REPORT OF THE LEGAL REVIEW GROUP

NATIONAL TASK FORCE ON HEALTH CARE REFORM

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INTRODUCTION

The members of the Legal Review Group met in Washington for three two-day periods on April 29-30, May 6-7, and May 13-14, 1993. Other work was conducted in telephone conferences between Group members and between Group members and staff from the Health Care Reform Task Force. During the Washington meetings, the Group was joined by various members of the Health Care Reform Task Force, who presented to the Group summaries of discussions and tentative conclusions that had been reached by the Work Groups and the Task Force itself.

The Group was not presented with a detailed set of decisions about health care reform. Instead, discussions with staff often seemed to portray an ongoing, extremely fluid decisional process. It was not unusual for the Group to hear from different staff members widely-varying, sometimes mutually exclusive, versions of essential decisions about the reform. At the same time, many other fundamental decisions had apparently not yet been made at the times that the Group met. This high level of uncertainty greatly affected the Group's process, in that the exercise became mostly one of attempting to identify particularly troublesome issues in the general directions in which decisions seemed headed. Where, on the other hand, relatively final decisions had been made on various aspects of the reform package, the Group was able to discuss and evaluate the legal aspects of those decisions in greater detail.

The Group has prepared this document as a summary of writings and discussions on a number of the legal and legal policy issues the Group addressed, yet the specificity and detail of the Group's treatment of different issues vary depending on the amount of detail the Group had been given by the Task Force staff. Additionally, three two-day meetings provided too short a time to allow for a full exploration of all aspects of the proposed reforms. The Group's conclusions, therefore, can be regarded only as tentative, and must not be interpreted as any sort of final evaluation of the legal issues in the reform package.

In this report, the Legal Review Group has identified and described major legal issues in nineteen (19) different areas of the proposed health care reform. In general, the Group attempted to concentrate on those areas in which it thought that its members could offer special expertise in state, local, health provider, employer, and labor issues not otherwise readily available to the Task Force from the Departments of Justice, Treasury, and Health and Human Services. Other areas, though deemed by the Group to be essential to the overall design and implementation of the reform effort, have not been addressed by the Group in this document, and in the Group's estimation, would be better referred to existing federal legal staff.

These issues that should be addressed by federal agency and Department of Justice attorneys include: (1) delegation of taxing and enforcement powers from the federal government to the states and health alliances (HAs) for premium collection; (2) substantive due process under the federal constitution for patients and providers, in areas ranging from abortion and family planning services to maintenance of rights of professional livelihood and practice by individual providers in the new health plan arrangements; (3) federal procedural due process considerations in implementing and sustaining the reform; (4) contracts and takings clause issues related to the reform's potential disturbance of a multitude of pre-existing contractual arrangements for services; (5) First Amendment commercial speech rights of providers and health plans; and (6) potential gerrymandering practices related to the formation of HA areas. Further, although the Group has attempted to address some antitrust issues in this report, a more thorough evaluation should be undertaken by the Antitrust Division of the Department of Justice.

Finally, although this report reflects, in general, the consensus of the Group on the various issues addressed, individual Group members may disagree with some positions taken in this report. The views expressed in this report should not be interpreted as representing the positions of the organizations and institutions with which Group members may be affiliated. Group members' positions and organizations are provided for identification purposes only.

EXECUTIVE SUMMARY

Among the major areas of concern that the Group identified, five (5) areas appeared at once the most problematic and the most essential to the legal success of health care reform arrangements. These areas are summarized below, and are addressed in greater detail in the report itself. Other areas of great practical import for the success of the reform, such as premium collection mechanisms, distinguishing employees from independent contractors for premium collection purposes, and anti-injunction provisions in the reform legislation, are addressed in the body of the report.

As a preliminary matter, however, the Legal Review Group was struck during its deliberations by how far-reaching and ambitious the plans for health care reform appear to be. There appears to be no precedent for the enactment and implementation of a national reform that alters so many existing statutory, administrative, contractual, private, and moral arrangements as this reform would propose to do. Because of the extent of the alteration of these pre-existing relationships, the Group feels, strongly, that the watchword for the drafting of legislation must be caution. This caution should lead the legislation's drafters to be conservative about preempting federal, state and local laws in fields from quality of care regulation to antitrust to public health to confidentiality. The reform should change pre-existing laws only insofar as is necessary to assure the success of the reform itself. As the reform plan is implemented, changes in pre-existing laws can be undertaken gradually, with time for thought and reflection on consequences of these further reforms.

The Group also kept in mind throughout its deliberations the federalist notions espoused by most of the Work Group and Task Force personnel with whom the Group met. As a baseline legal strategy, the Legal Review Group believes that to the extent states will be called upon to bear much of the administrative responsibility for this reform (as it looks as though they will), the states must be given adequate flexibility, discretion and authority to discharge that responsibility. Those drafting the legislative proposals therefore should regard state flexibility and authority as indispensable to the success of the legislation, and ultimately, to the success of the reform itself.

With these cautions in mind, the Legal Review Group has identified these major areas of concern:

1. State Taxing Authority and the Collection of Premiums

Whether mandated payments by employers and individuals are characterized as percentages of payroll or as a flat capitated premium, these mandated payments may be construed to be a tax.

These issues will arise, for example, if part of the premiums to be collected will pay for health care for persons other than the employees or individuals paying the premium. To the extent, therefore, that health reform delegates from the federal government to the states the responsibility to assess and collect this premium or payroll percentage, state tax law limitations, many of them deriving from state constitutions, may be triggered. Legal issues therefore may arise as to whether and how the states may delegate the premium or tax assessing powers to "private" health alliances (HAs).

This issue merits further study and consultation with the National Association of Attorneys General (NAAG). One way to avoid such problems is that the premium or payroll percentage mandate be imposed directly by federal law, rather than by state law adopted to fulfill federal directions. In that case, the federal delegation of taxing powers to "private" entities like HAs emerges as a federal Constitutional question, which could at least be addressed in one body of law, rather than in the law of all states and territories. If this alternative is adopted, steps should be taken to separate, as much as possible, the HA structure and governance from state governments; the greater the relation of the HAs directly to the federal level, the less troublesome the states' laws become.

2. Nature of Health Alliances

Given the myriad functions that HAs will apparently perform, it seems unlikely that HAs would be construed, ultimately, to be anything other than federal or state governmental entities. The status of being a governmental unit carries with it numerous responsibilities and restrictions, including due process constraints on denying participation of providers or patients, "open meetings" laws, freedom of information obligations, and constitutional limits on appointment of HA governance bodies.

Of particular concern here for the formation and operation of HAs is the necessity of maintaining open enrollment "fee-for-service" plans in each HA, that in turn would accept, at least presumptively, each licensed provider as a participating provider. Failure to do this would mean that some providers, though licensed, could be denied source of livelihood, and that some patients would be denied any possibility of maintaining their regular provider. The Group therefore believes that "fee-for-service" may be an indispensable due process "safety valve."

3. Preemption of State and Local Laws

States and localities likely will be given many new responsibilities under the reform legislation, even as they

maintain traditional public health, professional licensing, and institutional licensing responsibilities. The reform proposal therefore must ensure that states and localities receive adequate authority, flexibility, and resources to allow them to perform these functions effectively. The Group believes strongly that the central standards in the federal health reform legislation must state with specificity and precision what areas of state and local law are intended to be preempted, and those in which no preemption is intended. Failure to be precise about preemption could have unintended effects in health law and regulation so enormous as to dwarf those occurring as a result of ERISA.

Reform legislation must make clear the intended fate of: (1) state regulation (or re-regulation) of health plans for employers with more than 1000 employees and for unions; (2) state antitrust laws and regulations; (3) state abortion and family planning regulations; (4) state quality of care standards and enforcement powers; and (5) state public health laws and programs, including patient treatment programs that will parallel and supplement health plans. As part of this state and local flexibility, the Group also recommends that the reform legislation exclude from its "global budget" calculation any expenses related to health, public health and prevention, or environmental health that are willingly incurred by states and localities as "add-ons" to the national comprehensive benefits package.

4. The Comprehensive Benefits Package and Legal Disputes

There will be many, varied disputes about what is covered in the comprehensive benefits package. These disputes will concern not only the definition of "medically necessary" and "experimental treatment," but will also involve considerations of what groups of licensed health care professionals are allowed to deliver what services in the package and under what conditions. The Group recommends the development of a system of institutionalized patient participation in categorical coverage decisions, as well as a mandatory mediation process for patients aggrieved by their health plans, with appeals into the state (not federal) administrative and/or court systems. States in turn may demand new resources for their administrative and court systems to handle this new set of claims.

For other potential litigation that may arise between providers and plans, between plans themselves, and between plans and HAs, the Group recommends the clarification of rights to bring suit for statutory violations under 42 U.S.C. § 1983, which, with its attorney's fees provisions, otherwise likely would be a source of massive litigation. Alternate litigation routes will need to be specified in the legislation.

5. Privacy and Confidentiality

In the proposals for outcomes measurements and disclosure of results as the primary mechanisms for assuring quality of care, patient and provider rights to privacy and confidentiality are called into question. For outcomes data, patient names or other identifiers would, in general, not be necessary. Provider identities (both individual and institutional), on the other hand, would apparently necessarily be linked to outcomes data, in order to fulfill the proposed disclosure requirements of the reform package. The Legal Review Group had substantial concerns, however, that disclosure requirements should be in place only for data that would be clearly relevant and meaningful to patient choice of provider. Otherwise, disclosure standards would be set so low that the general law of informed consent -- with disclosure required only of significant risks judged from the perspective of the rational patient -- would be eviscerated, and fear of legal liability would force providers into ever more disclosure, with surfeits of information to patients and diversion of scarce resources from care into disclosure.

The Group recommends that disclosure requirements not extend to individual provider impairments or handicaps, since to do so would provide major disincentives for providers to seek medical or other care for their disabilities or illnesses. The Group also recommends that existing restrictions on the National Practitioner Data Bank be retained, except that health plans should be given reasonable access and that health alliances (and consumers/patients) should have access to state licensure information.

The Group also was concerned that before disclosure would be indicated, outcomes data should be properly adjusted for underlying co-morbidity factors. Otherwise, provider reputations would be harmed simply by accepting patients with advanced illness or who previously had substandard care.

Further, to the extent that reform plans include a program of computerization and centralization of patient medical information, personal medical information on identified patients may be amassed in a quantity and with a completeness hitherto unknown in our nation's health care delivery system. Although the Group did not have sufficient time to detail the protections necessary for this information and the uses that should be allowed, substantial attention should be devoted to legislative protections for patient medical information under the reform package.

PART ONE: STRUCTURAL AND FINANCIAL ISSUES

I. PREEMPTION OF STATE LAWS

Issue

How should preemption of state laws be dealt with in federal health care reform legislation?

Solutions

1. There should be a general statement in the federal health care reform bill providing that no state laws are preempted except as expressly stated in the law.

2. To the extent possible the federal statute should identify by category or specific effect those state laws that are expressly preempted.

3. To the extent possible, provisions preempting unspecified state laws "inconsistent with" or "in conflict with" a particular provision of the federal law should be avoided.

4. Where state laws are intended to be only partially preempted, the federal law should expressly state the nature and degree of preemption (e.g., that state laws more or less restrictive than the federal are not preempted).

Discussion

Briefing books and presentations to the Legal Review Group have made clear that a variety of state laws may be preempted by the federal health care reform legislation.[1] There are a number of ways in which federal legislation can preempt state laws. One is by "occupying the field" covered by the federal law. That type of preemption supersedes all state laws on the subject. Another alternative preempts laws that are inconsistent or in conflict with the federal law. A third option preempts only those laws expressly identified in the federal statute.

The Group believes that federal health care reform legislation should employ the third approach. Preemption of state laws should

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[1] Attached to this report as Appendix A is a list of state laws that briefing papers have identified as possibly being preempted or otherwise changed under health care reform. Though lengthy, this list does not include every state law that may need modification or that may be preempted.

be achieved only by express provision, with as much specificity as possible, to avoid inadvertent "implied" preemption or preemption much broader than intended.

Experience with preemption under ERISA has demonstrated the dangers of preemption provisions that are not carefully drawn. ERISA provides for preemption of state laws that "relate to" covered employee benefit plans. With few exceptions, the courts have construed this provision as creating an extremely broad preemptive effect, nullifying even state laws that are consistent with and further the purposes of ERISA. One federal court has characterized the ERISA preemption provision as a "quicksand [that] is fast swallowing up everything that steps in it or near it."

Because of the breadth of the health care reform legislation, it is possible that courts will be tempted to construe it as intending a similarly broad preemptive effect, based either on the language of the law or on the federal government's "occupation of the field." To avoid expansive, unintended preemption of state laws, the Group strongly recommends that the legislation include a provision that eliminates that possibility of implied preemption by stating that state laws are preempted only as expressly provided.

Even where preemption is clearly intended, statutory language should be drafted with care. There will be some state laws that are to be preempted in their entirety. Others will be preempted only in certain respects that are in conflict with the goals of the federal law. Others will be permitted only to the extent that they are more or less restrictive than the federal counterpart. For example, some "anti-networking" laws may be entirely preempted. Certain practice restrictions in state licensure laws may be preempted, but in general those licensure laws will remain in force. Some state enforcement laws that differ from federal law may be permitted if they are more stringent that the federal law. Therefore, where express preemption is intended, the language should be written as narrowly and specifically as possible. Effort should be made to identify with clarity the types of state laws preempted and to specify the nature and degree of the preemption.

