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Divider Title: Studies

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Divider Title: Fed Govt. Announce

**PRESIDENT CLINTON RELEASES DIRECTIVES AIMED AT ASSURING THAT
FEDERAL HEALTH PLANS COME INTO COMPLIANCE WITH THE
PATIENTS' BILL OF RIGHTS**

February 20, 1998

Today, the President is releasing an Executive Memorandum directing all Federal health plans, which serve over 85 million Americans, to come into substantial compliance with the President's Quality Commission's Consumer Bill of Rights. The Executive Memorandum follows a report that the Vice President forwarded to the President on the current status of compliance with the Consumer Bill of Rights. The President is also re-issuing his challenge to Congress to pass legislation that assures that these patients' bill of rights will become the law of the land for all Americans. Today, the President is:

ANNOUNCING THAT THE NATION'S FEDERAL HEALTH PROGRAMS ARE LEADERS IN PROVIDING PATIENT PROTECTIONS. Today, the President accepted and praised the Vice President's report on the compliance status of Federal health programs with the Consumer Bill of Rights, including Medicare, Medicaid, Indian Health Service, the Federal Employee Health Benefits Program, the Department of Defense Military Health Program, and the Veteran's Health Program. Although citing shortcomings, the report concludes that Federal health plans are already largely in compliance. This finding illustrates that implementing consumer protections to help Americans navigate through a changing health care system, can be and has been done without excessive costs or regulations.

ISSUING AN EXECUTIVE MEMORANDUM TO ASSURE THAT THESE FEDERAL AGENCIES TO COME INTO SUBSTANTIAL COMPLIANCE WITH THE CONSUMER BILL OF RIGHTS. While the Federal government is taking a leading role to assure consumer protections are in place, the Vice President's report concluded it has the authority to do more. The President is issuing an Executive Memorandum to ensure the Federal programs come into substantial compliance with the Consumer Bill of Rights by no later than next year. His executive action:

- ✓ **Directs HHS to Take Administrative Actions to Ensure That Medicare Comes Into Compliance With Rights, Including Access to Specialists, By Next Year.** Medicare is largely in compliance with the Consumer Bill of Rights. However, Medicare currently does not assure access to specialists and adequate levels of participation in treatment decisions. The President is directing HHS to issue administrative actions in these and other areas by no later than next year to bring Medicare, which serves over 38 million older Americans and people with disabilities, substantially into compliance.
- ✓ **Directs HHS to Take Administrative Actions to Assure Greater Compliance for Medicaid, Including Access to Specialists, by Next Year.** HHS has also determined that there are appropriate administrative actions it could take to ensure that the Medicaid program, which serves 36 million Americans, comes into substantial compliance with all of the major elements of the Consumer Bill of Rights. The President is also directing the Department to issue directives to bring Medicaid into substantial compliance by no later than next year.

- ✓ **Directs HHS to Immediately Notify States That Emergency Room Services Are Covered Under Medicaid.** The President is directing the Department to send a letter to State Medicaid directors to clarify that States are required to cover emergency room services consistent with the recommendations of the Consumer Bill of Rights.
- ✓ **Directs the Federal Employees Health Benefits Program (FEHBP) to Ensure 350 Participating Carriers Come Into Compliance With the Consumer Bill of Rights by Next Year.** The President is directing Office of Personnel Management (OPM), which manages FEHBP and its 9 million enrollees, to notify all 350 participating carriers that they must come into compliance with the Consumer Bill of Rights, particularly with regard to access to specialists, continuity of care, access to emergency room services. He also is directing OPM to work with each participating carrier to ensure they come into full compliance with the Consumer Bill of Rights by the end of next year. OPM issues a call letter each March which sets forth FEHB Program and policy changes. To meet the President's directive, this year's letter will specifically address new expectations for participating carriers in areas such as, access to specialists, continuity of care, disclosure of financial incentives, and access to emergency room services.
- ✓ **Directs OPM to Publish New Regulations Prohibiting "Gag Clauses."** The President is directing OPM to publish a regulation in the next three months to ensure that gag clauses, which restrict physician-patient communications about medically necessary treatment options, not be a part of any provider agreement that includes FEHBP enrollees. These new actions build on OPM's existing consumer protections, including an internal and external appeals process and information disclosure rights.
- ✓ **Directs the Department of Defense (DoD) to Come Into Compliance Through A Series of Policy Directives and Contractual Modifications.** The President is directing DoD, which serves 6 million Americans to: (1) establish a strong grievance and appeal process for beneficiaries who have been denied services by managed care companies that are in contract with the Military Health System; (2) to issue a directive to promote greater use of providers who have specialized training in women's health issues to serve as primary care managers for female beneficiaries; and (3) to issue a directive to ensure that all patients in the military health system can fully discuss all treatments options, including prohibiting "anti-gag" clauses. These actions, to be completed by this fall, will bring the Military Health System into substantial compliance with the Consumer Bill of Rights.
- ✓ **Directs Veteran's Health Programs To Come Into Compliance With the Consumer Bill of Rights Through a Series of Policy Initiatives.** The President is directing the VA, which serves 3 million veterans, to use its administrative authority to ensure that an internal and external appeals process is in place and to issue a new directive to ensure that VA consumers meet the information disclosure recommendations in the Consumer Bill of Rights. The VA already assures many protections, such as access to specialists. This new action will bring the VA system into virtual compliance with the Consumer Bill of Rights.

- ✓ **Directs the Department of Labor to Use Its Limited Authority to Assure Adequate Information Disclosure and A Stronger Internal Appeals Process.** DoL is responsible for the administration and enforcement of the Employee Retirement Income Security Act (ERISA) which governs approximately 2.5 million private sector health plans, that cover about 125 million Americans. DoL has extremely limited authority to ensure that these plans can come into compliance. Understanding this fact, the President is directing DoL to take action, by no later than this spring, to propose regulations to protect consumers by: (1) improving information disclosure rights; and (2) strengthening the internal appeals process for all ERISA plans, to ensure that decisions regarding urgent care are resolved within not more than 72 hours and generally resolved within 15 days for non-urgent care.

RE-ISSUES CHALLENGE TO CONGRESS TO PASS FEDERALLY-ENFORCEABLE PATIENTS' BILL OF RIGHTS THIS YEAR. Today, the President renewed his call to Congress to pass a patients bill of rights this year. The Department of Labor's report underscores that most consumer protections cannot be assured to patients in private health plans without additional legislation. Without this legislation, the millions of Americans in private health plans will never be assured these protections.

RELEASES HHS CONSUMER SURVEY TO EMPOWER MEDICARE BENEFICIARIES TO MAKE INFORMED CHOICES. Today, the Consumer Assessment Health Plans Survey (CAHPS) is being released by HHS. This survey asks about how easily beneficiaries can access specialists, emergency care services, and seeks information on the general level of consumer satisfaction. Survey results, which will provide extensive information about all Medicare managed care plans currently up and running, will be sent to every Medicare beneficiary this fall, helping them make much-better informed choices about their health plan options.

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Divider Title: Executive Order

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Divider Title: VP Summary

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Divider Title: State Protections

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Divider Title: PTS Remarks

March 10, 1998

MEMORANDUM TO THE PRESIDENT

FROM: Chris Jennings

SUBJECT: Upcoming Patients' Rights/Quality Events and Legislation

cc: John Podesta, Rahm Emanuel, Bruce Reed, Larry Stein, Elena Kagan

On Friday, you are scheduled to receive the Quality Commission's final report. Next Tuesday, the Democrats are unveiling their "Patients' Rights" bill. Both of these events have potential to positively or negatively affect our chances of enacting strong consumer protection legislation this year. This memo outlines the reasons why and seeks your final decision on the advisability of appearing with the Democrats when they introduce their bill.

Background

The prospect of achieving a "Patients' Rights" legislative victory has been significantly enhanced over the last few weeks. Your Executive Memorandum directing all agencies to come into virtual compliance with the Quality Commission's Consumer Bill of Rights, your well-received speech to the American Medical Association, today's *New York Times* editorial praising your approach to the patients' bill of rights, and Speaker Gingrich's acknowledgment yesterday that consumer protection legislation will likely pass the Congress this year have positioned you extremely well on this issue. In addition, the House Republican Health Task Force (Hastert, Thomas, Bliley, etc.) has indicated that they will work with us in coordinating the development of legislation as long as we do not "overly politicize" this issue.

Final Quality Commission Meeting and Report

The Quality Commission's final report presents a good opportunity to build on the momentum you have achieved through your endorsement of their "Consumer Bill of Rights." The second part of their work product -- those recommendations dealing with quality standards -- are non-controversial, new measures designed improve health care quality. Your endorsement of the Commission's recommendations will be widely praised because there is a strong belief that developing evidence-based health care standards have great potential to improve quality and constrain costs. However, partly because these recommendations are relatively non-controversial, the news most likely to be reported will be the fact that the Commission did not achieve consensus on an enforcement mechanism for the patient protections. Although they were not expected to reach consensus, the press will likely use this to underscore the controversy surrounding this issue (further detailed below.)

Democratic Leadership's "Patients' Bill of Rights"

Your "Patients' Bill of Rights" serves as the foundation for the Democratic Leadership's bill. However, their legislation adds provisions that the business community, and in a number of cases the elite validators, would oppose because they believe they are excessively regulatory and costly. For example, it includes a number of mandated benefits such as requiring health plans to offer a mandatory point-of-service option, and to cover breast cancer reconstructive surgery and all clinical trials.

While CBO has yet to score any of these additional provisions, some could prove to be quite costly. For example, the initial estimates by the HCFA actuaries assume that applying the bill's provision to cover all clinical trials to Medicare and Medicaid -- generally consistent with your previous efforts to bring all Federal health plans in compliance with any new private sector requirements -- would cost Medicare approximately \$5 billion over five years and Medicaid \$4 billion over five years. Any costly scores from CBO would no doubt lend credence to criticisms that a patients' bill of rights would increase health care costs and, as a consequence, increase the number of uninsured.

The most controversial provision in the Democratic bill is the enforcement mechanism that relies on state-based, legally enforceable remedies. The Administration has consistently stated that patient protections must be assured but has yet to take an official position on the best enforcement mechanism. The business community strongly opposes the Democratic leadership's approach, arguing that the trial lawyers will use this new opening to sue and significantly increase health insurance costs. Because of their fear of this provision, some within the business community suggest that its very existence would leave them no other choice but to drop coverage. Although they are significantly overstating the case, their opposition would be formidable.

That being said, the Democrats' bill will be popular among most providers, physicians, and consumers who strongly support remedies, and some of the bill's mandatory benefits will have broad appeal. Moreover, the Democratic leadership strongly desires your participation in the event. Finally, notwithstanding Republican, business, and the elites' opposition to a number of the bill's provisions that go beyond the patients' bill of rights, they are likely to be popular among the general public and could potentially be helpful in developing outside public pressure for a bill.

Conversely, standing with the Democratic leadership does carry real risk. First, because CBO has not scored the Democratic leadership's enforcement provision and other controversial provisions, taking (or suggesting) a position of support before this analysis is complete would be ill-advised. In addition, some within the Republican leadership who are currently indicating their willingness to work with us on a bill may be alienated by their almost inevitable perception that we are "politicizing" this issue. Finally, a perceived endorsement by you of the Democrats' bill will guarantee a higher level of scrutiny and well-funded opposition by the business community.

Recommendation

DPC believes that it may be difficult for your attendance at the Democrat's unveiling on Tuesday to be perceived as anything other than unqualified support. We are particularly concerned about the lack of cost estimates of the bill. Finally, we believe that it has great potential to hamper the relationship we are trying to build with those Republicans who have indicated their interest in passing a bill in this Congress.

Although recognizing the possible risks, your political and communications advisors believe that you can lend your support without giving an all-out endorsement. They believe that it is very important that you respond to the Democrats' desire for a unity event and believe that it has the potential to increase outside public pressure for Congressional action.

Regardless of your decision, we all agree that if you do choose to go, the language you use will be critically important to both sides and will have to be carefully formulated. In addition, we will need to work closely with Larry Stein to give the heads up to those Republicans, particularly on the House side, who will be distraught about your close link to the Democratic bill.

I want to thank all of you for being here today and particularly those of you who have been active in health care. I thank Secretary Shalala and Deputy Secretary Higgins and Secretary Herman, who has worked very hard on this; and Hershel Gober, the Deputy Secretary of Veterans Affairs; Janice Lachance and Nancy Ann Min DeParle, all the people who are here from the administration. General Hill, thank you for being here.

I'd like to thank County Council President Leggett and all the local officials who are here. A special word of thanks to Chris Jennings in the White House. You know, the staff people who work on these things never get enough credit. This is great -- the Vice President and I get up here and we give these speeches, and you think how wise we are. (Laughter.) And the truth is -- (laughter) -- there is always somebody making us look smarter than we are. And I'm very grateful to all the people who worked on this, who passionately care about you and people like you all over this country who never get the acknowledgements they deserve.

I thank Beth Layton and all the people here at Holiday Park for the work you're doing. I've been feeling very sentimental here. Twenty-one years ago, I'm almost sure it was 21 years ago this month, when I was a very young public official in my very first office of service, I had the state's first conference on senior citizens affairs. I never will forget it. I had it in the same place where I had my high school prom. (Laughter.) And now I have my AARP card. (Laughter.) I'm amazed at how far-sighted I was back then to be concerned about this. (Applause.)

I thank Marty Wish for his remarkable statement, and for reminding us why we're working so hard. The first person I heard tell that story about As Good As It Gets was the Vice President. And every time anybody sees that movie they always cheer. I understand it's going to be disqualified for an Academy Award because it's too close to real life. (Laughter.)

I want to thank Representative Morella and Representative Stark for being here, and for their efforts to make health care quality a bipartisan American issue, not a partisan political issue. And I thank you both for being here. Thank you very much. (Applause.)

We were going to have one other person here today, a woman named Dian Bower from California, whose son has a very serious illness that's being treated in a veterans military -- excuse me, a military managed care program. And she's very well satisfied with it, but passionately committed to the concept of a Patient's Bill of Rights. But because of the very difficult weather our fellow Americans in California have been experiencing -- I'm sure you've

been keeping up with it -- she was unable to come. But I would like to thank her for efforts to be here.

I'm pleased to accept this report from the Vice President. I just have to say one word about him. I asked the Vice President to undertake a very -- what appeared to be a completely thankless job. When we took office, we had a deficit of \$290 billion, and I said, look, we have to find a way to reduce the federal payroll by a minimum of \$100,000, and we have to do it without throwing anybody in the streets, and we have to do it without losing the confidence of federal employees or breaking their morale, they have to feel good about this. In other words, I was asking him to take two and two and make three or five or something other than four.

And he worked with the federal employees groups. Five years later, with the strong support and work and partnership of the Fellow Employees Organization, the federal payroll is \$300,000 smaller than it was the day I took office. And -- and -- we have had good early retirement programs for the federal employee, we have worked with them in a constructive way, the government is working better, and it has freed up money to invest in putting another 100,000 police on the street, in improving education and advancing the environment and doing all these things.

But as part of our philosophy of government, we want a government that is both smaller and more active, that gives people the tools to make the most of their own lives and acts as a catalyst for new ideas. And that's what we're doing here today. And this is perhaps the best example of all the wonderful work the Vice President has done in five years of reinventing government, of how you can have a government that's smaller and still does more to meet the real needs of the American people. So I want to thank him for that. (Applause.)

What this report does is point out that we are quite close to making sure that our federal health plans actually comply with the Patient's Bill of Rights that I have proposed. And today after I speak I am going to sign a directive over here on this desk which directs all our federal agencies to finish the job by taking the necessary steps outlined in the Vice President's report to me.

Now, I want you to understand clearly what this will mean -- just this action will mean to the lives of the American people. With the authority of the federal government we will ensure that a third of all Americans -- a third of all Americans -- are protected by a Patient's Bill of Rights. Now, that's every person on Medicare, every person on Medicaid, including children and people with disabilities, all of our federal employees and their families that are covered, all of our military personnel, and members of the biggest health care system in America -- all of our veterans and all their families.

A third of the American people will have now a Patient's Bill of Rights that says this: You have the right to know all your medical options, not just the cheapest. You have a right to choose a specialist for the care you need. You have the right to emergency

room care wherever and whenever you need it. You have the right to keep your medical records confidential -- very important. You have the right to bring a formal grievance or appeal of a health care decision with which you disagree.

And we are proving we can make these rights real now for nearly 90 million Americans. That's how many people we're talking about. And we can do this without increasing the deficit, without burdening the system or consumers. With this step we are setting a standard for the nation.

But we must not stop here. And that's why I am so glad to see Congresswoman Morella and Congressman Stark here, because now the Congress must pass national legislation to protect all Americans with a Patient's Bill of Rights. We are doing all we can do here with the stroke of the President's pen, but it should be an example that the rest of America should follow.

I know there will be voices of opposition in the Congress and in the health care industry. But every American deserves the protection of a Patient's Bill of Rights. Those of you who are retired fellow employees who are still under a plan, you will be covered today. I bet you feel just as strongly as you did before I came here to sign this that everybody whose not in a plan you're in deserves the same protection. And we need to be clear and unambiguous about that.

I look forward to working together with members of Congress in both parties who have shown the determination to do something about this. This Patient's Bill of Right is in keeping with our profoundest obligations to our parents, to our children, to the neediest, to the most vulnerable among us -- in keeping with our oldest ideals enshrined in the Bill of Rights, and it is an essential part of our effort and our obligation to strengthen our nation for the 21st century.

We want the benefits of managed care. We all like it when health care inflation is not going up at three and four and five times the rate of inflation. It gives all of you who are on fixed incomes more disposable income for other things that are terribly important to you. But we must never, ever, ever sacrifice the fundamental quality of care and the security that gives people, knowing that they live in a country that not only has the best health care system in the world in theory, it's the best in the world, in fact, in their lives. (Applause).

Now, Vice President talks about some of the things we have been doing in the last several years. A couple of years ago, Congress passed a law I strongly supported that says you can't lose your health insurance if you change jobs because someone in your family has been sick. The balanced budget amendment that I signed into law last year extends the Medicare trust fund until 2010. And

we now have a Medicare Commission meeting and working on how to preserve and protect Medicare well into the 21st century.

The balanced budget law also contains an unprecedented \$24 billion over the next five years to add up to 5 million more children to the ranks of the insured. And we're working with the states to do that. And Secretary Shalala is doing a great job in working with the states to make sure that we pick up more of these kids that don't have any health insurance. And just last week I directed federal agencies with programs with children to do more to enroll children as quickly as possible.

This Patient's Bill of Rights is the next important step, to make sure every American family has the quality health care all families need to thrive. It's especially important as our health care system continues to change.

Now, 35 years ago, President Kennedy proposed a Consumer Bill of Rights to protect Americans from unsafe products. He said, we share an obligation to protect the common interests in every decision we make. Those rights are still protecting us today, those consumer rights. Every time we rent a car or use a credit card or buy a toy for a child, the rights we are helping here to establish with the Patient's Bill of Rights will protect our children and our grandchildren 35 years from now and beyond.

This is a good day for America, and I am proud to sign the executive memorandum to ensure the Patient's Bill of Rights to nearly 90 million of our fellow citizens.

Thank you very much. (Applause.)

END

11:12 A.M. EST

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Divider Title: Whistleblower / Remedies



The Campaign for
Health Care Accountability

* FAX COVER

DATE:

TO:

Chris Jennings

FROM:

MICHAEL HUDSON

303-604-1392

303-604-2692 (FAX)

COMMENTS:

As mentioned I'll be in DC w/ group
from Tex. Medical Assoc. the week of
Jan 26 - hope to see you then -

MH

NUMBER OF PAGES, WITH COVER:

7



The Campaign for
Health Care Accountability

January 15, 1998

Dear Colleague:

I wanted you to be aware of the exciting managed care reform project on which I am working -- the Campaign for Health Care Accountability.

The enclosed Issue Paper, "*Closing the Managed Care Loophole*," describes the need for federal legislation amending ERISA to insure that states like Texas have the authority to establish legal accountability for health care decisions. Texas was the first state to enact such legislation last year, and that law has been challenged in federal court based on the argument that ERISA preempts any state action in the liability area -- clearly a misinterpretation of ERISA in our view.

Bills pending in Congress have broad, bipartisan support, and the Administration appears to be making managed care accountability a major focus in 1998. On the other side, the insurance industry and business lobby are pushing the Republican Leadership to stonewall on managed care reform. It promises to be an interesting battle this year.

Please let me know if I can provide any further information on the managed care accountability issue and my role in the debate.

Best regards,


Michael Hudson

Enclosure



The Campaign for
Health Care Accountability

Closing the Managed Care Liability *Loophole*: A Question of Simple Fairness

Issue Paper/Media Backgrounder

Summary:

Over the past two decades America's health care system has changed dramatically with more and more citizens enrolling in some form of managed care system like health maintenance organizations (HMOs), preferred provider organizations (PPOs), etc. The Department of Labor estimates that 65% of Americans are enrolled in some form of managed care.

Efforts by managed care organizations to contain costs have injected them into decisions about what health care services are "medically necessary"-- decisions historically made by patients in concert with their health care provider. Often these judgments are made on an economic rather than medical basis and are in direct conflict with physicians and other providers. When these medical determinations lead to patient injury or death, however, the managed care plans claim immunity from any legal accountability because of a federal law, the Employee Retirement Income Security Act of 1973, known as ERISA. They argue that ERISA precludes liability under state law. *Approximately two-thirds of those in managed care programs receive their coverage through plans governed by ERISA.*

→ State legislatures are attempting to deal with abuses by managed care organizations by passing state laws that clarify the accountability of such organizations when they engage in medical treatment decisions. The state of Texas enacted such legislation in 1997 only to have Aetna Insurance Company immediately challenge the law claiming ERISA preempted any state action in this area. This legal challenge is currently working its way through the federal courts. Meanwhile, **at least 18 other states are considering similar legislation--all of which will undoubtedly meet legal challenges.**

abuses of managed care

Several bills have been introduced in Congress to amend ERISA to **clarify that federal law does not preclude states from establishing this accountability for managed care organizations**, and a well publicized political battle is shaping up for 1998. Two narrowly drawn bills by Rep. Charles Norwood and Sen. Richard Durbin **would not add any further federal regulation of health care**, but rather would follow the current theme of **states' rights and devolution** by ensuring that the **states retain authority** to establish accountability for medical treatment decisions. Other bills go further in establishing a new federal remedy.

History of ERISA:

In tracing the origin and evolution of ERISA, it is clear that Congress did not intend the 1973 law to preempt state action on medical liability. Twenty-four years ago, today's managed care system could not even have been imagined by lawmakers. In recent hearings before two House subcommittees, Rep. Norwood documented the extensive history of ERISA as it relates to managed care accountability. ERISA was designed principally to provide uniformity and protection for pension plans. The law was later applied to health benefit plans to avoid state mandated benefits on multi-state employers. This allowed a large employer to develop a consistent benefit plan for all employees regardless of geographical location.

Over the years, however, managed care philosophy began to integrate the decisions to pay for care with clearly medical judgements. Such situations empower managed care organizations to decide if care will be provided, not on the basis of whether such care is a covered benefit, but rather if such care is medically necessary. When these decisions lead to harm, the only recourse for the patient under ERISA is "the cost of the benefit denied". This remedy is appropriate when an employee has been denied a pension benefit, but is clearly inadequate when dealing with health benefits. In health care decisions, the cost of the benefit denied may be only the minor cost of a service. It does not include lost wages, pain and suffering, and in many cases even the medical expenses incurred as a result of the denied care. For example, if a woman dies of breast cancer because her managed care plan negligently denied payment for a specialist's consultation and mammogram that could have saved her life, the recovery would be limited to the cost of those health care services -- perhaps \$200.

Court Decisions:

Courts throughout the country are hearing cases in which individuals have been harmed as a result of negligent decisions made by HMOs, utilization review agents and other managed care organizations. These managed care organizations are avoiding accountability for their actions by claiming that they are immune from state legal actions because of ERISA. While decisions in such cases vary among the federal circuits depending on the fact situations, all too often the managed care defendant is non-suited not because it was not responsible for the harm, but rather because of a court's interpretation that under ERISA the managed care organization cannot be held accountable for its actions.

