



Health, Education and Human Services Division

B-280491

July 22, 1998

The Honorable James M. Jeffords
Chairman
Committee on Labor and Human Resources
United States Senate

Subject: Private Health Insurance: HCFA Cautious in Enforcing Federal
HIPAA Standards in States Lacking Conforming Laws

Dear Mr. Chairman:

Over two-thirds of Americans under 65 years of age rely on the private group or individual health insurance markets for health coverage. Through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Congress sought for the first time to provide a uniform set of minimum consumer protections that would apply to all health coverage available in all states. Although most states had passed laws designed to improve the access, portability, and renewability of private health insurance prior to HIPAA, the scope of the reforms varied, and gaps in protections remained within and among states. Further, self-insured employer group plans, which represent about 40 percent of all group coverage, are exempt from these state insurance reforms.

HIPAA sets minimum standards for access, portability, and renewability for fully and self-insured group and individual health coverage. Enforcement authority rests with three federal agencies—the Departments of Health and Human Services (HHS), Labor, and Treasury—and state insurance regulators. In the event a state fails to enact or enforce standards for health insurance carriers that conform to HIPAA, HHS—through the Health Care Financing Administration (HCFA)—is required to directly enforce the standards in that state.¹

¹HHS is also responsible for enforcing group market provisions of HIPAA for certain nonfederal government health plans.

HCFA may begin direct enforcement either by being notified by a state that it has failed to comply or by the agency's making a formal determination that a state is out of compliance and federal intervention is necessary. As of June 30, 1998, officials in three states—California, Missouri, and Rhode Island—had voluntarily notified HCFA that they failed to enact conforming legislation. Two other states—Massachusetts and Michigan—are widely known to not have enacted conforming legislation, but the states have not notified HCFA, nor has the agency initiated the process required to initiate its direct enforcement role.

Many policymakers expected states to quickly conform with the federal standards and did not anticipate that HCFA would be required to assume a direct regulatory role. Because not all states fully adopted standards that conform to HIPAA, you asked us to examine (1) the tasks required of HCFA to assume the role of insurance regulator for HIPAA provisions in states lacking conforming laws and the extent to which the agency has undertaken them; (2) the factors that influence HCFA's ability to fulfill these duties; and (3) the implications of this new federal regulatory role.

To address these objectives, we reviewed the statute and associated regulations and interviewed headquarter and regional representatives of HCFA and state insurance regulators in the five states known not to have adopted laws that fully conform with HIPAA. With these officials, we discussed each state's regulatory environment, reasons why the state did not pass conforming legislation, and any resulting gaps between state law and HIPAA standards. Also, we discussed HCFA's current and planned efforts to directly enforce HIPAA provisions in these states. We conducted our work in June of 1998 in accordance with generally accepted government auditing standards.

In summary, HCFA must undertake a variety of regulatory tasks, including responding to consumer inquiries and complaints, providing guidance to carriers about HIPAA requirements, reviewing carriers' policy forms and other relevant documents and practices, and imposing civil penalties on noncomplying carriers in states known not to have fully adopted conforming legislation. HCFA's efforts in the five states thus far, however, have varied. For example, in California, Missouri, and Rhode Island, HCFA developed guidance that delineated state and federal regulatory responsibilities and, in Missouri and Rhode Island, held informational meetings with carriers. HCFA has also begun to review carriers' policies sold in Missouri to ensure HIPAA compliance. However, HCFA has not initiated any direct regulatory activities beyond responding to consumer inquiries and complaints in

Massachusetts and Michigan because neither state has formally notified the agency that it has not passed conforming legislation and HCFA has not formally established that the states have failed to conform. In addition to its direct enforcement responsibilities, HCFA may also need to systematically review the laws, regulations, and state practices of the remaining 45 states to verify the extent to which they have adopted HIPAA standards, which it has yet to do.

HCFA officials attribute its limited regulatory efforts in these states to an insufficient staff capacity and issues surrounding its regulatory authority. HCFA currently has 39 full-time equivalent (FTE) staff allocated exclusively for HIPAA-related issues but anticipates needing additional and more specialized staff skilled in regulating private health insurance to be able to more fully undertake regulatory responsibility. However, it has been difficult for HCFA to precisely quantify its staff needs because its long-term responsibilities remain unknown, and the agency lacks experience in regulating private health insurance. Questions surrounding the manner in which HCFA may exercise its regulatory authority have also limited its involvement. For example, officials said that the Paperwork Reduction Act may hamper their ability to require all carriers to routinely report information necessary for HCFA to ensure compliance with HIPAA. HCFA must obtain approval from the Office of Management and Budget (OMB) to collect this information.

In states where HCFA must enforce HIPAA standards, the responsibility for regulating private health coverage is shared among the agency and state insurance departments for insured health plans as well as the Department of Labor for self-funded health plans. This creates a complicated array of oversight for consumers, employers, and carriers of health coverage. Since neither the state nor HCFA has complete regulatory authority over health insurance products sold in these states, HCFA's new regulatory responsibility adds to the potential for confusion for consumers and duplication in oversight.

