Financing Studies. 1998 Medical Expenditure Panel Survey – Insurance Component.

HIPAA’s Approach

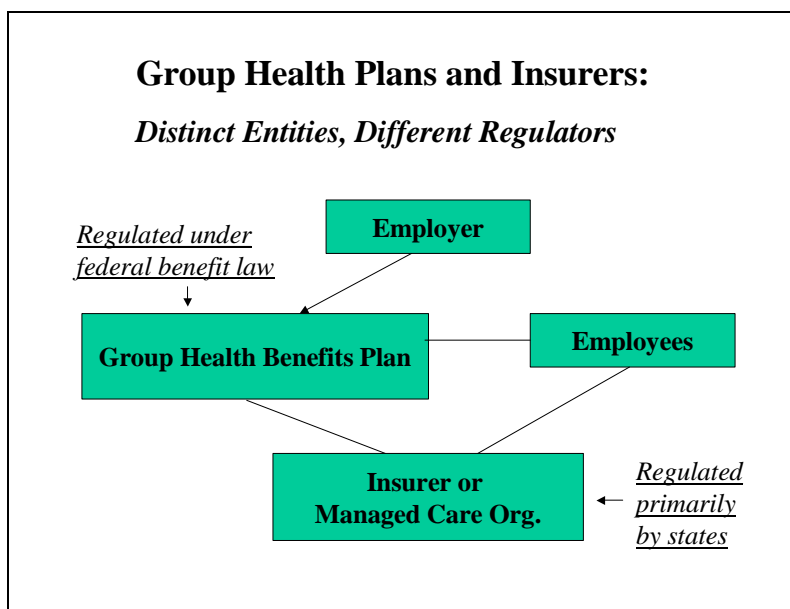
A collection of measures designed to increase access to health coverage primarily for people in group, employment-based health plans or people leaving them, HIPAA was enacted by a Congress with Republicans in control of both houses for the first time in more than four decades. A far more modest approach to health insurance reform than the Clinton administration’s failed effort to enact universal coverage, the bill garnered strong bipartisan support after a series of bitter policy disputes between the Congress and administration.

Aware of the regulatory divide created by ERISA preemption, the principal architects of HIPAA, Sens. Nancy Kassebaum (R-Kan.) and Edward Kennedy (D-Mass.), created a complex regulatory structure in order to bar discrimination based on health status and limit how plans may apply pre-existing-condition exclusions to new plan members across all ERISA plans, both insured and self-insured, as well as other types of group health plans.

To apply these core provisions across a broad part of the American population, HIPAA amended ERISA, the Internal Revenue Code (IRC), and the Public Health Service Act, directing three federal departments to coordinate efforts to enforce the provisions. As depicted on Table 2 below, these “shared” provisions set down uniform consumer protections standards for people in group health plans falling under ERISA (private-sector plans organized by employers or unions for employees); for group health plans as defined by the IRC (generally speaking, ERISA plans plus church plans), and for insurers under contract with group health plans including government and church plans.

By amending ERISA and the IRC to set standards for group health plans, HIPAA utilized a regulatory model that Congress had established under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) to require plan sponsors to offer people leaving certain group health plans the option of maintaining group health coverage at their own expense.⁴ In a sense, amending the Public Health Service Act to apply the same standards to insurers and some public-sector group health plans built on the “COBRA model,” adding new layers of complexity and creating new regulatory roles and responsibilities for the Department of Health and Human Services and the states. Although HIPAA sets down federal minimum standards, its designers intended for enforcement to occur at the state level as much as possible.

Diagram 1



The oversimplified diagram above is intended to show the distinction between private-sector health benefit plans, which are regulated under ERISA, and health insurers and managed care organizations, which are regulated primarily under state law. Under HIPAA, the U.S. Department of Labor enforces provisions with regard to employee health plans while the states or the U.S. Department of Health and Human Services enforce with regard to health insurers and risk-bearing HMOs under contract with ERISA plans.

It has been estimated that HIPAA's core portability requirements help ensure that millions of people changing jobs are able to maintain their health coverage. The GAO estimated that in 1993 more than 20 million people changed jobs.⁵ About 12 million of these workers (along with seven million dependents) had employer-sponsored health coverage. According to some observers, while HIPAA's core requirements are helpful to some people even in a time of very high employment, the value of the law will not be entirely evident until the nation enters a period of high unemployment, when many people find themselves between jobs and attempting to maintain access to health coverage.

Having established this regulatory structure with HIPAA, Congress subsequently utilized it when adding three benefit mandates, inserted in appropriations bills enacted in 1996 and 1998; these provisions mandate coverage requirements for minimum hospital stays in connection with childbirth; parity in the application of certain limits to mental health coverage; and coverage standards for reconstructive surgery following mastectomy. (See Appendix B for a summary of these laws.)

Gaps

There are gaps in the reach of HIPAA's core requirements (its anti-discrimination rules and limits on preexisting condition exclusions). Self-insured state and local government employee health plans are allowed to opt out of HIPAA's requirements and many have done so. Federal government plans, including the Federal Employees Health Benefits program (FEHB), and state-sponsored health plans that are not employment-based, are all exempt from HIPAA's

primary statutory requirements (although these programs must help establish proof of continuous coverage so that people may exercise rights under HIPAA). Under the Clinton administration, FEHB conformed with HIPAA's core standards by executive order. Whether Medicare and Medicaid and managed care companies contracting with these programs are exempt from HIPAA's requirements and the subsequent mandates has been under review by the Department of Health and Human Services (HHS) for several years and reportedly has not been resolved.