Federal and state court decisions across the country are moving to hold managed care plans accountable. In non-ERISA cases the courts are finding managed care plans accountable under theories of agency, vicarious liability and direct negligence when they make health care treatment decisions. In ERISA cases the courts are finding managed care organizations liable in agency and vicarious liability cases. The problem is that case law is slow to develop, and the courts continue to render inconsistent rulings interpreting ERISA. In the most egregious cases of an outright denial of necessary care, the courts are holding that ERISA preempts unless an agency

theory applies. *Meanwhile, patients are being harmed by negligent managed care decisions and left with no recourse.*

The controlling case in the 5th Circuit, where the Texas case will be decided, *Corcoran vs. U.S. Healthcare, Inc.*, underscored the problem and need for federal legislative action. There the Court said: "...the Corcorans have no remedy, either state or federal, for what may have been a serious mistake...Our system, of course allocates this task [reevaluation of ERISA] to Congress, not the courts..."

When physicians or other health care providers make medical decisions they are held legally accountable for the results of those decisions. Now we have these decisions being made by third parties who are escaping all legal accountability due to interpretations of federal law. This leaves physicians and other health care providers as the sole defendants in lawsuits where the harm to the patient was caused by an immune third party--the managed care organization.

It seems apparent that this problem will not be resolved any time soon through the courts and that a federal legislation solution is required.

Other States:

Texas was the first state to enact legislation holding managed care organizations accountable. Senate Bill 386 was enacted by the Legislature and allowed to become law by Governor George W. Bush in 1997. This law holds managed care organizations accountable in Texas courts when their negligent decisions to delay or deny care result in harm to an individual.

Now at least 18 other states are considering similar legislation, and that number will undoubtedly increase with the opening of state legislatures in January, 1998. Those states include: *Alabama, Georgia, New York, New Jersey, Missouri, Florida, California, Ohio and Colorado.* It is expected that when the other states enact similar bills, they will be immediately challenged in the courts based on the ERISA preemption argument.

Congressional Legislation:

During 1997, numerous bills have been introduced in Congress seeking changes in the managed health care system, including the issue of legal accountability. Rep. Charles Norwood, a conservative Republican dentist from Georgia has introduced the *Patient Access to Responsible Care Act, HR 1514*. The companion bill was introduced in the Senate by Sen. D'Amato of New York. These bills make extensive revisions to ERISA, including the liability provision. Mr. Norwood and Sen. Richard Durbin of Illinois have also introduced single-issue bills dealing only with amending ERISA to clarify the liability issue, *S 1136* and *HR 2960*. Other bills have been introduced by Reps. George Miller, Pete Stark and John Dingell, which call for even more sweeping changes in managed care including, in the Miller-Stark bill, a new federal cause of

states are moving forward on laws that will be challenged by ERISA.

action for injured patients.

In October, Rep. Norwood's PARCA bill -- with 218 co-sponsors -- was heard by subcommittees from the House Education and Workforce and Commerce committees. Mr. Norwood hopes to have the bill marked-up in committee early in 1998 and to press for floor consideration in the House.

The Senate bills have not been heard in committee, and media reports indicate that Majority Leader Trent Lott wants to delay any action on managed care reform.

The Insurance Industry's Political Campaign Against Reform:

A recent syndicated article in Congressional Quarterly was headlined, "Fight Brewing Over Managed Care," and the Wall Street Journal headline read: "All Sides Get Ready for Push to Regulate HMO's." Each of the national television networks has included major recent stories about managed care abuses, with compelling stories of patients denied care and their lack of equitable remedy.

In response to the groundswell of media and public concern and movement of bills in Congress, the insurance and business industries have begun an aggressive campaign to defeat managed care reform. According to press accounts, Republican leadership in the Senate and House have joined in this strategy calling it a "war." House Majority Leader Dick Armey has circulated a lengthy memo characterizing the managed care reform bills as "Clinton Care 2," and *urging business and insurance forces to gear up and lobby members of Congress against the bills during the holiday recess.*

Impact on Employers and Business:

Not surprisingly, the insurance industry has attempted to project the business community as the most visible opponents to managed care reform, claiming that changes in ERISA will drastically increase insurance costs and cause employers to reduce or even eliminate insurance coverage. This ploy was attempted in Texas during the legislative session as well.

The Texas legislation, however, included a clear and comprehensive exemption of employers from liability--unless the employers themselves were actually making health care treatment decisions. The Norwood single-issue bill, HR 2960, includes this employer exemption, and Sen. Durbin intends to add it to his bill.

Explosion in Litigation:

Another "red herring" advanced by insurers is the claim that allowing states to enact managed care accountability would lead to a further explosion in litigation and increased costs in health insurance--passed on, of course, to business and consumers in increased premiums.

In fact, the lawsuits are already being initiated against doctors, hospitals, nurses and other providers, and this reform would simply allow states to add managed care decision-makers into this proportional liability situation.

In Texas this issue was also hotly debated. Finally, the insurance industry admitted that the new law might add only 3% to overall costs. Milliman and Robertson recently completed an actuarial determination of the cost of the Texas liability legislation to a Texas based HMO and set the cost at 34 cents per member per month. While the Texas statute went into effect in September, 1997, there have been few, if any cases filed under that Act.

While opponents would argue that this ERISA clarification would increase litigation across the country, the important fact not pointed out is that the federal change does nothing more than allow each state to decide how to deal with managed care organizations. States are free to apply to these lawsuits any tort reform measures such as alternative mediation, caps on recoverable damages, or other such protections. This legislation simply allows each state to take responsibility for what has historically been a state role--overseeing the quality of health care services delivered to the citizens of the state.

Public Support for Reform:

Public opinion surveys have indicated very strong public support for managed care accountability. In a survey by the Republican Wirthlin Group, 85% indicated support for holding managed care plans accountable.

The Campaign for Health Care Accountability:

Under the leadership of a broad coalition of consumers and health care providers who worked for passage of the Texas law, a national campaign has been created to advocate for enactment of the federal ERISA amendment. The Campaign is seeking support from health care provider and citizen groups in all the states and nationally. Currently the focus is on working in the states to *encourage co-sponsorship of the Norwood and Durbin bills and counter the misinformation campaign being mounted in opposition to managed care accountability reform.*

For more information about the Campaign, contact Connie Barron or Harold Freeman at (512) 370-1300 or Mike Hudson at (303) 604-1392.

IMPROVING REMEDIES FOR IMPROPER CLAIMS DENIALS UNDER ERISA-COVERED PLANS

CURRENT LAW — Need For Change

- Persons who administer an employee benefit plan are not responsible to participants and beneficiaries for the consequences of wrongfully delaying or denying a claim for benefits.
- Under ERISA, a participant, whose request for medical services has been improperly delayed or denied by the plan administrator, can only recover the benefits that should have been provided, but not damages such as lost wages, additional medical costs, pain and suffering, or wrongful death. A successful participant is not even assured of recovering his or her costs, attorneys fees or expert witness fees.
- In addition, courts generally give deference to the plan's decision. They will not overrule a benefit denial unless the plan's decision was unreasonable (*i.e.*, arbitrary and capricious, or abuse of discretion).
- At the same time, ERISA preempts the state law remedies available to persons not covered by ERISA plans. This is true whether the plan funds its benefits through an insurance policy or directly from the employer's assets.
- These restrictions on available remedies reduce any economic incentive for an administrator to provide fair and expeditious resolution of benefit claims. The person who determines whether to approve claims may be under pressure to deny them because he or she works for the entity responsible for paying the claims.
- Improper delays or denials of claims for benefits can affect the quality of care afforded to participants.
- Persons outside of an ERISA plan (*e.g.*, in the individual insurance market, or in non-ERISA plans) can generally avail themselves of a broad range of remedies.

OPTIONS — We see four potential approaches:

- **A Federal Law Approach:** Amend ERISA to make available economic damages (e.g., cost of care, lost wages) where personal injury or wrongful death occurs in connection with an improper denial or delay in deciding health benefit claims under an ERISA plan. Additional damages, such as for pain and suffering, would be available where the delay or denial was unreasonable.
- **State Law Approach:** Modify ERISA preemption to permit states to apply their existing substantive laws and remedies, or enact new ones, specifically for the improper denial or delay of health benefit claims which result in personal injury or wrongful death. Under this approach, a state could decide whether or not to provide any such substantive law or remedy.
- **State Law Remedies for Insured Plans and a Federal Law Remedy for Self-Funded Plans:** Establish a federal standard for self-funded plans, and permit state insurance laws to apply to plans that are funded through insurance policies. This approach would allow the states to fully enforce their insurance laws, but would not subject self-funded plans (which are usually larger plans) to the diversity of state remedies.
- **Civil Penalty Approach:** Establish a scheme of dollar denominated civil money penalties for improper claims delays or denials. Various options exist under this approach depending on whether the penalty would be imposed by the courts in private actions or assessed by the Secretary, and on whether the penalty would apply to individual cases or only upon a showing of a pattern and practice of improper claims handling.

An element of any of the approaches summarized above could be that employers should be insulated from liability unless they directly engage in making determinations on benefit claims. As part of this element, agreements requiring employers to indemnify HMOs for their liability could be prohibited.

DESCRIPTION OF POTENTIAL APPROACHES

A. A Federal Law Approach — New ERISA Standards

- Amend ERISA to: (1) make available damages for economic losses (e.g., cost of care, lost wages) when an improper denial or delay in deciding health benefit claims under an ERISA plan results in personal injury or wrongful death; and possibly (2) make available additional damages (e.g., pain and suffering) where the delay or denial of the benefit is unreasonable (i.e., arbitrary and capricious, abuse of discretion)
 - Economic damages would be available if the court disagreed with the plan's determination. No deference would be granted to the plan's decision. A finding that the plan acted unreasonably would not be required.
 - Additional damages would be available against the entity that administered the claim if the delay or denial of the claim was objectively unreasonable or arbitrary. It would not require proof of an evil motive.
 - The damages would be available for all types claims regardless of amount as long as there was a personal injury or wrongful death. (Option: Have threshold requirements, e.g., dollar amounts or qualitative.)
 - Scope of Review for Recovery of Benefits
 - Submission to the court of information that was not before the plan would be allowed.
 - Reasonable costs, attorneys fees, and expert witness fees must awarded to the successful claimant.
 - Remedies Options in Addition to Recovery of the Benefit (available under current law):
 - Economic Remedies (for Improper Benefit Denials):
 - Option A: Compensatory Economic Damages (e.g.,

cost of care, lost wages) Resulting From the Personal Injury

- Option B: Compensatory Economic Damages Whether or Not They Result from the Personal Injury (e.g., claimant sells house to pay cost of care)
- Other Types of Remedies (for Unreasonable Benefit Denials) (any combination)
 - Physical Pain and Suffering (with Caps?)
 - Emotional Distress (with Caps?)
 - Punitive Damages with Caps

B. A State Law Approach — Limit ERISA Preemption

- Modify ERISA preemption to permit states to apply their existing substantive laws and remedies, or to enact new substantive laws and remedies, addressing the improper denial or delay of health benefit claims.
 - States would be able to impose any standard for awarding damages under this approach. They would also be able to award any type of damages, including damages for emotional distress and punitive damages.
 - Option: Impose federal caps on damages that a state court can award in a case involving an ERISA plan.
 - Under this approach, a state could decide not to provide any such remedy.

C. A Combination Approach — State Law Remedies for Insured Plans and a Federal Law Remedy for Self-Funded Plans

- Establish the above-described federal standard for self-funded plans, and permit state insurance laws to apply to plans that are funded through insurance policies.

- This approach would allow states to fully enforce their insurance laws, but would not subject self-funded plans (which are usually larger plans) to the diversity of state standards and remedies.
- It may cause confusion for participants by creating two different legal schemes, particularly for participants of self-funded plans that are administered by an insurance company, or for employees of employers who provide both insured and self-funded coverage options.

D. A Civil Penalty Approach

Option 1 — Mandatory Civil Penalty Awarded by Court in Cases Brought by a Participant or Beneficiary to Enforce the Terms of the Plan

- Amend ERISA to require a court to impose a civil money penalty against the plan in an amount of at least \$5,000 and up to, at the court's discretion, \$25,000 (Option: or more) where an improper denial or delay in deciding health benefit claims under an ERISA plan results in personal injury or wrongful death.
- The penalty would be payable to the participant or beneficiary in addition to whatever equitable relief (e.g., provision of the claimed benefit) was ordered by the Court.
- Attorneys fees, expert witness fees and costs would be mandatory for successful claimants.

Option 2 — Add to Option 1 a Civil Penalty in Cases of a Pattern and Practice of Improper Claims Handling

- If the court finds that the benefit denial at issue was part of a pattern and practice of improper claims denials, the court would be required to

impose an additional civil money penalty of at least \$15,000 up to, at the court's discretion, \$150,000.

- The court, in setting the penalty amount in a given case, would be permitted to take into account the penalties that the plan has already paid for the same pattern and practice.
- "Pattern and practice" would mean improperly denying or delaying claims with such frequency as to indicate an intent to materially reduce costs to the plan through the improper denial or delay of claims
- The penalty would be payable to the participant or beneficiary in addition to: (1) whatever equitable relief (e.g., provision of the claimed benefit) ordered by the court and (2) the mandatory penalty.
- Attorneys fees, expert witness fees and costs would be mandatory for successful claimants.

Option 3 — Option 1 and/or Option 2 for Self-Funded Plans and Penalties Set by State Law for Insured Plans

- For plans that are not self-funded (i.e., insured plans, including plans that shift risk to HMOs, etc.) all claims dispute cases would be decided by state courts (not removable to federal court). States could enact their own penalty amounts providing that they were higher than the penalties under the Federal law.

Option 4 — Discretionary Civil Penalty Assessed by the Secretary of Labor in Cases of a Pattern and Practice of Improper Claims Handling.

- If the plan has engaged in a pattern and practice of improper claims denials, the Secretary could assess a large penalty amount (e.g., up to \$10 million, at the Secretary's discretion, or an amount based on the value of claims processed by the violator).
- The penalty would be payable to the government.

- Liability for the penalty would be determined after an administrative hearing with Federal court review in cases where assessment of the penalty is challenged.

Option 5 — Option 1 (with or without Option 3) and Option 4

Option 6 — Option 1, Option 2 (with or without Option 3) and Option 4

AFL-CIO: What We Need Most in a Whistle blower Bill (based on parts of the New Jersey Law¹)

- ▶ Whistle blower protections to apply to licensed and certified health professionals.
- ▶ Coverage of employees in institutions (e.g., clinics, hospitals, nursing homes, MR-ICF facilities) as well as health plans.
- ▶ Broad definition of retaliation that includes not just discharges but other adverse employment action taken against the employee.
- ▶ Protections against reprisals cover reporting potential violations of regulations or improper quality care and participating in investigations by state oversight agencies or private accrediting agencies.
- ▶ Protections would also cover reporting potential violations of state regulations or quality concerns to health management.
- ▶ Posting of health care worker rights in the institution.

¹ The New Jersey law is generally broader — with the exception that we want coverage for reporting violations to private accrediting agencies as well as public bodies. Among the broader NJ provisions are: separate legal remedies, limited protections for all health care workers (broader protections for certified and licensed health professionals); protections for workers who refuse to participate in what they reasonably believe to be violations of state regulations or improper quality of care; or who report allegations of improper quality to the press.

13 March 98

NOTE TO: Chris Jennings

FROM: Jane Horvath

RE: Comments on S. 1712, "Health Care QUEST Act"

As per your request, we have compiled preliminary comments on Senator Jeffords' quality legislation.

At the outset, we note that the bill does include the major consumer protections provisions that we would want to see in any legislation, namely:

- ▶ Anti-gag rule;
- ▶ Information disclosure;
- ▶ Prudent layperson; and
- ▶ External appeals.

In addition, the bill contains provider protections, which as drafted, would be acceptable. The legislation amends ERISA and the Public Health Service Act, relating to group health plans. The remedies available would be those currently permitted -- equitable relief and civil monetary penalties under ERISA, and State law remedies for issuers. If HHS has jurisdiction due to the fallback mechanism under HIPAA, civil monetary penalties similar to those permitted under ERISA would be permitted.

Beyond the former provisions, the whole administrative structure of the bill is complicated and convoluted.

- It creates a "Health Quality Council" which from a policy standpoint may or may not be a good thing. However, if we were to support its creation, the structure of the Council is problematic. Members of the Council are appointed by the Comptroller General.
- It appears that the Agency for Health Care Policy and Research would be working directly for the Council.
- There is an intertwining of the Council and how it must consult with different groups (National Academy of Science / Institute of Medicine) and to what degree they must be involved in developing recommendations.
- There is confusion on the role of the Council and in turn, how it overlays with the roles of the Secretary's of HHS and Labor.

- AHCPR is tasked with collecting data from plans and issuers, but bill is silent on enforcement and financing. We would not want AHCPR to become a regulatory agency.
- There are redundant provisions through out the bill which also causes confusion -- e.g. comparative information is required of plans and the employer as a sponsor of the plan. Some of the requirements are also imposed on the plan administrator. In both cases, the information required is already set forth under HIPAA.

In short, the bill is drafted very poorly. It is difficult to follow what the Senator is intending to accomplish without sitting down and having staff walk us through the bill.

THE HEALTH BENEFITS COALITION

for Affordable Choice & Quality

PARTICIPANTS

Aetna U.S. Healthcare

American Association
of Health Plans

American Automobile
Manufacturers Association

American Insurance
Association

Associated Builders
and Contractors

Association of Private
Pension and Welfare Plans

Blue Cross and
Blue Shield Association

The Business
Roundtable

CIGNA

Citizens for a
Sound Economy

Council for Affordable
Health Insurance

The ERISA Industry
Committee

Food Distributors
International

Food Marketing
Institute

Health Insurance
Association of America

Healthcare
Leadership Council

Humana Inc.

International Mass
Retail Association

National Association
of Health Underwriters

National Association
of Manufacturers

National Association of
Wholesaler-Distributors

National Business
Coalition on Health

National Federation of
Independent Business

National Restaurant
Association

National Retail
Federation

New York Life/
NYLCARE Health Plans

Premier

Prudential HealthCare

Self-Insurance Institute
of America, Inc.

Society for Human
Resource Management

U.S. Chamber of Commerce

January 27, 1998

Memorandum to Members of the U.S. House and Senate

From: The Health Benefits Coalition

Subject: Health Care Mandates

The Health Benefits Coalition represents more than three million employers and 100 million employees. As the enclosed print ads and press release indicate, we are launching a campaign against excessive and costly government mandates on employers and health plans. While we are committed to providing affordable quality health care for our employees, it is our firm belief that prescriptive federal legislation in this area will backfire—increasing health care costs and driving up the number of uninsured Americans.

As the debate over health care mandates unfolds, we hope you will keep in mind the following facts:

- **Health cost inflation:** Last week, the U.S. Congressional Budget Office warned that health premium costs could rise 5.5% in 1998, vs. 3.8% last year—and climb even faster if federal "patient protection" mandates become law. (Projections of National Health Expenditures: 1997-2008)
- **The impact of mandates on cost:** A national actuarial firm recently estimated that one popular mandate bill would drive premiums up an average of 23% nationwide. (Milliman & Robertson cost-impact analysis of H.R. 1415/S.644, the proposed "Patient Access to Responsible Care Act")
- **The impact of mandates on coverage:** According to The Lewin Group, a widely respected consulting firm which advised the Clinton administration on its "Consumer Bill of Rights," a premium increase of just *one percent* nationally causes an estimated 400,000 Americans to lose their health care coverage. That's because mandates make coverage unaffordable for employers *and* their employees and dependents.
- **How Americans really feel:** A just-released national poll shows three out of four Americans favor enactment of the Consumer Bill of Rights—until they learn about its potential impact on cost and coverage. Once told that large numbers of employers might be forced to drop coverage, three out of four **OPPOSE** its enactment. (Kaiser Family Foundation/Harvard University National Survey, 1/21/98)

If you have any questions regarding the Health Benefits Coalition, please contact Dan Danner, chairman of the Health Benefits Coalition, at 202-554-9000.

IMPROVING REMEDIES FOR IMPROPER CLAIMS DENIALS UNDER ERISA-COVERED PLANS

CURRENT LAW — Need For Change

- Persons who administer an employee benefit plan are not responsible to participants and beneficiaries for the consequences of wrongfully delaying or denying a claim for benefits.
- Under ERISA, a participant, whose request for medical services has been improperly delayed or denied by the plan administrator, can only recover the benefits that should have been provided, but not damages such as lost wages, additional medical costs, pain and suffering, or wrongful death. A successful participant is not even assured of recovering his or her costs, attorneys fees or expert witness fees.
- At the same time, ERISA preempts the state remedies available to persons not covered by ERISA plans. This is true whether the plan funds its benefits through an insurance policy or directly from the employer's assets.
- These restrictions on available remedies reduce any economic incentive for an administrator to provide fair and expeditious resolution of benefit claims. The person who determines whether to approve claims may be under pressure to deny them because he or she works for the entity responsible for paying the claims.
- Improper delays or denials of claims for benefits can affect the quality of care afforded to participants.
- Persons outside of an ERISA plan (e.g., in the individual insurance market, or in non-ERISA plans) can generally avail themselves of a broad range of remedies.

Grievances
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Norwood

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up Norwood

→ puts everyone
into state law
plan.

Federal law approach

→ strengthen current
law.

~~few~~ large administrative
burden.

→ big penalties.

PREFERRED APPROACH — Recognize Need for Better Remedies Without Expressing a Preference for a Particular Approach

- We recognize that current law provides inadequate remedies with respect to the administration of health benefit claims and that this may detrimentally affect the quality of health care. We believe that any new legal structure should make the entity responsible for the unreasonable delay or denial of benefits financially accountable for the injuries caused by such improper administration of claims.
- We see three potential approaches:
 - **A Federal Law Approach:** Amend ERISA to make available economic damages, as well as damages for physical pain and suffering and wrongful death, which result from an unreasonable denial or delay in deciding health benefit claims under an ERISA plan.
 - **State Law Approach:** Modify ERISA preemption to permit states to apply existing, or enact new remedies, specifically for the improper denial or delay of health benefit claims.
 - **State Law Remedies for Insured Plans and a Federal Law Remedy for Self-Insured Plans:** Establish a federal standard for self-insured plans, and permit state insurance laws to apply to plans that are funded through insurance policies. This would overturn the Supreme Court's interpretation of ERISA preemption in the Pilot Life decision. It would allow the states to fully enforce their insurance laws, but would not subject self-insured plans (which are usually larger plans) to the diversity of state remedies.

Testify - w/o position.
could support various
approaches.

→ employer

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enforceable,
no punitive
no damages.

DESCRIPTION OF POTENTIAL APPROACHES

Option No. 1: A Federal Law Approach — New ERISA Standards

- Amend ERISA to make available economic damages, as well as damages for physical pain and suffering and wrongful death, which result from an unreasonable denial or delay in deciding health benefit claims under an ERISA plan.
 - This would be an objective standard, based on current state insurance law, under which the entity which administers claims would be liable if there was objectively unreasonable conduct which caused a delay or denial of a claim. It would not require proof of an evil motive.
 - It may be necessary to require that the entity which administers claims meet financial responsibility criteria to ensure its ability to pay potential damages and to insulate employers from liability.
 - This cause of action would be available for all claims regardless of amount or type. (Option: Have threshold requirements, e.g., dollar amounts or qualitative)
 - Standard and Scope of Review
 - The standard of review would be *de novo* (i.e., without deference to the plan's decision)
 - Submission of information that was not before the plan would be allowed.
 - Remedies Available
 - Recovery of Benefit
 - Reasonable Costs, Attorneys Fees, Expert Witness Fees for either party
 - Compensatory Economic Damages
 - Physical Pain and Suffering (with caps?)
 - Damages for Wrongful Death (with caps?)
 - Option: Punitive damages with caps

Option No. 2: A State Law Approach — Limit ERISA Preemption

- Modify ERISA preemption to permit states to apply their existing substantive laws and remedies, or to enact new laws, addressing the improper denial or delay of health benefit claims.
 - States would be able to impose any standard for awarding damages under this approach. They would also be able to award any type of damages, including damages for emotional distress and punitive damages.
 - Option: Impose federal caps on damages that a state court can award in a case involving an ERISA plan.
 - This approach would not permit states to mandate benefits.