In particular, the relationship between large employer health coverage and state regulatory law will require careful attention both during the transition into the new system and after it is established. Currently, the broadly-interpreted ERISA preemption provision precludes state regulation of self-funded employer health benefit plans that are within the jurisdiction of ERISA.[2] In addition, courts have held a variety of state health care reform

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[2] These same issues arise with respect to union health plans administered pursuant to Taft-Hartley trusts.

measures preempted with respect to ERISA plans.[3] As states move toward the new health care system, they will need flexibility that the current ERISA preemption rulings may not allow. After the system is in place, if states are expected to regulate in some measure large employer plans that remain outside the health alliance, it will be necessary to insulate them from preemption by the new legislation and to relieve them from existing ERISA preemption.

Another area that warrants specific note is abortion regulation. The briefing papers indicate that reproductive services will be included in the comprehensive benefit package. If the principle of "only express preemption" recommended in this report is followed, a variety of state laws regulating access to abortions, such as parental consent/notification laws and mandatory waiting periods, will remain in effect unless specifically preempted. Therefore, if it is the intent of the legislation to supersede those state laws, the federal law should say so explicitly.

II. PRE-ENACTMENT ERISA PREEMPTION ISSUES

Issue

Should the new health care reform legislation provide retroactive relief from ERISA preemption?

Solution

For years after enactment, states are to be given considerable flexibility in formulating health policies so long as they follow specified federal guidelines. The Legal Review Group has urged that specific statutory language be crafted to make clear which state actions with respect to large employers are preempted and that anything not specifically preempted should be permissible. Nevertheless, litigation may continue with respect to prior years' arrangements. Applying the new preemption rules retroactively would bar those suits that are not inconsistent with the new federal policies. On the other hand, barring such suits will raise claims of unfairness.

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[3] The United States Court of Appeals for the Third Circuit recently ruled that Congress did not intend ERISA's preemptive effect to be as broad as other courts have held, reversing the widely-publicized decision in United Wire v. Morristown Memorial Hospital that provisions of a New Jersey hospital rate-setting law were preempted. This single decision is, however, a lonely voice in a chorus of decisions that have found extremely broad preemption of state laws by ERISA.

Discussion

A number of recent cases, including Travelers Insurance Co. v. Cuomo, 1993 WL 39923 (S.D.N.Y., Feb 3, 1993), have interpreted the ERISA preemption of current federal law as prohibiting DRGs and surcharges on large employers. Additional cases are in process; e.g., Trustees of the Pension., Hospitalization Benefit Plan of the Electrical Industry v. Cuomo, E.D.N.Y. No. CU-92-5589 (Nov. 25, 1992). These cases call into question a wide variety of state actions, including, for example, Maryland's single payer program, which has been quite successful in containing growth in health care costs. Retroactive application of the new rules narrowing ERISA's preemptive effects would preclude such challenges and put a halt to unproductive litigation, but might raise claims of unfairness.[4]

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[4] Two bills were introduced in the Senate in 1992 which would have amended ERISA's preemption, but neither passed. To date, the bills have not been reintroduced. On September 10, 1992, a bipartisan group of senators introduced the "State Health Care Financing Equity Act" (S.3223) which would have waived ERISA preemption requirements for states that intend to set up universal health plans or private health insurance premiums to help fund the risk pools. The bill also would have provided ERISA waivers to allow state prospective payment systems. Currently, states are permitted to impose a lower tax rate, or none at all, on plans that provide coverage to all employees regardless of health status. This allows states to institute a pay-or-play system. The Departments of Labor and Health and Human Services would have to approve all such ERISA waivers.

The bill would have also amended ERISA to permit states to levy non-discriminatory, broad-based health care taxes on hospitals, doctors, and other health care providers to finance universal health care programs. The fact sheet accompanying the bills specifically noted that 22 states currently impose such a tax and that the bill would overrule United Wire, Metal & Machine Health and Welfare Fund v. Morristown Memorial Hospital, 793 F. Supp. 524 (D.N.J. 1992). United Wire was, however, reversed by the United States Court of Appeals for the Third Circuit in May 1993.

On August 12, 1992 two Democratic senators proposed the "State Care Act" (S.3180) which would have amended the Social Security Act to provide grants for the establishment of state demonstration projects for comprehensive health care reform. The plans must meet access and cost-containment goals. The bill would have established a federal commission and a "one-stop shop" waiver approval process that would approve narrowly crafted waivers from ERISA, Medicare, and Medicaid.

On May 13, 1993, the House Subcommittee on Labor-Management Relations of the House Committee on Education and Labor reported

III. HEALTH ALLIANCES AND STATE CONSTITUTIONS

Issue

The reform proposal will mandate that employers, employees and other individuals pay for a package of health insurance in a specified amount or a percent of wages ("wage-based premium"). The amount required to be paid will be set by a state-chartered health alliance (HA), and will vary geographically. It is not clear what proportion of these amounts will go toward the purchase of the individuals' own insurance or will fund insurance for others. Questions have been raised whether this might be a tax under state law and possibly trigger state procedural or super-majority requirements or run afoul of other state constitutional limitations. How would the proposed health alliances (HAs) be affected by state constitutional provisions governing state and local taxation and expenditures?

Solution

Resolving these questions requires further refinement of the Task Force's proposal and considerable 50 state research concerning the details of the states' restrictions on state and local taxing and spending. Much may turn on the nature of the payment employers must make and on the role of the HAs in determining those payments. If the function of the HA in calculating and collecting employer payments is relatively ministerial, with individual employer payments determined according to a pre-set federal formula, courts might conclude that the employer contributions are the product of a federal mandate, not state or local action. Hence, state constitutional restrictions on state and local fiscal activity might not apply. The more discretion HAs have, then the more HAs will resemble state or local government entities, and the more difficult it will be to argue that HAs are purely federal.

Whether employer payments to state HAs are state/local taxes; whether HA taxing and spending are subject to state constitutional fiscal provisions; and whether states can delegate taxing powers to private entities, should be referred to the National Association of Attorneys General (NAAG) for further consideration on a state-by-state basis. Given the novelty of the HAs and the entire federal-state-local relationship contemplated by the Task Force, it may be that in some states there may be no clear answer until the state courts have spoken.

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out a bill that would provide a time-limited exemption from ERISA preemption for states' all-payor reimbursement systems.

One possible way of maximizing the federal nature of the mandate might be for the federal law to specify a "wage-based premium," or capitated amount, that would be paid to the federal Treasury to satisfy the federal mandate for health insurance coverage and employer contributions. The federal law would also specify in great detail how the required contribution (the "benchmark premium") is to be calculated by the health alliance. The federal levy would be deemed complied with by any employer or individual who filed a certificate from the appropriate health alliance (or perhaps large employer) indicating that required payments had been made and that insurance coverage had been secured. The federal levy should be set at an amount greater than the highest expected health alliance amounts so that there is no incentive to pay the federal fee rather than purchase health insurance. The federal premium would thus serve as an enforcement mechanism for the employer and individual mandates. It would also help defeat the arguments that Congress had delegated to the states' health alliances the imposition of a tax or that the health alliances were imposing taxes under state law, although a clear answer to this question may require further research. The obvious drawback is that this levy can be characterized as a federal tax, the distribution of which will be heavily on the middle class. The response, or course, is that the federal government does not expect to collect a nickel; it is merely enforcing its mandate.

Discussion

The central mechanism of national health care reform is likely to be health alliances (HAs). The federal government would induce states to create HAs. Among other powers, each HA would determine how much each employer within its jurisdiction would be required to contribute toward local health care coverage, and, using the employer contributions and other funds, each HA would purchase coverage for area residents.

Most state constitutions extensively regulate the fiscal practices of state and local governments. The specifics and the magnitude of the regulation differ significantly from state to state, but one or more state constitutions contain one or more of the following provisions: (1) balanced budget requirements; (2) restrictions on the overall rates of growth of taxes and/or expenditures: (3) restrictions on the creation of new taxes; (4) restrictions on the delegation of the power to tax; (5) procedural requirements, such as a super-majority veto within the state legislature, or voter approval in a referendum, as a prerequisite for some new taxes.

Would an HA's collection and expenditure of funds be subject to any of these restrictions? This question has several aspects.

1. Is the HA engaged in taxation?

This may turn on the nature of the employer's payment. A contribution styled as a "wage-based premium" may be less likely to be seen as a tax than one expressly labelled a "payroll tax"; yet, as long as "premium" payments are compulsory and they are used for the purchase of coverage for persons other than the payer's employees, it is arguable that this is a tax.

It may also turn on the nature of the state law restriction in the specific state. Some states restrict only specified taxes, especially taxes on real property. Some states restrict only taxes levied by specific entities, such as municipalities. On the other hand, some restrictions may be phrased more broadly.

It may also turn on the extent of the HA's discretion in determining an employer's payment. If the HA's function can be characterized as largely ministerial, applying relatively specific federal criteria to local facts, then the HA may be seen as "assessing" rather than "taxing," and state restrictions on state/local taxation might not apply. On the other hand, if the HA has broader discretion, the "ministerial" argument might be more difficult to sustain.

2. Is the HA an entity subject to state and local fiscal constraints?

As noted, many state constitutional restrictions apply only to specific named bodies -- the state itself, cities, counties, etc. In such a state, then, so long as the HA is not considered to be a part of the state itself, it would not be subject to a restriction. With state constitutions that regulate more broadly -- California's Proposition 13 constrains "special districts," for example -- the HA might be subject to constraint. In addition, in some states the HA might be considered to be a part of the state itself.

One would anticipate that many states may attempt to form HAs as quasi-private, not-for-profit organizations. It is likely that state constitutional restrictions on taxing and spending would not apply to truly private HAs. But, as discussed below (see Section IV), there are numerous, serious questions about whether the state can delegate the power to tax and other regulatory powers to private organizations.

3. Even if the HAs are not constrained by state constitutional provisions limiting state and local taxing and spending, can the states delegate the power to tax to "private" HAs?

Taxation is generally seen as a legislative power, and most state constitutions restrict the delegation of the taxing power. The power to tax may be granted to local governments, but can it be granted to quasi-autonomous private entities? Again, the question may turn on whether the HA is engaged in taxation when it determines how much an employer pays.

IV. POTENTIAL LIABILITY OF HEALTH ALLIANCES

Issue

Health alliances (HAs) may be exposed to significant potential liability under federal health care reform legislation. How can the reform proposal minimize potential liability for HAs? Can state liability be minimized by making the HA a "private" entity?

Solution

If federal reform legislation intends to place an ultimate burden on the states to form HAs and to ensure that the HAs are functioning consistent with federal mandates, then the legislation must afford the states considerable discretion and authority in establishing, structuring, monitoring, and delegating responsibility to health alliances. Other than specific directions relating to the setting of the premium contribution, federal legislation should avoid granting specific authority to health alliances. Rather, states should be given permissive authority to delegate to health alliances. In this manner, states, assuming they are given responsibility to administer the system, will have the requisite authority and enforcement power to do so.

Because the majority of proposed functions of the health alliances are regulatory in nature, it is unlikely they could be constituted as purely private entities. Even if so constituted, courts may well regard the activities of privately-structured health alliances as state action. If a state wishes to establish a health alliance as a private entity, it should consider delegating to the alliance only non-regulatory functions, such as brokering and information dissemination activities.

Discussion

The current health care reform proposal contemplates a central role for the health alliances. Although the health care reform proposal generally contemplates the HA as an employer/employee cooperative which functions as a health plan purchasing broker, many possible functions of the HAs were described to the Legal Review Group. These include: (1) negotiating and entering into purchasing agreements with health plans; (2) gathering and disseminating information to consumers about types of available

health plans; (3) acting as a clearinghouse for outcomes and other information gathered by HAs from health plans; (4) monitoring and assuring quality of care within health plans; (5) determining eligibility of plans to participate in the system (including possible certification of plans and denial of ability to participate); (6) determining the risk adjustment applicable to health plans for certain populations; (7) approving and denying major expenditures of health plans; (8) setting standards for health plans regarding quality of care or access to care; (9) determining benchmark premiums; (10) regulating fees that may be charged by plan providers; (11) participating in the dispute resolution mechanism established to handle consumer and provider grievances; (12) enforcing budgetary restraints and provision of required benefits by health plans; and (13) collecting premiums.

Although it has been specifically stated that the HAs are not to be regulators or "mini-HCFAs," most of these potential functions of HAs appear regulatory in nature. The Group believes that an HA constituted as a purely private entity could not legally carry out many of these functions. In any event, such activities carried out by a private HA established by the state may be regarded by courts as state action. Because this characterization has benefits and drawbacks and affects the potential liability of both the HAs and the states, states should be afforded wide authority and discretion in accomplishing the functions proposed for HAs.

For example, if the HA is a state agency, it would likely fall within the state action exemption to antitrust law recognized by courts. However, as a state agency, an HA would be constrained by constitutional requirements, such as substantive and procedural due process. In addition, if the HA is established as a state entity, it would be subject (unless exempted by federal or state legislation) to state administrative procedure acts, freedom of information acts, anti-deficiency acts, and procedural and substantive constitutional guarantees. These sources of liability are in addition to those generally applicable by virtue of the activities of HAs, such as contract law and record-keeping and privacy laws.

As outlined above, states can minimize challenges to the HAs and the consideration of HA activities as state action by retaining authority over the regulatory functions and delegating only the non-regulatory functions to HAs established as purely private entities. As there are federal and state constitutional limits on states' ability to delegate certain functions, the Legal Review Group recommends broad authority and discretion for states so each can determine its own limitations in this regard, and so that the regulatory functions of the HAs can be minimized, with the states retaining most regulatory functions.

Because of the significant potential liability stemming from the contemplated actions of the HAs, the Group therefore recommends

that federal health care reform legislation provide considerable discretion to states in establishing, structuring, delegating responsibility to and monitoring HAs. This provides states with the ability to control those aspects of the HAs for which the state will necessarily be responsible. If HAs are established by the state legislatively, broad state discretion allows states to enact statutory exemptions for HAs to pertinent state laws. Broad state discretion and permissive authority to states to delegate to health alliances also limits direct federal liability for actions of HAs.