BACKGROUND

HIPAA includes minimum standards that seek to improve the access, portability, and renewability of health insurance coverage in employer-sponsored group and individual insurance markets. Among other standards, HIPAA includes requirements that carriers guarantee that (1) health coverage in the small group market is available to all small employers that apply (guaranteed issue), (2) eligible individuals leaving group coverage have

access to coverage in the individual market (group-to-individual portability), and (3) all health coverage be renewed upon expiration of the policy (guaranteed renewal). (Enclosure I contains a summary of HIPAA access, portability, and renewability standards by market segment.)

Responsibility for enforcing HIPAA standards is divided among three federal agencies and the states. The Department of Labor is responsible for ensuring that group health plans comply with HIPAA—an extension of its current regulatory role under the Employee Retirement Income Security Act of 1974 (ERISA).² The Department of Treasury enforces HIPAA requirements on group health plans by imposing an excise tax under the Internal Revenue Code as a penalty for noncompliance with the HIPAA standards. In states that have standards that conform to HIPAA, state insurance regulators have primary enforcement authority over insurance carriers. In states that do not adopt and enforce statutes or regulations that meet or exceed the HIPAA standards, HCFA is responsible for directly enforcing HIPAA's standards on carriers in the group and individual markets.

Five states are known to have not passed HIPAA conforming statutes or regulations. HIPAA does not require states to report to HCFA their conformance with HIPAA standards. However, three states—California, Missouri, and Rhode Island—voluntarily notified the agency of their nonconforming status, a necessary precursor to HCFA involvement. The nonconforming status of Massachusetts and Michigan became known through informal dialogues among federal and state officials, but neither state has formally notified HCFA of its failure to enact conforming laws. Absent formal notification from these two states, HCFA must undertake a determination process to establish the states' nonconformance and, thus, obtain the authority to become involved. Elements of this determination process are set forth in federal regulations and provides for several iterative steps. However, HCFA officials have not undertaken this effort in either of these states.

²ERISA allows employers to offer uniform national health benefits by preempting states from directly regulating employer benefit plans. As a result, states are unable to directly regulate self-funded health plans but can regulate health insurers.

HCFA'S REGULATORY EFFORTS HAVE BEEN LIMITED

To directly enforce HIPAA standards, HCFA is required to assume many of the responsibilities typically reserved for state insurance regulators. To date, however, HCFA's regulatory and enforcement activities have been limited primarily to responding to consumer queries and complaints in each of the five nonconforming states, providing guidance to carriers in the three states that had formally notified HCFA of their nonconformance, and reviewing carrier policies in one state. Although evidence suggests that most of the remaining 45 states have access, portability, and renewability standards—either prior to or as a result of HIPAA—isolated gaps within states likely remain, and HCFA has not evaluated each state's laws, regulations, or practices for conformance with HIPAA.

Conformance With HIPAA Standards
Varies Among the Five States

HCFA's regulatory duties in the five states depends, in part, on the extent to which the states have existing laws that conform with at least some of the standards mandated under HIPAA. Each of the five states already had in effect similar insurance market reforms that provided consumers with some, but not all, of the protections included in HIPAA. In some areas, the existing state provisions exceeded HIPAA's requirements; however, in other areas the state provisions fall short of HIPAA. For example, HIPAA requires that eligible individuals losing group coverage who apply for individual coverage within 63 days be guaranteed access to at least two products in the individual market without preexisting condition exclusions. While Michigan requires its Blue Cross/Blue Shield (Blues) plan to guarantee the issuance of its products to all individuals, the Blues plan, unlike HIPAA, may impose a 6-month preexisting conditions exclusion. Similarly, Rhode Island law provides for guaranteed access to coverage for individuals losing group coverage—that is, group-to-individual portability—but unlike the federal standard, does not permit any gap in coverage, according to state officials.

For other HIPAA standards, the five states do not have comparable reforms in place. For example, neither California nor Missouri provide guarantees of access to individual market coverage without preexisting condition exclusions for anyone losing group coverage, including those eligible under HIPAA. Only one of the five states (California) has enacted legislation that conforms to HIPAA's nondiscrimination provision, a provision that seeks to prevent group plans from excluding any individual within the group from coverage for reasons related to health status and medical history. Finally,

none of the five states has enacted legislation that conforms to HIPAA's certification provision. Under this provision, issuers of coverage in all markets must provide enrollees terminating coverage with documentation of the length of time they had coverage as a way of helping consumers exercise their portability right. Table 1 compares key access, portability, and renewability standards under HIPAA in both the small group and individual insurance markets with existing laws in each of the five states. (Enclosure I more fully describes each HIPAA requirement.)

Table 1: Comparison of Selected HIPAA Provisions With Existing State Laws in the Five States That Have Not Fully Passed HIPAA Conforming Legislation, as of June 1998

	Existing state insurance laws				
	Calif.	Mass.	Mich.	Mo.	R.I.
HIPAA small group standards					
Guarantee issue of all products to groups of 2 to 50	●	●	○ ^a	○ ^b	○ ^c
Guarantee renewal	●	●	●	○ ^b	●
Limits on preexisting condition exclusions periods (6/12) ^d	●	●	○ ^a	○ ^b	●
Certificate of creditable coverage	-	-	-	-	-
Nondiscrimination	●	-	-	-	-
Credit for prior coverage with allowable 63-day gap in coverage (portability)	●	○ ^e	-	○ ^b	○ ^c
HIPAA individual market standards					
Guarantee issue of two or more products to individuals leaving group coverage with allowable 63-day gap in coverage	-	○ ^e	○ ^a	-	○ ^c
Guarantee renewal	●	●	●	-	-
Certificate of creditable coverage	-	-	-	-	-

(Table notes on next page)

Legend:

- Indicates state law conforms to or exceeds standard.
- Indicates state law partially conforms to standard.
- Indicates state does not have a law that conforms to standard.