Option No. 3: A Combination Approach — State Law Remedies for Insured Plans and a Federal Law Remedy for Self-Insured Plans

- Establish the above-described federal standard for self-insured plans, and permit state insurance laws to apply to plans that are funded through insurance policies.
 - This approach would overturn the Supreme Court's interpretation of ERISA preemption in the Pilot Life decision.
 - This approach would allow states to fully enforce their insurance laws, but would not subject self-insured plans (which are usually larger plans) to the diversity of state standards and remedies.
 - It may cause confusion for participants by creating two different legal schemes, particularly for participants of self-insured plans that are administered by an insurance company.

(The above alternative approaches make no reference to any administrative external review process that could be established. If such a process were established, each of the approaches may need to be changed somewhat to accommodate it.)

REASONS WHY A CIVIL PENALTY APPROACH SHOULD NOT BE ADOPTED

- A system of civil penalties for improper claims administration would result in payments to the government, but would not provide any recovery to the injured participant and therefore participants may not have an adequate incentive to file complaints or cooperate in investigations.
- Such a system would only provide an effective deterrent against improper claims handling if it is operated on a large scale. Very large investigative and complaint handling resources would be required in order to sanction the improper handling of any meaningful number of benefit claims.
- Even if sufficient resources were committed to such a system, inevitably, the enforcement agency's handling of some egregious claims denials would subject it to adverse publicity.

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OPTIONS FOR EXTERNAL REVIEW OF CLAIMS DENIALS UNDER ERISA-COVERED PLANS

CURRENT LAW

- ERISA requires that every employee benefit plan provide adequate written notice to a participant or beneficiary whose claim is denied, and afford a reasonable opportunity for a full and fair review of the denial by an appropriate named fiduciary.
- The statute does not require any external review of benefit claims other than the participant's right to file a civil action for review by a court. Although the participant may file the action in a state court, the plan may have the action removed to federal court. ERISA preempts any state law remedies that might otherwise be available.
- Regardless of the jurisdiction in which the matter is decided, the court must apply ERISA, not state law, and may only provide "equitable remedies." That is, the court may order that the denied benefit be provided. It may not award damages for any injury caused by the denial.
- In addition, the courts generally grant significant deference to the plan fiduciary's decision, overturning it only if they find that the plan acted arbitrarily. Moreover, courts often do not permit the claimant to introduce evidence that was not presented during the plan's internal decision-making and review procedure.
- Because claims determinations are generally made by persons who are employed by the entity responsible for paying the claim, an internal claims determination process is subject to an inherent conflict of interest.

OVERVIEW OF OPTIONS

Shortcomings of External Review Without Improving Remedies

- External review measures, by themselves, do not fully address the imbalance of incentives in the current system. Under ERISA, a plan fiduciary who fails to assure compliance with current statutory and regulatory requirements, or any future external review requirements, is not accountable for that failure.
- There are many examples of claims decisions that are simply wrong. Even if ultimately corrected, some of these wrong decisions will cause injury before they are corrected. The lack of remedies under the current statutory scheme prevents the injured parties from receiving compensation.
- An external review system without remedies would provide no disincentive for plan fiduciaries to arbitrarily deny care with the expectation that many participants will not pursue the matter to the external tribunal.
- The options described below are based on the assumption that a truly independent, expeditious and inexpensive external review process could be established.

OPTION 1 — Provide External Review for All Claims

- Amend ERISA to provide for external review of a denied or delayed claim within a time period appropriate to the claim.
 - *E.g.*, a denial of emergency care could be reviewed within a matter of hours, other types of claims might need to be reviewed within a few days.
 - The external review organization would have appropriate guidelines or could decide on a case by case basis how quickly a request for review should be processed.

Option 1 cont'd

- The reviewer would have access to independent medical and legal expertise.
- The external review organization would decide the claim on principles of contract law, and would issue decisions binding on the plan and the participant.
 - Option: The decision could be subject to an "appellate review" by a court limited to the record and with an arbitrary and capricious standard of review.
 - Option: No further review of the merits of the external review decision (only review of jurisdictional or procedural issues).
- The external review organization could be authorized to:
 - Option: Award costs, attorneys fees and expert witness fees to:
 - Option: Either party
 - Option: Successful participants only
 - Option: Successful p's and to plans for frivolous claims
 - Option: Assess penalties payable to the government (without a showing of bad faith unless damages also available)
 - Option: Award compensatory damages to a participant (perhaps capped for pain and suffering and other non-economic damages)
 - Option: Award capped punitive damages (what showing would be required?)

(If the external reviewer awards any type of damages, then, for Constitutional reasons, the plan would probably have to be given the right to *de novo* review by a court with a jury trial. The jury could be limited to reviewing the damage award, and not be able to overturn the award of the benefit)
- Standard and Scope of External Review
 - The standard of review would be *de novo*,
 - Submission of information that was not before the plan would be allowed.

Option 1 cont'd

- **Exclusivity of External Review Process**
 - Option: The external review forum would be the exclusive forum for claims denials.
 - Option: External review would be optional for the participant
 - Option: Only participants with large or serious claims could waive external review and go directly to court where they could obtain:
 - Option: state law remedies, or
 - Option: expanded ERISA remedies.
- **Cost of the External Review Process**
 - Option: borne by the plan in all cases;
 - Option: borne by the claimant if unsuccessful;
 - Option: borne by the Federal government.

Option 2 — Provide External Review for Small Claims Only

The purpose of an external review procedure for small claims would be to provide an expeditious and inexpensive forum for the great majority of claims. Federal district courts are not well suited for reviewing such matters, and the expense of going to court makes this an infeasible option for dissatisfied claimants who have small claims.

Amend ERISA to require the external review in Option 1 for small claims only, *i.e.*, claims that meet all the following conditions:

- (1) below a certain threshold amount (based on the \$ value of the claim, *e.g.*, \$5,000),
- (2) no injury is alleged, and
- (3) do not involve imminent threat to life, further serious deterioration of health or intractable pain)

- In some states, the tribunal could be existing forums such as small claims court.
- Private entities could be certified to provide external review, but development of safeguards against inherent bias may be difficult.

Option 2 cont'd

- The tribunal would have the power to order payment of the benefit.
 - Option: The tribunal could award attorneys and expert witness fees to a successful claimant.
 - Option: The tribunal could assess penalties for egregious conduct.
- The external review forum would be the exclusive forum for claims denials that meet its conditions. Claimants could not choose to go directly to court.
- Judicial Review of External Review Decision
 - Option: limited to the external review record and under an arbitrary and capricious standard.
 - Option: limited to jurisdictional and procedural issues.
- Treatment of Claims Not Subject to External Review
 - Claims larger than the threshold amount, claims where an injury is alleged and claims involving imminent threat to life, further serious deterioration of health or intractable pain would be exempt from this process, regardless of the \$ amount — the claimant could go straight to court.
 - In order for this option to make sense, the court's standard or review for such claims would need to be *de novo*, that is without deference to the plan's decision, and to allow the introduction of new evidence.
 - Option: The court would be required to award costs, attorneys fees and expert witness fees to:
 - Option: Either party
 - Option: Successful participants only
 - Option: Successful p's and to plans for frivolous claims
 - Option: The court could assess penalties payable to the government (without a showing of bad faith unless damages also available)
 - Option: The court could award compensatory damages to a participant (perhaps capped for pain and suffering and other non-economic damages)

- Option: The court could capped punitive damages (what showing would be required?)
- Option: Prohibit removal of civil actions to Federal court except for very large claims (e.g., over \$50,000)

Option 3 — Provide External Review for Large Claims Only

The purpose of providing external review for large claims is to have a much smaller, and therefore, less expensive system that would decide only those matters where a great deal is at stake either for the participant or the plan. The purpose of an expeditious external review would be to decrease the likelihood of serious injury resulting from a wrong decision by the plan.

- Amend ERISA to require the external review process described in Option 1 for serious claims only, *i.e.*, claims that meet threshold conditions:
 - imminent threat to life, further serious deterioration of health, or intractable pain,
 - injury resulting from the denial is alleged, or
 - minimum dollar amount
 (The dollar threshold, which would only apply if the health or injury threshold did not, should be set fairly high, say \$5,000 or more, to avoid overwhelming the external review system.)
- Exclusivity of External Review Process
 - Option: The external review forum would be the exclusive forum for claims denials that meet its conditions.
 - Option: A participant with a claim that is eligible for external review could choose to go directly to court.
- Treatment of Claims Not Subject to External Review
 - Small Claims, and claims not involving imminent threat to life or of serious further deterioration of health or intractable pain would be exempt from the external review process, and claimants

Option 3 cont'd

could go to court to obtain payment of the benefit, but not damages. (Due to the cost of going to court, and the limited remedies available, this would have the practical effect of limiting small claims to internal review)

- Option: Require that courts not give deference to the plan's decision, and allow submission of new evidence.

Note: Under any of the above options, claims that do end up in court, could be decided by either Federal or State courts at the option of the participant — the plan would not be able to remove a claim filed in State court to Federal court.

have a system to receive reports of quality concerns from providers and enrollees. And, it would have the capability of producing standardized clinical data. Federally qualified health maintenance organizations (HMOs) and plans accredited by a recognized accrediting organization would be deemed to comply with this requirement.

The estimate assumes that all health plans except those that are federally qualified HMOs or currently accredited by the National Committee on Quality Assurance would have to develop a new quality assurance unit (or upgrade an existing one), with a physician director, data analysts, nurse abstracters, and clerical support personnel. CBO estimates that establishing or upgrading these units would increase costs by 0.2 percent across all employer-sponsored plans.

Section 112—Collection of Standardized Data. The bill would require the collection and analysis of standardized data on the utilization of health care services, the demographics of enrollees, disease-specific mortality and (if feasible) morbidity, satisfaction with the plan, health outcomes, and indicators of quality. The exact requirements for data collection and analysis would be specified by the Secretary of Health and Human Services (HHS), subject to the recommendations of the Health Care Quality Advisory Board. The costs of collecting and analyzing data would depend on the data items selected and required by the Secretary. Because information systems vary widely, the costs of these reporting systems would fall unevenly on different types of plans. Some measures would be harder for tightly managed HMOs to produce, while others would be harder for broad network plans to produce.

Based on trends in data collection and quality measurement under the Medicare program, CBO assumed that the data items required by the Secretary would include all of the Health Plan Employer Data and Information Set (HEDIS) measures currently required under Medicare contracts, plus additional measures to be required for HEDIS accreditation in 1999, as well as new measures specifically required in the bill, such as disease-specific mortality. The proposed Quality Improvement System for Managed Care under development by the Health Care Financing Administration (HCFA) for all Medicare+Choice Plans would require them to produce HEDIS measures as well as other quality measures. So far, HCFA has made no separate arrangements for PPOs or other broad network plans, and the estimate assumes that the Secretary would make no special arrangements under this bill for such plans.

Some HEDIS measures could be compiled from administrative data (for example, electronic claims forms), especially if claims forms are altered to capture specific items required under HEDIS. However, most of the HEDIS measures required by Medicare involve reviewing the medical records (or charts) of a sample of beneficiaries—about 400 for each measure. Moreover, the HEDIS manual requires plans to perform chart reviews to verify some measures when administrative data are inadequate. The estimate assumes that data

requirements would be expanded gradually to include severity of disease or other risk-adjustment measures that could be measured reliably only through chart reviews.

Medicare's current rules for risk plans require two direct surveys of patients: a survey of consumer access and satisfaction and a survey of general health status. HCFA requires each Medicare plan to survey 1,000 enrollees. The estimate assumes that these surveys would also be required of private insurers, only in larger numbers because of the need to cover all age groups. The need for a survey of health status would be important for adjusting outcomes for differences in risk profiles among plans, so CBO assumes that sooner or later it would be part of the information package.

The estimate takes into account the likelihood that the minimal dataset would change from year to year, requiring continual software development. It also assumes that each health plan would be required to review the medical records of 2,000 patients each year. Some of these records would be in physicians' offices. The cost of this exercise would be higher for health plans with larger and more diffuse networks. CBO estimates that the provision would increase premiums by 0.3 percent on average.

Section 113—Process for Selection of Providers. This section would require plans that selectively contract with health care professionals to develop and maintain a written process governing their selection. The plan would have to verify the provider's professional license and determine whether the license had ever been suspended or revoked. The section would prohibit plans from excluding professionals on the basis of their location in areas with high-risk patients. Plans could not exclude certain kinds of professionals from participating solely on the basis of the class of certification or licensure, as long as the services the individual would deliver were within the scope of his or her license.

This provision would entail administrative costs to verify and update the status of licensure for both potential and currently participating professionals. Most plans already verify the credentials of participating providers, at least initially. In addition, these costs would largely overlap those of section 143 (regarding the participation of health care professionals). Consequently, CBO has included them in the estimate of section 143.

Section 114—Drug Utilization Program. Although the bill would require health insurers to operate a drug utilization review program, pharmacies and pharmaceutical benefits managers are currently providing these services. Thus, the incremental costs associated with drug utilization review would be small.

Section 115—Standards for Utilization Review Activities. This section sets out requirements for the conduct of utilization review activities. It would require plans to specify

clinical review criteria that are based on outcomes of care, to the extent feasible. The requirements of the section are largely consistent with current practice in health plans that rely on utilization review and therefore would involve little additional cost.

Section 116—Health Care Quality Advisory Board. This section would establish an appointed health care quality advisory board to identify, update, and distribute quality measures for health plans; advise the Secretary of HHS on the minimum data set; and advise the Secretary on standardized formats for this information. CBO estimates that the operations of the Health Care Quality Board would cost \$20 million over the 1999-2003 period, assuming appropriation of the necessary amounts.

Patient Information

Subtitle C would require health plans to provide information about policies governing their operations, as well as the quality-assurance data called for in subtitle B. It also requires health plans to protect the confidentiality of individually identifiable information. Finally, it calls for federal grants to states or nonprofit entities for new health insurance ombudsmen, whose job would be to assist consumers in their interactions with group health plans.

Section 121—Patient Information. The section contains a long list of information that plans would be required to provide to enrollees annually or to make available upon request. Much of the required information is typically provided now as part of a plan's handbook or could easily be incorporated into that document. Although a plan's documents would have to be amended to meet the requirements of this provision, such documents are continually updated in any event. The provision of this information as part of the plan document would not appreciably raise health care costs. Although the requirement that the plan provide information on all participating providers (for example, name, address, telephone number, availability, and credentials) might represent a new operation for many plans, the costs of this requirement should also be modest.⁴

Section 122—Protection of Patient Confidentiality. The provision requiring plans to safeguard enrollee information may impose a small additional cost on those employee health plans that do not have formal policies on data confidentiality, but discussions with health insurance and managed care plan executives indicate that the requirements of this provision are general practice in the insurance business today. Thus, this provision would not have a significant effect on premiums.

4. U.S. General Accounting Office, *Consumer Health Care Information: Many Quality Commission Disclosure Recommendations are Not Current Practices*, April 1998 (GAO/HEHS-98-137).

Section 123—Health Insurance Ombudsmen. This section would authorize the appropriation of such amounts as are necessary to provide grants to states to establish a health insurance ombudsman program. The ombudsman would be directed to assist consumers in choosing health insurance coverage and to help dissatisfied enrollees with appeals and grievances. If a state did not provide an ombudsman, the Secretary of HHS would provide one. CBO estimates that outlays for these grants would total \$60 million during the 1999-2003 period.

Grievance and Appeals Procedures

Subtitle D would require all group health plans and health insurance issuers to establish a system for handling enrollees' grievances, which would include a two-tier process for reviewing appeals of plans' decisions. The first stage would involve appeals to professionals within the plan. Enrollees who were not satisfied with that internal decision could then appeal certain grievances to an external appeals board.

CBO estimates that these provisions, which are highly interrelated, would jointly raise premiums by 0.3 percent. Because plans could require enrollees to exhaust all internal appeals before taking a grievance to the external review board, the number and type of claims that the external review board would consider would depend on the stringency of the internal appeals process. Conversely, having an external appeals process with binding authority over plans would affect both the number of internal appeals and the likelihood that the plan would decide in favor of the beneficiary.

Section 131—Establishment of Grievance Process. The bill would require group health plans and health insurance issuers to establish a system to provide for the presentation and resolution of grievances brought by enrollees or their representatives, including their health care providers, regarding any aspect of the plan's services. Plans would have to provide written notification to enrollees of whom to contact in the event of a grievance or appeal, establish systems to record and document all grievances and appeals and their status, develop a process for timely processing and resolution of grievances and for follow-up actions, and ensure that the continuous quality improvement program would be informed of any grievances relating to the quality of care.

Section 132—Internal Appeals of Adverse Determinations. This section would establish an enrollee's right to appeal a wide range of decisions by their health plan, including denial, reduction, or failure to provide or pay for a benefit; failure to provide emergency coverage, choice of providers, qualified providers, access to specialty care, continuation of care if an enrollee's provider was terminated, access to necessary prescription drugs, or coverage of

Nonetheless, CBO assumes that the enactment of this bill would raise internal appeals rates among ERISA plans, as well as among the non-ERISA plans that would be required to comply. Because of the provisions for external review of denied appeals and the penalties for health plans that did not comply with the legislation, the bill would provide much stronger incentives for internal appeals than the DoL regulations alone.

Costs per appeal would also rise for ERISA and non-ERISA plans as a result of the legislation. Factors contributing to higher costs include:

- o The requirement for review by a clinical peer, which will result in higher professional costs for internal appeals and
- o Higher rates of appeals being overturned in favor of enrollees, reflecting plans' desire to avoid external review.

Plans would attempt to reduce the cost of appeals by applying less stringent utilization review standards to appealable decisions, provided that such responses would lower their overall expected costs.

Cost increases would be larger for the small minority of health plans and issuers that do not currently have systems for internal review of grievances in place. They would experience a significant increase in administrative costs as well as the costs associated with overturned decisions resulting from appeals.

Section 133—External Appeals of Adverse Determinations. This section would require all health plans and health insurance issuers to establish a process whereby enrollees could appeal grievances to an external review organization, which would provide a *de novo* determination of the merits of the claim. Decisions in any of the internal appeal categories would be eligible for further appeal if the costs at issue exceeded a significant threshold, or if the patient's life or health would be jeopardized. The plan or issuer could require the appellant to exhaust the internal appeals process first before taking a claim to external review. But enrollees could take a claim directly to external review if the plan failed to comply with the deadlines for internal appeals in the law. The decision of the external review organization would be binding on the plan or issuer but would not affect the enrollee's right to seek judicial remedies in the courts. Decisions would have to be made within 60 days of filing notice of appeal (or 72 hours in the case of expedited appeals).

Plans and issuers would have to contract with qualified external appeals entities. States could designate such entities for health insurance issuers and the appropriate Secretary for group health plans. External review organizations would have to meet certification and

clinical trials; adverse utilization review decisions; and arbitrary interference with the physician's decision on the manner or setting of care, when the care was medically necessary or appropriate.

The bill would require individuals conducting internal reviews to include clinical peers who had not previously been involved in the decision under appeal. Clinical peers would be physicians or other health professionals with qualifications in the specialty that typically managed the condition or treatment involved in the appeal, but only a physician would be considered the clinical peer of another physician.

Group health plans and health insurance issuers would face limits on the time for resolving an appeal, which would vary according to the urgency of the situation. They would have to resolve expedited appeals within 72 hours of receiving them and all other appeals within 30 working days.

CBO's estimate assumes that although most health plans have functioning internal review systems, they would experience an increase in the rate of internal appeals per enrollee, as a result of greater consumer knowledge of the appeals process and the availability of external review. A recent study by the General Accounting Office suggests that data on internal appeals rates are highly unreliable and vary widely among HMOs.⁵ The range of self-reported appeal rates was 0.07 to 69.4 per 1,000 enrollees, with a median of 3.5. Those rates, however, included appeals for the denial of emergency services, which might occur less frequently under the bill because of the "prudent layperson" provisions. CBO's estimate, therefore, assumes a current average appeal rate, excluding appeals relating to emergency services, of 2.5 per thousand enrollees.

Health plans and health insurance issuers with internal appeals processes in place would still incur cost increases under the bill because of higher rates of appeal and higher costs per appeal. But appeal rates and costs will rise somewhat even without the legislation. Increases will occur under current law as a result of regulations affecting internal claims procedures for ERISA health plans that the Department of Labor (DoL) will release soon in response to a Presidential memorandum.⁶ The regulations will require ERISA plans to provide enrollees whose claims are denied with information on their appeal rights and will require plans to meet tighter timeframes both for the initial review of claims and for subsequent appeals.

5. U.S. General Accounting Office, *HMO Complaints and Appeals: Most Key Procedures in Place, but Others Valued by Consumers Largely Absent*, GAO/HEHS-98-119 (May 1998).

6. Testimony of Ofelia Berg, Assistant Secretary, Pension and Welfare Benefits Administration, U.S. Department of Labor, before the Senate Committee on Labor and Human Resources, May 19, 1998.

recertification requirements imposed by the states or the Secretary of Labor. But if a state did not establish an adequate certification and recertification process, the Secretary of Health and Human Services would fulfil that function.

In the 16 states that already require external appeals processes, few claims are appealed. Various factors appear to have contributed to that outcome, including:

- o Lack of awareness by enrollees of their external appeal rights because programs are new or not widely promoted;
- o Coverage of certain functions only, such as experimental procedures;
- o Uncertainty about whether the state's requirements are preempted by ERISA; and
- o Sentinel effects of having an external review program, which causes plans to modify their internal review procedures.

Only Florida appears to have a program that is functioning at much more than a minimal level. And even Florida's rate of external appeals, about 1 per 10,000 enrollees, is only about one-tenth of the external appeals rate in the Medicare program.⁷ The Medicare rate, however, is higher than would be expected under the bill because every form of denial in Medicare is subject to appeal, and all appeals that plans deny are automatically referred to external review.

For the purposes of this estimate, CBO assumed that the legislation would significantly increase external appeals rates, even in those states that nominally have external review requirements. Moreover, those rates would rise over time as enrollees became more aware of their rights to such reviews. Nonetheless, external review rates would remain relatively low when compared to internal appeals rates (which plans would be more likely to resolve in favor of the enrollee if an external review option was available). Specifically, CBO estimated that external appeals rates would rise to about 4 per 10,000 enrollees after 5 years. The estimate also assumed that the majority of external appeals would be resolved in favor of health plans and issuers.

⁷ Allen Dobson and others, "Consumer Bill of Rights and Responsibilities Costs and Benefits: Information Disclosure and External Appeals" (report submitted by The Levin Group, Inc. to the Presidential Commission on Consumer Protection and Quality in the Health Care Industry, November 1997).

Protecting the Doctor-Patient Relationship

Subtitle E contains four provisions governing plans' contracts with providers.

Section 141—Prohibition of Interference. This section, an anti-gag-rule provision, would void any provision of a contract that limited a provider's freedom to discuss or communicate with a patient about aspects of his or her care. Several studies have shown that few plans impose such restrictions today. For those that do, their costs would be minimal.

Section 142—Prohibition of Improper Incentive Arrangements. This section would prohibit provisions in contracts between health plans and providers that transferred liability for decisions of the plan to the provider or rewarded the provider for decisions regarding specific patients. Although health plans might seek to reduce their own potential liability for medical negligence under the bill by transferring that liability to providers, their costs would not be affected because they would have to pay more to providers to cover the transferred costs of liability. The prohibition of physician incentive plans that financially reward or penalize physicians for decisions involving specific patients would also not have a measurable impact on premiums, provided that capitation agreements or payment withholdings based on a physician's aggregate financial performance were not ruled inappropriate under this provision.

Section 143—Participation of Health Care Professionals and Section 144—Protection for Patient Advocacy. These sections would establish protections for providers that generally do not exist in health plans today. Section 143 would specify due process standards for selective contracting between plans and health care professionals. Section 144 would protect providers (and enrollees) from retaliation for participating in the appeals and grievance process or for disclosing information on the quality of care to a plan or regulatory agency. Under title III, physicians and other professionals could appeal adverse contractual decisions by ERISA health plans to the Secretary of Labor on the basis of this provision. Title III also would prohibit retaliation against professionals by institutional health care providers.