V. POSSIBLE LIMITATIONS ON CONGRESSIONAL SPENDING POWER

Issue

Can the legislation condition the receipt by states of federal funds (for health and/or non-health purposes) on implementation by the states of federal health care reform initiatives?

Solution

Conditions placed upon the release of federal funds for a particular national program must have some reasonable relationship to the program.

Discussion

Congress has broad power to condition the release of federal funds. This spending power under Art. 1 § 8 is limited by four factors: (1) the exercise of the spending power must be in pursuit of the general welfare (however, broad deference to Congress is given on this issue), (2) the conditions attached to the release of funds must be unambiguous, (3) the conditions must be reasonably related to a federal interest in particular national projects or programs, and (4) the exercise must not conflict with other Constitutional provisions.

Recent applications of the reasonable relationship test have all found the necessary "reasonable" relationship between the federally funded program and the conditions. South Dakota v. Dole, 483 U.S. 203 (1987), "suggests" that conditions may be illegitimate if they are unrelated to particular programs, Id. at 207-208.

Therefore, the legislation should link state compliance to funds that are related to health care services. In addition, if a sanction of eliminating the tax deductions for premiums is used, it should be applied incrementally in order to make it more likely that it will be effective. Experience with issues relating to non-profit hospitals indicates that a singular, draconian sanction will rarely, if ever, be used.

VI. CONTROLLING HEALTH CARE COSTS OF LARGE EMPLOYERS THAT JOIN HEALTH ALLIANCES

Issue

Large employers are concerned that if they enter health alliances, their costs will increase at a rate faster than if they remain outside the alliance and independently purchase benefits for their employees (even if they are required to comply with community rating requirements).

There are also issues relating to the scope of any federal preemption of state flexibility under the new system, given the history of judicial interpretations that have extended the ERISA preemption far beyond anything explicitly contemplated during the enactment of ERISA two decades ago.

Solution

It is possible to apply global budget targets and limitations to large employers to limit the size of annual rates of increase in health insurance costs to the same level applicable to smaller employers purchasing through health alliances. It does not seem practical to limit large employers to slower rates of growth than that applicable to other alliance purchasers. It is, of course, not possible -- short of a Constitutional amendment -- to guarantee that a future Congress will not raise the budget ceilings in response to changes in circumstances or political tastes. Nor does it seem possible to require that super-majorities are necessary for future Congresses to change the global budgets. On the other hand, either the House of Representatives or the Senate could amend its own rules (e.g., the Byrd amendment) to require super-majorities for such changes.

With respect to the ERISA preemption, it is impossible to be specific at this stage until additional policy decisions become known. As a matter of general guidance, however, history strongly suggests great advantage in explicitly preempting in the new federal statute only those state actions that are intended to be forbidden with respect to large employers and stating in the statute that only those things explicitly preempted are precluded. Great caution is warranted here. In the absence of such specificity, given recent precedents, courts might hold that states are barred from taxing large employers, for example, to fund public health endeavors or from regulating provider rates applicable to large employers.

VII. DISTINGUISHING EMPLOYEES FROM INDEPENDENT CONTRACTORS

Issue

A proposal to require employers to contribute some fixed percentage, for example 80 percent, of some "benchmark" amount to the cost of health insurance coverage of their employees makes it critical to know whether an individual is an "employee" or an "independent contractor." Such a determination under both state law and the Internal Revenue Code now turns on application of some 20 common law factors, such as whether the person performing the services is paid by the hour or week or by the job, whether the hours of work are set or flexible, whether the relationship is a continuing one, whether the person is free to provide services to two or more unrelated persons at the same time or to hire assistants, whether the services must be rendered personally, who supplies the tools, whether the payor can control how the results are achieved, or whether the service provider is responsible only for results.

Application of this test is so inconsistent, its results so uncertain, that Congress in 1978 generally prohibited the IRS from challenging an employer's erroneous treatment of an employee as a independent contractor if the employer has a "reasonable basis" for such treatment. Congress also prohibited IRS from issuing regulations or rulings addressing the status of workers as employees or independent contractors until it "has adequate time to resolve the many complex issues involved in this area." In 1982, Congress extended this "interim" measure indefinitely.

The Treasury Department in 1982 and again in 1991 said that "applying the common law test in employment tax issues does not yield clear, consistent or satisfactory answers, and reasonable persons may differ as to the correct classification." The General Accounting Office in July 1992 described the rules as remaining "as unclear and subject to conflicting interpretations as we found them in 1977." The House Government Operations Committee called the twenty factors "an inadequate guide to compliance with tax and other laws," and described misclassification of workers as a "pervasive and serious problem." The IRS has estimated that many billions of tax revenues are lost due to employees being misclassified as independent contractors.

Because of the amounts of money involved in the employer mandate for contributions to employees' health insurance, the incentives for noncompliance will be great. This can take the form of misclassifying employees as independent contractors, engaging in non-traceable cash transactions, "leasing" employees, substituting overtime for hiring, etc.

Solution

Despite repeated calls for "cleaning up" the definition of an "employee" under the Internal Revenue Code, no appropriate or acceptable definition has emerged, and none seems likely in the interval before the health care reform proposal goes forward. Probably the best that can be achieved is to indicate that the determination of whether someone is an employee or an independent contractor will be the same as under current law, but that anyone who is claiming independent contractor status must notify both those for whom she works and the "premium collection authority" (the health alliance or whoever else that turns out to be) that the individual is making such a claim and is solely responsible for purchasing the mandated insurance coverage (or paying the payroll tax). Consideration should also be given to requiring coordination with the IRS of claims of independent contractor status. Experience under the Social Security, FUTA and income tax suggests that noncompliance will be rampant even with a requirement of such information reporting, but no better option seems available.

VIII. COORDINATING PUBLIC HEALTH LAW AND PRACTICE WITH HEALTH CARE REFORM

Issues

How should public health powers and programs (as expressed in state and local laws and mandates) be treated under the proposed health care reforms?

Solutions

1. Health care reform statutes must be drafted so as not to preempt local and state laws relating to exercises of public health powers, including such interventions as mandatory screening and vaccination, disease reporting, contact tracing and evaluation, case management, isolation or detention of persons with infectious disease, implementation of public health measures in clinical settings, and environmental inspections.

2. Proposals for reform should consider including payment to public health agencies from health plans, to reimburse for patient-specific (as opposed to population-wide) interventions provided by public health agencies. Otherwise public health programs, in fulfilling their various legal mandates, may effectively be subsidizing health plans.

3. Proposals for reform should exclude the cost of public health interventions from the "global budgets" assigned to various state or health alliance areas. States and localities should retain flexibility to offer "add-on" public health interventions to

address local public health needs.

4. To ensure that public health interventions are implemented in clinical settings, states and/or localities should retain sufficient regulatory authority over clinical settings. Since such interventions are often not susceptible to "outcomes" measures, and since interventions may be immediately necessary for disease control, states and/or localities should retain authority to conduct chart reviews and institutional inspections and surveys, with penalty and facility licensing powers.

Discussion

States and localities traditionally have exercised wide powers to promote health and sanitation and to control epidemic disease and environmental hazards. Many of these functions, even though designed to promote population-wide health, are implemented in patient-specific ways. Usually provided on a low- or no-cost basis, these include: (1) school-based nursing programs providing immunizations and primary care to children in public schools; (2) child health centers providing basic pediatric care; (3) neighborhood health centers; (4) sexually-transmitted disease (STD) clinics; (5) tuberculosis clinics; (6) pre-natal care centers; (7) case management services; (8) laboratory screening programs, such as for lead levels in children; (9) isolation or quarantine in hospitals and other facilities of persons with infectious conditions; and (10) environmental inspections of homes or businesses, as indicated by suspicion of environmental pathogens.

Since many of these functions appear identical to services expected to be provided by health plans and required by federal standards, federal legislation must be crafted so that the exercise of these traditional public health functions and mandates is not preempted or otherwise rendered legally suspect. Recent unfortunate experiences with the unintentionally preemptive effects of ERISA (see Sections I and II, supra) indicate that extreme caution is needed in the drafting of implementing legislation.

Further, the continued provision of these patient services by public health agencies is consistent with economies of effort and scale. Health plans could not, for example, easily post nurses in all public schools, nor would they have the power to exercise such purely governmental functions as contact tracing for partners of STD clinic patients, mandatory abatement of lead hazards in private homes and businesses, and commitment of non-compliant tuberculosis patients to long-term care facilities. For this reason, drafters of the reform legislation must carefully seek to integrate these public health practices (and the underlying statutes). If, for example, health plans are not required to reimburse public health departments for patient-specific services provided to health plan enrollees, then health plans will have great incentives to refer patients, directly or indirectly, to public health services, and

public health budgets in effect will be subsidizing unscrupulous health plans. Alternately, public health departments may curtail free services, some of which could be jettisoned appropriately, while others, like STD and TB clinic services, must be retained because of the uniquely governmental role in the service (e.g., contact tracing and medication management to prevent further disease transmission).

Public health interventions must be crafted to address local needs and underlying disease conditions, which vary widely between states and localities. New York and Georgia might, for example, choose to have much more aggressive tuberculosis control efforts than states with lower tuberculosis incidence, and cities with high infant mortality rates might choose to launch population-wide (not necessarily patient-specific) infant health promotion campaigns. Since states and localities must retain authority to address these local needs, they must retain budgetary flexibility to do so. State and local public health budgets therefore should not be calculated into the "global budget" figures set for the states and/or health alliance areas.

Finally, public health departments must retain authority to order health professionals and health facilities to implement public health measures in their practices. Public health authorities must retain the ability to enforce legal duties of providers to report diseases, to isolate infectious patients, to refer patients with STDs to contact tracing programs, to screen children for lead, to give specific immunizations, and to integrate specific prevention messages into health care delivery. These legal mandates may vary between geographic areas, depending on trends and prevalence of specific diseases. Yet many of these public health interventions are not conducive to "outcomes" measures; may be of such an emergency nature that "outcomes" measures are insufficient to enforce health plan compliance; and may be so far removed from patient perceptions of "satisfaction" that consumer choice may not force health plans to comply.

In the case of legal duties to isolate infectious patients, for example, providers must act immediately to contain disease spread. It would be folly to wait for the "outcome" measure of how many patients were isolated and how quickly the isolation took place. Similarly, in the case of legal mandates to deliver HIV prevention messages in all HIV primary care, most patients (and therefore most health plans) may not care about how often such messages are delivered; the connection of such a mandate to immediate betterment of the health of most patients is too attenuated. Instead, public health departments must be able, through provider investigations, surveys, and chart reviews, to act quickly to enforce these mandates. For this reason, health care reform legislation must contemplate and allow states and localities to continue to enforce public health standards through these survey mechanisms, with penalty and licensing powers.

PART TWO: RIGHTS AND RESPONSIBILITIES OF PROVIDERS AND PATIENTS

IX. ASSURING QUALITY OF CARE FOR PATIENTS

Issue

Which entities (the federal government, the state government, health alliances, health plans, providers) should have what legal powers to assure quality health care?

Solution

As presented to the Legal Review Group, the health care reform package has serious potential for weakening quality of care. Reliance on outcomes data to police providers assumes both that reliable data exist and that consumers can be trusted to make informed choices. Yet reliable outcomes data do not exist -- and may never exist -- for a great deal of medical care, and even when the data is reliable, all consumers likely will not have sufficient knowledge to act on the data they receive. Fear of malpractice liability is at most a limited deterrent to poor care and is irrelevant to providers who serve the elderly and other groups not inclined or able to sue. Practice guidelines are not easy to fashion and do not guarantee appropriate implementation and good care. In order to ensure that the cost-reduction activities of providers do not jeopardize patient care, the traditional enforcement powers of state health agencies should be retained, and not reduced.

A. Data Gathering

Solution

The federal government should have the legal authority to gather data from HAs, plans, and providers; to mandate the data states must gather; and to receive data gathered by the states. The federal government should only exercise data gathering powers if the state fails to do so. HAs, plans, and providers should not have data-gathering authority.

Discussion

The power to gather data was the first power vested in nascent public health agencies in the 1800s. Only in recent years have some states begun to use the wide array of data collected by them to inform standard setting and to create new evaluation tools like risk adjusted outcome comparisons.

The health care reform proposal should encourage states to gather data and not seek to preempt or detract from state data gathering powers where they exist. However, since states may not be able or willing to gather data, the proposal should give the federal Health Board data gathering powers to be exercised in that event. The Board should also indicate what data must be gathered by the states and submitted by HAs, plans and providers. This will ensure some baseline uniformity of data across the country.

Any federal law should not vest federal data gathering powers in the alliances or plans or force the states to delegate state powers to alliances or plans. The HAs may, and the Plans certainly will, cover only parts of states. The plans may overlap geographically. This could lead to inconsistent, if not chaotic, data gathering within states.

Another reason not to give HAs and plans data gathering powers is that the data gathered is unredacted and highly sensitive. Confidentiality is better maintained by state governments with a history of data protection. Federal law should set confidentiality standards for state data gathering and provide for federal assumption of data gathering responsibility if the states fail to preserve confidentiality.

B. Data Evaluation

Solution

The federal and state governments should both have the legal authority to evaluate data. The federal government should take primary responsibility for data evaluation but should have the authority to contract assessment work to states and private entities.

Discussion

Data evaluation is a difficult and most states, HAs, and plans will lack the sophistication and resources to do it well. Evaluation may properly be the task of the federal Health Board, though states should be free to assess data if they can, independently or under contract with the Board. The Board should also be able to contract out assessment work to alliances and plans.

The proposal will have to address whether the entity doing the data evaluation must have access to unredacted data. If access to unredacted data is necessary, confidentiality concerns would argue against alliances and plans having broad assessment authority and against states having that authority unless the states have laws and practices protecting confidentiality.