***In Michigan's small group market, the Blues plan must guarantee issue all products to all groups and is prohibited from imposing any preexisting condition exclusion periods on groups of any size. In the individual market, the Blues plan is also required to guarantee issue all products to all individuals who apply. However, the Blues plan imposes a preexisting condition exclusion period for individuals who previously received coverage from another carrier or were uninsured.**

***Missouri's small group reform laws apply only to groups of 3 to 25, and its guaranteed-issue provision only includes two state standardized plans. Also, state law only allows for a 30-day gap in coverage.**

***In the Rhode Island small group market, carriers must only guarantee issue of two state standardized plans to groups of 3 to 50. Also, state law only allows for a 30-day gap in coverage. In the individual market, the guaranteed-issue provision only applies to individuals who have no gap in coverage.**

***The designation "6/12" means that an insurer may look back 6 months to determine whether a person has received medical advice, diagnosis, or care for a condition and may exclude coverage for that preexisting condition for 12 months.**

***Massachusetts' law only allows for a 30-day gap in small group coverage and requires the guaranteed issue of only one standardized product in the individual market.**

HCFA's Regulatory Role Has Been Minimal in Most States Lacking Conforming Laws

To ensure that HIPAA's health insurance standards are being implemented in each state that does not enact fully conforming legislation, HCFA must assume functions typically reserved for state insurance regulators, including the following:

- respond to consumer inquiries and complaints,**
- provide guidance to carriers about HIPAA requirements,**
- obtain and review carriers' product literature and policies for compliance with HIPAA standards,**

- monitor carrier marketing practices for compliance with each HIPAA standard, and
- impose civil monetary penalties on carriers who fail to comply with HIPAA requirements.

HCFA's direct regulatory efforts thus far have consisted primarily of responding to consumer inquiries and complaints in each of the five states (see table 2). State insurance regulators have often served as the first point of contact for consumers' HIPAA-related inquiries, addressing many of the questions before referring consumers to HCFA. According to HCFA officials, the number of inquiries addressed by HCFA has ranged from only a few in Massachusetts and Rhode Island to roughly 1,700 between January and April 1998 in California. Consumer inquiries commonly relate to the applicability of HIPAA protections to their unique circumstances and the difficulty of obtaining access to individual market coverage without preexisting condition exclusions. Relatively few of these inquiries have evolved into the filing of a formal complaint; although as of May of 1998, HCFA had intervened with carriers on about 30 and 10 occasions in California and Missouri, respectively, according to HCFA officials. In addition to responding to consumer queries and complaints in California, Missouri, and Rhode Island, HCFA and the state insurance departments jointly developed and disseminated to carriers guidance that delineated the regulatory responsibilities of the state and federal regulators. HCFA also hosted informational meetings in Missouri and Rhode Island to explain provisions of the law and its enforcement to the industry. Although California state officials voluntarily notified HCFA of its noncompliance in October 1997, the agency has yet to hold informational meetings.³ HCFA has begun the review and approval process of carriers' policies in Missouri but has delayed undertaking this task in Rhode Island and California, pending clarification of procedural aspects of its regulatory authority. Although neither Massachusetts nor Michigan enacted conforming legislation by the January 1, 1998, statutory deadline, HCFA does not intend to undertake any further regulatory activities in these states until the states

³HCFA's regional office scheduled three informational meetings in California but postponed them when the Congress rejected a \$16 million supplemental appropriation that included \$6 million for HIPAA enforcement efforts. Subsequently, the Congress approved a \$2.2 million supplemental appropriation intended specifically for HCFA's HIPAA enforcement activities. HCFA has since rescheduled the three meetings for August 1998.

either formally notify the agency of their nonconformance or until HCFA formally establishes the states' failure to pass conforming legislation.

Table 2: HCFA Regulatory and Enforcement Activities Undertaken, as of June 30, 1998

Activity	Calif.	Mass.	Mich.	Mo.	R.I.
Respond to consumer inquiries, complaints	●	●	●	●	●
Establish guidance for carriers	●	-	-	●	●
Collect and review insurance policies for compliance with HIPAA	-	-	-	○ ^a	-
Monitor carriers' marketing and underwriting practices	-	-	-	-	-
Impose civil penalties for failure to comply with HIPAA ^b	-	-	-	-	-

Legend:

- Indicates HCFA has begun performing this enforcement responsibility.
- Indicates HCFA has partially begun performing this enforcement responsibility.
- Indicates HCFA has not begun performing this enforcement responsibility.

^aHCFA has requested voluntary reporting of policies by the nine largest individual and small group insurance carriers and begun reviewing them.

^bRegulations regarding civil enforcement of HIPAA remain under development.