The year after HIPAA's passage, church plans successfully lobbied Congress to exempt some of them from HIPAA's ban on discrimination based on health status. The Balanced Budget of Act of 1997 amended the IRC to lift this requirement for church plans with regard to "both any employee of an employer with 10 or less employees...and any self-employed individual" or "any individual who enrolls after the first 90 days of eligibility under the plan."⁶ Depending on how health plans are structured, it is possible for a plan offered by a church-operated hospital, school, or other type or organization to be defined as a church plan, according to a Treasury official.

HIPAA's core standards also do not apply to insurers selling non-group products and to very small group health plans (those with fewer than two participants who are current employees.) This definition of "small," however, allows group health plans composed only of retirees to be excluded from the requirements.

Jurisdictional Overlaps

HIPAA requires three federal departments to interpret its core provisions similarly. To do this, the departments promulgate regulations jointly. Staff meet regularly to coordinate implementation efforts, share information, and discuss issues that have arisen. According to federal officials, although this level of coordination among three departments creates difficulties, implementation of regulations pertaining to group health plans has proceeded well.

HIPAA's enforcement scheme involves a great deal of overlapping jurisdiction, especially with regard to insured, private-sector employee health plans falling under ERISA. For example, an employee of a private-sector firm who was excluded from an insured group health plan by virtue of his or her health status could conceivably call the Labor Department, the Internal Revenue Service (IRS), or either a state agency or HHS' Health Care Financing Administration (HCFA) in order to enforce his or her rights under HIPAA. (See Table 2 below.) Roughly half of those protected under HIPAA's core provisions (about 73 million people) fall in this category.

Self-insured Plans (Rules Apply Through Sponsors)	YES (About 56 million people) <u>GREEN</u>	YES (But some church plans excepted) <u>ORANGE</u>	NOT BINDING (Employers can opt not to comply) About 11 million people	NO (Standards apply by executive order, not under statute)	Not applicable (These people are uninsured.)	??? Under Review by HHS
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Gray = Enforcement by HCFA/states, IRS, and/or DOL

Green = Enforcement by IRS and/or DOL.

Yellow = Enforcement by HCFA/states and/or IRS

Orange = Enforcement by IRS.

Blue = Enforcement by HCFA/states

In large part, HIPAA's complex structure and jurisdictional overlaps reflect the balkanized nature of Congress' committee structure. Passing a law designed to help people keep their health insurance as they move from job to job and from state to state, as HIPAA aimed to do, meant having to amend laws that fell under many committees' jurisdiction. For example, ERISA, which covers private-sector employee benefit plans, is jointly enforced by the DOL and IRS. Congressional committees claiming jurisdiction over amendments to ERISA include the labor committees — the House Committee on Education and the Workforce and the Senate Committee on Health, Education, Labor, and Pensions (HELP)—and the tax committees — the House Committee on Ways and Means and Senate Finance Committee. The tax committees also have jurisdiction over church plans, which, like ERISA plans, enjoy preferential tax treatment (but the labor committees do not have jurisdiction here because ERISA specifically excludes church plans). Congress applied new rules to health insurers and state and local government employee plans through the Public Health Service Act, which falls under the House Committee on Commerce and the Senate HELP committee. Applying the new rules to other populations, such as federal employees, would have meant having to navigate yet more committees.

Notwithstanding the jurisdictional overlaps posed by HIPAA, many state regulators say that the law has served a purpose by applying similar standards to self-insured ERISA plans as to insured plans. State insurance regulators have estimated that up to 30 percent of the health-related complaints they receive come from people in self-insured, private-sector employee health plans outside their jurisdiction.

Although the three federal departments have made some attempts to determine which should take the lead in handling various types of complaints arising under HIPAA, it is still confusing from a consumer's point of view about where to go for assistance. Where consumers might want to go for help in enforcing portability and other rights may depend in part on the enforcement tools HIPAA provides. For example, in some instances DOL may sue the sponsors of group health plans to compel them to adhere to HIPAA's requirements but it cannot impose

finances for this purpose.⁸ The IRS, however, can levy an excise tax on group health plans failing to comply. If portability rights are being denied by an insurer or managed care company covering people in a group health plan, states can enforce HIPAA's requirements having to do with insurers. DOL cannot take action against an insurer or managed care company to enforce HIPAA. If states do not enforce HIPAA's requirements, then DHHS may assert federal authority to enforce the requirements against insurers and can impose sanctions including civil monetary penalties of up to \$100 a day per violation. If an insurer persists in not conforming, although DOL can not enforce HIPAA's provisions by taking action against the insurer, it can take action against the plan sponsor to enforce the law; furthermore, could also refer the case to the IRS, which has the ability to levy the excise tax, according to DOL officials interviewed. So far, neither of the federal agencies has fined, taxed, or sued a group health plan or insurer to enforce HIPAA. As noted later, HCFA officials say they have come close to imposing a fine in cases that ended up with negotiated cash settlements to cover denied claims. Also, DOL investigations have led to corrective action of HIPAA violations in employer plans, both self-insured and fully insured. Group plan participants and beneficiaries also may enforce their rights by suing ERISA, which allows them to win "equitable relief" (the benefits due them) in court but not damage awards.

Regulating Group Health Plans

As noted above, under HIPAA the labor department is responsible for regulating employee health benefit plans, not the insurers contracting with them. Under ERISA, employee benefit plans with 100 or more participants are required to file form 5500s. Based on the information in these forms, it can be estimated by almost 40,000 employee benefit plans offered by employers or unions and covering 100 or more participants provided health coverage to at least some of them. Because ERISA plans with fewer than 100 participants are not required to submit these forms, it is hard to know exactly how many exist but the number could run into the millions. According to the Small Business Administration, slightly more than half of the nation's workforce works for the roughly 5.5 million businesses with fewer than 500 employees. About 16,000 U.S. firms have 500 or more employees.