C. Standard Setting

Solution

The federal government should have the authority to set standards of care, but states should not be prevented from establishing stricter standards. The federal Health Board should have power to identify and attempt to reverse any standard setting that has the principal effect of increasing costs but not quality of health care. HAs and plans should be authorized to include particular quality expectations in HA/plan and plan/provider agreements.

Discussion

Standard setting is another task which could be performed at the federal level to take advantage of superior federal resources and to assure nationwide uniformity of standards. However, federal law should not preempt state standard setting.

State standard setting is not "embroidery." It can take into account public health problems particular to a particular area (e.g., AIDS/HIV, tuberculosis, Lyme disease). It can respond to the particular demands of groups disproportionately located in a state (e.g., the power of religious groups on issues like DNR, health care proxies, determination of death). It can reflect a particular community's preferences for a type of care (e.g., an inclination to alternative medicine). It can reflect a heightened community commitment to quality of care (e.g., New York's pre-CLIA laboratory proficiency testing program, New York's imposition of limits on residents' hours, New Jersey's laws on medical waste and Florida's prohibitions against physician self-referral).

The proposal should not, as a general policy, stifle state efforts to establish quality standards enforceable against plans and providers. Of course, the reform proposal should not permit states to establish standards "lower" than federally set standards.

If the reform proposal permits state standard setting, it must distinguish between state laws which regulate quality and those laws which, in the name of quality, hinder the implementation of the reforms. This will not be an easy task. For example, how will the proposal treat New York's prohibition against for-profit hospital chains? The New York law reflects the political power of large voluntary providers in New York and genuine concerns about the motives and practices of for-profit chains.

It may be possible to preempt explicitly states powers and prohibitions that directly contradict the precepts of the proposal whatever their positive impact on quality (e.g., state corporate practice of medicine prohibitions) while permitting other state quality standards. States would be deterred from "overregulating"

by the impact of additional regulatory burdens on premiums in the state and the possible drain on state resources to make up for excessive premium growth. It may, however, be appropriate to grant the federal Health Board some back-up authority to attempt to reverse state standard-setting that has the principal effect of increasing costs rather than health care quality.

HAs and plans may set quality expectations in HA/plan and plan/provider agreements. If a plan or provider fails to meet these expectations, it will be subject to usual contract enforcement remedies. The expectations would not apply to persons and entities that are not parties to the agreement.

D. Surveys and Investigations

Solution

The federal and state government both should have the legal power to survey providers and investigate complaints of poor care. This responsibility is best left to states that are willing and able to do so. HAs and plans should not have the power to survey and investigate. Private entities should be allowed to survey under contract with government.

Discussion

Surveys and investigations of providers are best done at a state level closer to the trenches. These tasks cannot be directed from Washington or from understaffed and underenergized federal regional offices. Surveys and investigations will be necessary components of quality assurance, even when outcome measurements become available, since outcomes measurements may not be applicable to such areas as public health requirements (e.g., disease reporting, isolation of infectious patients), conditions of geriatric or other long-term care patients, and patients' rights assurances. Moreover, outcome measurements will still leave room for a range of facility quality of care activities. Surveys and investigations will assure that such activities are performed properly.

The states' legal powers to survey and investigate cannot be vested in HAs. By design, alliances will not include persons with expertise in health care. The HA's role as a health care purchaser minimizing premiums may conflict with the exercise of power to survey and investigate Plans and providers. Similarly, the plan's interest in selling services to HAs may taint its surveys and investigations of "its own" providers.

If a state fails to carry out its survey and investigatory functions, the federal government should be authorized to survey and investigate in place of the state. The reform proposal will

have to enunciate criteria for judging the quality and intensity of expected state surveys and investigations.

The state or federal government may choose to contract with a private entity like JCAHO to carry out surveys of providers. The reform proposal should permit this to occur although the government should remain accountable for the survey process.

E. Enforcement of Standards

Solution

The federal and state governments should enforce provider compliance with quality of care standards. Enforcement should include the imposition of a range of sanctions and due process protections to providers. HAs and plans should have contractual remedies to compel compliance with or penalize failures to meet quality expectations in the HA/plan and plan/provider agreements. The reform proposal should include due process protections for providers threatened with contract enforcement actions by HAs or plans.

Discussion

Permitting individuals and institutions to provide health care, penalizing them for providing poor care, and, ultimately, revoking the permission to provide care are essential governmental functions which should continue to be exercised by government. For the reasons set forth above, the states are in the best position to exercise this function. The reform proposal should authorize state enforcement, but allow progressive federal takeover of enforcement functions if the states will not or cannot enforce the law. The proposal should avoid the current melange of concurrent federal and state enforcement powers.

Loss of participation by a provider in a plan or HA may have a negative impact on patient access to care. Creation of a mechanism whereby providers have a right to notice and an opportunity to be heard prior to termination minimizes the likelihood of exclusion for arbitrary reasons. In addition, such a procedure protects against Constitutional due process arguments that may otherwise be made once participation in an HA or plan becomes an essential prerequisite for continued professional practice in a given geographic area.

X. STATE PRACTITIONER LICENSURE ISSUES

Issue

How should the reform proposal deal with state licensure and scope of practice issues for providers?

Solution

A cost-effective system should allow for a broad scope of practice for providers and for broad delegation from physicians to other providers.

Discussion

Licensure for health care professionals and institutional providers would remain at the state level to be handled under existing state mechanisms. The federal law may either preempt or create a basic standard for state scope of practice laws to avoid limiting the ability of individuals to act in an expanded practitioner role. Federal action may be indicated here, given the traditional reluctance of state legislatures to expand the scope of practice of nurse practitioners and other non-physician providers.

Any preemption of state law concerning licensure should be explicit. There is a potential problem that states could be too expansive and quality could suffer; the national Board therefore may want to retain oversight ability (particularly since physicians and hospitals paid on a capitated basis may have incentives to use low-cost staff at the expense of quality.) The federal law could also allow for broad delegation of authority from licensed individuals to licensed or unlicensed individuals who are otherwise qualified by education, training or experience to perform selected acts where the acts fall within the scope of practice of the delegator's license and will be performed under supervision. Expanded scope of practice delegation, properly monitored, would allow for cost-effective care.

XI. "MEDICAL NECESSITY" AND THE BENEFITS PACKAGE

Issues

1. The concept of "medical necessity," especially as concretely applied, is controversial and indeterminate. It routinely implicates important interests, including Constitutional ones. How can the reform plan take this into account in a reasonably sophisticated fashion without engendering crippling amounts of litigation?

2. What degree of variation in benefits (purchase, insurance, provision of services) should be allowed? Should individuals be able to purchase, and plans to offer, supplemental insurance? Should individuals and employers be able to opt out to any degree and receive lower prices or rebates for a lower option plan (and should plans be able to offer such options)?

Solutions

1. Phraseology alone will not solve the problem, but wording such as "appropriate medical treatment" usefully underscores that medical expertise provides vital information and evaluation, but lay values should ultimately decide. The proposal should place high priority on creating extensive disclosure to consumer-patients and requiring extensive participation of lay persons in decision-making about care, policy formulation and dispute resolution.

2. While universal access and fairness are the goals, overly rigid standardization of health care is both difficult and undesirable. A market in supplemental services and insurance for spreading cost should be allowed to exist. Individuals, employers and states all may wish to add to the standardized benefit package. Such supplementation should be paid for with after-tax dollars. Opt-down or -out plans and/or rebates should not be allowed at the outset but should be considered over the longer term.

Discussion

1. Two primary insights have come to the fore in the last 25 years in health law and policy. One is that where resources are limited, decision-making about consumption of care must connect real responsibility for costs with meaningful judgments about benefits. The other is that such judgments are not ultimately matters of professional expertise. Rather, medical expertise informs and recommends, but lay judgment must be the primary source of decision. This is so for a number of reasons. First, medical expertise does not yield determinate answers. Medical experts frequently differ; their knowledge is inevitably uncertain and incomplete. Moreover, the need to respond rapidly both to emergent developments in the lives of individuals and to a constantly changing climate of research and application undermines the determinacy of judgments. Perhaps most important of all, uncertainty is radically accentuated because medical decision-making necessarily takes place at an individual rather than a categorical level. Standardized analysis is only a starting point; answers must be chosen and implemented at a personal level that takes account of myriad variations of individual bodies, circumstances, and values.

Second, it is lay persons who experience the physical benefits and burdens of health care in their lives and bodies. Lay persons also pay the economic bills, either as individuals or as members of

groups ranging from purchasers' collectives to taxpayers (albeit the indirectness, professional control and cost-spreading characteristics of the current delivery system often allow consumers to avoid or fail to recognize that fact). Most fundamentally, individual values differ about everything from the meaning and definition of life, to tolerance for pain and risk, to the importance of various outcomes that money can provide. Democracy affirms value pluralism and individual autonomy, particularly where interests as vital as those in health care are implicated.

Terms like "medically necessary" obscure the fact that medical recommendations are critically important to informed decision but medical expertise does not settle what choices should be made. "Medical necessity" seeks to avoid political and values problems by implying that some invisible hand of expertise can make "right" decisions.[5] In so doing, it threatens to erode the primary gains of recent ethics debate and of increased consumer influence. It invites a return to professional dominance and undermines doctors' claim to act in individual patients' interests by forcing them to function as societal referees for the distribution of care. Instead of this approach, the term "medical" should modify "information" or "recommendation" rather than being used to characterize "necessariness" which is actually a balancing-type judgment about value and cost. Decisions about "necessity" inevitably involve cost-benefit trade-offs that should be made by individuals and society, i.e., by those who pay the bills and

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[5] A few examples of differences in value, as well as of the individualized nature of health care judgments, serve to illustrate the inadequacy of expert "right" answers. Case 1: A patient with severe asthma comes to the hospital having a life-threatening attack. She rejects treatment with steroids because of uncomfortable and dangerous side effects that she has previously found to be personally intolerable. With steroid treatment she could go home in a few hours. Without it, she will have to stay in a costly intensive care facility in order to remain alive. Is ICU care "medically necessary?" Case 2: Parents of a very ill young child wish, for psycho-social and emotional reasons, to care for him at home. To do so, they need round-the-clock nursing care that is more expensive than hospitalization. Is the nursing care "medically necessary?" Case 3: A young woman has vegetative growth on her heart valves that will cause death if the valves are not replaced or repaired. Her use of injection drugs is the likely cause of the problem. Her surgeon does the life-saving surgery once, but warns her that if she keeps taking the drug, the valves will become infected again and he will not do the surgery a second time. She cannot find a drug treatment program, remains addicted, and 18 months later returns with re-infected heart valves. Without the surgery she will die. Is the surgery "medically necessary?"

receive the benefits.

To incorporate these insights, disclosure of information to and provisions for decision-making by lay persons must be built into all levels of the system. Extensive information and discussion at the point of diagnosis and treatment are essential to preserving individual autonomy and value choice. The importance of these concerns has been the focus of legal and medical informed consent norms and of patient consumer movements in recent years. In addition, patients, who may be paying more directly through co-payments, choice of health plan, and tax-based redistribution, need information that facilitates expression of their genuine preferences. In a system of capitated spending limits, individuals also need information to protect them against plan and provider incentives to underservice. Moreover, telling patients what procedures and conditions really feel like and what outcomes are really to be expected has consumption and cost-cutting potential that has been seriously underutilized in a fee-for-service world.

Individuals should have broad access to dispute resolution procedures with plans (see Section XVI), and such procedures could mandate, as their first stage, an exchange with whoever is denying a patient's request. Requirements for lay participation in development of grievance procedures could be established by states or health alliances. Description of dispute resolution procedures should be mandatory for plans in recruiting enrollees.

At the macro level, consumer-taxpayers must have central roles in decisions in the states, in the health alliances, and in the national Board -- wherever cost and benefit decisions are being made. Informed by medical research and recommendation,[6] lay persons as consumers and as payers should have major input into decisions about such matters as what benefits are to be provided; how changes in research and technology should alter care under the standard package; what types of services and professionals are to be covered; what risk adjustment categories are to be accounted for; what budgets are to be established, how premiums and geographical boundaries should be set; how plans should be certified; how criteria and policies are to be determined, what data should be gathered, etc.

2. Given uncertain knowledge, individualized decision-making, and value pluralism, rigid standardization of medical care is

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[6] Medical expertise must be relied upon to make essential distinctions between therapies and treatments of proven value and those that are purely experimental. The national Health Board should have the authority to assemble medical and scientific experts in the relevant field to review the evidence and make rapid determinations as to what new treatments should be included in the comprehensive benefits package.

impossible and probably not desirable. Broader, fairer access and cost containment are both essential, but standardization carried to extremes will be undesirable -- lacking in efficiency (defined as delivering those benefits that are valued the most by those bearing the physical, emotional, and economic costs) and perhaps illegal (as interfering with Constitutional rights). Consequently, after-tax dollars should be spendable to purchase services that are not provided by the standardized benefits package (either categorically, or as determined for individual cases by relevant provider, plan or national Health Board decisionmakers). Sale of insurance for such services could probably be prohibited as a legal matter, but such measures seem inappropriate. Supplementation re-introduces some "tiering" in health care, but the personal and Constitutional significance of the interests involved is sufficiently great that some supplementary market should probably be maintained.

States as well as individuals may wish to add services to the federally mandated benefits package because of variation in political priorities, health status, or environmental characteristics of their populations. Assuming they absorb economic responsibility for such additions, the model of flexibility in and primary responsibility at the state level suggests that such variations should probably be allowed (see Section VIII.)