According to HCFA officials, although the agency's regulatory efforts thus far have been limited, by responding to consumer inquiries and complaints in all states and by reviewing carriers' policy forms in Missouri, the agency

should become aware of, and be in a position to address, egregious HIPAA violations should they occur. Consequently, according to the officials, the agency is positioned to respond to HIPAA violations in the short term, while more systematic oversight procedures are being put into place for the longer term.⁴

HCFA Has Not Systematically Determined Compliance of Remaining 45 States

HCFA has not yet systematically determined the extent to which the remaining 45 states have passed conforming legislation.⁵ Preliminary surveys suggest that most states already had comparable HIPAA standards in place or have since adopted them, but limited gaps may remain.⁶ For example, several regulators suggest that many states have not adopted the certificate of creditable coverage issuance requirement or the definition of small group insurance.

HCFA'S ENFORCEMENT SLOWED BY LIMITED STAFF CAPACITY AND ISSUES SURROUNDING ITS REGULATORY AUTHORITY

HCFA officials acknowledged that the agency has thus far pursued a minimalist approach to regulating HIPAA and largely attribute HCFA's limited involvement to date to two interrelated factors: a lack of staff with appropriate experience in the complexities of private health insurance regulation and uncertainty surrounding the manner in which it may exercise its authority. HCFA's ability to determine the appropriate number and expertise of staff required will be difficult until questions concerning the nature and extent of its regulatory authority are resolved.

⁴We recently reported that many consumers had little or no knowledge of HIPAA and that consumer education was needed. See Health Insurance Standards: New Federal Law Creates Challenges for Consumers, Insurers, Regulators (GAO/HEHS-98-67, Feb. 25, 1998). The lack of informed consumers could diminish the effectiveness of complaint monitoring as HCFA's primary method of identifying carrier noncompliance.

⁵HIPAA does not require states to report to HCFA their conformance with HIPAA standards.

⁶GAO/HEHS-98-67, Feb. 25, 1998.

Limited Staff Capacity Has Contributed to HCFA's Minimal Level of Enforcement

HCFA primarily attributes its limited regulatory involvement to date to a lack of available staff—particularly those with experience regulating private health insurance. Assuming that states would adopt conforming legislation, HCFA originally reassigned a relatively small number of staff from the central office and the regions to address HIPAA direct enforcement issues. The reassigned staff came from other divisions and generally had no previous experience in private health insurance, although some received specialized HIPAA training after their reassignment. According to HCFA officials, since the agency learned of Missouri's nonconformance relatively early, it was able to authorize four new staff in the Kansas City region in 1997—three were hired with specialized expertise in reviewing health insurance policies, and one was promoted internally.

As of July 1998, HCFA had authorized 39 FTEs to all HIPAA-related issues. Twenty-two of the 39 FTE staff will be located in the four regions with jurisdiction over the five states known to not have HIPAA conforming legislation.⁷ The supplemental appropriation provided to HCFA in May of this year enabled the agency to increase the number of staff working on HIPAA issues to a total of three to eight staff in each of the four regions with enforcement responsibilities. However, HCFA officials anticipate that the new hires will still primarily focus on responding to consumer inquiries and complaints. Table 3 shows the number of staff involved in implementing and enforcing HIPAA in the central office and the four regional offices.

⁷Although staff in other regional offices may also work on HIPAA implementation issues on a part-time basis, only those regional offices with a direct enforcement role have been allocated FTEs exclusively for this effort.

Table 3: HCFA Staff Dedicated to HIPAA Enforcement, as of July 1998

HCFA office location	Staff authorized for HIPAA issues
Central office	17
Boston	3
Chicago	5
Kansas City	6
San Francisco	8

Although HCFA officials indicate that they will need additional staff and expertise to conduct further enforcement activities, they are unable to precisely quantify their staff needs because they are inexperienced in the regulation of private health insurance and are uncertain of their long-term level of responsibility.

HCFA's Regulatory Activities Have Been Impeded by Questions Concerning the Manner in Which HCFA May Exercise Its Authority

HCFA's efforts to regulate insurance have been hampered by questions about the manner in which it may exercise its authority to (1) conduct direct enforcement in Massachusetts and Michigan, (2) require carriers to submit data, and (3) impose civil penalties on carriers that do not comply with HIPAA.

Absent formal notification from Massachusetts and Michigan that they have not passed conforming legislation, HCFA must undertake a determination process whereby it establishes the states' nonconformance, thus providing the agency with the authority to become involved. This determination process is set forth in federal regulations and provides for several iterative steps, including an initial notification by HCFA to state officials of the state's nonconformance, a required 45-day period for states to respond, followed by HCFA's preliminary determination of nonconformance, additional time for state corrective actions, and HCFA's final determination of nonconformance. However, HCFA officials have not yet undertaken this effort—which they characterized as cumbersome—in either Massachusetts or

Michigan, preferring to provide these states with every feasible opportunity to enact conforming legislation before becoming involved. According to HCFA officials, the agency is currently in the process of determining the next actions to be taken in these states.