Although these protections would be largely procedural (for example, requiring written rules on participation but not dictating the content of those rules), they would require plans to establish regulatory compliance operations for their contractual interactions with providers. Plans would not only need to establish compliance with sections 113, 143, and 144, but they would also have to defend against the threat of appeal through careful documentation of all contract actions. Thus, although these sections fall well short of constituting any-willing-provider provisions, they would entail some administrative costs.

The provisions would fall most heavily on the more loosely organized managed care plans, such as preferred provider organizations and independent practice associations, which do not have exclusive arrangements with physicians and hospitals. CBO estimates that the incremental costs of these provisions would be 0.1 percent of premiums.

Promoting Good Medical Practice

Subtitle F contains two specific benefit mandates and a more general provision prohibiting arbitrary interference with medical practices. Both benefit mandates relate to treatment of breast cancer.

Section 151—Promoting Good Medical Practice. This section would prohibit plans from arbitrarily interfering with the manner or setting of care when that care is medically necessary or appropriate. Manner or setting would be defined as the location of treatment and the duration of a service but would exclude decisions on the coverage of particular services or treatments. The section defines medically necessary or appropriate as care that is "consistent with generally acceptable principles of professional medical practice." Grievances regarding the plan's conformance with this section could be appealed under subtitle D. Members of ERISA plans could also sue in federal court to seek remedies under this provision.

The section would establish a right of appeal of plans' decisions about the appropriateness of inpatient, outpatient, or home care for procedures or treatments, monitoring of high risk patients, and administration of medications, as well as all decisions about lengths of inpatient stays. Any decisions regarding those categories of care would be subject to the provision's definition of medical necessity. Consequently, its cost would depend ultimately on how the external review bodies interpreted the term "consistent with generally acceptable principles of professional medical practice." This provision would increase the volume of internal and external appeals above and beyond the volume expected from other provisions. Not only would the provision provide additional incentives to appeal decisions by plans, but it would probably also lead to a higher rate of reversal on appeal. Although the external appeals bodies and the courts might eventually settle on uniform and easily interpreted standards of medical necessity, the variability of medical practice styles across the country would ensure continuing challenges to decisions by plans over the 10-year estimating period.

One way for plans to avoid appeals under this provision would be to reduce the frequency with which they challenged physicians' decisions. CBO took account of the likelihood that plans would adopt defensive utilization review practices when the costs of such changes to

the plan were lower than the expected costs of the internal and external review actions required to defend the UR policies.

The burden of this provision would fall more heavily on more loosely managed health plans, which typically rely on utilization review to influence patterns of care. Traditional indemnity plans with utilization review components, preferred provider organizations, and independent practice associations would face more challenges than would group- or staff- model health maintenance organizations. CBO estimates that the higher volume of internal and external reviews and the higher probability of decisions that would be unfavorable to plans would raise premiums by 0.8 percent overall.

Section 152—Standards for Breast Cancer Treatment and Section 153—Standards for Reconstructive Breast Surgery. Section 152 would prohibit health plans from limiting hospital lengths of stay for mastectomies to less than 48 hours and for lymph node dissections for breast cancer to less than 24 hours. The provider would not have to obtain prior authorization for any length of stay for those conditions. Section 153 would require plans to pay for breast reconstructive surgery following mastectomy or lumpectomy, including surgery on a nondiseased breast to establish symmetry with the diseased breast. CBO estimated that these two provisions would add less than 0.05 percent to health plan premiums.

Changes to the Employee Retirement Income Security Act

Title III of the bill would apply the patient protection standards of title I to group health plans and group health insurance coverage under ERISA. The estimated costs of these standards were discussed above. In addition, title III would impose additional regulatory costs on the Department of Labor and would alter the legal liability of health insurance plans under ERISA.

Enforcement by the Department of Labor. Section 301 would permit any health care professional who has been discriminated against or retaliated against to file a complaint with the Secretary of Labor. The Secretary would be required to investigate these complaints to determine if a violation had occurred. If a violation occurred, the Secretary would issue an order to ensure that the health professional did not suffer any loss of position, pay or benefits from the plan. Costs associated with this enforcement include the expenses associated with tracking and investigating complaints by providers. CBO estimates that these costs would total \$175 million over the 1999-2003 period, assuming appropriation of the necessary amounts.

Legal Liability for ERISA Plans. As a result of ERISA, enrollees in employer-sponsored health plans are generally unable to seek legal remedies under state law for damages resulting from the actions or decisions of their health plans. They may seek redress only in federal court under the provisions of ERISA, which limits any damages to the cost of the plan benefits under dispute and, in some cases, attorneys' fees and court costs. In recent years, ERISA case law has evolved, with some federal courts ruling that enrollees can sue their plans in state courts for vicarious liability for the medical negligence of the plan's providers. But disputes over benefits and administration have largely been preempted by ERISA.

The bill would amend ERISA to allow enrollees in employer-sponsored plans (or their estates), under certain circumstances, to sue their health plans under state law for damages resulting from personal injury or wrongful death. Specifically, enrollees could sue a person if personal injury or wrongful death resulted from that person's provision of insurance, administrative, or medical services to or for a group health plan, or arose out of their arrangement for the provision of insurance, administrative, or medical services by others. The bill would protect employers and other plan sponsors from suits as long as the action that led to the suit did not reflect the exercise of discretionary authority by the employer or sponsor. The cost of this provision depends on assumptions for which the supporting data are extremely limited or nonexistent. CBO therefore consulted with many experts nationwide on the likely outcomes of this provision and received a broad range of opinions.

Some experts believe that ending the ERISA preemption for health plan liability would increase costs only slightly. They maintain that the bill would do little more than speed up trends that are already underway in the courts of holding ERISA plans accountable for the medical negligence of their providers and treating adverse outcomes resulting from decisions on medical necessity by health plans as medical negligence. Health plans could limit their liability for decisions on medical necessity by including more explicit coverage statements in their contracts and by using binding arbitration or other alternative dispute resolution techniques. Moreover, the external review requirements in the bill would limit the number of cases that would be litigated, and the caps on tort liability that exist in more than half of the states would limit the size of awards. These experts also argue that the experience of state and local government health plans and in the individual insurance market, all of which are exempt from ERISA and potentially subject to litigation, suggests that litigation over issues relating to denial of coverage is likely to be small.

Others believe that ending the ERISA preemption would fundamentally change the environment in which private employer-sponsored plans operate and increase their costs considerably, not only as a result of litigation but also because of the defensive utilization review strategies that plans would adopt. They predict that health plans would be sued along with providers for medical malpractice much more frequently when patients were injured,

because of the plans' "deep pockets" and because lawyers would not have to deal with potential issues of ERISA preemption and would be attracted by the large damages that juries might award. A big increase in suits over decisions on medical necessity and denial of coverage would probably occur, they contend, with providers as well as beneficiaries seeking damages. Health plans' attempts to limit coverage contractually could be thwarted by arguments that such contractual restrictions were another form of practicing medicine and, hence, subject to suit. Whether state tort liability caps would apply to health plans is uncertain and would probably vary among the states. In addition, the language in the bill protecting employers and sponsors who were not exercising discretionary authority would not protect the fiduciaries of ERISA plans who, by definition under the law, exercise such authority. Proponents of these views also argue that the experience of non-ERISA plans does not throw much light on what would probably happen in the ERISA market because of differences in the covered populations (including the degree of unionization), appeals processes, plan generosity, and choice of plan, as well as states' ability to limit their legal liability. They envision the emergence of an aggressive plaintiffs' bar that would declare open season on health plans.

The bill includes several provisions designed to address some of those concerns:

- o Only plan participants and beneficiaries (or their estates) would have standing to file suit;
- o The term "personal injury" is defined to mean physical injury, including an injury arising out of the treatment, or failure to treat, a mental illness or disease;
- o The limitation on suits against employers and plan sponsors also includes their employees when acting within the scope of their employment; and
- o A construction clause establishes that nothing in section 302 should be construed as permitting a cause of action under state law for the failure to provide an item or service that the group health plan did not cover.

Regardless of the extent to which they are subject to suit under current law, all health plans are already, directly or indirectly, incurring significant liability costs. Most of those costs relate to medical negligence, as litigation over coverage questions has been relatively rare (in part, because of the ERISA preemption). Tightly managed plans are at risk for being held vicariously liable for the medical negligence of their providers. To offset that risk, they may purchase liability insurance, establish mandatory arbitration procedures, or increase their oversight and monitoring of providers. Loosely managed and indemnity plans pay liability costs indirectly through the rates that they pay to providers, which include those providers'

liability insurance costs. Those types of plans also pay for additional services that result from physicians' defensive practices. CBO estimates that health plans' liability costs average about 2 percent of their premiums (not counting defensive medicine by providers).

Several factors could cause plans' expected liability costs to rise.

- o More medical negligence suits would be filed against ERISA plans, and the amount of damages awarded would rise, as plaintiffs would have another party to sue in addition to the provider. Although some of those suits are occurring now, dealing with the issue of ERISA preemption is a disincentive for many medical malpractice lawyers and reduces the number of suits that are filed.
- o Expected liability costs associated with decisions on medical necessity and coverage would increase significantly. At present, there are few coverage suits against ERISA plans as a result of the preemption, and the associated liability costs are low. Ending the ERISA preemption would mean not only that more plans would be successfully sued but, more importantly from a cost perspective, every judicial decision awarding damages to a plaintiff for a plan's coverage decision would increase the risk of suit for all other plans with similar coverage policies. Several of the experts whom CBO consulted mentioned the *Fox v. Health Net* suit as an example of that phenomenon.⁸ The jury in *Fox* awarded the plaintiff, a breast cancer patient, \$89 million for denial of coverage of autologous bone marrow transplantation (ABMT). Although the case was subsequently settled for a much lower amount, expected liability costs rose for all health plans with similar coverage standards for ABMT. Consequently, many plans apparently took action to reduce their risks from such suits, changing their utilization review criteria for ABMT so that the treatment became much more widely utilized. (Plans could have handled the increased risk in a variety of ways, of which loosening their utilization review criteria was just one. Alternatively, they might have increased their liability insurance or changed the coverage standards written into their contracts with enrollees.)
- o The bill is likely to result in a variety of unintended lawsuits against health plans—including suits instigated by providers and suits against plan fiduciaries. Section 302 would raise new issues regarding the extent of the ERISA preemption that could take the courts a long time to address.

8. *Fox v. Health Net*, Riverside Superior Court, March 26, 1994.

- o In addition to the increase in direct liability costs that plans would face, plans would also have to consider the indirect costs associated with the adverse publicity that litigation engenders. Adverse publicity could result in loss of market share, adding to plans' expected liability costs.

Taking all of those factors into account, CBO estimates that ending the ERISA preemption of legal liability for private employer-sponsored plans would increase liability costs by 60 to 75 percent, in the case of PPOs, POS plans, and HMOs, and by a lesser percentage in the case of indemnity plans. Those increases represent, on average, about 1.4 percent of the premiums of ERISA plans and about 1.2 percent of the premiums of all employer-sponsored plans. Those estimates take into account all of the actions that plans take to lessen their liability costs, including the purchase of liability insurance and changes in utilization review criteria and coverage standards intended to reduce the probability of lawsuits.

Under CBO's assumptions, more than half of the increase would arise from potential suits associated with decisions on medical necessity and coverage (and the associated behavioral responses by plans), as well as unintended lawsuits involving providers and plan fiduciaries. Most of the remainder would result from more medical negligence suits against plans, reflecting the financial resources of health plans and the effects of the new legal environment. The estimate also assumes that a further loosening of review criteria and standards of medical necessity (with a corresponding increase in costs) would result from the desire of plans to avoid the adverse publicity of litigation.

Questions have been raised about the impact of the health plan liability provisions on small self-insured firms. Advocates for small businesses argue that liability insurance is not currently available for such firms, and they would be unlikely to remain self-insured without liability coverage if the ERISA preemption was lifted. Purchasing a fully-insured plan from an insurer or an HMO, which the firms might feel compelled to do, would increase their insurance costs because they would have to pay for benefits mandated by the state as well as state premium taxes. In addition, they could face a one-time cash flow problem because they would have to start making premium payments to an insurer while they were still paying off the tail of claims from their own plan.

Although temporary dislocations might occur when these provisions first came into effect, insurance markets would almost certainly respond to the demand for liability coverage for health plans. Third-party administrators that service small self-insured plans, and insurers that offer risk-sharing arrangements to such plans, would have a strong incentive to develop the means for self-insured plans to obtain liability coverage. In order for liability insurers to be willing to provide such coverage at a reasonable premium, however, the plans might have to accept more oversight and standardization of their coverage policies, which could

increase their costs. In addition, obtaining liability coverage for punitive (as opposed to compensatory) damages might be a problem in the 15 or so states in which the courts have ruled that punitive damages are not insurable. But punitive damage awards are capped in at least some of those states, which would limit the risk for a firm without coverage for punitive damages.

The transition period until liability coverage was more generally available could be difficult for some self-insured firms, with some of them opting to purchase fully insured products rather than face an uncertain risk of liability. To the extent that response occurred, average premium costs would be higher than they otherwise would be, but the effects would diminish over time as markets for liability insurance developed. Offsetting any subsequent decline in premiums, however, would be rising costs resulting from the growth in liability suits as more consumers (and their lawyers) became aware of their rights to sue health plans.

Two other factors would have offsetting effects on the costs of ending the ERISA preemption for health plan liability. On the one hand, some experts believe that the courts will continue on their current path of limiting the extent of the ERISA preemption, not only for medical negligence but also for decisions on medical necessity and coverage. Insofar as that occurred, then the additional costs resulting from this legislation would be lower, although there is considerable doubt about how long it would take to establish this expanded body of ERISA case law. On the other hand, ending the preemption could have long-term consequences for the development and adoption of costly new technologies. Research suggests that the spread of managed care may have slowed the rate of adoption of new medical technologies, helping to contain the rate of growth of health spending.⁹ Because the bill would allow enrollees to sue plans for their decisions on medical necessity and coverage, the dissemination of new technologies would speed up, encouraging further technological development and raising costs.

PAY-AS-YOU-GO CONSIDERATIONS

Section 252 of the Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The net changes in outlays and governmental receipts that are subject to pay-as-you-go procedures are shown in the Table 3. For the purposes of enforcing pay-as-you-go procedures, only the effects in the current year, the budget year, and the succeeding four years are counted.

⁹ David M. Cutler and Louise Shimer, *Managed Care and the Growth of Medical Expenditures*, (NBER Working Paper No. 6140, Cambridge, MA: National Bureau of Economic Research, August 1997).

TABLE 3. ESTIMATED PAY-AS-YOU-GO EFFECTS OF THE PATIENTS' BILL OF RIGHTS ACT

	By fiscal year, in millions of dollars									
	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Change in Revenues	-28	-446	-752	-911	-1,066	-1,177	-1,265	-1,355	-1,450	-1,553
Change in Outlays	0	5	15	30	40	55	65	70	75	80

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

The Public Health Service Act allows state, local, and tribal governments to elect not to have certain federal requirements apply to their own group health plans. The requirements for state, local, and tribal governments in this bill would also be optional under the provisions of the act. Consequently, the bill does not contain intergovernmental mandates as defined in UMRA. The bill would affect the budgets of state, local, or tribal governments only if they chose to comply with the requirements on group health plans. Because the bill imposes a number of new requirements on health insurance issuers, state and local governments also may face increased costs if they offer fully insured products as part of their employee benefits plans. The bill would provide grants to states to establish a health insurance ombudsman, but in the absence of state activity, the federal government would assume responsibility for the office.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains several private-sector mandates as defined in the Unfunded Mandates Reform Act. CBO estimates that the direct cost of those requirements to private sector entities would significantly exceed the threshold specified in UMRA (\$100 million in 1996, adjusted annually for inflation) every year after 1999 (see Table 4).

Most of the provisions of title I would impose requirements on both group and employer-sponsored health plans and on health insurance issuers. The mandatory point-of-service requirement in section 102 would affect only group and employer-sponsored plans, however, and the continuity of care requirement in section 105 would have almost all of its effect on that market as well. The provisions establishing the Health Care Quality Advisory Board (section 116) and the Health Insurance Ombudsman (section 123) would not impose mandates on private sector entities. CBO estimates that the total direct costs of the mandates in title I would be about \$100 million in 1999 but would reach about \$9 billion in 2003. The

Myths and Facts

Myth: An enterprise liability law would not affect the cost of health care.

Fact: Enterprise liability does drive up health care costs by 1) forcing plans to practice defensive coverage and 2) adding layer upon layer of new liability insurance. Enterprise liability squanders our scarce health dollars on services that have nothing to do with quality of care.

- The General Accounting Office (GAO) catalogued studies indicating that medical liability costs already could be as much as \$22 billion annually.
- GAO estimates that nearly 60 percent of all claims filed against physicians are dismissed without a verdict, settlement or payment to plaintiff.
- According to the Hudson Institute, direct and indirect costs of liability added a total of \$450 per patient admitted to a hospital, increasing hospital medical costs at the hospital by 5.3 percent.
- GAO studies show, when factoring the costs of the overall system, only 43 cents on the dollar is paid in compensation to deserving claimants.

Ask yourself this: Have you ever seen enterprise liability provisions in a bill applicable to a state's Medicaid program? Of course not *because it's a waste of your tax dollars!*

Myth: Enactment of enterprise liability legislation would successfully place responsibility for medical liability on the appropriate party.

Fact: Enterprise liability actually extends medical liability from physicians to health plans. However, health insurers are not doctors and do not practice medicine. Carriers simply establish guidelines for care.

Myth: Enterprise liability is the answer to America's dysfunctional medical malpractice system because it shifts liability from doctors to other responsible parties.

Fact: Enterprise liability doesn't shift liability, it multiplies it, thereby opening the door for an enormous increase in costly and unnecessary lawsuits. Trial lawyers will effectively have an additional "deep pocket" to sue. In addition, physicians would be dragged into these suits and actually experience more litigation.

Florida Gov. Lawton Chiles wrote in a 1997 letter vetoing an enterprise liability bill: "The key to any dispute resolution system for health care claims is that it be fast, fair and efficient. The tort system is often none of those."

Myth: If enterprise liability legislation is enacted, people can expect better quality and more affordable health care.

Fact: Unfortunately, quality of care could be jeopardized. Enterprise liability legislation would erode the whole premise behind managed care — to provide and maintain appropriate care and affordable coverage. It does this by virtually eliminating managed care's ability to use cost effective tools such as utilization management and review. These tools will become obsolete when managed care companies have to practice "defensive coverage," and inappropriate care kills people!!

Myth: Currently, consumers have no methods of redress against Health Maintenance Organizations (HMOs).

Fact: It is both possible and commonplace to take HMOs to court. By filing a breach of contract claim or a grievance, HMO subscribers can sue an HMO for breach of contract when it refuses to pay for a necessary treatment.

Myth: Enterprise liability would not change the roles of health plans and physicians.

Fact: Enterprise liability would require health plans to become *much* more involved in the physician/patient relationship. Today, the major roles health plans play is to provide health coverage and to develop and maintain panels of qualified providers; to offer resources supporting provider's activities; safeguard and maintain financial resources needed to pay for patients' health care; and to make decisions about coverage pursuant to the benefits contract.

Talking Points

- When asked *whether people would support a law allowing them to sue a health plan directly*, 64% of respondents were in favor while 31% opposed. **However**, if the law would *increase costs*, only 48% were in favor with 45% opposed. When told that the new law would increase government involvement, 38% were in favor, and 54% opposed. Finally, when informed that employers could be forced to drop insurance coverage, a mere 36% percent were still in favor, but 58% opposed.*
- Extending malpractice liability to health insurers and employers would foster an increasingly litigious environment consequently driving up health care costs. Health plans and employers would feel compelled to abide by the mantra "more is better" in an effort to protect themselves from potential liability.
- In much the same way physicians have been forced to practice defensive medicine, an enterprise liability law would force health insurers to provide *defensive coverage* for duplicative, unnecessary or otherwise inappropriate and potentially harmful services. These services do not benefit patients, they are solely to avoid costly litigation.
- Health plans and employers would have no choice but to increase insurance premiums or co-payments to cover the cost of new liability insurance protecting them against the threat of costly litigation and potential awards.
- Extending liability is unnecessary because consumers already have redress against health plans. The health insurance industry is governed by state statutory licensing requirements, regulatory requirements, the tort system, voluntary accreditation standards and private sector demands in the marketplace.
- Increasing health care costs reduce the number of Americans who can afford the safety and peace-of-mind of health insurance. According to the Congressional Budget Office, for every one percent increase in health insurance premiums, 200,000 people can no longer afford to purchase insurance.
- Expanding the scope of medical liability from trained physicians to insurers, plans and employers is bad medicine. Doctors are the ones who make medical decisions, not insurers or employers.

* Source: Kaiser Family Foundation/Harvard University, January 1998

The genetics of reform

By Merrill Matthews Jr.

Have you noticed how much health care reform legislation has passed since the dismal failure of the Clinton health care plan just a few years back? A coincidence? Hardly. In a Sept. 15 speech to the Service Employees International Union, President Clinton said, "Now, what I tried to do before won't work. Maybe we can do it another way. That's what we've tried to do, a step at a time until we eventually finish this. . . . We've got to do it right so we can go on to the next step and the next step and the next step."

Ironically, given the strong Republican opposition to Clinton's health care plan, the president now sees a more cooperative spirit: "You know, when you think about the rhetoric of the health care debate just a couple of years ago, and now you've got 80 percent of the Congress in both houses voting for the biggest increase in health care coverage since Medicaid passed in '65, we have come a long way." One reason for the Democrats' successful implementation of their agenda is that they have learned how to package their proposals in a way that few politicians can oppose.

How many politicians would want to be branded as opposing health insurance for poor uninsured children? And the next "step" in this agenda — implementing privacy legislation — is no different. The stated purpose of the legislation is to protect genetic privacy in hopes of preventing genetic "discrimination" so that people are not denied a job or health insurance because of a genetic predisposition to a particular medical condition. There are currently about 450 genetic tests — with more coming in the future — that can tell doctors whether a person is predisposed to certain diseases.

Most people won't get the disease, but they are at greater risk than others who lack the genetic predisposition. As a result of the growing availability of these tests, 20 states have passed legislation preventing insurers from discriminating against people because of test results. However, most of these bills use an appropriately narrow, scientifically grounded definition of genetic test. By contrast, people looking to expand the Clinton plan by stealth seek to impose a much broader definition — and that is where the danger lies.

Just consider a recent recommendation from the Department of Health and Human Services (HHS), which later emerged as a column on genetic privacy and discrimination in The Washington Post by three authors, one of whom, Francis S. Collins, is director of the National Human

Genome Research Institute. "First, except in a few states, the [genetic privacy] laws focus narrowly on genetic tests rather than more broadly on genetic information generated by family history, physical examination or the medical record. Meaningful protection requires that insurers be prohibited from using all information about genes, gene products or inherited characteristics to deny or limit health insurance coverage."

Note that in this broad definition of genetic discrimination, "family history" and "inherited characteristics" must be excluded for purposes of issuing an insurance policy. Thus, no health insurer could ask applicants if they have a family history of breast cancer, colon cancer, high blood pressure, heart disease or almost any other type of condition that might have a genetic element. Nor would they be able to take a blood sample, since blood has a genetic base. In addition, broad-definitionists oppose letting insurers charge a different premium for those who might be more susceptible to a medical condition if it is ascertained from such information — which most conditions certainly will be. What this means is that anyone will be able to get a health insurance policy regardless of their medical condition (known as "guaranteed issue") for the same price as healthy people ("community rating").

Letting anyone buy health insurance at any time at a level price was the ultimate goal of the Clinton plan. Even though this goal may sound good at first glance, it causes a real problem: if people can get a health insurance policy for a reasonable price after they get sick, why would any healthy person buy a policy? The administration knew this was a problem when it promoted its plan, which is why it was going to force everyone to have health insurance — or go to jail. The irony in all this is that under current law there is no need to go to all this trouble to get people insured or protect their genetic privacy. The Kassebaum-Kennedy health insurance bill that passed last year makes provisions for just about everyone, even those who are uninsurable. Though Kassebaum-Kennedy doesn't control the price of health insurance, it does make it available, and it prohibits insurers from canceling or refusing to renew a policy based on genetic information.