Table 3
Distribution of ERISA plans that include health benefits
by number of participants: 1997

Number of Participants	Number of Plans
Total with 100 or more	39,390
100-249	16,300
250-499	9,416
500-999	5,896
1,000-2,499	4,310
2,500-4,999	1,727
5000-9,999	868
10,000-19,999	503
20,000-49,999	269
50,000 or more	101

SOURCE: Form 5500 series reports filed with the Internal Revenue Service for plans years beginning in 1997.

When interviewed in 1999, DOL officials said that more than half of the hundreds of thousands of inquiries (including complaints) they received in the previous year pertained to health coverage issues. The largest category of health inquiries concerned how to keep continuation coverage under COBRA. Many people also expressed an interest in how to maintain their access to coverage under HIPAA. In almost all instances in which group health plan sponsors had been in violation of HIPAA, simply notifying them of the new requirements sufficed to bring them into compliance; of the more than 150 cases referred to DOL's HIPAA implementation team in fiscal year 1998, only two or three had to be referred to field offices for further investigation, according to DOL officials.

Since 1995, DOL's Pension and Welfare Benefits Administration (PWBA) added considerable staff to respond to benefit inquiries concerning pensions and other benefits including health coverage. In 1995, the agency had only 12 benefit advisors, all located in Washington, and did not have its current capacity to investigate individual health benefit complaints. By 1999, PWBA had 58 benefit advisors, three to four of whom are assigned to each of the department's 15 regional and district offices, and was authorized to hire another 20. Representing a significant change in PWBA administrative practice (PWBA officials called it an improvement in "customer service"), the benefit advisors had begun regularly investigating individual disputes over health coverage and trying to resolve them. By the summer of 2001, DOL officials reported having 100 more benefit advisors.

In recent years, if talking with the plan sponsors does not resolve a coverage dispute or other issue, DOL in some instances now may advise participants of their legal options or refer them to legal aid organizations, where available. The department's authority to go to court on behalf of individuals is ambiguous. The department usually will not sue a plan unless what is at issue (a benefit denial or violation of HIPAA, for example) impacts the plan's entire membership. ERISA permits individuals themselves to sue their plan for equitable relief. Many state insurance regulators continue to express skepticism about DOL's ability to adequately assist consumers in self-insured plans in resolving disputed claims.

PWBA officials interviewed in 1999 said that they were in the early stages of implementing HIPAA (focusing primarily on developing regulations and educating people about the law) and that they are developing a long-run capacity to enforce consumer protections for participants and beneficiaries in group health plans.

By this year, PWBA had developed and implemented a system to conduct random compliance reviews so that it could estimate the extent of HIPAA compliance nationwide.⁹ This type of regulatory approach was a new one for DOL. Although DOL has had long-standing responsibility for making sure that private-sector employee health plans meet fiduciary, reporting, and disclosure standards under ERISA, its enforcement approach has been largely complaint-driven.

As part of a pilot project, DOL reviewed a random sample of about 230 employee health plans in fiscal year 1999 and another 356 plans from fiscal year 2000 through the second quarter

of fiscal year 2001, according to the GAO. In the fiscal year 1999 reviews, the department found noncompliance rates of about 21 percent for certain HIPAA standards, 12 percent for Mental Health Parity Act standards, and 26 percent for the Newborns' and Mothers' Health Protection Act standards. According to GAO, DOL reported that many of the violations were "largely technical" in nature. For example, employers or plan administrators sometimes did not update plan documents to reflect changes in the law or provide notice to employees about them. Another common violation was imposition of a "hidden" preexisting condition exclusion clause in plan documents. While DOL has yet to take anyone to court for violations of HIPAA, agency investigations (as noted above) have resulted in corrective actions involving both employee health plans and insurers and third-party administrators contracting with them.

The Department of Treasury's role in enforcing HIPAA and related statutes has been minimal, relying on voluntary employer compliance and referrals from DOL. Treasury told the GAO that it regularly provides guidance to its employee benefits advisors to help ensure that employee benefit plans are designed in accordance with federal standards. Treasury officials said they did not believe the agency has assessed an excise tax associated with noncompliance but added that they would impose such an excise tax in response to any violations identified and referred by the labor department (none has yet been received).

Regulating Insurers

As noted above, HIPAA prevents both group health plans and health insurers selling products to those plans from refusing to cover individual members or charging them higher prices based on health status. In addition, health insurance issuers (state-regulated insurers and managed care plans) are required to renew coverage for group health plans and are required to make all products available to small group health plans (covering 2–50 employees) if they sell in that market segment.¹⁰

HIPAA also imposes standards for insurers selling to individuals. These standards are primarily directed at helping people coming out of group plans maintain access to coverage. Unless a state implements an "acceptable alternative mechanism" such as a high-risk pool, insurers in the individual market must guarantee issue certain products and apply no pre-existing condition exclusions to "federally eligible individuals." These are people who have had at least 18 months of continuous coverage, most recently in a group health plan, and who have exhausted any available continuation coverage under COBRA or similar state laws as well as other coverage options. (To be eligible, their previous coverage also must not have been canceled due to non-payment of premium or fraud.) Health insurers serving the individual market also must renew policies, not only for the "federally eligible" people just described, but market-wide. As discussed in greater detail later, HIPAA does not restrict what insurers may charge.