Choosing less expensive life-styles (e.g., non-smoking) or care options (e.g., refusal of life support near the end of life) would reduce health care spending. Distribution of resulting savings to individuals in the form of rebates or lower premiums could create desirable incentives to reduce consumption. However, allowing individuals to select, or plans to offer, low option alternatives threatens to open debate about the fundamental principle of community rating, and may therefore not be tolerable at the outset of this reform. States already have experience with insurance companies seeking to use "wellness" incentives or criteria to achieve experience-rating through the back door. (Constitutionally-based religious opt-outs, e.g., by Christian Scientists, raise related but distinguishable problems; see Section XIV.)

Once the principle of community rating is firmly established, however, serious consideration should be given to such low cost options as desirable incentives for health care choices. "Opt-out" or "opt-down" alternatives would require resolution of difficult questions. The first critical problem would be to determine when reduced consumption flows from factors beyond the individual's control (and is therefore not a legitimate basis for lower cost) and when it is the product of meaningful choice (and thus may reasonably be rewarded to create incentives for health-enhancing and cost-reducing behavior). While voluntariness is sometimes clear, it often is not. Even given clear choice, the imposition of

illness/ death or potentially crushing medical costs without any mechanism for cost-spreading may not be appropriate social policy. Second, low cost options premised on commitments to use less care would raise hard questions about when and whether individuals could change their minds about prospective decisions (e.g., to forego expensive care). Finally, if opt-down plans created too much of a pull toward wealth-tiered health care, political support for a quality level of universal comprehensive care could be unacceptably compromised. On the other side, however, is the fundamental and Constitutional nature of values involved, the need to create health-enhancing incentives, and the genuine variation of preferences having nothing to do with economic factors.

XII. PATIENTS' RIGHTS OF PRIVACY AND CONFIDENTIALITY

Issue

What special protections for patients' rights of privacy and confidentiality should be included in the legislation?

Solution

Wherever feasible, the legislation should restrict the availability of information about identified patients. Employers' access to health information about employees should be limited as much as possible.

Discussion

The extensive data collection required by the proposal, and the fact that such data is in computerized form, is likely to increase consumers'/patients' anxiety about the confidentiality of information regarding their health status. Data sent by providers to the health alliances or national Board should not include individual identifying information. Data provided to plans, including data exchanged among plans when a patient shifts coverage, should include such information only if clearly necessary to enable the plan to achieve legitimate objectives. Employers who participate in the health alliance should not have access to health information regarding their employees. Large employers who self-insure should be required to enforce a "Chinese Wall" between those responsible for their insurance functions and others in the organization (e.g., the Americans With Disabilities Act's requirements in this area should remain in effect.)

State statutes about such matters as minors' rights to seek treatment without parental knowledge or consent, families' rights to review medical information, subpoenas for medical or research areas, and other confidentiality issues should remain in effect.

XIII. PROVIDERS' RIGHTS OF PRIVACY AND CONFIDENTIALITY

Issue

What rights of privacy and confidentiality will health care providers have under the proposal? What personal and professional information about providers will be available to the health alliances, the plans, and consumers/patients?

Solutions

The need for consumers/patients, plans, and health alliances to make informed choices regarding providers must be balanced against (1) the need to encourage individual providers to seek treatment for impairments; (2) the need to encourage meaningful peer review by providers of each other (frequently the most effective means of quality control); (3) the need to protect the privacy rights of individual providers; and (4) the need to uphold overarching standards of informed consent law and practice.

As informed consent doctrine indicates, access by consumers, HAs and plans to provider-specific data should be limited to information that is clearly relevant and meaningful. If, for example, federal or state regulations require disclosure of "outcomes" or other provider-specific data that does not have a provable and meaningful relationship to rational consumer choice, then common law disclosure and informed consent standards could be placed in jeopardy. Excessive statutory disclosure requirements could result in patient demands, and legal duties, that providers disclose increasingly insignificant or irrelevant information. The result would be to overwhelm patients with data, while diverting provider energy into supplying that data instead of rendering care. In designing disclosure requirements, therefore, legislative drafters must keep in mind the informed consent standard that requires disclosure to patients only of significant factors or risks, judged from the perspective of the rational patient.

The Legal Review Group recommends that federal and state statutes protecting the confidentiality of information regarding persons (including providers) in drug or alcohol treatment programs should be retained. The Group also recommends retaining the current limitations on access to information in the National Practitioner Data Bank, with the exceptions that plans should be permitted to see such data and that health alliances (and consumers/patients) should have access to state licensure actions. Plans should be required to credential the physicians and other providers with whom they contract, should be liable to patients injured as a result of their failure to do so, and should have access to the information necessary for them to make such judgments. Plans are, therefore, the best mechanisms for protecting patients' interests.

Health alliances and consumers/patients should have more limited access to sensitive information about providers. If a physician's alcohol or drug problem or mental illness has been resolved to the extent that, in the opinion of the state licensing authorities, he or she is fit to practice, the history of his or her impairment should not be available to the health alliances or consumers/patients. Access to information regarding the HIV status of a practitioner should be governed by current state and federal law on this issue. Clearly, to the extent that individual providers are forced to disclose personal impairments or disabilities to patients, those providers would self-defer from seeking treatment for their conditions -- a result ultimately inimical to both providers' and patients' best interests.

XIV. RELIGIOUS EXEMPTIONS

Issue

How should the reform proposal deal with religious employers and consumers or patients with conflicting religious beliefs, and providers affiliated with religious groups, with regard to potential First Amendment claims? For example, some churches may challenge an employer mandate to provide health benefits to ministers. Christian Scientists may challenge the individual mandate to purchase health insurance. Catholic hospitals may refuse to provide basic benefits relating to contraception, and conservative Jewish facilities may challenge any limitations on care at the end of life.

Solution

Although some of these challenges may prove to be successful, the proposal should not at the outset provide specific exemptions or elections to opt out on religious grounds to religious employers, consumers/patients or religious-affiliated providers. Congress may well decide to provide special rules in some of these instances as it has in other laws, but there is no easy general solution to this problem. Individual states may have laws on these points as well. Religious providers cannot be excluded as providers because of religious objections, but the plan may have to make separate arrangements for certain services. There are difficulties in knowing when religious claims are properly grounded, rather than being made to modify benefits packages, but this issue will have to be left to the courts. Keeping exceptions to a minimum has legal (as well as political) advantages, and it seems best simply to ignore this problem in legislation, as initially proposed.

PART THREE: ACCESS TO LITIGATION

XV. MEDICAL MALPRACTICE

Issue

Will the medical malpractice reforms in the reform proposal be effective? Should additional reforms be enacted?

Solution

As explained to the Legal Review Group by Task Force staff, enterprise liability -- the placement of liability for negligence on health plans rather than on individual providers -- could help assure quality of care, and the Legal Review Group urges very serious consideration and support of this option. The reforms should reduce access to the courts and the risk of an adverse tort award, and, therefore, reduce premiums and defensive medicine. They will not redistribute tort awards to a broader group of injured parties. Reducing attorney's fees will reduce transactional cost in medical malpractice litigation. Non-dispositive alternate dispute resolution (ADR) may increase transactional costs and should be avoided. The Group members have different views on the effect of prohibiting limits on economic damages and imposing limits on non-economic damages. The reform proposal should not disturb current state laws effecting the reforms in the proposal or create a new federal malpractice law. If the proposal is to encourage states to effect significant malpractice reforms on their own, it should include some changes in current federal law.

Discussion

Periodic payments, uniform statute of limitations, and collateral source deductions should make the tort system more rational. Periodic payments may prevent wasteful use of large awards. Uniform statutes of limitations should prevent some gaming of disparate state claim filing deadlines. Collateral source deductions should prevent some double dipping. Since the reform proposal will make health services available to more victims of negligent care, it will increase the impact of collateral source deductions attributable to that care on malpractice awards and premiums. These three reforms are already in effect in many states but have not prevented "high" premiums.

Limits on attorney fees should significantly deter plaintiffs' lawyers from taking cases of lower value and higher risk. This reform will force lawyers to raise their threshold for cases they are willing to bring and reduce transactional costs for cases that

are brought. This should retard premium growth. It will not redistribute tort awards to a broader group of victims, but successful plaintiffs will receive a greater share of their awards.

Some Group members strongly support prohibiting limits on economic damages in order to ensure adequate lifetime support for injured persons. Others believe the calculation of economic damages is inherently speculative and subject to abuse. In addition, if the reform proposal includes a prohibition against state laws limiting economic damages, it could prevent a state from capturing and redistributing these damages as part of a non-fault based system providing an array of support mechanisms to more malpractice victims.

A limit on non-economic damages is a big ticket item for providers. If pain and suffering are severely constrained, premiums should decline substantially. However, standing alone, this benefit to providers will result in a windfall to providers and no direct redistribution to other victims. As demonstrated recently in some states, malpractice premium reductions are not necessarily passed on to consumers in the form of lower prices. The Committee members were divided on the merits of this change and on the potential mechanisms for capturing windfalls.

Enterprise liability preserves the deterrent effect of the tort system while focusing primary responsibility for ensuring that quality care is delivered on the enterprise, in this case, the plan -- the same entity that is also responsible for resource allocation and cost containment.

Enterprise liability may help to safeguard quality of care that may be jeopardized by the proposal's emphasis on cost reduction. Enterprise liability will help achieve the quality assurance goals of the proposal if the plans fearing malpractice liability have the capacity to improve quality among the providers in the plan. If the plan can improve quality of care, actual malpractice (and premiums) will decline.

ADR may help to resolve some disputes before resort to litigation. However, if ADR does not preclude litigation, it may become another transactional cost in the inevitable litigation like the pre-trial conferences in New York, and another source of delay in an already lengthy process. If use of ADR is not mandatory, it may become a high tone but little used alternative to litigation like arbitration.

Since many states already have one or more of these reforms in place, the proposal should not disturb existing state laws which do not contradict the proposed federal reforms. The proposal should also avoid creating a new federal malpractice law. To achieve these goals, the federal law should (a) state explicitly that it does not intend to create a federal right of action, and (b)

preempt only inconsistent state law. If there is any question about the authority of the federal government to preempt state law, the proposal, as an alternative to (b), could condition state receipt of federal money or other federal benefits on state enactment of these reforms.

If the proposal encourages states to adopt their own medical malpractice reforms, particularly those aimed at redistributing existing awards to more victims, certain federal impediments should be removed. Any state effort to redistribute current tort awards, like New York's current proposal for impaired newborns, must address (a) federal limits on taxes and fees imposed on less than an entire class of providers (e.g., obstetricians only) necessary to fund redistributed benefits and (b) limits on Medicaid as a payor of last resort if a new state benefit fund is not to replicate Medicaid benefits.' Specific exceptions to these two laws would facilitate broader tort reform on the state level.

XVI. MANDATORY ADJUDICATION OF CONSUMER/PATIENT DISPUTES

Issues

What type of dispute resolution should be considered for consumer/patient disputes over the benefits offered by the plan?

Solutions

Dispute resolution for in-plan benefits should include an internal grievance procedure for each plan followed by mandatory mediation within the plan followed by an appeal to a state administrative body (example: an existing board such as a State Consumer Complaints Board or a newly created State Government Board) followed by an appeal to state court. There is also a need for a reporting mechanism of the final outcome of grievances (without patient names or identifiers) to a state quality program (SQP or equivalent) which would then aggregate information and send it to the national Board for ongoing evaluation of the mandated benefits packages.

Discussion

Dispute resolution for plan benefits will be necessary when claims are brought by consumers/patients within plans over actions or inactions by the plan. These could include decisions to exclude specific practitioners, but are most likely to be based on service problems experienced by patients within the plans (from impolite clerks up to failure to provide alleged "lifesaving' benefits). In general, the Legal Review Group feels that claims should be reviewed first by an in-plan dispute resolution mechanism followed

by mandatory mediation within the plan with limited rights of appeal to state court after exhaustion of administrative remedies.

For in-plan patient complaints, the proposal should require discussion between patient and care-giver which could be facilitated by an ombudsperson. If this does not achieve resolution, then there would be an informal but expedient (10 days for most issues, but 24-48 hours for emergent life threatening issues) grievance procedure. This would be similar to procedures presently employed by HMOs for disputes over benefit coverage. For "gripes" (suggestions for improvement, impolite clerks or other non-benefit issues), this grievance procedure would be final.

For lack of access, benefit coverage and other significant questions, the process would then allow mandatory mediation within the plan. The structure would be spelled out in each plan based on general federal standards and would include a defined hearing board chaired by an individual with significant administrative responsibility from the plan, expedited hearing, no formal rules of evidence, written decisions within 24 hours from the end of the hearing and a notice of appeal rights for unsuccessful applicants.

Mandatory mediation should resolve most disputes. For those still unresolved, states might choose to allow an appeal to an already established state mechanism. For example, the Michigan Department of Public Health has a Health Facilities and Agencies Advisory Commission to hear complaints from HMO enrollees. If no such mechanism exist, appeal could be to a state created board of review established pursuant to general federal standards.

For any complaint unresolved after state administrative review, there would be an appeal to state court. The appeal would be limited to whether the state administrative findings are supported by competent evidence and to mistakes of law. There would be a presumption of proper administrative findings and exhaustion of administrative remedies prior to suit would be required.

It is preferable to rely on state administrative review and the state court system rather than the a federal system. This allows for the states to be creative but could result in a lack of uniformity. Diversity jurisdiction should not be permitted; federal cases should be limited to claims that the federal law or national Board should have included a specific benefit. Individual claims that an available benefit was denied by the plan (bone marrow for metastatic cancer, whether a therapy is efficacious, genetic testing for patients without a suspicious history, etc.) would be resolved in each state.

In order to have quality assurance and obtain benefit uniformity over time, reports on the final outcome of grievances would be sent on a regular basis by each plan to the State

established quality program. For privacy reasons, those reports would not include patient names or identifying information. The state, in turn, would do a report to the national Board so the Board would have data to consider in the design of future benefit packages and for quality assurance purposes.