So what we have is an attempt to take the next "step" in the Clinton health care plan — anyone can get health insurance at any time for a reasonable price — by piggybacking the plan on legislation, in some cases sponsored by Republicans, meant to prohibit genetic discrimination. The administration is smart enough to know that by inserting the broad definition, it would destroy health insurance, opening the door for real national health insurance. Perhaps that's what the president meant when he said "until we eventually finish this."

Merrill Matthews Jr. is vice president of domestic policy for the National Center for Policy Analysis.

THE HEALTH BENEFITS COALITION

for Affordable Choice & Quality

PARTICIPANTS

Aetna U.S. Healthcare
American Association of Health Plans
American Automobile Manufacturers Association
American Insurance Association
Associated Builders and Contractors
Association of Private Pension and Welfare Plans
Blue Cross and Blue Shield Association
The Business Roundtable
CIGNA
Citizens for a Sound Economy
Council for Affordable Health Insurance
The ERISA Industry Committee
Food Distributors International
Food Marketing Institute
Health Insurance Association of America
Healthcare Leadership Council
Humana Inc.
International Mass Retail Association
National Association of Health Underwriters
National Association of Manufacturers
National Association of Wholesaler-Distributors
National Business Coalition on Health
National Federation of Independent Business
National Restaurant Association
National Retail Federation
New York Life/NYLCARE Health Plans
Premier
Prudential HealthCare
Self-Insurance Institute of America, Inc.
Society for Human Resource Management
U.S. Chamber of Commerce

January 27, 1998

Memorandum to Members of the U.S. House and Senate

From: The Health Benefits Coalition

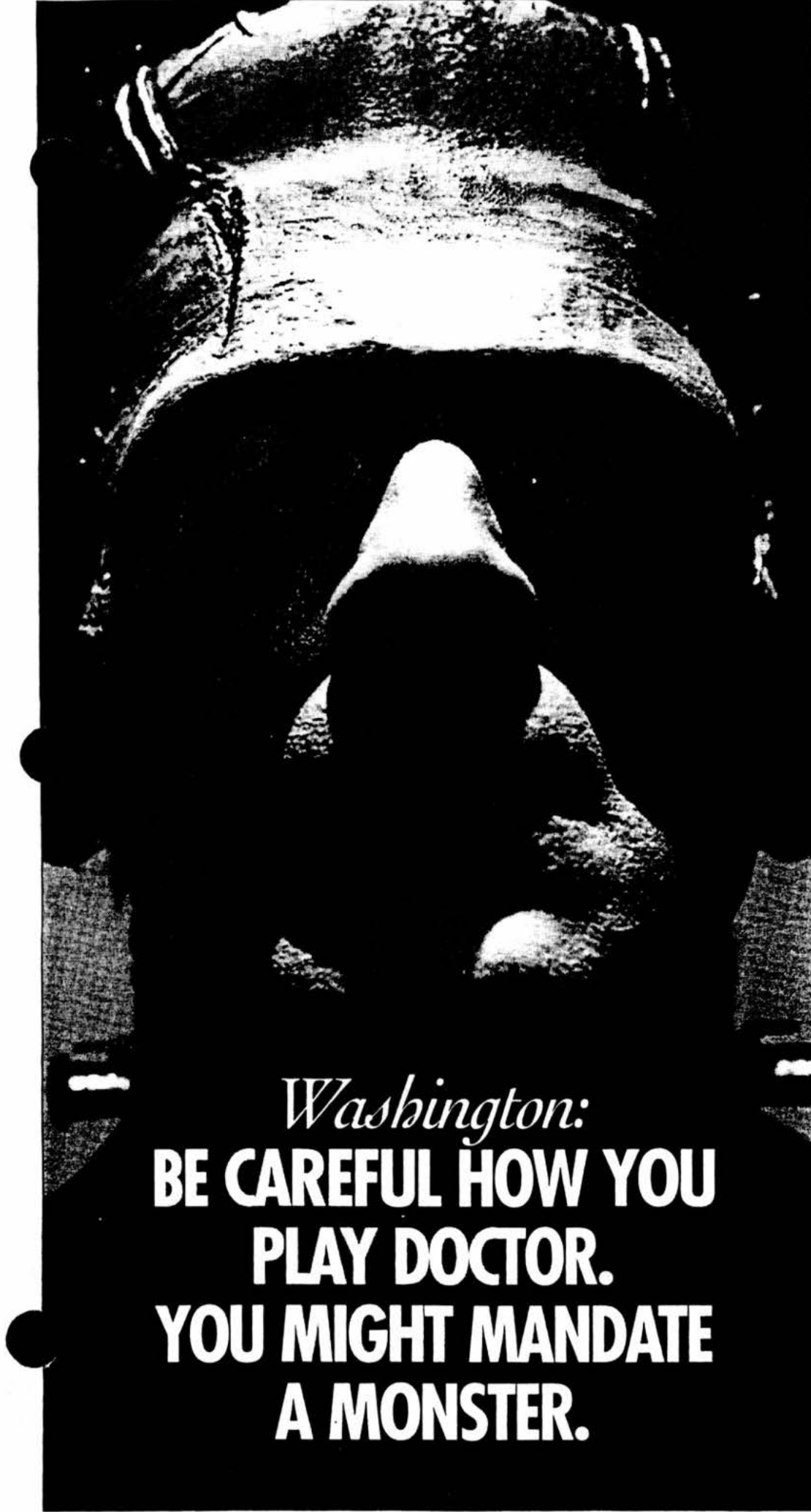
Subject: Health Care Mandates

The Health Benefits Coalition represents more than three million employers and 100 million employees. As the enclosed print ads and press release indicate, we are launching a campaign against excessive and costly government mandates on employers and health plans. While we are committed to providing affordable quality health care for our employees, it is our firm belief that prescriptive federal legislation in this area will backfire—increasing health care costs and driving up the number of uninsured Americans.

As the debate over health care mandates unfolds, we hope you will keep in mind the following facts:

- **Health cost inflation:** Last week, the U.S. Congressional Budget Office warned that health premium costs could rise 5.5% in 1998, vs. 3.8% last year—and climb even faster if federal "patient protection" mandates become law. (Projections of National Health Expenditures: 1997-2008)
- **The impact of mandates on cost:** A national actuarial firm recently estimated that one popular mandate bill would drive premiums up an average of 23% nationwide. (Milliman & Robertson cost-impact analysis of H.R. 1415/S.644, the proposed "Patient Access to Responsible Care Act")
- **The impact of mandates on coverage:** According to The Lewin Group, a widely respected consulting firm which advised the Clinton administration on its "Consumer Bill of Rights," a premium increase of just *one percent* nationally causes an estimated 400,000 Americans to lose their health care coverage. That's because mandates make coverage unaffordable for employers *and* their employees and dependents.
- **How Americans really feel:** A just-released national poll shows three out of four Americans favor enactment of the Consumer Bill of Rights—until they learn about its potential impact on cost and coverage. Once told that large numbers of employers might be forced to drop coverage, three out of four OPPOSE its enactment. (Kaiser Family Foundation/Harvard University National Survey, 1/21/98)

If you have any questions regarding the Health Benefits Coalition, please contact Dan Danner, chairman of the Health Benefits Coalition, at 202-554-9000.



Washington:
**BE CAREFUL HOW YOU
PLAY DOCTOR.
YOU MIGHT MANDATE
A MONSTER.**

Health care reform has taken on a frightening new look.

The White House and some in Congress are proposing mandates that will drive up costs, forcing millions of Americans to lose their health insurance.

One bill, the Patient Access to Responsible Care Act, would mandate a monstrous bureaucracy with more than 500 new requirements, forcing premiums up an average of 25 percent.

On behalf of 5 million employers and more than 100 million employees and their families, we urge you to oppose health care mandates. Because every one percent increase in costs forces 200,000 to 400,000 Americans to lose their health insurance.

Now that's scary.

THE HEALTH BENEFITS COALITION

*For Affordable
Choice & Quality*

National Federation of Independent Business
U.S. Chamber of Commerce
The Business Roundtable
National Association of Manufacturers
National Restaurant Association
Associated Builders and Contractors
National Association of Health Underwriters
American Automobile Manufacturers Association
National Business Coalition on Health
American Insurance Association
Food Marketing Institute
The ERISA Industry Committee
National Association of Wholesaler-Distributors
Food Distributors International
CIGNA
American Association of Health Plans
Association of Private Pension and Welfare Plans
National Retail Federation
Blue Cross and Blue Shield Association
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Aetna U.S. Healthcare
Prudential HealthCare
Health Insurance Association of America
Healthcare Leadership Council
Humana Inc.
International Mass Retail Association
Self-Insurance Institute of America, Inc.
New York Life/NYLCARE Health Plans
Premier

3 Million Employers and
more than 100 Million
Employees and Their
Families have a Message
for Washington:

**"DON'T RAISE
OUR HEALTH CARE
COSTS."**



Members of the Health Benefits Coalition provide health care coverage to a large segment of working Americans. Every day we answer to their demands for affordable, quality health care. Now we're voicing the concerns of 86% of Americans who fear government mandates will drive up health care costs.

The White House and some in Congress are proposing mandates that would undermine our ability to cover our employees. One bill, the Patient Access to Responsible Care Act, is estimated to drive up health care costs an average of 23 percent, forcing from 5 to 9 million workers to lose their coverage.

We all want affordable, quality health care for more Americans. But government mandates to "protect" health care quality could leave millions of Americans unprotected.

THE HEALTH BENEFITS COALITION

*For Affordable
Choice & Quality*

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Prudential HealthCare

Self-Insurance Institute
of America, Inc.

Society for Human
Resource Management

U.S. Chamber of Commerce

For Immediate Release

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Employers Mount Campaign To Fight Federal Health Care Mandates

Washington, DC, January 21, 1998--Warning that federal health care mandates will increase costs and cause millions of Americans to lose their health insurance, a coalition representing the country's largest and smallest employers today launched a campaign to oppose passage of mandates proposed by the White House and some in Congress.

The leadership of the Health Benefits Coalition, a group of 31 organizations representing more than 3 million companies and more than 100 million employees, outlined their concerns at a Wednesday press conference in the U.S. Capitol (H-137) at 11:00 a.m. They announced that they are planning a major grassroots effort and a million dollar plus advertising campaign in Washington-area media and selected congressional districts.

"We will work hard to educate members of Congress about the devastating unintended consequences of these proposed mandates," said Jack Faris, CEO of the National Federation of Independent Business, the nation's largest small-business advocacy organization. "Small businesses, already struggling to provide health insurance to their employees, would be particularly hard hit by increased costs resulting from more government regulation."

One leading mandate proposal is H.R. 1415/S. 644, the Patient Access to Responsible Care Act (PARCA), introduced by Rep. Charlie Norwood (R-GA) and Sen. Alfonse D'Amato (R-NY). A study by the actuarial consulting firm of Milliman & Robertson estimates PARCA would increase health care premiums by an average of 23 percent nationally. Since data from the Congressional Budget Office and the Lewin Group indicates that every one percent increase in health care premiums could force 200,000 to 400,000 Americans to lose their health insurance, the Health Benefits Coalition said PARCA could lead to an additional 5 to 9 million uninsured.

- more -

Tony Burns, Chairman, President and CEO of Ryder System Inc., and chairman of the Health and Retirement Task Force of The Business Roundtable, said increased federal regulations would stifle quality innovations taking place in the private market. "The health care marketplace is evolving at breakneck speed. If Congress attempts to 'fix' the system through legislation, they will literally do no better than promising yesterday's medicine to tomorrow's patients."

Jerry Jasinowski, president of the National Association of Manufacturers (NAM) called PARCA "a dangerous prescription that the American public will ultimately have a hard time swallowing. Hundreds of new federal mandates will spike health care costs for families, cause employers to reduce benefits and stifle innovation." He pointed to a legal analysis of PARCA released by NAM that detailed more than 300 new federal requirements for group and individual health insurance plans, and more than 200 new federal requirements for self-insured plans.

The Chamber of Commerce highlighted provisions in the bill that would subject employers—not just health plans—to massive product liability-like lawsuits for acts beyond their control. Bruce Josten, Executive Vice President of the U.S. Chamber of Commerce, called the PARCA bill a "trial lawyer's dream, but an employer's nightmare."

The group released the first in a series of print ads. One ad features a graphic of Frankenstein accompanied by the headline, "Washington: Be Careful How You Play Doctor. You Might Mandate a Monster." The ad points out the unintended consequences of mandates—rising costs, more uninsured and a "monstrous bureaucracy." A second ad reads: "3 Million Employers and more than 100 Million Employees and Their Families have a Message for Washington: 'Don't Raise Our Health Care Costs.'" The copy ends with the statement that "government mandates to 'protect' health care quality could leave millions of Americans unprotected."

The coalition also released a letter to members of Congress urging them to "keep government out of the business of micromanaging health benefits," and polling results indicating that "regulating HMOs is significantly less likely to be supported when people realize it would raise premiums which could lead to more people not being covered." The polling memorandum was prepared by Public Opinion Strategies based on findings from a national survey conducted from January 11-14, 1998 among 800 registered voters.

The Health Benefits Coalition is a broad-based organization that believes the way to achieve affordable, quality health care is through broader coverage, choice and competition in the marketplace—not through government mandates.

###

105TH CONGRESS
2D SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

M. introduced the following bill; which was referred to the Committee on

A BILL

[To promote the establishment of HealthMarts to foster
greater quality and choice in health care coverage.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Health Care Consumer
5 Empowerment Act of 1998".

6 **SEC. 2. FINDINGS; PURPOSE.**

7 (a) **FINDINGS.**—Congress finds the following:

8 (1) [to be provided]

1 (2) Under section 106 of the Internal Revenue
2 Code of 1986, employers may permit their employees
3 to select health care coverage while maintaining the
4 tax exclusion of employer payments for such cov-
5 erage.

6 (b) PURPOSE.—The purposes of this Act are—

7 (1) [to be supplied]

8 **SEC. 3. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.**

9 The Public Health Service Act is amended by adding
10 at the end the following new title:

11 **"TITLE XXVIII—HEALTHMARTS**

12 **"SEC. 2801. DEFINITION OF HEALTHMART.**

13 "(a) IN GENERAL.—For purposes of this title, the
14 term 'HealthMart' means a legal entity that meets the fol-
15 lowing requirements:

16 "(1) ORGANIZATION.—The entity is operated
17 under the direction of a board of directors (or equiv-
18 alent body) which is composed of representatives of
19 the following (and includes representatives of each of
20 the following):

21 "(A) Employers with fewer than 500 em-
22 ployees.

23 "(B) Consumers.

— under direction
board

1 “(C) Health care providers, which may be
2 physicians, other health care professionals, and
3 health care facilities.

4 “(D) Entities, such as insurance compa-
5 nies and health maintenance organizations, that
6 underwrite or administer health benefits cov-
7 erage.

8 “(2) OFFERING HEALTH BENEFITS COV-
9 ERAGE.—

10 “(A) IN GENERAL.—The entity makes
11 available—

12 “(i) health benefits coverage that
13 meets the requirements of subsection (b);

14 “(ii) to members described in sub-
15 section (c)(2) who are associated with enti-
16 ties that have entered into a contract with
17 the entity;

18 “(iii) at rates that [do not vary
19 among members electing the same benefit
20 package and] comply with applicable State
21 requirements.

22 “(B) NO FINANCIAL UNDERWRITING.—The
23 entity does not assume financial or underwrit-
24 ing risk with respect to the coverage so offered.

*— makes coverage
available
at rates that
comply w/ state
requirements*

1 “(3) PROVISION OF ADMINISTRATIVE SERVICES
2 TO CONTRACTING ENTITIES.—

3 “(A) IN GENERAL.—The entity provides
4 administrative services for entities contracting
5 with the entity in cases in which the entity of-
6 fers health benefits coverage to members who
7 are eligible for such coverage because of em-
8 ployment or other relationship with such con-
9 tracting entities.

10 “(B) CONSTRUCTION.—Nothing in this
11 subsection shall be construed as preventing
12 such an entity from serving as an administra-
13 tive service organization to any other entity.

14 “(4) DISSEMINATION OF INFORMATION.—The
15 entity collects and disseminates consumer-oriented
16 information on the scope, effectiveness, and cost of
17 all coverage options offered through the entity to its
18 members and individuals who are eligible to enroll or
19 are enrolled through such members.

20 “(5) COMPLIANCE WITH STATE PARTNERSHIP
21 DISCLOSURE REQUIREMENTS.—The entity complies
22 with State financial disclosure requirements insofar
23 as such requirements would apply if the entity were
24 considered a partnership.

1 “(6) FILING INFORMATION.—The entity files
2 with the Federal Trade Commission such informa-
3 tion as the Commission may require to evidence its
4 compliance with the applicable requirements of this
5 title, including such rules as the Commission estab-
6 lishes to carry out this title. Such rules shall incor-
7 porate the principle of ‘file and use’ with respect to
8 such information.

9 “(b) HEALTH BENEFITS COVERAGE REQUIRE-
10 MENTS.—

11 “(1) COMPLIANCE WITH CONSUMER PROTEC-
12 TION REQUIREMENTS.—

13 “(A) IN GENERAL.—Any health benefits
14 coverage offered through a HealthMart shall be
15 underwritten by a carrier that meets all appli-
16 cable State and Federal standards relating to
17 consumer protection.

18 “(B) AFFECT OF ACCREDITATION.—A car-
19 rier may be treated as meeting the require-
20 ments of subparagraph (A) if the carrier is ac-
21 credited by a nationally-recognized accrediting
22 body as meeting such requirements or com-
23 parable standards.

24 “(2) TYPES OF COVERAGE.—The coverage of-
25 fered through a HealthMart may include any of the

1 following it if meets the other applicable require-
2 ments of this title:

3 "(A) Coverage through a health mainte-
4 nance organization.

5 "(B) Coverage that includes preferred pro-
6 vider benefits through a preferred provider or-
7 ganization.

8 "(C) Coverage through a provider-spon-
9 sored organization.

10 "(D) Indemnity coverage through an insur-
11 ance company.

12 "(E) High-deductible coverage offered in
13 connection with a contribution into a medical
14 savings account.

15 "(3) STANDARDIZATION OF BENEFITS.—Noth-
16 ing in this title shall be construed as preventing a
17 HealthMart from providing for uniformity in the
18 benefits provided in health benefits coverage offered
19 through the HealthMart.

20 "(c) CONTRACTING ENTITIES AND MEMBERSHIP.—

21 "(1) CONTRACTING ENTITIES.—

22 "(A) IN GENERAL.—The entity permits
23 any to contract with the entity for the provision
24 of health benefits coverage to members related

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[2nd Draft]

H.L.C.

7

1 to such an entity if the entity is in the service
2 area covered by the entity:

3 "(i) Any multiple employer welfare ar-
4 rangement (as defined in section 3(40) of
5 the Employee Retirement Income Security
6 Act of 1974).

7 "(ii) An employer that employ on av-
8 erage fewer than 500 employees.

9 "(iii) Self-employed individuals.

10 "(B) PERIOD OF CONTRACT.—The entity
11 may not require a contract under subparagraph
12 (A) to be effective for a period of longer than
13 12 months. The previous sentence shall not be
14 construed as preventing such a contract from
15 being extended for additional 12-month periods
16 or from the contracting entity voluntarily elect-
17 ing a contract period of longer than 12 months.

18 "(2) MEMBERS.—

19 "(A) IN GENERAL.—The following are in-
20 dividuals who are eligible to enroll for coverage
21 offered through a HealthMart (under rules es-
22 tablished to carry out this title):

23 "(i) With respect to a multiple em-
24 ployer welfare arrangement that is a con-
25 tracting entity with the HealthMart under

1 paragraph (1)(A), individuals who are em-
2 ployees (or dependents of such employees)
3 who are covered under the arrangement.

4 "(ii) With respect to an employer that
5 is that is a contracting entity with the
6 HealthMart under paragraph (1)(B), indi-
7 viduals who are employees (or dependents
8 of such employees) of the employer.

9 "(iii) With respect to a self-employed
10 individual who that is a contracting entity
11 with the HealthMart under paragraph
12 (1)(C), such an individual and the individ-
13 ual's dependents.

14 "(B) ENROLLMENT.—A HealthMart may
15 not deny coverage to an individual who is eligi-
16 ble to be so enrolled based on health status or
17 other factors, but may condition enrollment
18 (and continued enrollment) upon payment of re-
19 quired premiums and continuation of eligibility.

20 "(C) ANNUAL OPEN SEASON.—In the case of mem-
21 bers enrolled in health benefits coverage offered by a
22 HealthMart, the HealthMart shall provide for an annual
23 open season period during which such members may
24 change the coverage option in which the members are en-
25 rolled.

open season

1 SEC. 2802. PREEMPTION FROM CERTAIN STATE REQUIRE-
2 MENTS.

3 "(a) PREEMPTION FROM MINIMUM BENEFIT AND
4 GROUPING REQUIREMENTS.—State laws insofar as they
5 relate to any of the following are superseded and shall not
6 apply:

7 "(1) Minimum benefit requirements for health
8 coverage offered through a HealthMart.

9 [review need:] "(2) Requirements relating to
10 grouping and similar requirements that prevent the
11 pooling of risk within a HealthMart.

12 "(3) Requirements relating to required con-
13 tributions for purposes of pooling of premiums.

14 "(b) CONSTRUCTION.—Nothing in this section shall
15 be construed as preempting State laws relating to the fol-
16 lowing:

17 "(1) The regulation of underwriters of health
18 coverage, including solvency requirements.

19 "(2) The application of premium taxes and
20 similar levies.

21 "(3) The application of consumer protections
22 (other than those specifically relating to an item de-
23 scribed in subsection (a)).

1 SEC. 2803. ADMINISTRATION THROUGH FEDERAL TRADE
2 COMMISSION.

3 "(a) IN GENERAL.—The Federal Trade Commission
4 shall administer this title and is authorized to issue such
5 regulations as may be required to carry out this title.

6 "(b) ADMINISTRATION THROUGH HEALTH CARE
7 MARKETPLACE DIVISION.—

8 "(1) IN GENERAL.—The Federal Trade Com-
9 mission shall carry out its duties under this title
10 through a separate Health Care Marketplace Divi-
11 sion.

12 "(2) ADDITIONAL DUTIES.—In addition to
13 other responsibilities provided under this title, the
14 Health Care Marketplace Division is responsible
15 for—

16 "(A) oversight of the operations of
17 HealthMarts under this title;

18 "(B) the periodic submittal to Congress of
19 reports on the performance of HealthMarts
20 under this title under section 2804(b); and

21 "(C) establishing rules that define those
22 entities that will be recognized as nationally-
23 recognized accreditation bodies for purposes of
24 this title.

1 -SEC. 2804. EFFECTIVE FOR 10-YEAR PERIOD.

2 “(a) IN GENERAL.—The previous provisions of this
3 title shall only be effective during a 10-year period begin-
4 ning on the effective date of the rules promulgated by the
5 Federal Trade Commission to carry out this title.

6 “(b) PERIODIC REPORTS.—The Federal Trade Com-
7 mission shall submit to Congress reports every 30 months
8 during such 10-year period on the effectiveness of this title
9 in promoting coverage of uninsured individuals.”.

Scak
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File at the end
of "The Quality
Notebook."