Varying Levels of Preemption

In applying standards to insurers, HIPAA is an amalgamation of several models of federalism, defined here as how the federal government and states divide responsibility for

determining policy and enforcing it. Nothing in HIPAA modifies the strong federal preemption expressed in ERISA's sec. 514, which prevents states from regulating self-insured group health plans. In general, HIPAA's standard of federal preemption for its substantive provisions regarding accessibility, portability, and renewability is far narrower: HIPAA establishes a federal policy "floor" upon which states may add requirements for insurers serving group health plans as long as state laws do not weaken the federal standards. Federal preemption under HIPAA, however, is more potent for the statutory requirements limiting the application of preexisting conditions exclusions by insurers serving group health plans. In this area, state laws may not differ from federal requirements except as specifically permitted under HIPAA.

Enforcement a State Option

Although they built a federal policy floor, most of those who designed HIPAA assumed that enforcement of insurance provisions would take place primarily at the state level. States have the option of enforcing HIPAA's access, portability, and renewability standards applying to insurers in the group and individual markets.¹¹ If states do not pass laws that substantially enforce these standards, however, HHS must do the enforcing itself, thereby assuming a new regulatory role. When HIPAA was enacted, it was generally believed in Congress and the administration that all the states would opt to enforce these standards and not allow federal officials to enforce regulations in the insurance markets, a traditional state domain guarded by the National Association of Insurance Commissioners (NAIC). (The McCarran-Ferguson Act of 1945 reinforced states' role as primary insurance regulators by stating that no federal law should be interpreted as overriding state insurance regulation unless it does so explicitly, while exempting the business of insurance from federal antitrust regulation to the extent it is regulated by the states.)

HCFA's New Role

Most federal policymakers were surprised by the number of states that initially failed to enact legislation allowing state enforcement under HIPAA. In 1999, HCFA faced the prospect of enforcing of HIPAA's provisions in five states — Missouri, California, Rhode Island, Massachusetts, and Michigan — where legislatures for a variety of reasons had failed to enact laws to conform with all or some of HIPAA's requirements. At the time, HCFA officials thought that in the long run the agency's regulatory role might widen because HIPAA also requires the federal agency to enforce in states that have conforming laws but that fail to sufficiently enforce them. As of 1999, HCFA had not studied the laws of the 45 states that had made an effort to pass conforming legislation to ensure that they actually did so. HCFA officials also realized that they might not be aware of lapses in enforcement by state agencies, in part, because the agency lacked a mechanism to monitor enforcement activity and had to depend in large part on state regulators to report what types of consumer complaints were being received and how they were being resolved.

HCFA's regulatory role has since diminished. Yet, federal officials are aware that the agency's role as insurance regulator might rise suddenly with the passage of patients' right legislation. By early this year, the agency had completed its review of state laws to ascertain

whether they conformed with HIPAA as well as two of the three subsequent statutes with structurally similar new federal health insurance standards. With regard to HIPAA, the federal agency has continued a direct enforcement role only in Missouri. Two of the three states in which HCFA had assumed an enforcement role, Rhode Island and California, passed conforming legislation in 2000. HCFA also has determined that Wisconsin does not fully conform to the Newborns’ and Mothers’ Health Protection Act and Colorado, Delaware, and Massachusetts do not fully conform to the Women’s Health and Cancer Rights Act.¹² HCFA has not yet reviewed state laws to see whether they conform with the Mental Health Parity Act.

Table 4
States Not Conforming with HIPAA and Two Other Similarly Structured Federal Laws as of May, 2001

	HIPAA	Newborns’ and Mothers’ Health Protection Act	Women’s Health and Cancer Rights Act
Colorado			X
Delaware			X
Massachusetts			X
Missouri	X		
Wisconsin		X	

Source: GAO (“Private Health Insurance: Federal Role in Enforcing New Standards Continues to Evolve,” GAO-01-652R) and HCFA officials.

As noted above, in order to ensure that certain former members of group health plans have access to individual coverage, regardless of health status, HIPAA presents states with a series of policy choices. First, a state must choose between the “federal fallback” approach, which requires all issuers in the individual market to offer eligible individuals at least two health plans, or an “alternative mechanism,” which can be a high-risk pool or other means of providing guaranteed access to coverage for this population. If states fail to act, then HCFA must enforce the federal fallback approach.

Under the federal fallback approach, used in about one-quarter of the states, insurers have three options for selling policies to eligible individuals. An issuer may offer (a) all of its individual market plans; (b) only its two most popular plans; or (c) two representative plans — offering higher and lower coverage levels — that are explicitly subject to a mechanism for spreading risk or financial subsidization.¹³ In 1998, the GAO reported that several problems had cropped up in the states using the “federal fallback” approach, including carrier marketing and

pricing practices that restricted consumers' ability to purchase. GAO reported that insurers were charging premiums ranging from 140 percent to 600 percent of the standard rate to federally eligible people. At the time, the GAO also reported that 36 states and the District of Columbia had opted to use an alternative mechanism. Twenty-two of these states had chosen a high-risk pool as a way to provide access to this group of people.

As of early 1999, HCFA's Office of Insurance Standards had announced that it would enforce HIPAA provisions in three of the five states that had not enacted laws conforming to HIPAA. In Rhode Island and Missouri, HCFA was responsible for enforcing all requirements applying to health insurers under the law while in California the federal agency had to enforce only the provisions guaranteeing access to individual coverage for federally eligible people. California passed legislation enabling the state to enforce the other HIPAA provisions affecting its insurance market. HCFA officials were in the process of determining whether the agency would have to enforce HIPAA in Massachusetts and Michigan and, if so, to what degree.