In addition, HCFA officials said that their efforts to review carriers' policies may be restricted by the Paperwork Reduction Act. The act establishes standards for how most federal agencies may collect, maintain, and use collected information and sets governmentwide goals for reducing paperwork. The act requires federal agencies to evaluate the need for information as well as identify any burdens that responding to agency requests may impose on respondents. It also establishes a process for approval of any collection of information, defined as collections from 10 or more persons. With regard to implementing HIPAA standards, HCFA would need to obtain approval from OMB before requiring carriers to submit policies for review.⁸ Although HCFA has the authority to obtain this information in response to specific consumer complaints without following Paperwork Reduction Act procedures, the act limits HCFA's ability to collect this information from all carriers on a regular basis—as most state insurance regulators do—without approval from OMB. Due to these constraints, HCFA officials in Kansas City have relied on voluntary reporting by the nine largest carriers in Missouri's individual and group insurance markets, which account for about 80 percent of policies sold in these markets. The HCFA regional office in California may soon begin requesting voluntary submissions from carriers in that state; however, HCFA officials in other regions with jurisdiction over nonconforming states do not intend to ask carriers to voluntarily submit policies, opting to wait until their authority under the act is definitively established.

Finally, HIPAA is largely silent about the standards and process by which HCFA will carry out its regulatory role in states. Most of HIPAA's legislative language articulates the access, portability, and renewability standards rather than delineate a regulatory scheme for HCFA. The statute provides

⁸Agencies must provide 60 days' notice in the Federal Register of the proposed collection of information and seek public comment. The agency must then submit to OMB a request for the collection of information and publish a second notice in the Federal Register. OMB is then allowed 60 days to review the submission and may approve a collection of information for no more than 3 years.

for the imposition of a civil monetary penalty⁹ on noncomplying carriers. However, according to HCFA officials, absent detailed standards to follow in carrying out its role as insurance regulator in states, HCFA's authority to impose the penalty may be challenged. Agency officials have just begun to develop detailed enforcement regulations and do not expect to have them issued before the end of 1998.¹⁰

**FEDERAL INVOLVEMENT IN ROLE TRADITIONALLY
RESERVED FOR STATES MAY COMPLICATE
OVERSIGHT OF PRIVATE HEALTH INSURANCE**

In addition to uncertainty over appropriate staffing levels and its authority, HCFA has adopted a cautious approach in its initial efforts to enforce HIPAA standards as it considers appropriate measures to minimize potential conflicts between state and federal oversight. The regulation of insurance has traditionally been the responsibility of the states. In 1945, the Congress endorsed this arrangement with enactment of legislation often referred to as the McCarran-Ferguson Act. Even though ERISA preempts states from regulating employer benefit plans, it maintains the states' prerogative to regulate insurance carriers.¹¹ HCFA's new responsibility for directly regulating health insurance under HIPAA establishes a new federal-state framework for health insurance oversight. While HCFA's role as an insurance regulator in these states is limited to HIPAA-related issues, this dual oversight of health insurance sold in a state may, in some cases, further fragment and complicate the regulation of private health insurance.

In the states where HCFA assumes regulatory responsibility for HIPAA, multiple entities will have partial responsibility for regulating consumers'

⁹HIPAA provides for the imposition of a civil monetary penalty of up to \$100 per day per violation for each individual affected by a carrier's failure to comply.

¹⁰The majority of HIPAA's implementing regulations—developed jointly by HHS (through HCFA) and the Departments of Labor and Treasury—were issued on April 1, 1997, on an interim final basis. The agencies anticipated that the development of HIPAA regulations would be an ongoing process and recognized that further regulatory guidance would be necessary.

¹¹As a result of ERISA, states lack the authority to regulate employers' self-funded health plans. States can regulate insurance products purchased by employers and individuals.

health coverage. For example, in California, two state agencies have responsibility for regulating health benefits. According to HCFA officials, the California Department of Insurance regulates more than 1,000 carriers that sell life or disability insurance policies, including health insurance, while the California Department of Corporations oversees over 100 "health care services plans," including the state's 42 full-service health maintenance organizations (HMO). In addition, the Department of Labor oversees employer health benefit plans, including self-funded health plans. HCFA joins this existing array of regulatory bodies with its responsibility for HIPAA issues, particularly in the individual insurance market where California lacks conforming state standards. While California is unique in having separate regulatory agencies for insurance companies and HMOs, the oversight of health benefits in Missouri and Rhode Island (and in Massachusetts and Michigan should their transitional nonconforming status become permanent) is similarly divided among state insurance regulators, the Department of Labor, and HCFA.

In addition, the piecemeal nature of this framework means that neither the states nor the federal government has complete authority for regulating health insurance products. For example, in Missouri, state law requires the guaranteed issue of two standardized plans to groups of 3 to 25 individuals. In contrast, HIPAA's small group standard requires carriers to guarantee issue all products sold in the small group market to groups of 2 to 50 individuals. Therefore, in addition to ensuring that carriers guarantee issue to groups of size 2 and 26 to 50, HCFA also has responsibility to ensure that groups of 3 to 25 have access to more than the two standardized plans.¹² Thus, which entity has authority hinges on the size of the group—a distinction that may not be easily understood by consumers. To minimize confusion among consumers, insurance regulators in these states have generally served as the initial source of contact for consumer inquiries or complaints, referring HIPAA-related issues to HCFA.