DRAFT

Comparison of Proposed Federal Legislation for Managed Care Plans

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Scope and Preemptions	- Establish new federal regulatory structure for all network-based health plans, including group health plans operated under ERISA. All network-based health plans must comply with a broad range of new requirements - Indemnity plans are not subject many of the bill's requirements. - The bill shall not be construed to preempt any state law that provides protections for individuals that are equivalent to or stricter	- Applies to group health plans and health insurance issuers - State laws that prevent application of provisions preempted; more stringent state laws would not be preempted - Amends Public Health Service Act and ERISA to require plans to comply with provisions - Effective date is January 1, 1999	- Executive order directing all federal health plans to come into "substantial compliance" with Bill of Rights	- Applies to all group health plans and issuers of health insurance - Does not preempt state laws - Amends ERISA and the Public Health Service Act to establish various standards for group health plans and health insurance issuers in the group and individual markets - Establishes Health Quality Council to provide health care quality information and reports to Congress, the President, and consumers	- Requires all citizens to obtain a comprehensive benefits package, mostly from large purchasing cooperatives - Establishes National Health Board for regulation, and national health budget - States required to establish purchasing alliances - Employer mandate to finance 80% cost of basic benefits package, individual mandate for the remaining cost - State authority to establish single payer program

11-20

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Scope and Preemptions (cont.)	than the protections provided in the bill.			- Expands duties of Agency for Health Care policy & Research (AHCPR) to include the collection, analysis, and dissemination of health care quality information, and provide support to Health Quality Commission - HHS to contract with IOM to conduct studies concerning methods of collecting quality data and continuous quality improvement	- Applies ERISA preemption of state law only to regulation of employers and health plans in large employer plans - Amends ERISA to establish regulations, such as providing a guaranteed minimum benefits package and complying with information provisions, for employers and corporate alliances sponsoring health plans - Preempts State anti-managed care laws and State benefit and provider mandates - Premiums could grow no faster than the GDP

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
General Access	- Health plans required to provide access to a sufficient number, mix, and distribution of providers, in a variety of service sites, with reasonable promptness and reasonable proximity to the residences and workplaces of enrollees	- Health plans required to provide access to a sufficient number, distribution, and variety of qualified providers to ensure that all covered services are available and accessible in a timely manner	Bill of Rights: - Health plan should provide access to sufficient number, mix, and distribution of providers - Plan should ensure access to out-of-network providers at no greater cost to enrollee if appropriate provider is not available in-network	- No provision	- Minimum comprehensive benefits package guaranteed for all citizens - Specific copayments defined - Out-of-network cost-sharing, no balance billing by out-of-network physicians

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Emergency and Urgent Care	Health plans required to provide access to emergency and urgent care services within the service area at all times - "Prudent layperson" standard for determining emergency service, including "severe pain" - Coverage required for emergency services provided without prior authorization by both in- and out-of-network providers - Preauthorization determinations must be made within 30 minutes of request for urgent care services	- Health plans that include emergency services as covered benefits must cover emergency care provided by network and non-network providers without prior authorization - "Prudent layperson" standard for determining emergency service, including "severe pain" - Prohibits cost-sharing differentials between in- and out-of-network providers for emergency services - Requires plans to reimburse non-network providers at least as much as network providers would be reimbursed for the same services; does not prevent providers from balance-billing plans - Mandates coverage of maintenance and post-stabilization care,	Bill of Rights: - Patient has right to access emergency services when and where need arises - "Prudent layperson" standard for determining emergency coverage, including "severe pain" - Plans should cover out-of-network ED screening and stabilization, non-network providers should not bill patient charges in excess of plan's routine payments - ED personnel should contact patient's PCP as soon as possible	- Health plans provide coverage for emergency services must: - ensure that emergency services are available 24 hours a day and 7 days a week - cover emergency services provided by a non-network provider - Enrollees receiving emergency services from non-network providers are not liable for any amount greater than what would have been paid to network provider - Plans must pay non-network providers no less than what would be paid to network providers for same services - No prior authorization required - Plans must comply with post-stabilization guidelines developed by HHS Secretary	- Coverage included as part of the basic benefits package

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Emergency and Urgent Care (cont.)		as covered by guidelines established by Social Security Act or the Secretary, by non- network provider; cost- sharing and reimbursement provisions same as emergency care		- Prudent layperson standard, including "severe pain"	

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Access to Specialty Care	- Health plan must ensure access to medically or clinically necessary specialized treatment expertise, in the judgment of the <i>treating</i> health professional, in consultation with the patient - Direct access to relevant specialists for members with chronic illnesses or special health care needs, when medically or clinically indicated in the judgment of the <i>treating</i> health professional, in consultation with the patient	- Women allowed to designate a network Ob/Gyn as primary care provider - No prior authorization or referral from primary care provider required for routine gynecological care from in-network Ob/Gyn - For patients with conditions that require ongoing specialty care, specialist may be designated as PCP or may receive standing referral to specialist - If plan does not have appropriate specialist to treat enrollee within the network, plan must refer enrollee to non-network provider at no additional cost to enrollee	Bill of Rights: - Women should be allowed to choose a provider (including a gynecologist) for the provision of routine women's health care services - Direct access to specialty care for patients with complex or serious medical conditions that require ongoing specialty care	- Plan must provide plan sponsor and enrollees with a description of the procedures for obtaining specialty care referrals (see Consumer Information)	- Coverage included as part of basic benefits package

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Breast Cancer Treatment		- Plans prohibited from restricting length of stay to less than 48 hours following mastectomy, or 24 hours following lymph node dissection - Plans providing coverage for mastectomy must provide coverage for reconstructive surgery			
Continuity of Care	- Health plan must provide for continued coverage of services furnished by a provider for a "reasonable period of time" if change of provider would disrupt continuity	- Patients may continue to receive care from a terminated provider for a "transition period" of 90 days; longer time periods are permitted for pregnant, terminally ill, hospitalized or institutionalized people - No transition period if provider terminated for quality or fraud - Plan may require providers to accept plan's rates and abide by plan's policies	Bill of Rights: - Patients with chronic or disabling condition should be able to continue to receive care from provider for 60 days if provider is terminated or consumer changes plan - Providers must accept plan's rates as payment in full	- No provision	- No provision

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Medical Necessity	- Allows treating health professional, in consultation with the patient, to determine medical necessity for the purposes of specialty referral or direct access for the chronically ill or those with special health care needs	- Plan prohibited from "arbitrarily" interfering with or altering decision of physician for services that are "medically necessary or appropriate" - "Medically necessary or appropriate" defined as a service "consistent with generally accepted principles of professional medical practice" - Does not prohibit plan from conducting utilization review activities	- No provision	- No provision	- Federal government may amend basic benefits package to include technological and other medical advances deemed medically necessary

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Prescription Drugs	- No provision	- A plan limiting prescription drug coverage to a formulary is required to: - involve physicians in development of formulary - disclose nature of formulary restrictions to providers and enrollees - provide exemptions non-formulary alternative is indicated (subject to plan review) - Plan covering prescription drugs or medical devices may not deny coverage of a drug or device on the basis that the use is investigational if the use is included in the labeling authorized by the Federal Food, Drug, and Cosmetic Act	- No provision	- Upon request of enrollee or plan sponsor, plans using a formulary must provide a description of the specific prescription medications included in the formulary (see Consumer Information)	- Coverage included as part of the basic benefits package

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Clinical Trials	- No provision	- Plans prohibited from denying a "qualified individual" participation in approved clinical trial - Approved clinical trials must be funded by one or more of the following: - National Institutes of Health (NIH) - a cooperative group or center of NIH - either the Department of Veterans Affairs or Department of Defense, subject to several restrictions - "Qualified individual" defined as enrollee with life-threatening or serious illness for which no standard treatment is effective, enrollee meets the trial's eligibility protocol, and participation "offers meaningful potential for significant clinical benefit for the individual"	Recommendation: - Increase Federal funding for health care research, including basic, clinical, prevention, and health services research; sustain network of research centers through NIH, AHCPR, CDC, etc. - Collaboration between researchers and public and private organizations to support research, make patients available for clinical trials, and provide training	- Plan must provide enrollee and plan sponsor with a description of access to clinical trials (see Consumer Information)	- No provision

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Clinical Trials (cont.)		- Referring physician must conclude, or enrollee must provide medical and scientific information establishing, that participation in trial is appropriate - Plans required to pay for costs of routine patient care of such enrollees, but not costs that "are reasonably expected to be paid by the sponsor of the trial." - Plan must pay non-network provider the same as a network provider for covered items and services			

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Choice of Provider	- Enrollees may select a personal health professional from participating providers, and change that selection as appropriate.	- Enrollees may select PCP from any network PCP who "is available to accept" the enrollee - Enrollee may select any qualified network specialist who is available to receive "medically necessary or appropriate specialty care," pursuant to "appropriate referral procedures"	Bill of Rights: - Consumers have a right to a choice of health care providers that is sufficient to assure access to appropriate high-quality health care	- Plans must provide plan sponsors and enrollees with a description of - the extent to which an enrollee may choose a primary care provider - upon request, the names, locations, accreditation status, and tax status of participating providers (see Consumer Information)	- Health plans must contract with "essential community providers" and academic health centers

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Choice of Plan/Mandatory POS	- Health plan required to offer POS option - Plan must reimburse out-of-network providers at rates not less than those for participating providers; enrollee may be "balanced billed" by out-of-network provider	- Plans would be required to offer POS product to employees who are offered only one closed-panel HMO; employer not responsible for contributing to premium	Bill of Rights and Recommendations: - Public and private purchasers should offer consumers a choice of health plans wherever feasible - Small employers should be provided with greater assistance in offering a choice of health plans Recommendations: - Group purchasers should use quality as a factor in selecting plans to offer, and implement strategies to improve quality	- No provision	- Alliances and large employers must offer a choice of at least three plans: low cost-sharing, high cost-sharing, and a combination of the two - Any plan offering a low cost-sharing option must also offer a POS option - Alliances required to contract with all certified plans (unless plan's premium exceeds a certain target)

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Non-Discrimination Against Enrollees	- Health plans prohibited from discriminating against enrollee on the basis of race, national origin, gender, language, socio-economic status, age, disability, health status, or anticipated need for health care services	- Health plans prohibited from discriminating against enrollee in the delivery of services on the basis of race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment	Bill of Rights: - Prohibits discrimination against consumers on the basis of race, ethnicity, national origin, religion, sex, age, current or anticipated mental or physical disability, sexual orientation, genetic information, or source of payment - Consumers have a right to considerate, respectful care	- No provision.	- Certified health plan required to guarantee issue and renewal to every eligible person enrolled by an alliance, and cannot terminate or limit coverage - Mandates community rating - Plans prohibited from engaging in any practice that has the effect of attracting or limiting enrollees on the basis of personal characteristics, anticipated need for health care, age, occupation, or affiliation with any person or entity - On full implementation, prohibits plans from imposing preexisting condition exclusions; exclusions allowed during transition

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Utilization Review	- UR program required for all plans - Mandatory UR standards - Provider input required for all medical policies, UR policies, quality and credentialing activities, and medical management procedures - Must use licensed, accredited, or certified providers for review determinations - Peer review required for adverse determinations by professional in same or similar specialty - Prohibits financial incentives for denials	Plan must have UR program, or contract with outside entity to perform UR; program must meet the following standards: - UR standards must be written - Previously authorized services may not be changed during retrospective review - UR program must be administered by qualified health care professional - Peer review required for at least a sample adverse determinations - UR program may not provide incentives for reviewers to make inappropriate decisions or base compensation on the quantity and type of adverse determinations rendered	- No provision	- Plans must have procedures in place for making coverage determinations, notifying enrollee and treating health care professional of determination, and responding to oral or written request for determinations For routine prior authorization determinations: - plans must make prior authorization determinations within 15 days of receipt of request - plan required to make determination within 2 working days after complete information is obtained	- Plans must meet federal standards for data management reporting and utilization management established by National Health Board

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Utilization Review (cont.)	- 30 minute standard for prior authorization of urgent care; 24 hours for other services - 30 day standard for notice of initial determinations when no prior review required - Favorable prior authorization determination must be treated as final for payment purposes - Disclose names and credentials of reviewers to providers, upon request, subject to reasonable safeguards	- Health care professional providing services may not be involved in review decision - Enrollee or provider acting on behalf or enrollee must have opportunity to discuss adverse review decision with medical director of plan involved - Prior authorization determinations provided as soon as possible, and no later than 3 business days after date of receipt of necessary information - Concurrent review determinations provided as soon as possible, and no later than 1 business day after receipt of necessary information - Retrospective review of services within 30 days of receipt of necessary information		- plan required to notify treating health professional within 24 hours after determination is made, and must provide written or electronic confirmation within 2 working days of initial notice for approved request, 1 working day for adverse determination For expedited prior authorization determinations: - plan required to make expedited prior authorization if treating health professional certifies that time frame for a routine prior authorization would seriously jeopardize enrollee's life, health, or ability to regain maximum function	

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Utilization Review (cont.)		- Written notice required for adverse determination, including reasons for determination and instructions for appeal		- Plan required to make determination and notify enrollee and treating health professional of determination within 72 hours of receipt of request, with written confirmation required within 2 working days of initial notice For concurrent review determinations: - Plans required to notify treating health professional within 1 working day of making determination and provide written or electronic confirmation to treating health professional and enrollee within 1 working day of initial notice	

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Utilization Review (cont.)				For retrospective review determinations: - plan required to make determination within 30 working days after receiving all necessary information - plan required to provide written notice to health care provider and enrollee within 5 working days after determination	

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Internal Grievance and Appeals	- Internal grievance process required for adverse UR determinations and for enrollee complaints of inadequate access - Review of prior authorization decisions within 1 hour for urgent care, 24 hours for other care - Initial determination in claims payment within 30 days - Reviewers must be appropriate clinical peer professionals in same or similar specialty	Grievances: - Internal grievance process required for written or oral grievances brought by enrollees, or providers or other individuals acting on behalf of enrollee - Grievances may be brought with regards to access to services, quality of care, choice and accessibility of providers, and network adequacy - Grievance system must include: - written notification - system to record and document grievances and appeals for at least 3 years - process for timely resolution - procedures for follow-up action - notice to quality improvement program of all grievances and appeals	Bill of Rights: - Internal appeals system, including written notification of decisions, resolution in a timely manner, review by appropriate medical personnel Recommendations: - Internal and external appeals processes should comply with Bill of Rights	Appeals of Coverage Determinations - Written notice of adverse determination must include reasons for determination, procedures for obtaining additional information, and instructions on rights and procedure for appealing decision - Enrollee (or individual acting on behalf of enrollee) and treating provider with consent of enrollee must have opportunity to appeal adverse determinations orally or in writing - Internal appeals must be conducted by individuals not involved in initial determination and who are health professionals knowledgeable about the condition and treatment involved	- Plans must meet federal standards established by National Health Board

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Internal Grievance and Appeals (cont.)		Appeals of Adverse Determinations - Plans must have internal appeal process - Standard of 72 hours for review of expedited appeals, no longer than 15 days for other care - Expedited appeals process when normal time frame could "seriously jeopardize the life or health ... so ability to regain maximum function" of enrollee Enrollee or provider or other person acting on behalf of enrollee may appeal: - denial, reduction, termination of, or failure to pay for a benefit - a benefit normally covered but denied because it is deemed experimental, investigational, or not medically necessary or appropriate		- Any medical necessity determination must be made by a physician with expertise in the field of medicine involved - Plans must maintain written records of all appeals - Plans required to make routine internal appeal determinations within 30 days after receipt of request, and notify treating health professional and enrollee within 2 working days after decision is made - Plans required to make expedited appeal decisions if treating health professional certifies that routine internal appeal would seriously jeopardize an enrollee's life, health, or ability to regain maximum function	

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Internal Grievance and Appeals (cont.)		- failure to cover emergency services or post-stabilization care - failure to provide: - choice of provider - qualified health care providers - access to specialty and other care - continuation of care - coverage of routine patient costs in connection with clinical trial - access to needed drugs - discrimination in delivery of services - adverse determination under utilization review program - Review must be conducted by health care professional and clinical peer not involved in initial decision - Plan must provide written notification of denial		- Plans required to make expedited appeal decision and to notify treating health professional and enrollee of the decision in writing within 72 hours of receipt of request - If routine or expedited internal appeal decision is adverse, notice must include information on how to appeal to an external review panel	

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
External/ Independent Review of Appeals	- Provides for independent review of appeals determinations and enrollee complaints about inadequate access - Reviewer must be appropriate clinical peer - Reviewer must not be involved in plan operation	- Plan must provide external appeal process for adverse determinations that: - involve an amount that exceeds a significant threshold; or - the patient's life or health is jeopardized as a consequence of the decision - Plan may require that enrollee exhaust internal appeal process - "Qualified external appeal entities" designated by state for health insurance issuers, by Secretary for group health plans - Plan contracts with external appeal entity and pay for cost of appeal; plan not liable for cost of enrollee's representation - Review process must provide for fair, de novo determination	Bill of Rights: - External appeals system available after internal processes exhausted, including review by appropriate medical personnel in a timely manner, evidence-based decision making - External appeals applied to coverage decisions concerning treatment that is "experimental or investigational in nature," services that are "medically necessary" and "the amount exceeds a significant threshold or the patient's life or health is jeopardized"	- Adverse appeal determinations must include written information on how to appeal to external entity - Health plans must have written procedures for enrollee, or treating health care professional with the consent of the enrollee, to appeal adverse determination of covered services that cost at least \$1,000 - Appropriate State agent designates individuals eligible to serve on external review panel - Enrollee must file for external review within 30 days of receipt of adverse internal appeal determination - Plan liable for cost of external review	- Plans must establish a benefit claims dispute procedure, providing consumers the right to appeal to alliance ombudsman or pursue other legal remedies - Expedited preauthorization requirements - Plans must meet federal standards established by National Health Board

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
External/ Independent Review of Appeals (cont.)		- Each party may use the assistance of representation, including an attorney - Determinations binding on plan, not binding on enrollee - Determination must be made within 72 hours for expedited appeal, 60 days for all others - Enrollees not prohibited from exercising additional legal rights under State and Federal law		- External review panel designated from among organizations and individuals who are licensed to conduct appeals by an agent of a State, by the State itself, or if the State declines to perform licensure, HHS or DOL; individuals designated to panel required to meet conflict of interest requirements and would be protected from liability for determinations of the panel - Panel appointed by: - State agent, for fully-insured plans or plans where plan sponsor directly provided health care under plan - plan fiduciary, for self-insured plans - Enrollee may either accept or reject review panel within 15 days of	

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External/ Independent Review of Appeals (cont.)				initial designation; if rejected, enrollee may select alternative eligible individuals - External review must be completed within 30 days of approval of panel or receipt of all necessary information - Panel must follow standard of review that promotes evidence-based decision making and must take into consideration benefits and coverage under terms and conditions of plan - Panel must provide notification of decision to plan, enrollee, involved health care profession, and State agent responsible for panel designation - Determination by external appeals panel binding on plan, but would not prevent civil action	

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Provider Contracting	Health plans must: - Allow all providers in service area to apply to network at least once per year - Provide for each application to be reviewed by credentialing committee - Select providers based on objective, publicly-available standards of quality - Adjust economic profiling to recognize patient characteristics that may affect utilization - Make profiling results available to purchasers, enrollees, provider - Notify providers undergoing credentialing of any information indicating that they do not meet plan standards - Offer such providers the opportunity to review information and submit	- Health plan required to have written procedures and standards for provider selection - Plans prohibited from basing exclusion of provider on health status of his/her patients - Plans prohibited from discriminating in selection of providers based upon license or certification - Plans allowed to exclude providers to the extent that they have already met the needs of the plan's enrollees - Plans prohibited from discriminating against providers on the basis of race, color, religion, sex, national origin, age, sexual orientation, or disability - Plans must provide rules of participation to providers	- No provision	- Plans required to establish procedures governing selection of participating health care professionals and to provide written notice to health care professionals of these procedures, as well as adverse participation decisions and process for appealing such decisions - Group health plans required to assure the organization responsible for maintaining provider network complies with same requirements - No prohibition of termination of provider contracts without cause	- Plans prohibited from discriminating against providers in the selection of providers for its network on the basis of personal characteristics, anticipated need for health care, age, occupation, or affiliation with any person or entity - Plans must meet federal standards for verification of provider credentials established by National Health Board - Physicians allowed to contract with multiple plans

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Provider Contracting (cont.)	supplemental or corrective information - Prohibits "without cause" termination provisions in provider contracts, plan must provide reasonable notice of decision to terminate for cause - Appeals process must conform to Health Care Quality Improvement Act of 1986 - Health plans prohibited from discriminating against selection of network provider also on the basis of race, national origin, gender, age, disability, or lack of affiliation with a hospital - Health plans prohibited from discriminating against providers in participation, reimbursement, or indemnification on the basis of licensure or certification	- Plans must provide written notice of participation decisions to providers, and have a process for providers to appeal adverse participation determinations - Prohibits contracts between plans and providers that transfer liability relating to activities, actions or omissions of the plan to the provider - Plans prohibited from retaliating against health care professional for "whistleblowing" conducted in good faith - "Whistleblower" still subject to federal and state confidentiality standards			

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Physician/Patient Communication	- Prohibits contract agreements between health plans and providers that restrict provider from engaging in "medical communications" with patients - "Medical communication" includes communications between provider and patient with respect to health status, medical care, and utilization review requirements or financial incentives that may affect treatment	- Prohibits contract agreements between health plans and providers that prohibit or restrict providers from engaging in medical communications with patients	Bill of Rights: - Physicians should discuss all treatment options with patient - Physicians should abide by treatment decisions made by patients Providers should: - Discuss methods of compensation, ownership or interest in health care facility, etc., that could influence treatment decision - Assure that contracts do not include restrictions on patient/provider communication - Protect health care professionals from retribution resulting from patient advocacy	- Prohibits plans and issuers from penalizing providers for advocating on behalf of enrollee or assisting enrollees in appeals	- No provision

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Incentive Plans	Health plan's provider incentive plan, defined as compensation arrangement that may directly or indirectly have the effect of reducing or limiting services provided, must meet the following requirements: - no payment made directly or indirectly to provider as inducement to limit medically necessary services - plans placing provider or provider group at substantial financial risk must provide appropriate stop-loss coverage and conduct periodic surveys of current and previously enrolled to determine access and satisfaction measures - plan must provide Secretary with information regarding incentive plans to determine compliance	- Health plans prohibited from establishing physician incentive plans other than those permitted by Medicare and Medicaid	- No provision	- No provision	- No provision

Issue	D'Amato (S. 644)/ Norwood (H.R. 1415) "The Patient Access to Responsible Care Act of 1997"	Dingell (H.R. 3605)/ Daschle (S. 1890 and S. 1891) "Patients' Bill of Rights Act of 1998"	Presidential Advisory Commission: Consumer Bill of Rights and Summary of Recommendations	Jeffords (S.1712) "Health Care QUEST Act"	Clinton (H.R. 3600/S. 1757) "Health Security Act," 1994
Consumer Information	Health plans must provide current and prospective enrollees with information in the following areas: - coverage and excluded benefits - enrollee financial obligations - number, mix, and distribution of providers, ratio of providers to enrollees - description of prior authorization/UR processes - grievance and appeals processes - quality indicators - utilization data - provider selection standards - provider financial incentives/payment methods - UR criteria - plan loss ratios	Health plans required to provide information to current and prospective enrollees, and the public, information in the following areas: - service area - coverage and excluded benefits - enrollee financial obligations - out-of-network benefits - choice of providers - process for determining experimental coverage - use of a prescription drug formulary - the number, mix, and distribution of covered providers - any POS option - procedures for selecting or changing providers - referral procedures - provider addresses and telephone numbers, as well as availability to accept patients	Bill of Rights: Health plans should provide consumers information concerning: - covered benefits - cost sharing - dispute resolution mechanisms - licensure, certification, and accreditation status - quality and consumer satisfaction measures - network composition - access to specialists and emergency care - provider credentials - provider-specific and facility-specific quality and satisfaction measures - experience of health care facilities Recommendations: - Develop consumer education strategy to encourage the use of quality information when choosing plans,	- Plan sponsors of group health plans required to furnish participants with a summary plan description of each health plan option upon the beginning of an individual's employment and at the beginning of any open enrollment period - Plan sponsors required to provide most recent summary plan description at least annually (if a material modification occurred) and upon the request of a participant or beneficiary - Plan sponsor required to notify participants and beneficiaries within 30 days of any material changes in benefits; service area; out-of-area or out-of-network coverage; prior	- Plans required to provide information on cost, consumer satisfaction, provider qualifications, utilization, quality assurance procedures, rights and responsibilities of consumers and patients - National Health Board required to develop a health information system to collect, report, and regulate the collection and dissemination of health information - Plans selling through alliances prohibited from distributing false or misleading marketing material. All marketing material must have prior approval of alliance.