In Missouri, the first state in which HCFA began enforcing HIPAA, a Democratic governor facing a potential battle over various aspects of insurance reform decided not to pursue legislation enabling the state to enforce the law because he thought consumers would be better off under federal enforcement than under reforms the legislature would likely pass. After some opposition arose in both Rhode Island's executive and legislative bodies, enabling legislation also failed to pass there. Among the factors cited by a state regulator who helped draft the legislation were a general lack of interest in reform, a historic aversion to regulation, and a feeling by some that this was an unfunded federal mandate. Massachusetts had enacted insurance reforms that technically did not conform with HIPAA just before the federal law passed and insurance regulators there began taking steps to implement an alternative mechanism (guaranteed issue of one standard plan). By 1999, a stalemate in the state legislature, however, left state regulators in position of operating with an alternative mechanism, while the federal regulators were faced with deciding whether and how to enforce the federal fallback rules. State regulators on occasion enforced some of HIPAA's requirements in the absence of state legislation to address HIPAA.

In 1999, officials in HCFA's Kansas City and San Francisco regional offices said that, in effect, they are trying to function as insurance regulators. To accommodate this new role, the Kansas City office had hired staff from three state insurance departments. The San Francisco office had assembled an eight-member HIPAA enforcement unit, including an attorney, to enforce individual market requirements in California and potentially assist with HIPAA-related issues that might arise in other western states. The Boston office also had added staff.

At the time, one regional official said that enforcing HIPAA had been a new experience for HCFA in more than one sense. For one thing, the federal agency was regulating insurance coverage that it is not also buying; secondly, it was attempting to regulate an industry already heavily regulated at the state level. Another regional official noted that HCFA regulators were used to using "large hammers" in other areas of activity but were discovering that state insurance departments in practice often use less dramatic interventions to enforce rules.

Both the Kansas City and San Francisco offices had been responding to complaints and have begun reviewing policies offered by insurers in the individual market. According to an official in HCFA's central office, enforcement tools available to the federal agency include "market conduct surveys," which involve monitoring insurers' practices in response to

complaints, and “policy form reviews,” which involve periodic examination of insurance policy forms and other documentation. If violations are discovered, HCFA may imposed civil monetary penalties of up to \$100 a day per violation or refer a case to the Office of Personnel Management, which may attempt to influence insurers with whom it contracts to provide coverage for federal employees to comply with the HIPAA requirements. In 1999, HCFA was in the early stages of developing an enforcement strategy and had not yet levied such fines.

By April 2001, HCFA had completed or initiated market conduct examinations of eight insurance carriers that together cover about 60 of Missouri’s health insurance market. According to the GAO, a common problem identified during these reviews was lack of guaranteed access to individual coverage for individual eligible under HIPAA. Problems with the guaranteed issue requirement in the small–group market were also identified.

HCFA has yet to impose a fine under HIPAA but has settled cases after taking steps or threatening to do so. Officials in the Kansas City regional office report having negotiated voluntary settlements totaling \$187,000 with several insurance carriers that agreed to pay for wrongly denied claims. Kansas City regional office officials interviewed in July 2001 said that they continue to rely in large part of state insurance regulators to refer complaints to them. Once federal regional office officials are satisfied that a consumer has been harmed by a HIPAA violation, such as being denied access to individual insurance if they are eligible, they approach the carrier. Complaints often arise after an individual generates medical expenses that a carrier refuses to cover, officials said.

Because of the expertise that it has developed in its ongoing regulatory role in Missouri, HCFA has decided to centralize responsibility for enforcing insurance standards under HIPAA and related laws in its Kansas City regional office. In part because several of the once–defaulting states now have enacted laws to enforce HIPAA, the number of HCFA staff dedicated to HIPAA implementation and enforcement has dropped significantly, from about 39 full–time equivalent (FTE) staff in July 1998 to 16 FTEs as of April 2001. Of these 16, 10 worked in HCFA’s Center for Medicaid and State Operations in its central office while 3.5 FTEs were allotted to the Kansas City regional office and about 0.25 FTE was allotted to each of the remaining regional offices.

Officials in the Kansas City regional office said that enforcing HIPAA insurance standards nationwide from one regional office would not necessarily present a problem for them. They noted that most of the carriers that they deal with in Missouri are domiciled in other states.

Regional office officials did note that “co–regulating” the insurance industry alongside Missouri state insurance department was awkward. Although federal officials report maintaining good relations with state regulators, insurers have complained that it is a hassle to have to undergo two sets of compliance procedures. For example, both federal and state regulators review policy forms. According to HCFA regional office officials, about one–quarter of the roughly 300 insurers licensed in Missouri do business in the small–group and individual markets with 25 to 30 insurers handling about 80 percent of the total health business. Regulators said they tend to the focus most of their attention on carriers covering the most people.

From a consumer’s point of view, regulators noted, HIPAA has simplified gaining access to insurance by superimposing minimum federal standards across state boundaries. For example, before HIPAA, a consumer moving to the next state might encounter major changes in the rules governing the application of pre–existing condition exclusions and medical underwriting.

According to the GAO, HCFA’s enforcement of HIPAA standards for self–insured state

and local government health plans has been limited. Unlike private-sector employee health plans, these plans are generally not subject to ERISA. While ERISA reporting requirements allows DOL to gather information about ERISA health plans with 100 or more participants, HCFA has no similar mechanism for collecting information about the existence and characteristics of non-federal employee health plans. Furthermore, as noted above, if these state and local government employee plans are self-insured, then can opt out of complying with HIPAA's rules.