XVII. SECTION 1983 LITIGATION

Issue

Should a private claim for relief under 42 U.S.C. § 1983 be available for alleged violations of the federal health care reform statute?

Solutions

Section 1983 should not be available as a remedy for alleged violations of the statute, and the law should expressly say so. Instead, the legislation should create a comprehensive system for resolution of disputes that may arise at all levels of the health care system. The legislation should expressly describe who can assert which kinds of claims, as well as where each type of claim will be heard. For most types of claims, the system should provide for use of alternative dispute resolution methods, followed by administrative adjudication and limited judicial review. Claims of Constitutional, as opposed to statutory, violations would not be limited by this process.

Discussion

Because the health care reform system will be established in federal law, the potential for section 1983 litigation is enormous. A private litigant could maintain an action under section 1983 for alleged violation of the federal health care reform statute against any participant in the system found to be acting "under color of state law." Since much of the system would be implemented under state law enacted pursuant to federal guidelines, not only state officials, but health alliances and, potentially, health plans might be deemed to be acting under color of state law. Section 1983 actions are not subject to an exhaustion of administrative remedies requirement, and attorneys fees are available to a prevailing plaintiff under 42 U.S.C. § 1988. Therefore, without a limitation on the use of section 1983, there will be a possibility of suit in federal court for any dispute arising under the statute without exhaustion of administrative remedies, and with the enticement of a potential attorney's fee award.

It is not desirable to have all disputes over health coverage or treatment or even administration of the new system litigated in federal court under the rubric of section 1983. Rather, the

legislation should specifically identify which categories of disputes under the statute should be heard in administrative tribunals, state courts, or federal courts or some combination. An appropriate remedial mechanism should be provided for all types of claims. To eliminate the possibility of a claimant by-passing the intended claims resolution process in favor of a direct court action under section 1983, the legislation should expressly provide that claims based on violation of the federal health care reform statute are not within the scope of section 1983. An alternative way to achieve the same result is to state in the law that the claims resolution processes provided are the exclusive means for adjudication of those disputes. This express limitation should not, however, include claims alleging violation of the constitution or other specific civil rights laws.

XVIII. ANTI-INJUNCTION PROVISIONS

Issue

Can an anti-injunction provision be included in federal legislation so as to insulate the health reform law from attempts to block its initial implementation?

Solution

Yes, to a degree. Although federal court jurisdiction of pre-implementation challenges will be limited to some extent by ripeness and similar issues, in order to more fully protect the legislation from injunctions, the statute must explicitly provide that remedies are limited at the pre-implementation stage. However, statutory restrictions cannot foreclose all remedies for Constitutional claims.

Discussion

Federal remedies available for Constitutional claims arising under a statutory scheme may be limited by the terms of the statute provided that an alternative remedial mechanism is provided, Schweiker v. Chilicky, 487 U.S. 412, 421-23 (1980). In an area where Congress has provided an explicit, exclusive remedy the courts will be hesitant to infer a Bivens-type Constitutional cause of action. [7] Thus, for example, remedies for a possible Constitutional claim involving a taking or a wrongful denial of benefits could be limited in a statutory scheme that provided for

[7] In Bivens v. Six Unknown Named Agents, 403 U.S. 388 (1971), a federal cause of action was implied under the Fourth Amendment.

retroactive benefits.[8] Subsequent interpretations of Schweiker have indicated that this deference to Congressional intent is not without limits; a statutory remedial scheme may not limit Constitutional claims if Congressional intent is not explicit or if the remedy available is not an "adequate" one.

Challenges that may be undertaken before the statutory scheme is in place will also be limited by ripeness problems. The jurisdiction of federal courts is limited by Art. III's "case or controversy" standard. Courts require that a controversy be "ripe" for resolution:

> to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.

Flowers Industries v. F.T.C 849 F.2d 551, 553 (11th Cir. 1988) (citing Abbott Laboratories v. Gardner, 387 U.S. 136, 148-49 (1967)).

Federal remedies are also limited by sovereign immunity. The United States may not be sued at common law without its consent. Similarly, the federal government may be sued on statutory grounds only to the extent a right of action is created by the statute. Thus, Congress may frame a statutory provision that explicitly limits the means by which a person may advance a claim under the statute.

Federal court jurisdiction may be similarly limited in actions against States arising under the Constitution or federal law. California v. Grace Brethren Church, 457 U.S. 393, 408 (1982.)

The Group disagreed as to whether the legislation should include a limitation on pre-implementation injunctions. Some members were concerned that relatively minor disputes could disrupt the entire program; others believed that a statute with such profound implications for so many citizens should not be specially exempted from legal challenge.

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[8] Due process claim over the denial of disability benefits was limited to the retroactive benefit payment provided for in the applicable statutory scheme. Schweiker at 425-27.

XIX. ANTITRUST ISSUES

Issues

1. How would the health alliances be affected by state and federal antitrust laws?

2. If two or more hospitals combine to purchase and share a piece of equipment, i.e., a joint venture, will state or federal antitrust laws prevent this from happening?

3. Can hospitals form market allocation agreements whereby services, patients, or territories are divided up among the hospitals without running afoul of the antitrust laws?

4. Should insurance companies which acquire institutional providers continue to be exempt from antitrust scrutiny?

5. Should a national antitrust policy be established with respect to the application of federal and state antitrust laws to health alliances and provider networks?

Solutions

1. A health alliance or purchasing cooperative can agree among its members on a premium price and other terms and conditions for health plan contracts, without antitrust exposure, provided that the HA operates in a manner consistent with the state action exemption from the antitrust laws. If the formation and the governing charter or articles of organization of an HA are submitted for approval to the appropriate state agency overseeing the implementation of national health reform at the state level, and the agency approves the structure and operation of the HA and provides oversight or supervision of the HA, the HA will be exempt from state and federal antitrust laws by virtue of the state action doctrine. State enabling legislation can be structured to provide the requisite criteria for state action immunity.

It is also possible for a health alliance or purchasing cooperative to bargain with health plans and agree on a premium price and other conditions without running afoul of state or federal antitrust laws. Since HAs will be required by law to apply community rating to consumers, no antitrust problem may arise that requires application of the state action doctrine. However, in cases in which the HA is very large and in effect constitutes a true monopsony, the state action doctrine should apply to prevent the abuse of market power or predatory conduct in relation to plans and providers.

Another approach, in order to avoid the limitations of the state action doctrine, would be to amend the antitrust laws to

protect, explicitly, the HAs from any antitrust liability.

2. Usually, the joint purchasing and sharing of equipment among hospitals is considered pro-competitive and efficiency-enhancing conduct. These agreements are judged by the "rule of reason" test, and federal and state authorities have indicated that these arrangements are not contrary to state or federal antitrust laws. There are numerous such arrangements already existing throughout the country.

3. Ordinarily market allocation agreements among horizontal competitors, including hospitals, are considered to be per se violations of the antitrust laws. Market agreements among hospitals therefore may run afoul of current antitrust laws. One solution would be to provide a mechanism for state pre-approval of any such arrangements, enabling them to be protected under the state action exemption. Alternately, the antitrust laws could be specifically amended to make such agreements legal without the limitations inherent in the state action exemption, or subject to a "rule of reason," rather than a per se, approach.

4. Insurance companies that acquire health care providers in an effort to form provider networks should be subject to the same antitrust scrutiny as providers would be if they were collaborating with other providers. While insurance companies could continue to have antitrust immunity as long as they were carrying on the business of insurance, insofar as that is regulated by state entities (a statutory state action exemption), insurance companies should not receive special antitrust treatment for conduct that is essentially the provision of health care services, as opposed to insuring the risk of such services. Of course, movement toward HMOs tends to combine the functions of insurance and provision of medical services.

Another option is to repeal the McCarran-Ferguson Act, which currently exempts the business of insurance from the antitrust laws to the extent such business is regulated by the states.

5. A mechanism needs to be created to coordinate federal and state antitrust review in order to facilitate pro-competitive and efficiency-enhancing market arrangements. The Department of Justice, the Federal Trade Commission and the Antitrust Task Force of the National Association of Attorneys General should form a policy group and develop quickly overall policy guidelines with respect to mergers, joint ventures and market allocation agreements in the health care field.

Discussion

1. Under the so-called "state action doctrine", which has been developed through judicial interpretation over the past 50 years, conduct that would otherwise run afoul of the antitrust

laws, both federal and state, is shielded from such exposure provided that the state has (1) clearly articulated a policy to displace competition with regulation and (2) established and implemented a system of regulation and active supervision over the conduct at issue.[9] The state action doctrine, when found to be applicable, protects otherwise anti-competitive conduct from antitrust challenges, including those brought by private parties and federal and state governments.

The first prong of the state action doctrine is easily established by inclusion in the enabling health care reform legislation of language which sets up a regulatory or oversight scheme. The second prong of the test requires supervision by a state agency over the collaborative market conduct carried out by otherwise private entities. In the case of HAs, private employers and individuals will be collectively determining the terms and conditions upon which they will solicit bids from health plans.

Regulation and oversight of an HA consistent with a state action exemption would require regulatory and due process safeguards such as reporting of HA meetings to state regulatory authorities; open processes for members in establishing the premium price; prohibition of conduct that is intended to injure the marketplace, such as deliberately misrepresenting costs or claims experience in an effort to secure low rates of payment to health plans; and discrimination against HA members who may have a negative impact on the premium that is being sought.

Since HAs may enjoy monopsonist market power over many health plans, state oversight of their collective purchasing conduct is appropriate in order to ensure that the exercise of this market power will not result in predatory practices and, ultimately, consumer harm. If, on the other hand, the alliance is not a monopsonist, that is, if it is only one of several cooperatives seeking to purchase a health plan's services, an alliance respecting community-rating principles could be allowed to function without state regulation or oversight of its collective purchasing conduct.

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[9] The state action exemption, first established by the United States Supreme Court in Parker v. Brown in 1943, provides market flexibility for companies in industries which the state has determined need protection from the antitrust laws in order to carry out a mission that cannot be carried out under normal marketplace rules. A wide array of industries have functioned under the state action doctrine with appropriate state oversight. In the past, this doctrine has shielded industries such as freight and passenger motor carrier, rail, and air transportation; public utilities; automobile insurance; agricultural collaboratives; and hackney services in numerous cities.

An alternate approach would be to amend the antitrust laws so that HAs would be specifically exempt from antitrust liability.

2. Most joint purchasing arrangements are very local in nature and do not require any formal notice to state authorities with respect to the joint purchase and sharing of such equipment. Unless the state has a certificate of need or determination of need process, hospitals can jointly purchase any equipment that they could not afford individually or that they could not operate at an efficient level of capacity on their own. Hospitals contemplating this type of arrangement often now seek, and should continue to seek under the reform package, competent antitrust counsel to provide them with some comfort that the conduct will not run afoul of the antitrust laws.

In situations in which there is a joint venture among two or more hospitals, and each hospital is sharing the risk of the capital expenditure or of loss for the equipment, the proposed project is likely to promote efficiency among the hospitals participating in the joint venture, and is likely to provide pro-competitive benefits to consumers. The sharing of a single piece of equipment by two or more hospitals will reduce unnecessary costs to each entity, thereby ultimately reducing health care costs.

It is possible that in some rural settings, where there are very few hospitals spread over great distances, some hospitals could form joint ventures and exclude a competing hospital from sharing the equipment or facility that is the subject of the joint venture. Under those circumstances, the exclusion of the single hospital could be for the purpose of driving that particular hospital out of the marketplace. Where there is not excess capacity, this would not be pro-competitive, and could result in one set of hospitals exercising monopoly power. Ultimately, hospitals (and the health plans with which they have established contracts) in such geographic areas would be in a position to raise the price at which the HA is buying services. Under these circumstances, the application of the antitrust laws might require that all hospitals in an area be able to access the single piece of equipment.

3. Antitrust law views agreements among horizontal competitors to allocate services, territories and/or customers as harmful to the market. There are situations, however, where such arrangements can reduce costs to the hospitals that are part of the agreement, and those reductions in cost could be passed on to health care purchasers. Market allocation agreements may also, in

some circumstances, promote quality of care.[10]

One way to permit appropriate market allocation agreements is to impose a state regulatory scheme to oversee the allocations and to ensure that efficiencies are achieved and passed on to consumers. A simple state scheme could be established whereby hospitals wishing to engage in such conduct could file the allocation agreement with an appropriate state health department agency, which would review the arrangement for its efficiency enhancing and cost reduction features. The health agency could have 30 days within which to review such agreements, and at the end of 30 days, if the parties to the agreements have not been notified that the agreement is problematic, the parties could simply move forward to consummate the agreement. Enabling legislation could also provide that any discussions leading up to the filing of the agreement would be free from any antitrust exposure, even if the agreement itself were later challenged. These agreements should also be filed with the appropriate state antitrust authorities within a particular state as well as with the health care agency.[11]

However, the state action exemption would not automatically protect hospitals from antitrust challenges by private parties or the federal government, although state approval processes could be constructed to offer significant insulation from antitrust liability. In addition, in some states, resource constraints may preclude oversight by state health care authorities sufficient to trigger a state action exemption.

In the Legal Review Group, however, there was a some opinion that preferred to avoid such pre-approval processes for market and service allocation agreements among providers and health plans. In this scheme, antitrust enforcement could still be undertaken by federal and state authorities and private parties under a "rule of reason" standard, but there would be no "pre-approval" mechanism. Another solution would be to exempt these allocation agreements entirely from the antitrust laws, but this might give rise to anti- as well as pro-competitive conduct.

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[10] Expertise is more easily achievable if a facility routinely performs certain procedures or uses certain equipment. Moreover, it is easier to afford expensive equipment if a facility performs many similar procedures, and it reduces the enormous waste to the system that comes from the duplication of staff and facilities that sit idle for long periods of time for lack of patients.

[11] Similar legislation has been passed in about six states and is pending in several others.