In addition to the potential for consumer confusion, the federal-state regulatory framework may lead to duplication. For example, some states require carriers to submit policies to the state for approval prior to

¹²According to HCFA officials, since very few small employers purchase the standardized products, the agency effectively has the responsibility for enforcing the guaranteed-issue requirement throughout the small group market.

marketing these policies.¹³ However, if HCFA initiates policy reviews to ensure compliance with HIPAA standards, then carriers will also need to submit these policies to HCFA for review. (As noted above, to date only in Missouri has HCFA initiated a limited review of policies.) Furthermore, if HCFA requires modifications to the policies, carriers may need to resubmit amended policies to the state for review. Thus, without careful coordination between HCFA and the states, carriers could face an increased administrative burden.

CONCLUDING OBSERVATIONS

HCFA's new, largely unanticipated regulatory responsibility under HIPAA broadens the agency's mission and the federal government's role in regulating private health insurance. The potential for direct federal regulation has not provided a sufficient impetus for all states to adopt fully conforming legislation. Unless these states enact fully conforming standards in the near future, HCFA's regulatory role is likely to expand as it assumes additional duties to ensure full conformance with HIPAA. A larger HCFA role would better ensure that consumers and small employers receive the full benefits and protections that HIPAA intended. At the same time, however, HCFA's new role could potentially increase the regulatory burden faced by health carriers and require consumers to navigate between state and federal agencies, none of which has complete authority for enforcing applicable consumer protections.

In establishing minimum federal standards for health insurance, one important consideration is the appropriate role for federal regulatory agencies in monitoring and, in some cases, directly enforcing compliance. If a broader federal role is appropriate, federal regulators should have sufficient resources and clear regulatory authority to undertake this responsibility. On the other hand, if this dual federal-state regulatory structure proves inappropriate or too complex, alternative approaches may need to be developed to encourage more states to meet federal standards and assume enforcement responsibilities.

¹³Other states require insurance carriers to file policies, but they may proceed to market these policies without prior state approval.

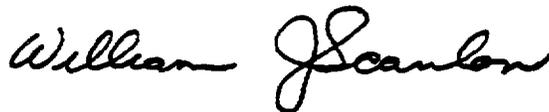
AGENCY COMMENTS AND OUR EVALUATION

In commenting on a draft of this correspondence, HCFA emphasized the significant challenges it has faced in undertaking its new responsibilities under HIPAA and its progress to date in developing a new regulatory framework for enforcing these particular provisions, given limited additional resources. (See enclosure 2 for HCFA's comments.) We acknowledge that this task is a significant new challenge and that HCFA has made progress in this regard. We commented in an earlier report that this unexpectedly large regulatory role under HIPAA could strain HCFA's resources and its oversight effectiveness.¹⁴ HCFA also provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this letter until 30 days after its issue date. We will then make copies available on request to others who are interested.

This correspondence was prepared by Susan Anthony and Randy DiRosa under the direction of John Dicken. Please call me at (202) 512-7114 if you or your staff have any questions concerning this information.

Sincerely yours,



William J. Scanlon
Director, Health Financing and
Systems Issues

Enclosures - 2

¹⁴GAO/HEHS-98-67, Feb. 25, 1998.

HIPAA ACCESS, PORTABILITY, AND RENEWABILITY STANDARDS

To achieve its goals of improving the access, portability, and renewability of private health insurance, HIPAA sets forth standards that variously apply to the individual, small group (2 to 50 employees), and large group (more than 50 employees) markets in all states. Most HIPAA standards became effective on July 1, 1997; group plans do not become subject to the applicable standards until their first plan year beginning on or after July 1, 1997. Each of HIPAA's health coverage access, portability, and renewability standards is summarized in table L1 by applicable market segment. A description of each standard follows.

Table L1: Summary of Applicability of HIPAA Access, Portability, and Renewability Standards by Market Segment^a

	Individual	Small group employer (2-50 employees)	Large group employer (over 50 employees)
Certificate of creditable coverage	Yes	Yes	Yes
Guaranteed access/availability	Only for eligible individuals leaving group coverage	Yes	No
Guaranteed renewability	Yes	Yes	Yes
Limitations on preexisting condition exclusion periods	No ^b	Yes	Yes
Nondiscrimination	NA	Yes	Yes
Portability	No	Yes	Yes
Special enrollment periods	NA	Yes	Yes

Note: NA = not applicable.

^aSome of these standards also apply to certain federal, state, and local government insurance programs, such as Medicaid or state employee health plans.

^bCarriers may not impose preexisting condition exclusions upon individuals eligible for group-to-individual guaranteed access.

Certificate of Creditable Coverage

HIPAA requires issuers of health coverage, to provide certificates of creditable coverage to enrollees whose coverage terminates. The certificates must document the period during which the enrollee was covered so that a subsequent health issuer can credit this time against its preexisting condition exclusion period. The certificates must also document any period during which the enrollee applied for coverage but was waiting for coverage to take effect—the waiting period—and must include information on an enrollee's dependents covered under the plan.

Guaranteed Access/Availability

In the small group market, carriers must make all plans available and issue coverage to any small employer that applies, regardless of the group's claims history or the health status of enrollees. Under individual market guaranteed access—often referred to as group-to-individual portability—eligible individuals must have guaranteed access to at least two different coverage options. Generally, eligible individuals are defined as those with at least 18 months of prior group coverage who meet several additional requirements.¹⁵ Depending on the option states choose to implement this requirement, coverage may be provided by carriers or under state high-risk insurance pool programs, among others.