Substantive Issues

While HCFA's ability to enforce HIPAA remained an open question in 1999, most of the consumer complaints received by state and federal regulators have more to do with HIPAA's substance, particularly with regard to the group-to-individual market mandate.¹⁴ Among the most prevalent consumer issues concerning the group-to-individual mandate were the following:

- Very few people were eligible;
- The cost of coverage in many states was very high;
- Not many people knew about their rights under HIPAA;
- Carriers sometimes created barriers to purchasing by processing applications too slowly, taking applications only on certain days of the month, or steering HIPAA eligibles toward standard individual coverage where medical underwriting might take place.

To be eligible for post-group coverage in the individual market without medical underwriting under HIPAA, a person must pass through several hoops. Besides having no break in coverage longer than 63 days since being in a group health plan, the most formidable barrier is exhausting continuation rights under COBRA, which means paying premiums for 18 or more months at 102 percent of group rates. Many people cannot afford to stay on COBRA for that long, particularly if they are unemployed. Those that do persevere tend to be sicker than average, thereby causing insurers to charge them more than the standard rate (unless state law imposes rating restrictions such as community rating). In response to a question about the price of coverage in California for HIPAA eligibles, a HCFA regulator commented in 1999 that from the consumer's point of view: "It's 'sticker shock' all along the way." Price shocks occurred as a person moved from paying only the employee's contribution toward group coverage to paying a little more than the group rate under COBRA, and, finally, in California at least, to paying 250 to 300 percent of the standard rate for individual health insurance. Compounding the shock is the fact that the standard rate for individually purchased health insurance is usually significantly higher than the cost of comparable coverage at a group rate.

Although HIPAA set a federal floor intended to guarantee federally eligible people access to insurance, the number of policy options available to states and insurers to accomplish this goal, coupled with virtually no federal rules concerning what insurers might charge for such coverage, means that the federal "floor" can be experienced at a wide variety of levels by consumers in different states. For example, in states that require community rating in the individual market, such as New Jersey and Vermont, HIPAA eligibles like anyone else have access to insurance at an average price; assuming that these people are sicker than average, their insurance would be subsidized by younger, healthier individuals. In states offering access to

HIPAA eligibles through high-risk pools, the law caps their premiums at 200 percent of the standard rate. In 1999, Arkansas' HIPAA eligibles had access to coverage through a state high-risk pool at about 115 percent of the "new business" rate in the marketplace (with a rate increase possibly on tap), while premiums in Minnesota's and South Carolina's high-risk pools were set at 125 percent and 200 percent of the standard rate respectively.

Rates in several federal fallback states tend to be higher still. For example, in 1999 North Carolina regulators surveyed insurance carriers and found that 24 offered HIPAA eligibles insurance on a guaranteed availability basis (five insurers chose to offer the representative plans with options for higher or lower levels of coverage and 18 opted to offer their two policies with the largest premium volume). On average, these policies were priced at about 300 percent of the standard rate, a level that one state insurance regulator said was probably not merited by the health status of the HIPAA eligibles but rather caused by insurers' fear of taking on too much risk. Rates in Colorado ranged from 200 percent to 300 percent of standard, prompting one regulator there to comment that, without rate controls, guaranteed issue in the individual market "is largely a joke." Insurance officials in several other states agreed, observing that high prices make coverage unaffordable for most people. HCFA's regional office in Kansas City noted that rates for HIPAA eligibles in Missouri were reported to be up to 600 to 700 percent of the standard rate and a state legislator interviewed said that the upper limit might be even higher.

An insurance regulator in Delaware said that the state opted to enforce HIPAA as a federal fallback state for several reasons, including time constraints and the fact that it had not enacted individual market reforms before HIPAA. Developing an alternative mechanism at the last minute did not seem worth it for the fewer than 100 people that state officials estimated would be eligible for group-to-individual coverage.

With a few exceptions, state officials reported many fewer problems with implementation of the group market requirements under HIPAA, which were based on NAIC model laws that many had already enacted. Before HIPAA, most states, but not all, had enacted small-group insurance reforms, such as guaranteed issue and guaranteed renewability. (For example, 24 states did not guarantee issue products to small groups or did not have guaranteed issue legislation encompassing all groups from 2 to 50.)¹⁵ The biggest headache reported by most was having to sift through hundreds of pages of insurance law to make sure they were in technical compliance with the federal statute.

An insurance regulator in Arkansas, which did not require guaranteed issue of products in the small-group market before HIPAA, said in 1999 that while HIPAA portability and renewability requirements generally had been successful, guaranteed issue had been a "big mistake," helping to cause rate increases of more than 20 percent in that market segment. A regulator in Colorado reported some very small groups (of one to five people) had been "gaming" the guaranteed issue requirement by initially purchasing relatively cheap high-deductible coverage when members were healthy and later switching to plans offering first-dollar coverage once someone came down with a costly medical condition.

In 1999, federal regulators covering Missouri said that they had been focusing most of their energies on enforcing in the individual market, but did mention that the most frequent complaint about the group market was that many state and local plans had opted out of HIPAA's core requirements.

HIPAA As a Model

As federal and state officials have worked to establish HIPAA's complex regulatory structure, most of the patient protection proposals that Congress has considered would build on this model or modifications of it. The bill passed by Senate on June 29, 2001 (S. 1052), for example, would apply a series of new requirements to group health plans and insurers contracting with them and to state and local government employee plans. The Senate bill extends these regulations to the individual insurance market and to federal health programs including the federal employees' health plan, Medicare, and Medicaid.