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Consumer Information (cont.)	The Secretary, in collaboration with the Secretary of Labor, shall issue regulations to establish: - the styles and sizes of type to be used with respect to appearance of above consumer information; - standards for the publication of the information to ensure that the publication is readily accessible and in easily understandable language - the placement and positioning of information in health plan marketing materials	- plan process for meeting needs of non-English speaking enrollees or enrollees with special communication needs - out-of-area coverage - coverage of emergency services - medical loss ratio - prior authorization rules - grievance and appeals procedures - summary of quality data - provider financial incentives The following information must be made available upon request: - utilization review procedures - number and outcomes of grievances and appeals - method of physician compensation - credentials of participating providers - confidentiality policies	providers, and treatments - Strengthen role of public and private entities in providing information to consumers, including funding consumer information and assistance programs and conducting research on best methods of providing consumer information	authorization rules; and grievance and appeals procedures - Sponsors of group health plans with 100 or more participants required to provide participants with annual summary report on consumer satisfaction survey results (and disenrollment rates) for all health plan options involving a health insurance issuer with which the sponsor has had a contract for at least 2 years Within 12 months of enactment, issuers of health insurance coverage required to provide for disclosure to plan sponsors and enrollees, and, upon request, to potential sponsors and enrollees, the following information:	- Plans prohibited from marketing selectively.

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Consumer Information (cont.)		- formulary restrictions - participating provider list		- covered benefits, including in- and out-of-network benefits - cost-sharing, including annual and lifetime limits - optional supplemental coverage - service area - selection of a primary care physician - specialty referrals - summary data on enrollee satisfaction, including disenrollment rates - advance directives and organ donation - prior authorization requirements - grievance and appeals - emergency services - licensure, certification, and accreditation status - coverage of and access to experimental or investigation treatments and clinical trials - quality indicators and outcomes measures	

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Consumer Information (cont.)				Information to be made available upon request: - additional quality and health outcomes information - specific health care professional and facility information - description of methods used to compensate physicians - description of utilization review procedures - description of specific exclusions from coverage - description of specific covered preventive services - description of availability of translation and interpretation services - prescription medications included in the formulary - description of number and outcome of requests for external review the preceding year	

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Confidentiality	- Plan required to establish procedures to protect "individually identifiable medical information" consistent with State and Federal law	- Plans required to establish procedures to "safeguard the privacy of any individually identifiable enrollee information" - Plan required to maintain records and information in an "accurate and timely" manner - Plans required to "assure timely access of such individuals" to records and information	Bill of Rights: - "Individually-identifiable" medical information disclosed for health purposes only (including the provision of health care, peer review, health promotion, disease management, and quality assurance) - Consumers may review and copy their own medical records and request amendments to records - Written consent for disclosure required except in limited legal circumstances (under consideration) Recommendations: - Health care organizations take steps to protect confidentiality of patient information	- Plan must have procedures to safeguard privacy of individually identifiable enrollee information	- National Health Board must develop proposal for legislation to provide comprehensive scheme of Federal privacy protection for individually identifiable health information - National Health Board must establish federal standards to safeguard the privacy of individually identifiable health information

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Solvency	- Health plans required to meet financial reserve or other solvency-related requirements developed by the State authority, and establish mechanisms to protect enrollees and providers if the plan becomes insolvent - Such requirements could not "unduly impede the establishment" of health plans owned and operated by providers or non-profit community-based organizations	- No provision	- No provision	- No provision	- Plans must meet requirements developed by National Health Board - States responsible for ensuring plan solvency and operating guaranty funds

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Quality Improvement	- Health issuers must establish a quality improvement program that systematically and continuously assesses and improves the quality of care and plans' administrative functions	- Plan required to establish internal QA program that is administered by a "separate identifiable unit" of the plan - Plan must have written plan for the program that is updated annually - Program must provide systematic review of services and patient outcomes - Program must use various quality criteria - Program must have procedures for reporting quality concerns and initiating remedial actions - Plan must have drug utilization review program to improve quality - QA requirements waived for federally-qualified HMOs or plan accredited by approved accrediting body	Recommendations: Create Advisory Council on Health Care Quality; Council would: - create national aims and objectives for improving health care quality - develop core sets of quality measures for standardized reporting by each sector of health care industry - make available comparative quality information on health care organizations, providers, and insurers available to public - implement Consumer Bill of Rights - assess proposals to improve quality and recommend strategies to do so - issue annual report on findings and recommendations	- Health Quality Council of 9 members appointed by Comptroller General; consists of individuals with experience in various areas of the health care sector - Council members serve staggered 4-year terms; authorized to hold hearings, meet, take testimony, establish advisory committees, secure necessary information from Federal departments and agencies Council's general duties include: - provide information and develop impact statements on health care quality and consumer protection legislation to Congress and President	- Health plans offering standard benefits package must be State-certified (except self-insured plans) and meet specified federal standards for quality, solvency, and capacity - National Health Board must establish and oversee National Quality Management Program administered by National Quality Management Council - Council must develop national health measures of quality, set quality standards and goals - Council to develop and review clinically relevant practice guidelines - National Health Board must establish National Quality Consortium to establish continuing education programs,

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Quality Improvement (cont.)		Plans required to collect uniform quality data that include a minimum uniform data set, including data on: - utilization - demographic characteristics of enrollees - disease-specific and age-specific mortality and morbidity rates - satisfaction, including voluntary disenrollment and grievances - quality indicators and outcomes - Establishes Health Care Quality Advisory Board, comprised of Secretary of HHS and Secretary of DOL, and 20 Presidentially-appointed members representing a variety of health care constituencies	Create Forum for Health Quality Measurement; duties include: - devise plan form implementing data collection and reporting standards developed by Advisory Council - identify and update core sets of quality measures and reporting standards - assist council on research agenda - foster development of improved information systems - Increase focus on quality of care for vulnerable populations Quality oversight organizations should: - incorporate Bill of Rights into contractual oversight requirements	- develop and disseminate population-based quality indicators using process specified by IOM, and recommend indicators and measures to HHS and DOL; updated every two years - provide annual "state of the nation" report on health care quality; every 2 years, recommend to Congress and President national goals for quality improvement and how to achieve them - every 2 years, report to Congress and President on one of several health care issues - provide recommendations on measuring and reporting quality indicators in fee-for-service market	education program, develop regional professional foundations - Alliances required to publish annual reports on the performance of each plan and consumer surveys - AHCPR to develop and review practice guidelines

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Quality Improvement (cont.)		- Duties of the Board include: - identify, collect, and disseminate health care quality data (for network and non-network plans), in consultation with health care standard setting bodies (e.g., AHCPR) - advise Secretary regarding minimum data set and standardized formats for information - provide annual report on quality of health care in the U.S.	- assist Council and Forum in data reporting - take steps to increase confidence in oversight process - take steps to move to a common set of quality standards and coordinate their quality oversight processes - Develop health care error reporting system - Foster greater sharing of innovations, best practices, practice protocols, etc. among health care organizations - Take steps to improve health care workforce and work environment	- develop data sampling methods for monitoring quality and outcomes measures, in consultation with AHCPR - HHS to contract with IOM to conduct studies regarding: - development of population-based benchmarks - presentation of information to consumers, providers, and purchasers - national quality improvement process AHCPR duties expanded to provide administrative and scientific support to Council, including: - develop risk and case mix adjustments for data comparison	

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Quality Improvement (cont.)				- compile, disseminate, and develop standard format for data on quality indicators and outcomes - assist in developing improved information systems - maintain and disseminate population-based quality benchmarks developed by Council - coordinate quality activities with health plan accrediting bodies, federal agencies, and state governments - develop survey tool for measuring consumer satisfaction in group health plans - plans required to submit aggregate quality and outcomes data, without patient identifiers, to AHCPR	

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Liability	- The bill shall not be construed to preclude any State cause of action to recover damages for personal injury or wrongful death against "any person that provides insurance or administrative services to or for an employee welfare benefit plan maintained to provide health care benefits."	- Plans, including those operating under ERISA, would be liable under state causes of action for injury or death resulting from plan determinations	Recommendations: - Calls for national dialogue regarding current state of remedies for individuals injured as a result of inappropriate health care decisions	- No provision	- Secretary must establish a demonstration project to test the concept of enterprise liability, where health plan rather than individual physician assumes liability - Includes tort reforms, and all alliance plans would be required to adopt at least one ADR method developed by National Health Board
Ombudsman	- No provision	- Federal funding authorized for grants to States to establish health insurance ombudsman program - Secretary would establish ombudsman programs through an independent, not-for-profit organization in States not participating in grant program	- No provision	- No provision	- States must establish regional purchasing cooperatives that would perform ombudsman functions

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Pct - oho

- Pull Bill
- Protect
- Assure Quality

- Improve Quality - Forum started

NCOA

Business - Powerhouse.

WHY ERISA PREEMPTION MATTERS

In the debate about protecting consumers against potential managed care abuses, a federal law known as the Employee Retirement Income Security Act (ERISA) is more important than many people realize. ERISA was passed in 1974 to regulate all private employer-based benefit plans, including health care plans. Because the majority of American workers and their families receive their health care insurance through their employer, ERISA's influence is far-reaching. Today, ERISA covers approximately 122 million Americans or an estimated 63% of the non-elderly insured population in the United States.

ERISA was enacted primarily to address abuses in private sector pension plans. Although health plans and other employee welfare benefit plans were covered under ERISA, there was very little substantive regulation enacted within ERISA's initial framework. In the 24 years since ERISA was enacted, only a few laws have been passed to provide additional requirements for health care plans, and most of these have dealt with expanding the portability of insurance coverage rather than regulating the benefits the plans provide or their quality.

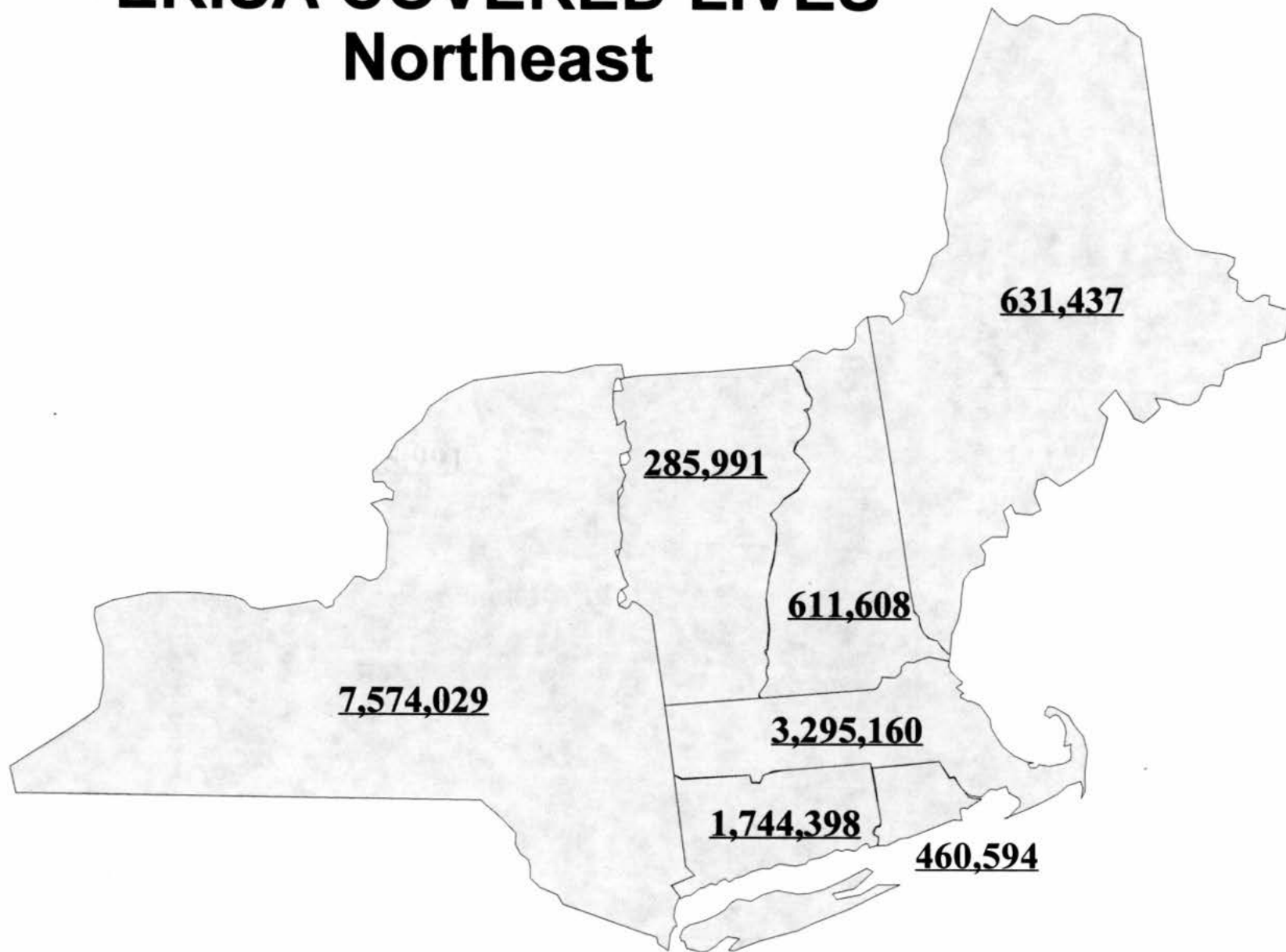
ERISA's minimal regulation of health plans is especially important because ERISA prevents many state laws from regulating these plans. The technical rules of ERISA preemption are complex and have continued to evolve as the federal courts have interpreted ERISA. The basic rules allow many state laws to apply to health insurance policies that an employer purchases from an insurance company. However, such state laws do not apply where the employer elects to "self-insure," or pays all of the costs of the plan directly. Today, an estimated 40% of individuals are in self-insured plans and therefore are not covered by any state laws. Under the Supreme Court's interpretation of ERISA, state laws that allow individuals to seek compensation for an injury caused by a plans' wrongful denial or delay of benefits do not apply to all ERISA plans, both self-insured and others. Following the court's interpretation, it is also possible that some other state laws that provide protections that ERISA addresses, including information disclosure and grievance and appeal procedure requirements, could be blocked from applying to all ERISA plans.

The ultimate impact of ERISA's preemption is that many state laws providing important consumer protections are prevented from applying to individuals covered by employer-based plans. The absence of meaningful regulation of many of these health care plans has become increasingly problematic for consumers with the dramatic increase in managed care enrollment in employer plans over the past decade, from 2% in 1980 to 81% in 1997. These managed care arrangements have raised concerns among consumers about the need for greater regulation to prevent abuses and provide protections when such abuses occur. The majority of states have responded to these concerns by enacting laws that provide protections for consumers enrolled in managed care organizations, including laws requiring direct access to Ob-Gyns and other specialists, banning physician "gag clauses," requiring that emergency services be provided according to a "prudent layperson" standard, and providing individuals with benefit disputes the right to an independent external review. However, even if every state were to enact such laws, most of them would not apply to the 50 million Americans in self-insured plans and some of them may not apply to the remaining 72 million Americans in other ERISA plans.

Because ERISA is a federal law, the only way to assure that all ERISA plan participants will be provided with appropriate consumer protections is for Congress to pass legislation to amend ERISA.

ERISA COVERED LIVES

Northeast

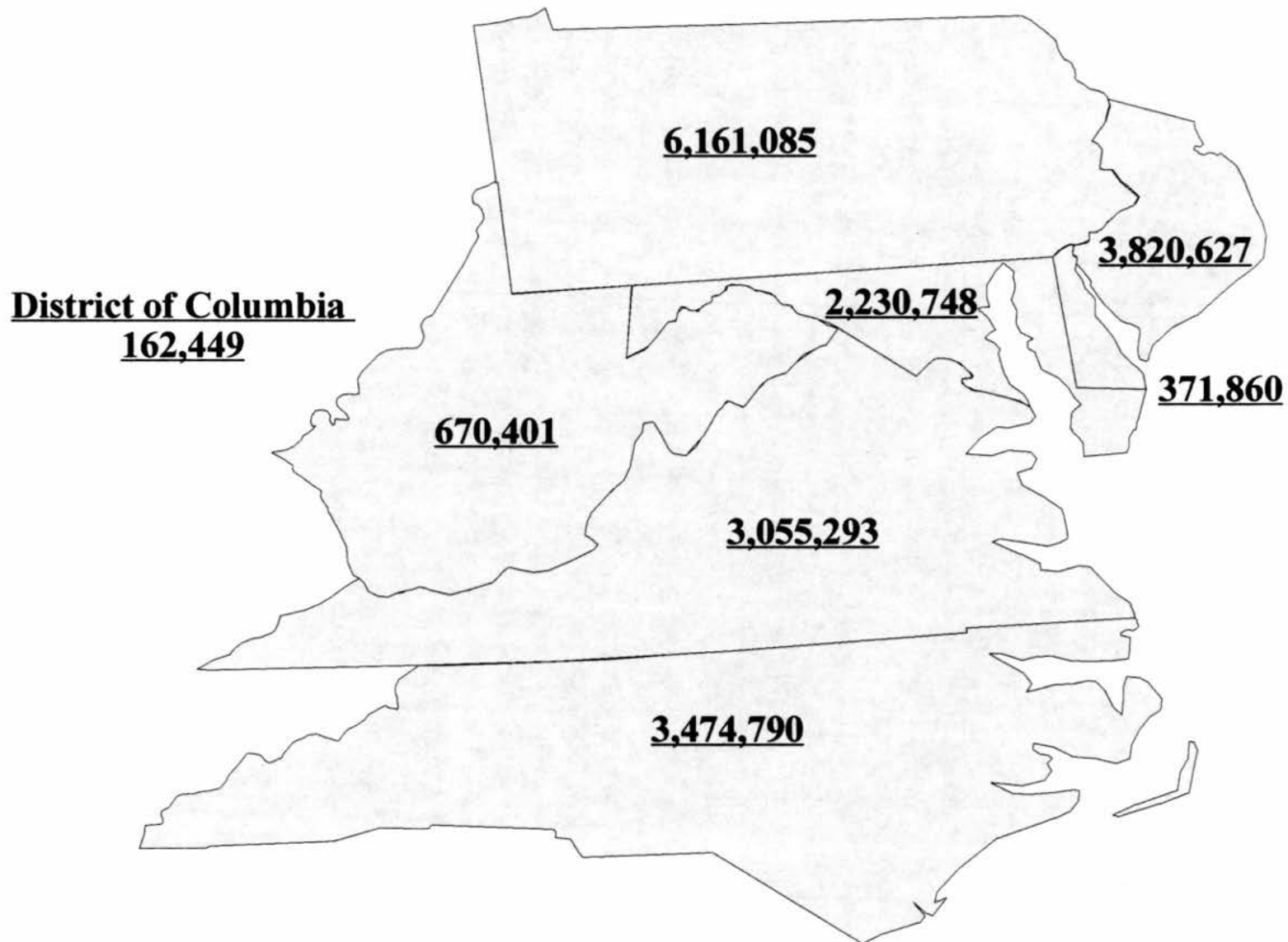


PRIVATE EMPLOYMENT BASED COVERAGE — Nonelderly (<65)

STATE	TOTAL	BY GENDER		By Insurance Status		
		Male	Female	Own Name	Spouse	Other Depen.
Northeast	14,603,216	7,309,129	7,293,463	7,417,372	2,563,744	4,641,664
Maine	631,437	317,425	313,989	337,963	111,737	182,096
New Hampshire	611,608	323,570	288,016	298,042	123,027	190,593
Vermont	285,991	143,371	142,631	133,873	58,788	93,895
Massachusetts	3,295,160	1,692,439	1,602,218	1,649,536	583,135	1,064,643
Rhode Island	460,594	227,428	233,075	236,769	90,940	133,130
Connecticut	1,744,398	832,914	911,637	827,090	339,982	579,318
New York	7,574,029	3,771,983	3,801,897	3,934,098	1,256,136	2,397,989

ERISA COVERED LIVES

Mid-Atlantic

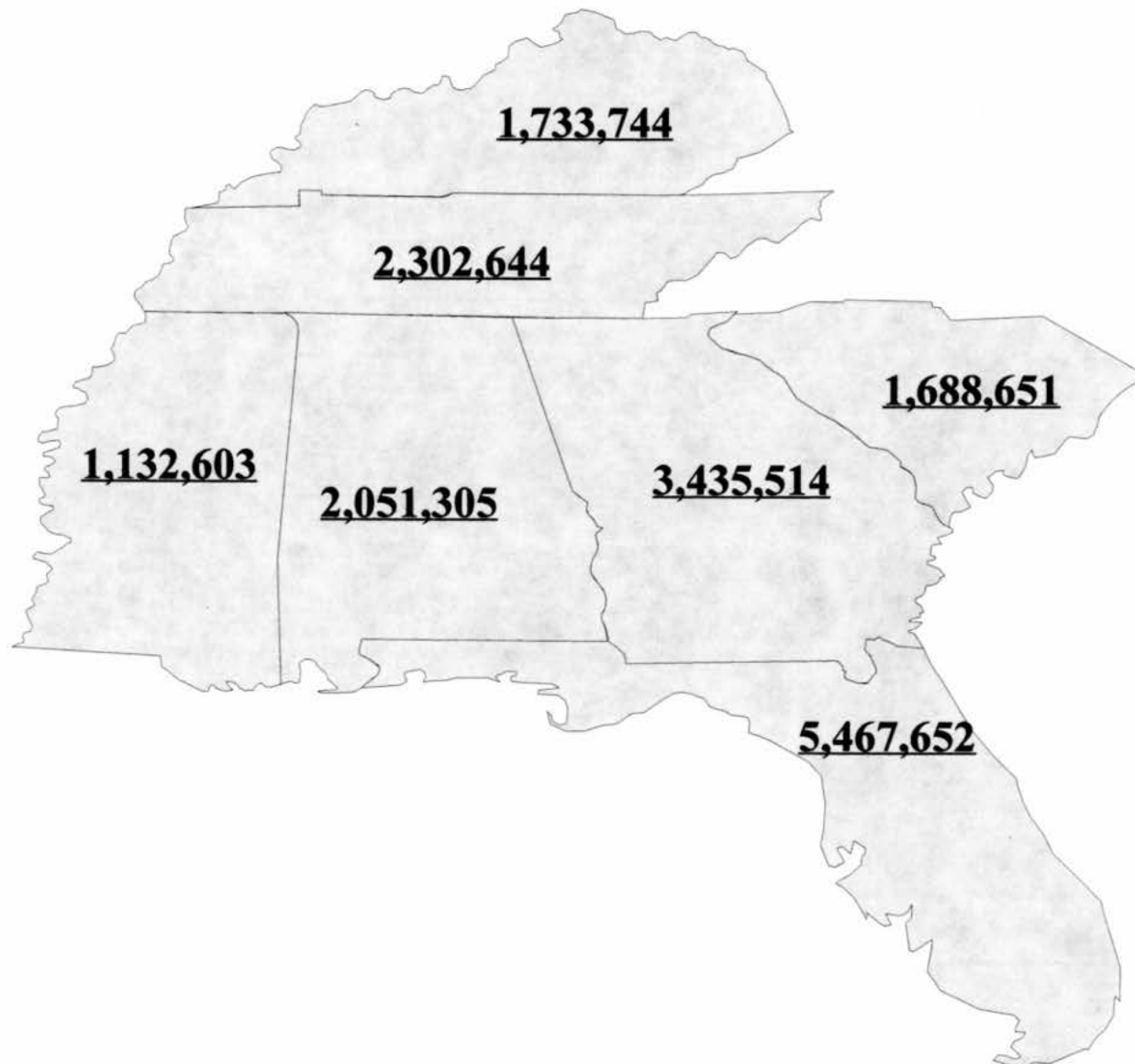


PRIVATE EMPLOYMENT BASED COVERAGE — Nonelderly (<65)