Guaranteed Renewability

HIPAA requires that all health plan policies be renewed regardless of health status or claims experience of plan participants with limited exceptions. Exceptions include cases of fraud, failure to pay premiums, enrollee movement out of a plan service area, membership in a bona fide association's health plan ceases, and when an issuer withdraws from the

¹⁵An eligible individual also must have had no break in the prior coverage of more than 63 consecutive days; must have exhausted any Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) or other continuation coverage available; must not be eligible for any other group coverage, Medicare, or Medicaid; and must not have lost group coverage because of nonpayment of premiums or fraud.

market.

Limitations on Preexisting Condition Exclusion Period

Group plan issuers generally may deny, exclude, or limit an enrollee's benefits arising from a preexisting condition for no more than 12 months following the effective date of coverage. A preexisting condition is defined as a condition for which medical advice, diagnosis, care, or treatment was received or recommended during the 6 months preceding the date of coverage or the first day of the waiting period for coverage. Pregnancy may not be considered a preexisting condition, nor can preexisting conditions be imposed on newborn or adopted children in most cases.

Nondiscrimination

Group plan issuers may not exclude a member within the group from coverage based on the individual's health status or medical history. Similarly, benefits provided, premiums charged, and contributions to the plan may not vary within similarly situated group plan enrollees on the basis of health status or medical history.

Credit for Prior Coverage (Portability)

Issuers of group coverage must credit an enrollee's period of prior coverage against its preexisting condition exclusion period. Prior coverage must have been consecutive with no breaks of more than 63 days to be creditable. For example, an individual who was covered for 6 months who changes employers may be eligible to have the subsequent employer plan's 12-month waiting period for preexisting conditions reduced by 6 months. Time spent in a prior health plan's waiting period may not count as part of a break in coverage.

Special Enrollment Periods

Individuals who do not enroll for coverage in a group 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 COBRA, or were covered as a dependent under a spouse's coverage and later lost that coverage. In addition, if an enrollee has a new dependent due to the birth or adoption of a child or through marriage, the enrollee and dependents may become eligible for coverage during a special enrollment period.

Other Insurance-Related Provisions

HIPAA also includes certain other standards that relate to private health coverage, including limited expansions of COBRA coverage rights, new disclosure requirements for ERISA plans, and new requirements for uniform enrollee and claims information, which are to be phased in through 1999. Tax law changes authorize federally tax-advantaged medical savings accounts for small employer and self-employed plans. Finally, although not included as part of HIPAA but closely related, there are new standards for mental health and maternity coverage, which became effective on January 1, 1998.

COMMENTS FROM THE HEALTH CARE FINANCING ADMINISTRATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Office of the Administrator
Washington, D.C. 20201

JUL 21 1998

Mr. William J. Scanlon
Director, Health Financing and Systems Issues
U.S. General Accounting Office
441 G Street, N.W.
5th Floor
Washington, D.C. 20548

Dear Mr. Scanlon:

Thank you for the opportunity to comment on the draft report by the U.S. General Accounting Office (GAO) entitled, "Private Health Insurance: HCFA Cautious in Enforcing Federal HIPAA Standards in States Lacking Comparable Laws" (GAO/HEHS-98-217R).

We believe that the current status of these efforts could be described in a more balanced fashion to reflect the substantial progress we have made in developing the regulatory framework for HIPAA enforcement. Moreover, we believe that your report should acknowledge more completely the significant challenges HCFA has faced in undertaking its responsibilities.

The most significant of these challenges has been that Congress, until very recently, had not provided any resources for HCFA to implement the provisions of the law in the manner required. This has particularly hampered our ability to adequately enforce HIPAA in the three States – Missouri, Rhode Island, and California – that have notified us of their noncompliance with HIPAA.

In the fall of 1996, immediately after HIPAA was enacted, we reassigned staff from other functions in the agency to begin the work of writing regulations to govern enforcement, as well as to implement the group and individual market portability provisions of HIPAA. These regulations were published by the statutorily mandated due date, a mere eight months from the date of the law's enactment. Other regulations and guidance, including a widely-distributed bulletin on insurer abuses, have also been issued on a timely basis. This includes regulations to implement the Mental Health Parity Act of 1996, which were published on December 22, 1997. On December 29, 1997 HCFA issued additional guidance concerning the relationship of HIPAA's group market rules and health flexible spending arrangements to individuals who were denied coverage due to a health status related factor. We are also close to publishing regulations to implement the Newborns'

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and Mothers' Health Protection Act of 1996. The publication of this initial body of regulatory guidance is a major accomplishment given the size and scope of the undertaking, the absence of additional funding, HIPAA's demanding implementation schedule, and the new working relationships required among HCFA, the Department of Labor, the Department of the Treasury, and the Internal Revenue Service.