States' Willingness to Play

As noted above, a critical element of HIPAA's enforcement strategy is states' willingness to enforce new minimum standards established by the federal government for insurance markets that states have traditionally have regulated. By 1999, 10 percent of the states had declined to do so with regard to HIPAA access and portability requirements. Although by 2001 only Missouri remained out of compliance with HIPAA, questions remain concerning whether a greater number of state might refrain from "playing ball" with regard to enacting and enforcing new managed care and claims regulations. Some insurance regulators have noted that managed care standards, such as rules determining the adequacy of provider networks, may be harder to define and may be more localized due to variation in health care markets. Others have commented that many states have enacted more stringent consumer protections and a federal floor that did not preempt such standards might not be too difficult to implement.

Partly in response to the tensions arising from federal preemption of states' traditional activity in regulating insurance, the patient protection bill passed by the U.S. Senate modifies the minimum federal standard defined in HIPAA by allowing state laws to be in "substantial compliance." The net effect of this refinement appears to be creation of a more variable federal floor or "fuzzy floor." As HIPAA itself does, the "fuzzy floor" standard presents policy trade-offs. It may allow state laws to conform more easily with federal standards, thereby allowing more states to maintain primary responsibility for regulating health insurers and preventing the potential awkwardness and duplication of federal co-regulation. On the other hand, on a substantive level, by weakening the standardization of rules across states, the "fuzzy floor" model might increase the potential for confusion among consumers, regulated entities, and regulators, themselves.

Conclusion

The model of federalism embodied by HIPAA presents policymakers with many trade-offs. Assuming that the substance of a law is something desirable, one positive attribute of HIPAA and similarly structured laws is that they set minimum consumer protection standards across broad sections of the American population. One might argue that HIPAA's rules guaranteeing access to health insurance for small groups and forbidding the discrimination based on health status for small groups and individuals in employee health plans imposed a degree of simplification that might have facilitated the workings of the insurance markets while providing

greater access to coverage.

One of the main problems that this model of regulation presents is its complex enforcement structure. In erecting a federal floor through HIPAA, Congress had to build on a balkanized regulatory scheme that had become further divided as market forces responded to ERISA's preemption of state law. Lawmakers were not building a new house but rather undertaking a messy remodeling job. Consequently, from a consumer point of view, the federal floor HIPAA and similar laws created may be far sturdier and more visible in some parts of the house than others. Furthermore, the floor does not extend to some populations such as federal employees, and, for the most part, people wanting to buy individual health insurance policies.

Enforcement of HIPAA's provisions seems especially weak among self-insured non-ERISA plans, such as church plans and state and local government employee plans. On the other hand, with regard to populations that seemingly have access to many regulatory bodies, the overlapping regulatory activity of the DOL, HCFA, IRS, and state insurance departments has the potential to cause confusion and result in uneven enforcement, especially if Congress substantially increases the number of laws using such an enforcement scheme.

While a handful of HCFA regulators are assigned to enforce federal insurance rules in non-complying states, many thousands of state regulators continue performing the core functions of health insurance regulation, which include making sure that carriers remain solvent, carrier market conduct is fair, and that claims are paid. HCFA staff charged with regulating insurance carriers report that co-regulating alongside state insurance departments can be awkward and duplicative. As Congress builds on this federal floor, that awkwardness may escalate. An area of particular tension may be how to structure and enforce claims review and appeals requirements in a way that might accommodate the need for state flexibility. The claims function is integral to both regulating employee benefit plans under ERISA and to regulating the business of insurance under state law.

Finally, as noted above, using the "fuzzy floor" approach of modifying HIPAA's federal standard to allow more state flexibility lessens one potential source of confusion by possibly keeping more states in the enforcement game, but may create another problem by possibly undermining the uniform application of national standards.

Appendix A¹⁶

HIPAA's Access, Portability, and Renewability Rules

Core Requirements Protecting Individuals

Enforced by the Internal Revenue Service and the Department of Labor for group health plans, and by the states or the Department of Health and Human Services' Health Care Financing Administration for insurers covering people in group health plans.

Nondiscrimination: Individuals may not be excluded from group health plans or by insurers covering group health plans on the basis of factors related to health status. Similarly, the benefits

provided, premiums charged, and employer contributions may not vary within similarly situated groups of employees based on factors related to health status.

Limitations on Preexisting Condition Exclusion Periods: Group health plans or insurers selling products to them may deny, exclude, or limit an enrollee's benefits arising from a preexisting condition for no more than 12 months following the date of enrollment. A preexisting condition is defined as condition for which medical advice, diagnosis, care, or treatment was received or recommended during the six months preceding the date of enrollment. Pregnancy may not be considered a preexisting condition.

Credit for Prior Coverage: Group health plans and insurers covering them must credit an enrollee's period of prior coverage against its preexisting condition exclusion period. To be creditable, prior coverage must have been consecutive, with no breaks of more than 63 days. For example, someone changing jobs who has been covered for nine months may be eligible to have the new employer's 12-month exclusion period for preexisting conditions reduced by nine months.

Certificate of Creditable Coverage: Group health plans, issuers, and other entities must provide certificates of creditable coverage to enrollees whose coverage ends. These certificates must document the period the enrollee was covered in order to credit this time against a preexisting condition exclusion period that may be imposed by the next group health plan or issuer.