APPENDIX A

STATE LAWS THAT MAY BE CHANGED OR PREEMPTED UNDER HEALTH CARE REFORM

I. Laws Regulating Providers and Related Entities

A. Anti-networking laws

1. "Any willing provider" laws

2. Mandatory assignment laws

3. Fair reimbursement laws

4 Anti-discrimination laws

5. Freedom of choice laws

6. Anti-gatekeeper laws

B. Laws restricting corporate practice of medicine

C. Employment laws that regulate provider arrangements

1. Fee splitting prohibitions

2. Anti-referral laws

D. Utilization review laws

1. Laws requiring reviewer to reside in same state

2. Laws requiring review by same specialty

E. "Consumer" laws that are used to restrict access to services

F. Laws that prohibit financing of health care entities by other providers

G. State and local quality of care standards

H. State and local public health laws applicable to health care providers and institutions

I. State and local patients' rights protections

II. Insurance laws

A. Transition measures

1. Premium caps

2. Restrictions on cancellation of coverage

3. Variations for states implementing insurance reform

4. Portability/barriers to coverage

a. Pre-existing conditions exclusion
b. Prohibit waiting periods for enrollment

5. Prohibit benefit cutbacks

6. Limit premium and cost-sharing increases

7. Claims processing/dispute resolution: minimum federal standards

8. Enforcement/private rights of action

9. Establish ADR projects that include de novo judicial review

10. Expand damage relief available

11. Impose penalties for bad actors

12. Attorneys fees available

B. Workers compensation - health care component

1. Preempt workers compensation laws inconsistent with merger into new system

a. Benefit package
b. Limits on choice of provider
c. Utilization review
d. ADR requirements
e. Premium surcharges

2. Indemnity part of workers compensation remains separate and intact

C. Auto Insurance - Medical costs

1. Partial preemption

2. Collateral source rules preempted to prevent duplicate benefit payments

D. Amend McCarran-Ferguson to allow states to apply antitrust laws to insurance industry

III. Laws regulating health alliances

Laws for health alliances must be coordinated with state insurance laws. Assumes states will enact new legislation regarding structure and authorities of health alliances, but many alliance issues are similar to current state insurance regulation issues (e.g., requirements to serve all enrollees, prohibition against cancellation of coverage, waiting periods and coverage gaps, risk and premium rating regulations).

A. Policy regulation: done by states

B. Marketing regulation: federal agency develops minimum standards

IV. Health plan regulation

A. Contingencies for insolvent health plans

1. State designates agency for takeover of insolvent health plans: similar to state responsibility regarding insolvent insurers?

2. State options for guarantee funds, but must comply with federal minimum standards

B. Fiduciary standards: state enforcement subject to federal minimum standards, except for ERISA-covered plans

V. Malpractice law reform

A. Establish enterprise liability

B. Require ADR

C. Allow periodic payment of judgments

D. Establish uniform statute of limitations with discovery provision and tolling for minors

E. Mandate offsets for amounts paid from collateral sources

F. Create sliding scale for attorney's fees

G. Prohibit limits on economic damages

H. Limit non-economic damages by establishing range of awards

TO: LEGAL REVIEW GROUP
FROM: JENNIFER KLEIN
DATE: 6/18/93

This will confirm that the Legal Review Group will meet on Wenesday, June 30, 1993 at 5:00 p.m., Thursday, July 1 at 9:00 a.m., and Friday, July 2, at 9:00 a.m.

Please feel free to call me at (202) 456-2316 with any questions.

But
one
thing
is
as
clear
to
you:

Office of TECHNOLOGY TRANSFER

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Potential Liability of Health Alliances

Problem: Health alliances may be exposed to significant potential liability under federal health care reform legislation. How can the reform proposal minimize potential liability for health alliances? Can state liability be minimized by making the HA a private entity?

Proposed solution: Federal health care reform legislation should afford the states considerable discretion and authority in establishing, structuring, monitoring, and delegating responsibility to health alliances. Federal legislation should avoid directing specific authorities to health alliances. Rather, states should be given permissive authority to delegate to health alliances. In this manner, states, which have been given responsibility to administer the system, will have the requisite authority and enforcement power to do so.

Because the majority of proposed functions of the health alliances are regulatory in nature, it is unlikely they could be constituted as purely private entities. Even if so constituted, courts are likely to regard the activities of privately structured health alliances as state action. If a state wishes to establish a health alliance as a private entity, it should consider delegating to the alliance only nonregulatory functions, such as brokering and information dissemination activities.

Discussion: The current health care reform proposal contemplates a central role for the so-called health alliances (HAs). Although the health care reform proposal generally contemplates the HA as an employer/employee cooperative which functions as a health plan purchasing broker, many possible functions of the HAs have been discussed. These include: 1) negotiating and entering into purchasing agreements with health plans; 2) gathering and disseminating information to consumers about types of available health plans; 3) acting as a clearinghouse for outcomes and other information gathered by HAs from health plans; 4) monitoring and assuring quality of care within health plans; 5) determining eligibility of plans to participate in the system (including possible certification of plans and denial of ability to participate); 6) determining the risk adjustment applicable to health plans for certain populations; 7) approving and denying major expenditures of health plans; 8) setting standards for health plans regarding quality of care or access to care; 9) determining benchmark premiums; 10) regulating fees that may be charged by plan providers; 11) participating in the dispute resolution mechanism established to handle consumer and provider grievances; 12) enforcing budgetary restraints and provision of required benefits by health plans; and 13) collecting premiums.

Although it has been specifically stated that the HAs are not to be regulators or "mini-HCFAs," most of the proposed functions of HAs appear regulatory in nature. We do not believe an HA constituted as a purely private entity could legally carry out

many of these functions. In any event, such activities carried out by a private HA established by the state are likely to be regarded by courts as state action. Because this characterization has benefits and drawbacks and affects the potential liability of both the HAs and the states, states should be afforded wide authority and discretion in accomplishing the functions proposed for HAs.

For example, if the HA is a state agency, it would likely fall within the state action exemption to anti-trust law recognized by courts. However, as a state agency, an HA would be constrained by Constitutional requirements such as substantive and procedural due process. In addition, if the HA is established as a state entity, it would be subject (unless exempted by federal or state legislation) to all laws applicable to state action pertinent to its activities, such as state administrative procedure acts, freedom of information acts, anti-deficiency acts, and procedural and substantive Constitutional guarantees. These sources of liability are in addition to those generally applicable by virtue of the activities of HAs, such as contract law and record-keeping and privacy laws.

As outlined above, states can minimize challenges to the HAs and the consideration of HA activities as state action by retaining authority over the regulatory functions and delegating only the nonregulatory functions to HAs established as purely private entities. As there are federal and state Constitutional limits on states' ability to delegate certain functions, the legal audit group recommends broad authority and discretion for states so each can determine its own limitations in this regard.

Because of the significant potential liability stemming from the contemplated actions of the HAs, the legal audit group recommends that Federal health care reform legislation provide considerable discretion to states in establishing, structuring, delegating responsibility to and monitoring HAs. This provides states with the ability to control those aspects of the HAs for which the state will necessarily be responsible. If HAs are established by the state legislatively, broad state discretion allows states to enact statutory exemptions for HAs to pertinent state laws. Broad state discretion and permissive authority to states to delegate to health alliances also limits direct federal liability for actions of HAs.

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To: Legal Review Group
May 10, 1993

Problem: Determination of a basic benefits package.

Question 1. What alternative health care providers will be allowed to participate? These may include recognized groups (chiropractors, podiatrists) and others, such as laetrile providers, crystal readers, massage therapists, aromatherapists. The difficulty with sorting groups between those with state licenses and those without is that many groups of highly trained professionals one would certainly wish to include as staff in any hospital or clinic (psychiatric social workers, child life professionals) are not state licensed although professionally accredited. What causes of action will excluded groups be able to bring against the Health Alliances/ Plans/ federal or state governments? What are the anti-trust implications? (cf. the chiropractors' action against the AMA.)

Benefit package will say only services provided by professionals

Proposed Solution: This question may be one of the most difficult to answer. At present, insurance companies have different views on willingness to pay alternative providers such as chiropractors. There are numerous decisions upholding their refusal to pay less-recognized providers, such as laetrile clinics, massage therapists, etc. Hospitals all over the country have been sued by chiropractors and podiatrists over refusal to grant them privileges. Private hospitals with by-laws delineating privileges to groups such as physicians, physician assistants, nurse practitioners, etc. have been successful in refusing to admit other groups to staff. I don't really know the status of these groups in public hospitals, but will try to find out before our next meeting.

Question 2: What restriction of privileges (if any) may plans or hospitals make based on Board certification of physicians? If quality control is based on a federal program, will hospitals and health plans continue to be able to make these determinations? If a national decision is made, for example, that only Board-certified surgeons will be compensated for surgical procedures, what will happen in rural areas where there are none? Conversely, what rights will non-Board-certified physicians have to continue to practice?

Proposed solution: This issue is best left as it currently is, with staff privileges determined by individual hospitals and medical groups.

Question 3: a. What body will determine, within what practice guidelines, what therapies will be made available, particularly in case of new therapies?

b. Should high-technology, expensive therapies (i.e. transplants, etc.) be offered at any institution that currently does them or might wish to do them or should their use be confined to a few nationally recognized institutions?

Proposed solution: An all-inclusive health system cannot possibly work if some therapies are included as a basic benefit in some areas and not in others. Where therapies are unusually expensive or complex, however, a decision to move patients to selected tertiary-care centers instead of having everything available everywhere would seem reasonable.

If the decision is made to restrict certain procedures to a few hospitals, will the health plans pay for transportation and out-patient living expenses for patients and family members who accompany them? If the procedure is covered as a basic benefit and the patient cannot otherwise afford to receive it, it would seem unlikely that the plan could avoid such expenses.

If procedures are geographically restricted and patients travel to a few medical centers, what provisions will be made to train physicians at other institutions to perform them so that new programs may be initiated when the procedure becomes standard therapy and probably less expensive?

It is unclear to me what recourse hospitals with existing programs will have if there is a decision to close such programs and refer patients to a few large centers.

It seems to me that these determinations are ones that only the National Health Board can make.

Question 4: If "experimental therapies" are excluded from coverage, who will define them and what will that definition be?

Proposed solution: In current case law, "experimental" is used to discuss both (a) bizarre "therapies" performed in such places as laetrile, etc. clinics and (b) patients on research protocols in medical institutions. We are, of course, considering only the latter.

As the law now stands, two insurance companies may come to opposite coverage decisions about patients receiving identical therapy from the same physician. For that matter, the same insurance company may come to opposite conclusions about two patients in different parts of the country receiving the same treatment. In one situation, the patient's coverage is denied on the grounds that the therapy is "experimental" and in the other, the payment is made. The situation is intolerable for patients, who don't find out that they are not covered until they are already seriously ill, and is an administrative nightmare for physicians. (See, e.g., Antman, et als, The Crisis in Clinical

Cancer Research: Third-Party Insurance and Investigational Therapy, 319 NEJM 46, July 7, 1988.)

There must a definition of "experimental" that is consistent, that recognizes advances in medicine and that mainstream specialists in the field who provide the therapy agree is reasonable. (See Bucci v. Blue Cross-Blue Shield of Connecticut, 764 F Supp 728, 1991 at 732 " A procedure may be found not to constitute accepted medical practice only where there is no reasonably substantial, qualified, responsible, relevant segment of the medical community which accepts the procedure as properly within the range of appropriate medical treatments, under the circumstances of the case, as judged by the standards of .. a reasonable number of practitioners qualified to treat the malady in question.") At present, insurance companies' determinations are made by physicians who may never have treated a patient with the disease in question and are frequently retired from all clinical practice. (See, e.g., Fuja v. Benefit Trust Life Insurance Company, 1992 WL 394216, ND Ill. and Adams v. Blue Cross/ Blue Shield of Maryland, 757 F Supp 661, DC Md 1991.)

With the institution of the fast-track drug approval process by the FDA, there is increased recognition that some uncertainty about safety and efficacy may be acceptable in cases of life-threatening illness where no effective therapy exists. This will increase pressure to permit other new forms of therapy, as well.

These determinations can, as a practical matter, be made only by the National Health Board, which presumably should have panels of specialists in the practice areas involved to which these questions may be referred for consensus. These panels must be able to act quickly in case of real break-throughs in treatments, lest people die while the issue is being debated.

Question 5: Will benefits include payments for treatment that will improve the quality of a patient's life but which will not affect the underlying medical problem? Rehabilitative services, at least theoretically, improve the patient's ability to function, but in some cases all medicine can do is to make the patient's condition more bearable. For example, very expensive neurosurgical procedures may be the only way to relieve a paraplegic's constant pain. Will the costs of such surgery be covered?

Proposed solution: As a political matter, it would be quite difficult to avoid coverage of such services, but it does not seem to me to be a legal question. As long as any particular treatment is not offered to anyone, no individual would have a claim to get it. It is only when the therapy is offered to some persons with condition X but not to others that claims will arise.

B. State accountability for system design.

A potential problem of state accountability involves state design of the health care reform system within their jurisdictions. Certainly their design must conform to the general federal guidelines and will undoubtedly be subject to some federal approval process. However, litigation over the adequacy of states' program designs could virtually derail the reform process at its inception both by diverting necessary resources and by tying up the process in lengthy court proceedings.

Thus, the process for federal approval of state system design should not only be streamlined and based on the general principles outlined above, it should be a matter between the federal and state governments. That is, states should be accountable only to the federal government for the adequacy of their state system design. Other participants should be provided an opportunity to comment on the state plans in the federal approval process, but should not be permitted to sue states on the basis that their plans do not satisfy federal criteria. Thus, a rural group could not sue a state over its designation of consumer health alliance boundaries and employers of a certain size could not sue a state over its decision that they must purchase health care through the alliance. [Leaves open the question whether the feds can be sued for approving a state plan that is allegedly not in compliance with the statute]

C. State accountability for operating health care system.

States will also be accountable once the system has been designed and put in place. States will be accountable to the federal government to assure that the system within the state is meeting the goals of the reform. In terms of evaluating state performance in this respect, the general principles discussed above should be applied.