STATE	TOTAL	BY GENDER		By Insurance Status		
		Male	Female	Own Name	Spouse	Other Depen.
Mid-Atlantic	19,947,252	9,892,242	10,053,862	10,698,893	3,250,478	6,037,845
New Jersey	3,820,627	1,900,381	1,920,275	2,079,861	612,206	1,134,501
Pennsylvania	6,161,085	3,037,729	3,123,405	3,151,012	1,052,880	1,966,111
Delaware	371,860	182,646	189,157	192,156	64,075	116,391
Maryland	2,230,748	1,104,246	1,126,406	1,174,225	331,468	734,514
District of Col.	162,449	81,854	80,556	116,398	14,077	32,714
Virginia	3,055,293	1,515,553	1,539,501	1,668,132	514,958	882,171
West Virginia	670,401	323,797	346,475	335,591	153,527	183,141
North Carolina	3,474,790	1,746,036	1,728,087	1,981,518	507,286	988,304

ERISA COVERED LIVES

South Atlantic

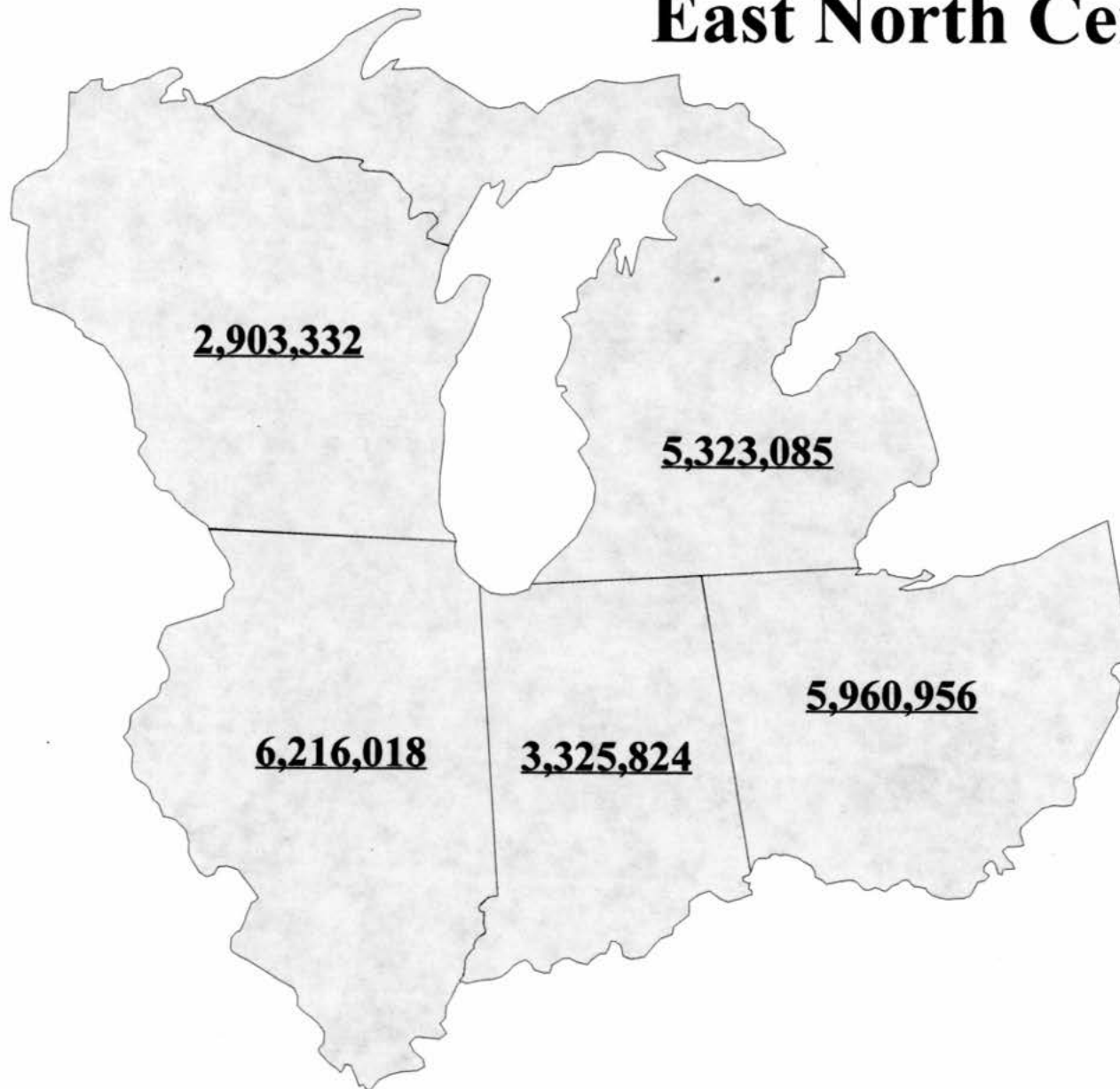


PRIVATE EMPLOYMENT BASED COVERAGE — Nonelderly (<65)

STATE	TOTAL	BY GENDER		By Insurance Status		
		Male	Female	Own Name	Spouse	Other Depen.
South Atlantic	17,812,113	8,913,849	8,893,997	9,597,463	2,865,179	5,357,093
South Carolina	1,688,651	843,176	844,807	914,693	279,997	494,143
Georgia	3,435,514	1,735,455	1,698,487	1,823,231	555,377	1,050,962
Florida	5,467,652	2,756,343	2,710,694	3,135,647	815,169	1,526,269
Kentucky	1,733,744	875,102	857,974	840,328	329,155	562,599
Tennessee	2,302,644	1,123,097	1,178,968	1,282,710	328,353	692,754
Alabama	2,051,304	1,013,231	1,038,022	1,021,908	378,729	654,723
Mississippi	1,132,603	567,446	565,044	578,946	178,398	375,642

ERISA COVERED LIVES

East North Central

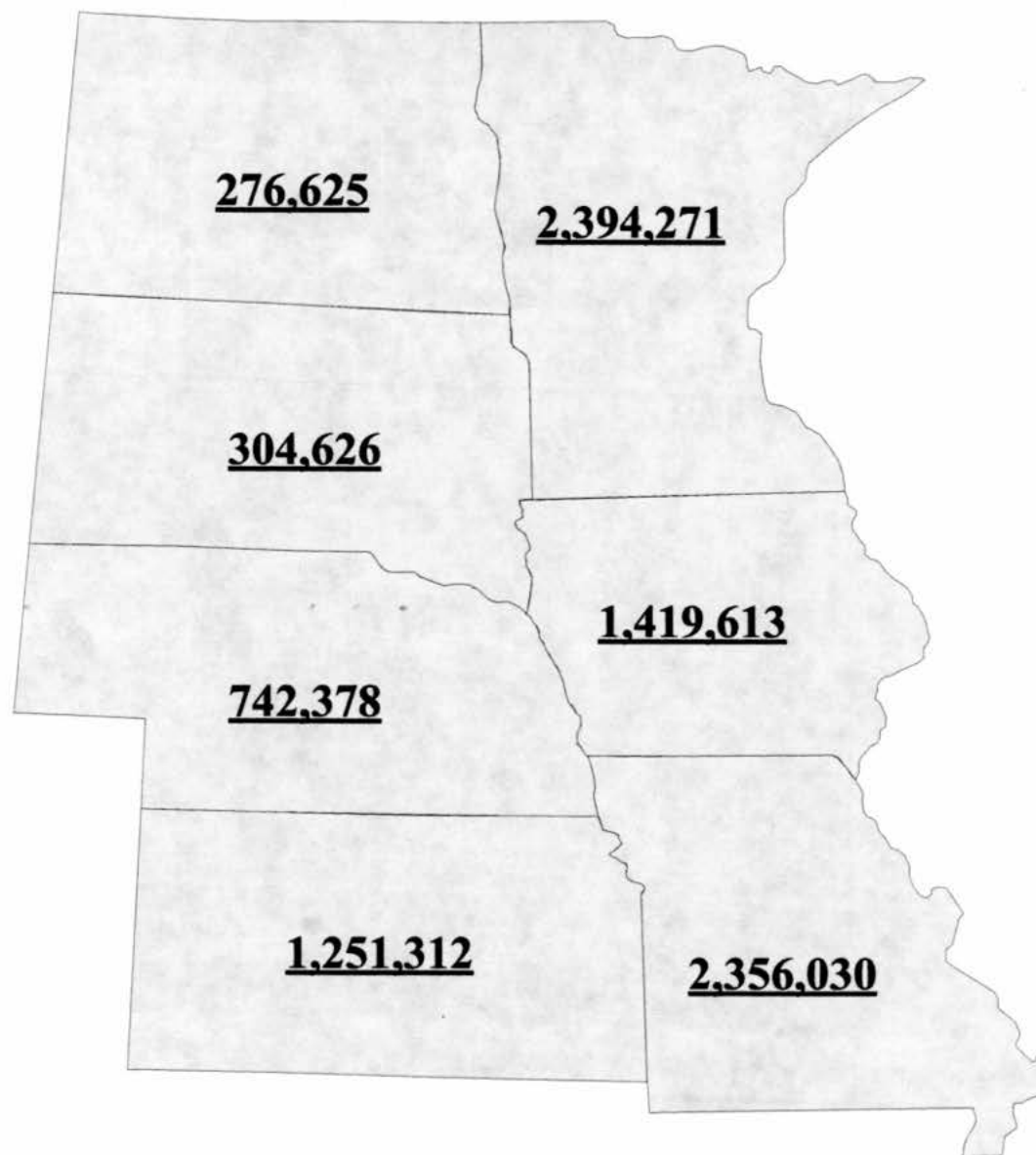


PRIVATE EMPLOYMENT BASED COVERAGE — Nonelderly (<65)

STATE	TOTAL	BY GENDER		By Insurance Status		
		Male	Female	Own Name	Spouse	Other Depen.
East North Cen.	23,729,215	12,067,044	11,661,195	11,617,857	4,164,372	7,964,761
Ohio	5,960,956	3,022,037	2,938,675	2,848,452	1,085,578	2,033,111
Indiana	3,325,824	1,724,748	1,601,021	1,696,217	567,658	1,060,316
Illinois	6,216,018	3,091,590	3,124,279	3,072,540	1,018,984	2,129,235
Michigan	5,323,085	2,765,927	2,556,712	2,553,572	975,004	1,799,790
Wisconsin	2,903,332	1,462,743	1,440,509	1,447,077	517,148	942,309

ERISA COVERED LIVES

West North Central

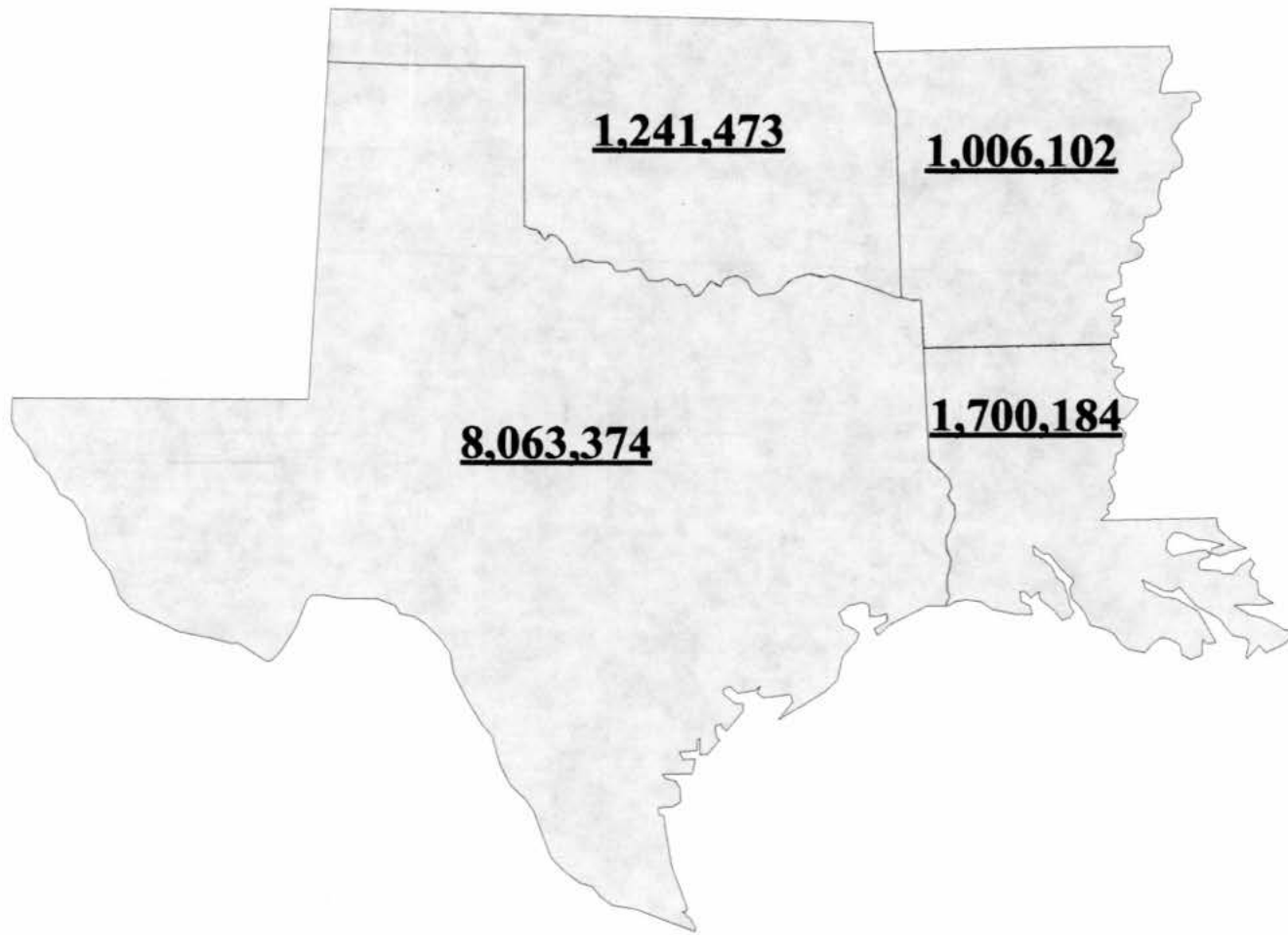


PRIVATE EMPLOYMENT BASED COVERAGE — Nonelderly (<65)

STATE	TOTAL	BY GENDER		By Insurance Status		
		Male	Female	Own Name	Spouse	Other Depen.
West North Cen.	8,744,854	4,543,335	4,200,758	4,333,453	1,449,133	2,972,910
Minnesota	2,394,271	1,273,126	1,120,694	1,176,132	419,588	800,254
Iowa	1,419,613	721,928	697,661	693,188	218,520	508,324
Missouri	2,356,030	1,193,439	1,162,484	1,209,289	379,875	774,163
North Dakota	276,625	143,407	133,208	141,104	44,489	91,118
South Dakota	304,626	153,205	151,430	149,132	48,827	106,987
Nebraska	742,378	403,205	339,060	379,849	120,820	241,634
Kansas	1,251,312	655,025	596,222	584,760	217,013	450,430

ERISA COVERED LIVES

West South Central

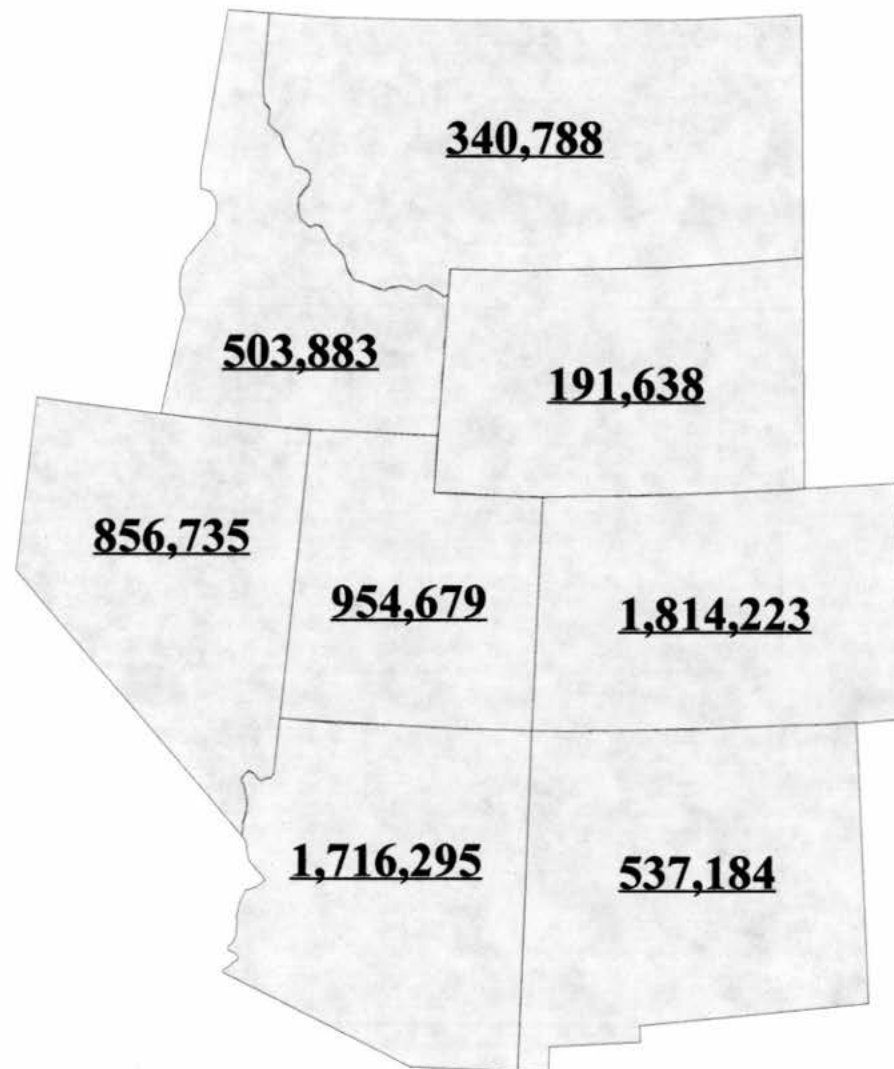


PRIVATE EMPLOYMENT BASED COVERAGE — Nonelderly (<65)

STATE	TOTAL	BY GENDER		By Insurance Status		
		Male	Female	Own Name	Spouse	Other Depen.
West South Cen.	12,011,134	6,148,254	5,861,215	6,199,218	1,954,717	3,865,904
Arkansas	1,006,102	505,473	500,597	486,308	174,403	346,375
Louisiana	1,700,184	872,728	827,328	890,430	310,562	500,848
Oklahoma	1,241,473	613,002	628,349	661,580	196,366	385,340
Texas	8,063,374	4,157,051	3,904,940	4,160,900	1,273,388	2,633,340

ERISA COVERED LIVES

Mountain

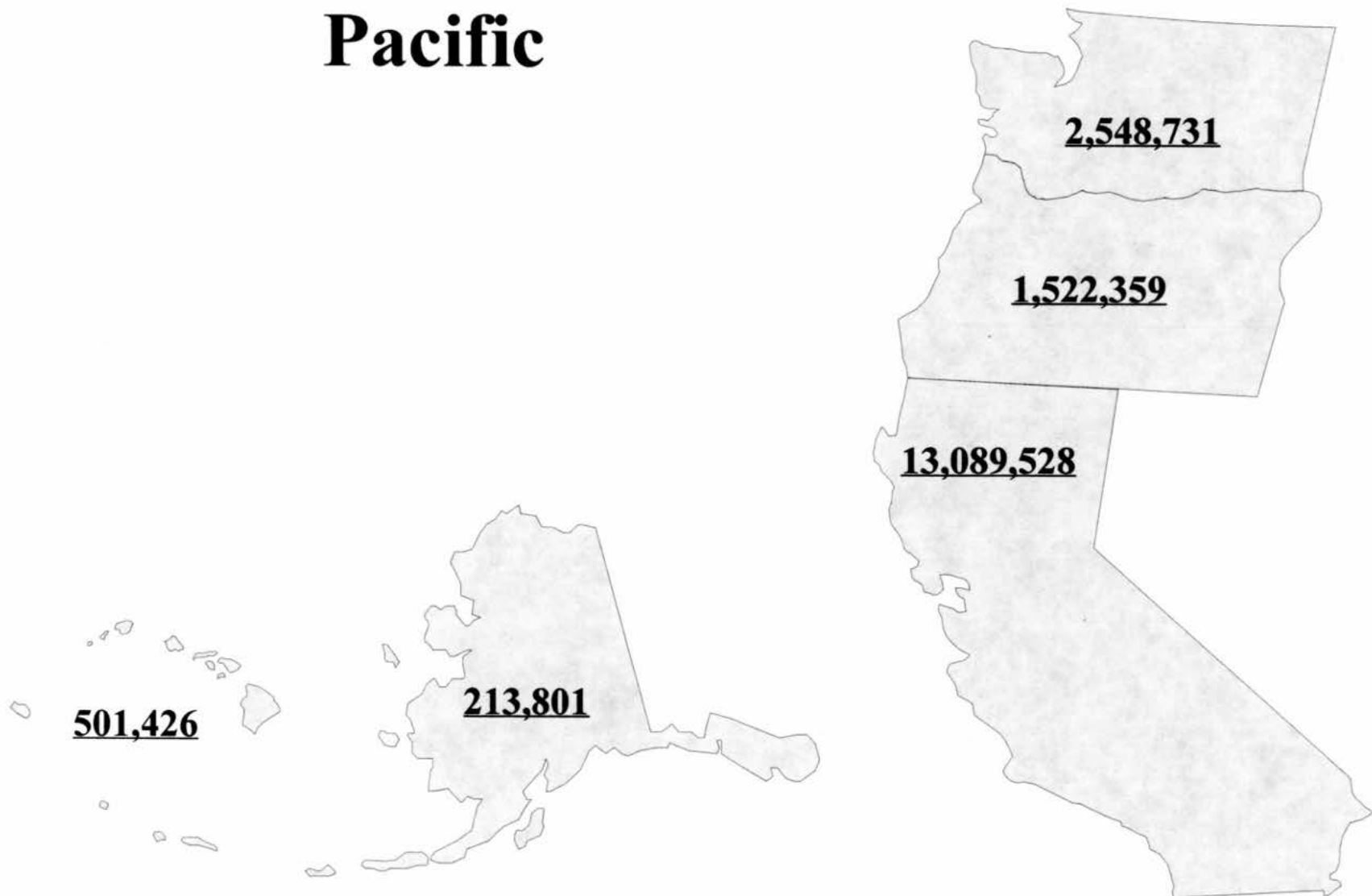


PRIVATE EMPLOYMENT BASED COVERAGE — Nonelderly (<65)

STATE	TOTAL	BY GENDER		By Insurance Status		
		Male	Female	Own Name	Spouse	Other Depen.
Mountain	6,915,424	3,563,703	3,351,176	3,407,867	1,186,386	2,335,767
Montana	340,788	175,561	165,244	172,262	57,351	111,429
Idaho	503,883	267,299	236,544	236,702	87,837	180,072
Wyoming	191,638	95,635	95,994	86,373	38,299	67,704
Colorado	1,814,223	921,346	892,922	953,304	285,437	576,548
New Mexico	537,184	279,915	257,260	248,588	97,343	194,020
Arizona	1,716,295	887,002	828,753	845,316	311,740	566,439
Utah	954,679	480,659	474,077	381,845	176,836	397,067
Nevada	856,735	456,286	400,382	483,475	131,542	242,487

ERISA COVERED LIVES

Pacific



PRIVATE EMPLOYMENT BASED COVERAGE — Nonelderly (<65)

STATE	TOTAL	BY GENDER		By Insurance Status		
		Male	Female	Own Name	Spouse	Other Depen.
Pacific	17,875,846	9,295,039	8,579,029	9,209,227	2,828,043	5,855,139
Washington	2,548,731	1,306,738	1,241,951	1,347,166	372,071	833,141
Oregon	1,522,359	770,731	751,410	800,745	260,950	462,079
California	13,089,528	6,853,956	6,233,977	6,648,369	2,106,511	4,343,477
Alaska	213,801	112,877	100,914	110,376	29,086	74,912
Hawaii	501,426	250,738	250,777	302,571	59,424	141,530