With regard to HIPAA enforcement, given tight resource constraints, we prioritized the required tasks and focused solely on the three States that had notified us of their failure to comply with HIPAA. We also began the long process of obtaining additional funding. While we were pleased to receive a small portion of our request under the supplemental appropriation, these funds came extremely late in the fiscal year and are not sufficient to allow us to move forward with the full range of HIPAA enforcement activities we believe we should pursue. For example, with this funding level, we do not have sufficient staff to review the body of insurance law in all of the States and territories in order to make an independent determination as to whether it is consistent with HIPAA. Instead, we have determined that with this level of resources, we must focus on (1) completing the development of regulations to enforce HIPAA; and (2) carrying out our direct enforcement responsibilities in the States where we have that responsibility because the State has failed to implement HIPAA. Toward that end, we have since rescheduled essential meetings with insurers in California that we were forced to cancel because we did not have the necessary funds for travel and convening meetings in three different parts of the State.

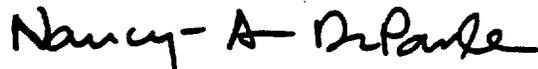
We have also moved quickly to hire and train 22 additional staff in our regional offices, where we expect most of the enforcement activity to occur. In addition, we have started the process of hiring contractors in the next few months before the end of the fiscal year to assist us in accomplishing several enforcement tasks.

At this time, we cannot predict the extent of our future needs, as there are no reporting requirements for the States, and no incentives to achieve HIPAA standards. Our actions and resource needs are heavily dependent upon States' actions, over which we have no control.

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However, within the constraints of our resources, we anticipate continued progress in our efforts to enforce HIPAA's provisions and enable vulnerable Americans to exercise their rights under HIPAA and obtain insurance coverage.

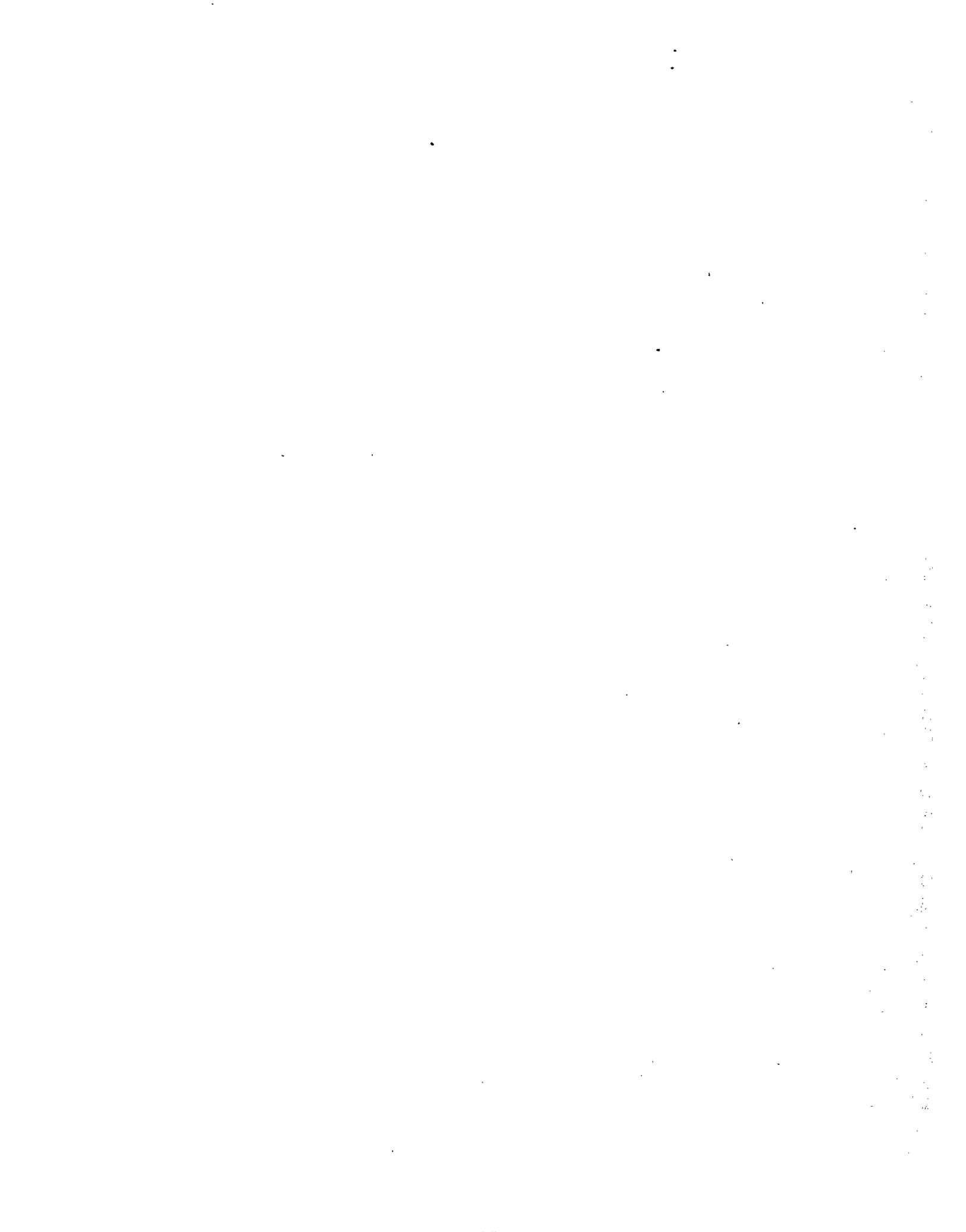
Sincerely,



Nancy-Ann Min DeParle
Administrator

Enclosure

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