States should not, however, be directly accountable to other participants in the system for their claims that the system is not working as it should. Rather, there should be a claims resolution mechanism that, at least in the first instance, establishes a structure of direct functional accountability. That is, a grievant would assert her claim directly against the entity responsible for that aspect of the system that has allegedly failed. A consumer dissatisfied with the quality of health care received would make her claim against the health plan responsible for providing her health care.[1] A consumer unhappy with the plan choices provided would bring his claim against the health alliance responsible for selecting the plans. A health plan that wanted to challenge the risk adjustment made for its population mix would assert the claim against the health alliance that made that determination.

To the extent a state agency directly carries out functions within the system, such as risk adjustment, the state would be the responsible entity against which a claim would be lodged. However, the state would not be subject to claims for deficiencies in the system because of its overall accountability. That would be a matter between the federal and state governments only.

The state's role in disputes between other participants in the system would be to provide a mechanism for their resolution and to monitor that process to make sure that both the dispute resolution process and the system in general are working. Part of the state plan subject to

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1. This assumes enterprise liability is adopted.

approval by the federal government would be establishment of a dispute resolution process. This might involve creation of a state administrative body to hear claims.[2] As suggested in some proposals, there should be a requirement of initial use of alternative dispute resolution procedures before moving to an administrative hearing. This would be particularly desirable for claims of individual consumers. The proposal for ERISA Early Expert Evaluation of pension benefit claims is one model that could be adapted in this area. The second aspect of the states' accountability for operating the system would be its enforcement function, described in part below.

D. State enforcement of health care rights.

A state's accountability to the federal government to assure that the goals of health care reform are met is coupled with a responsibility to ensure that other participants in the system are properly fulfilling their roles and that consumers' health care rights under the reform are protected. Through their attorneys general states could monitor the claims resolution processes described above. State attorneys general should have independent authority to bring action against any participant that, based on claims history or other evidence, is not fulfilling its responsibilities adequately under state or federal law.

State attorneys general have long been active in more direct consumer protection activities. These can logically be extended to the health care arena. For example, although the claims process created by the state will likely be intended to provide "user friendly" procedures and avoid court litigation, there will still be power imbalances and other factors that warrant extra assistance to consumers. One mechanism would be for the state attorneys general to provide ombudsmen to assist consumers in using the claims resolution system. Many state attorneys general already have experience with such programs.

In addition, traditional state regulatory systems would cover various other aspects of the health care system. Solvency issues and regulation of supplemental insurance could fall within the jurisdiction of existing state insurance authorities. Fiduciary issues could fall within the existing charitable trust regulation units of attorney general offices.

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2. Some proposals have suggested a federal administrative hearing process for health care claims. Whether state or federal, the common objective is to provide a simple, speedy and efficient process that avoids the complexity, expense and delays inherent in the court system.

LEGAL AUDIT GROUPS

Translated Group Wall Hangings
by Margaret Farrell - 5/7/93

RESPONSIBILITY | ISSUE

I. STRUCTURAL ISSUES

Margaret A. National Governance

1. Delegation of legislative authority to NHB
2. Separation of powers

Richard B. Federal-State Relations

1. State constitutional issues

   a. Balanced budget provisions
   b. Taxing authority
   c. Referendums

[Attach Rick's survey]

Rick 2. Presumption against preemption of state law: (ERISA issues)

   a. Explicitly preempt laws which are not consistent with federal objectives.

      (1) corporate practice laws
      (2) anti-net-working law
      (3) some malpractice laws
      (4) others

   b. Leave in place through presumption those state laws that are consistent:

      (1) state antitrust laws
      (2) state licensure laws
      (3) quality of care
      (4) public health
      (5) other

3. Define the areas in which states have discretion.

4. Assume states have unpreempted police powers to enforce the federal requirements.

   a. Authority to decertify Alliances
   b. State regulatory powers - insurance
   c. Taxing authority
   d. Rate setting for insurers and providers

e. Licensure
f. Other

B. Legal Status and Authority of Alliances

3 Richard

1. Public or private character

a. If public

(1) "state action" for constitutional purposes
(2) state action for antitrust purposes
(3) subject to 1983 actions
(4) subject to state (federal?) APAs/FOIA (state and federal)

4 Barbara

b. If private

(1) implied federal causes of action (like those against firms regulated by SEC)
(2) state law liabilities - contracts, torts, unpreempted state antitrust laws, etc.
5 Betsy
(3) contractual ADR mechanisms
(4) designation of appropriate judicial forms - state or federal to review ADR or administrative remedies
(5) delegations of taxing authority

6 Michael

2. What is an "employer" for purposes of the mandated purchase of insurance? Who is an employee? An independent contractor etc. The need for default rules.

6A Large Employers

C. Large or non-coop. firms - guarantees of contained liability

Peter

D. Quality of Care

7
1. general federal guidance/powers
2. state responsibilities
7a Malpractice
3. malpractice
4. preemption of public health laws

8 Barb A

E. Enforcement

8A
1. federal to state
2. state to alliances
3. patients to alliances
4. plans to providers

II. RIGHTS ISSUES

9 Mike — A. Religious opt-outs for enrollees, religious employers, providers, plans

10 Marj. — B. Medically necessary and appropriate decisions (its harder than you think!)

11 Angela — C. Private rights to purchase supplemental/insurance

1. benefit package

2. treatment

12 Angela — D. Privacy/confidentiality issues

13 Ed — E. Mandatory adjudication of rights:

1. through ADR
2. through administrative procedures - exhaustion
3. state licensure and scope of practice issues for providers.

14 Kathy — E. Due process rights of providers - Dr./Nurses/hospitals, health plan exclusions, state licensure.

15 § 1983 Rick Stowes

Notes for Legal Review Group

Benefits

1. Benefits package will state only that "professional services" will be delivered. A plan will be free to determine whether to hire specific types of health care providers to deliver those services appropriately. Particular restrictions on nurses will be overturned; nursing boards will make decisions as to whether a procedure can be performed by a nurse.

2. Preventive health services for high risk individuals will not be limited by the comprehensive benefit package. Additional and more frequent services are provided to high risk individuals.

Ethics Issues for a New Health Care System

RECOMMENDATION

PHYSICIAN AND NON-PHYSICIAN PROVIDERS

1. Intent: Equal access to a comprehensive benefit package is dependent on both universal insurance **and** adequate numbers of providers who are acceptable to all covered beneficiaries. Our experience with Medicare confirms that full insurance coverage does not necessarily provide equal access to benefits; despite equal coverage under Medicare, minority elderly have less access to covered services than do non-minority elderly.

The intent of this provision is to promote the full and most efficient use of physician and non-physician providers and to promote comparable professional standards for physician and non-physician providers so that they can work as professional colleagues in widening access to care. This recommendation acknowledges the overlapping competencies of non-physician and physician providers.

2. Scope: This policy applies to interprofessional issues arising between and among physicians and non-physician providers. Non-physician providers is meant to include, but is not limited to nurses, optometrists, dentists, midwives, mental health social workers, psychologists, chemical dependency counselors and other duly licensed or certified or qualified providers of covered health services.

3. Role: Qualified AHPs should fully utilize non-physician providers who are their employees or in their provider networks to the extent of privileges granted by licensure limited only by the individual competence of individual providers. To this end, qualified AHPs shall:

3.1 offer clinical privileges to all classes of non-physician providers consistent with licensure and/or certification.

3.2 provide physician and non-physician providers with malpractice insurance (including coverage of personal liability insurance and enterprise liability).

3.3 provide physician and non-physician providers with clinical facilities and equipment equally adequate to the performance of clinical duties.

3.4 allow non-physician and physician providers comparable opportunity to approve and design practice parameters used to guide care by the AHP.

3.5 establish referral procedures which do not unfairly encumber the use of non-physician providers.

3.6 otherwise establish policies which encourage the use of non-physician providers.

3.7 Nothing in this section should be interpreted:

3.7.1 as limiting the duties of AHPs to review the credentials, quality of care, qualifications, or competence of an individual health care provider. Such policies should be defined as appropriate for all classes of AHP providers or employees.

3.7.2 to mean that AHPs may or should assign the role of gate-keeping to non-physician providers.

3.7.3 to require AHP to pay non-physician or physician providers for types of services that are not covered by the benefit set.

4. Professionalism

4.1 Qualified AHPs should hold physician and non-physician providers accountable to substantially equivalent standards regarding:

4.1.1 patient confidentiality
4.1.2 patient privacy
4.1.3 patient advocacy
4.1.4 financial interests in decision making
4.1.5 chemical/substance dependency or abuse
4.1.6 sexual relationships with patients
4.1.7 neglect or abuse of patients
4.1.8 economic refusal of services
4.1.9 informed consent and refusal of services

4.2 Aside from provisions pertaining to 2.1, qualified AHPs should where possible hold physician and non-physician providers to ethical standards promulgated by appropriate professional societies.

Sara's Questions

May 6, 1993

LEGAL RIGHTS, PRIVATE RIGHTS OF ACTION, AND PROCEDURAL ISSUES

1. Individual Eligibility and enrollment issues

- eligibility for coverage (exclusion of undocumented persons)
- enrollment into a health security plan (time, place and manner issues -- delays, denials, prompt application, accessible application procedures, right to a written decision
- determination of state residency
- presumptive eligibility
- documentation of eligibility
- independent right of children to enroll
- determination of subsidy owed
- determination of eligibility for supplemental benefits
- enrollment in Alliance if terminated from non-alliance plan
- enrollment in benefit plan versus choice of accountable health plan -- is there a distinction?
- informed decision making about accountable health plan prior to enrollment
- language accessibility
- rights if choice of plans is unavailable
- right if only available plan is one in which your personal physician does not practice
- right to enroll in fee for service plan
- point of service enrollment in a plan
- cooling off period
- disenrollment from plan between formal enrollment periods

2. Patient rights against plans

- grievance procedures -- denial and delay of care?

- expedited grievance procedures for certain situations?
- external review of internal grievance process
- procedural protections for the plan grievance process
- allegations of plan malpractice

3. Patient rights against Alliances? States? Federal Government?
   - delay in / termination of enrollment
   - denial of coverage
   - denial of reasonable choice of plans
   - failure to assure quality care
   - failure to assure access to all benefits covered in package and through plan contracts?
   - failure to pay subsidy
   - failure to pay the plans the monthly capitation
   - failure of the plan itself
4. Patient rights against non-alliance plans
   - do same issues apply?
   - is there a legal right against the state
5. Provider rights
   - non-payment by alliance
   - refusal to certify as a plan
   - termination of certification
   - denial of special payments owed (essential providers, other providers)
   - when does "aggressive purchasing" cross the line and become actual rate setting, and what process should be followed for appealing rates?
6. What do we do about Suter issues?
7. What do we do about Wilder issues?

8. How much will clear articulation of Alliance/ state and federal duties plus usable enforcement tools lessen the need for articulated individual rights of action?

9. Do we have to spell out the applicability of the various civil rights acts, and if so, in what contexts? What process for enforcement should be followed?

- do civil rights acts apply? Is there a receipt of federal funding? By whom? Alliances? Plans? Individual providers?
- what constitutes possible cause of action?
    - plan redlining
    - alliance redlining
    - denial of plan certification
    - denial of contract to individual provider or clinic based on race/ethnicity of provider or patients served
    - failure to be language or disability accessible

10 What should we do about defining discrimination based on poverty (e.g., duty of plans to take subsidized patients who cannot pay full premiums, redlining by plans or alliances to avoid serving poor areas).

11. Will providers be able to bring grievance on patients' behalf for failure of plans to approve requested care?

IRA'S QUESTIONS FOR THE LEGAL REVIEW
May 6, 1993, The White House, Room 211

1. How can we limit liability for health care of large employers that enter the alliance?

2. Legal relationship of the alliance to the state.

3. Limits on supplemental benefits.

4. Should the state or alliance regulate quality or should it be left up to the state to decide or should plans be required only to meet federal standards?

5. Coverage/benefit issues/meaning of medically necessary and appeal mechanism for disputes.

6. Enforcement of individual mandate.

For comment:

for I.M.

POSSIBLE QUESTIONS on Budget

1. What expenses are covered by the disaggregated budget allocated to the states? Is this the same as the global budget? Are there health expenditures outside the budget? Who covers those expenditures?

2. How is the budget allocated to the Alliances? Is it a per capita allocation? Does it reflect costs + needs particular to area covered by the Alliance?
Will the federal govt be setting the budget for each Alliance?

3. ~~How~~ What are benchmark premiums? How are they set? By whom? How do these premiums relate to the Alliance budget.
What is the premium setting role of the HA - will the HA determine the community rating ~~number~~ OR PLAN for each of the benchmark premium areas?

4. How can an Alliance go bankrupt? What happens then?

5. What are the States' obligations to monitor and control Alliances' expenditures and activities? What are the states' tools to monitor and control?
→ or What are States' responsibilities with respect to Alliances' expenditures & activities? CAN THE STATE BE THE ALLIANCE?

6. Do Alliance expenditures above budget trigger penalties by the state or on the state? Do state expenditures above some limit trigger penalties on states? Can states obtain waivers? →

HW are poor people allocated between plans?
HA plans only or also employr plans?
(or the latter only to contribute $).

How will poor people or moderate income people who are not working be covered? What entities will be responsible for financing the subsidies that these people will require to afford coverage. Will there be a net increase in the financial resources available to provide coverage for these populations?

What will be the relative burden as between the State & federal governments with respect to these populations?