Special Enrollment Periods: People who do not enroll in a group health plan during their initial enrollment opportunity may be eligible for a special enrollment period later if they originally declined to enroll because they had other coverage, such as coverage under COBRA, or were covered as a dependent under a spouse's coverage and later lost that coverage. Also, if an enrollee has a new dependent as a result of birth or adoption or through marriage, the enrollee and dependents may become eligible for coverage during a special enrollment period.

Requirements for Insurers Covering Small Groups

Enforced by the states or HCFA.

Guaranteed Issue and Guaranteed Renewability: Insurers must make all plans available and issue coverage to any small employer applying regardless of the group's health status or claims history. Coverage must be renewed with standard exceptions.

Requirements for Insurers Covering Large Groups

Enforced by the states or HCFA.

Guaranteed Renewability: Coverage must be renewed with standard exceptions.

Requirements for Insurers Covering Individuals

Enforced by the states or HCFA.

Guaranteed Issue for Certain People Leaving Group Coverage: Eligible individuals must have guaranteed access to at least two different coverage options. These people are defined as those having at least 18 months of prior coverage the last of which was under a group health plan and having had no break in coverage of more than 63 consecutive days. They also must have exhausted any continuation coverage available under COBRA, must not be eligible for any other group coverage or Medicare or Medicaid, and must not have lost group coverage because of nonpayment of premiums or fraud. States may choose to implement this option either through guaranteed access to individual products or through a high-risk pool or other mechanism.

Guaranteed Renewability: Coverage must be renewed across the individual health insurance market with standard exceptions.

Appendix B¹⁷

Federal Laws with Enforcement Structures Similar to HIPAA's

The Mental Health Parity Act of 1996: prohibits group plans that provide mental health benefits from imposing annual or lifetime dollar limits that are more restrictive for mental health benefits than for other medical and surgical benefits (applies only to group with more than 50 employees).

The Newborns' and Mothers' Health Protection Act of 1996 prohibits plans that provide maternity benefits from restricting benefits for a hospital stay in connection with childbirth to less than 48 hours following a vaginal delivery or 96 hours following a caesarean section.

The Women's Health and Cancer Rights Act of 1998 requires all plans that provide mastectomy coverage to also provide coverage for related reconstructive surgery and other types of follow-up care.

¹ See "Private-Sector Health Coverage: Variation in Consumer Protections under ERISA and State Law," Patricia Butler and Karl Polzer, National Health Policy Forum, The George Washington University, June 1996, and "Employee Health Plan Protections Under ERISA," Karl

Polzer and Patricia Butler, *Health Affairs*, September/October 1997.

² To understand how to access their legal protections, employees must know whether they are in a self-insured plan (which states may not regulate) but for several reasons this may be difficult to determine. Neither the ERISA statute, the labor department, nor the Supreme Court has defined self-insurance explicitly. Second, firms may offer both self-insured and fully insured plans. Also, many plans use complex risk-sharing arrangements with providers that they claim do not constitute insurance. Finally, most self-insured plans purchase “stop-loss” coverage that is not considered to be health insurance even though payoffs are contingent on the health costs of either individuals in the plan or the entire group.

³ *Pilot Life Insurance Co. v. Dedeaux*, 481 U.S. 41 (1987).

⁴ Under COBRA, former employees and their dependents in firms with 20 or more employees are entitled to remain covered through the employee health plan for specific time periods.

⁵ General Accounting Office, “Health Insurance Portability: Reform Could Ensure Continued Coverage for up to 25 Million Americans,” GAO/HEHS-95-257, September 1995, p. 7.

⁶ Internal Revenue Code, Sec. 9802(c).

⁷ Population estimates supplied by Congressional Research Service based on March 2000 Current Population Survey and other surveys to extrapolate levels of uninsured.

⁸ DOL has the authority to sue a plan for equitable relief if what is at issue impacts the plan’s entire membership, but its authority to go to court on behalf of individuals is ambiguous. ERISA permits individuals themselves to sue their plan for equitable relief.

⁹ General Accounting Office, “Private Health Insurance: Federal Role in Enforcing New Standards Continues to Evolve,” GAO-01-652R, letter to the Hon. James M. Jeffords, chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, May 7, 2001.)

¹⁰ States may elect to treat groups of one as being either in the individual or small-group markets; about one-quarter of the states treat consider these to be small groups.

¹¹ General Accounting Office, “Health Insurance Standards: New Federal Law Creates Challenges for Consumers, Insurers, Regulators,” GAO/HEHS-98-67, February 1998. p. 18.

¹² General Accounting Office, “Private Health Insurance: Federal Role in Enforcing New Standards Continues to Evolve,” GAO-01-652R, letter to the Hon. James M. Jeffords, chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, May 7, 2001.)

¹³ GAO, “Health Insurance Standards...” p. 7.

¹⁴ In preparing this article, the author interviewed insurance regulators in 11 states and two HCFA regional offices as well as in HCFA’s central office, the U.S. Department of Labor, and the U.S. Department of Treasury in 1999 and followed up with selected interviews of federal officials in 2001.

¹⁵ Stephen H. Long and M. Susan Marquis with Ellen R. Harrison, Peter D. Jacobson, and Jennifer S. Sloan, “Baseline Information for Evaluating the Implementation of the Health Insurance Portability and Accountability Act of 1996: Final Report,” The RAND Corporation, Prepared for the Health Care Financing Administration, October 1998. (p. 3 of “Part II. Potential Effects of HIPAA: A Review of the Literature.”)

¹⁶ Sources: Text of HIPAA statute and regulations as well as GAO’s “Health Insurance Standards...,” cited above.

¹⁷ Source: GAO.