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Subject: : Revised Medical Malpractice Options Paper
Medical Malpractice Reform Options Memo July 9.doc

Deliberative Process Material

In preparation for our 11 a.m. meeting tomorrow morning, attached please find a revised version of the HHS options paper on med mal reform. This reflects a major revision from the last paper from before the 4th of July. It follows discussions this afternoon with OLC at DOJ regarding constitutional concerns about certain elements of the original proposal. We have attempted to respond to and reflect OLC's concerns, but because of the press of events, they will not have had the chance to preclear this before sending around to all of you, so please bear that caveat in mind.

MEDICAL MALPRACTICE LIABILITY REFORM

1. The Medical Malpractice Liability Crisis:

America is currently experiencing a medical malpractice insurance coverage crisis that causes increased cost, decreased access, and lower quality of care:

- Medical malpractice premiums have skyrocketed in recent years
  - 8 states reported premium increases of over 30 percent in 2002
  - Premiums account for 1% of health care costs and 10-25% of physician incomes
- Rising malpractice judgments and costs of litigation are forcing insurance providers out of the market, leaving doctors without coverage and causing doctors to move their practices
  - Most OB/GYNs in Las Vegas are refusing to take on new patients
  - Las Vegas' only trauma center closed its emergency department because physicians were unable to obtain liability insurance for emergency care.
  - Mississippi doctors moved to Louisiana because malpractice insurance is unavailable in Mississippi.
  - St. Paul Insurance, which covered at least 25% of the market in 12 states, is no longer writing malpractice insurance
  - Only one insurance carrier remains in West Virginia
- Fear of liability causes the practice of defensive medicine, increasing health care costs perhaps by as much as $50 billion per year.
  - 75% of physicians admit that fear of litigation led them to order more tests and refer more patients to specialists than they otherwise would
- The major cause of increased premiums is the rising size of malpractice judgments and the costs of litigation
  - The average jury award has tripled since 1994 to $3.5 million
  - In 2001 insurers paid $1.40 in claims for every dollar in premiums
  - Failure to anticipate the size of awards and the poor performance of investments may have exacerbated the situation
- The current system does not enhance the quality of care – it actually harms the quality of care and reduces access to care
  - Medical malpractice awards are not targeted to those who were injured by negligent medical care
    - Studies indicate that as little as 25% in professional liability insurance premium is returned to those who have been injured by medical error
  - Fear of liability prevents providers from performing quality self-evaluations and improvements
  - The high costs of insurance are causing providers to defer purchases of new medical equipment and the hiring of needed staff
  - Doctors are leaving certain locations, medical staffs or medical specialties due to litigation fears and unavailability of liability insurance, resulting in reduced access to care for many patients in many cities.
- The current system is not fair to injured patients

- Medical-malpractice litigation does not in most cases actually compensate patients truly injured by medical negligence and rarely identifies and holds providers accountable for substandard care (New England Journal of Medicine, July 25, 1991, vol. 325:245-251)
- Plaintiffs lawyers and clients have a conflict of interest because seriously injured patients desire prompt recovery of their out-of-pocket losses, but attorneys are willing to hold out and gamble for larger possible awards of non-economic damages in a few of their cases because they can spread the risk of loss over their entire portfolio of medical malpractice cases
- Litigation is slow, expensive, and traumatic for all involved; on average patients must wait almost 5 years before receiving any compensation.
- Providers are reluctant to make settlement offers because they will appear weak to plaintiffs attorneys and get nothing in return

- The medical liability crisis is a federal concern
  - The direct cost to the federal government of increasing malpractice costs is $6 billion per year. The federal government health programs cover approximately 50% of Americans
    - The 1000% increase in liability costs for nursing homes since 1990 is financed largely through Medicaid and Medicare
  - The indirect cost of defensive medicine to the federal government may be as much as $12 billion per year
  - The malpractice crisis directly impacts interstate commerce by causing doctors to practice in certain states and not practice in others, impacting not only doctors, but the interstate mobility of citizens who need access to quality health care
  - As the insurer of 1 in 4 Americans, the federal government has a critical concern for the quality of care that is provided and access to providers

2. Options for Reform:

Any successful medical malpractice reform proposal should serve two goals:

- Enhance health care quality by encouraging early recognition of medical errors and targeting fast compensation to those who have been injured by medical errors (similar to workers compensation models)
- Reduce excessive non-economic damages awards unconnected to remedying real errors (thus reducing health care costs and enhancing health care access)

a. Option 1: Actively support the Patient Safety and Quality Improvement Act

Real medical errors can be reduced through health care provider self-evaluations of bad incidents. Plaintiffs' attorneys, however, attempt to use these self-evaluations as evidence against providers in litigation. Most states have statutes that offer some confidentiality protections to these self-evaluations or adverse event reports, but the protections are inconsistent and often provide only partial protection for certain categories of review.

Senators Frist, Breaux, Jeffords, and Gregg have introduced the Patient Safety and Quality Improvement Act (S. 2590, introduced in the House by Rep. Johnson as H.R. 4889) to provide for uniform confidentiality, nondiscoverability, and inadmissibility of patient safety data generated for patient safety or health care quality purposes. (Underlying evidence not generated for these purposes would still be available to plaintiffs attorneys.) Two members of the Administration have already expressed support for this legislation.

Recommendation: The Administration should actively support enactment of this legislation as the first step towards health care quality-centered medical malpractice reform.

Pros:

- This is a basic step to improve quality of care and thus also reduce litigation
- This legislation already has tripartisan support

Cons:

- Could be portrayed as an effort to hide vital healthcare information and to protect bad actors (although it will only prevent plaintiffs attorneys from free riding off of the provider's self-evaluation work)

b. Option 2: Propose federal legislation to encourage States to implement early offer systems and medical review boards to speed claims evaluation, settlement, and resolution of meritorious claims

Early offers and medical review boards are procedural improvements that could be enacted either separately or in tandem to 1) encourage providers to make, and plaintiffs to accept, early offers to pay all of a negligently injured patient's economic damages and 2) encourage the use of expert medical review boards to resolve cases through expedited procedures prior to litigation.

Federal legislation could encourage States to enact their own medical liability reforms, which would include both an early offer and medical review panel system. The introduction of early offers and medical review panels by the States would lead to fast, efficient findings of liability and damages, with significant incentives not to challenge the findings in court.

The federal legislation would encourage State adoption of early offer and medical review panel systems by creating a preemptive federal malpractice action for those States that do *not* adopt such reforms. This federal malpractice cause of action would include protections similar to the Health Act (H.R. 4600, see p. 9) (e.g., caps on damages for non-economic damages; limitations on punitive damages; elimination of joint and several liability; elimination of collateral source rule).

Under the federal malpractice action, a patient's medical malpractice suit would continue to be heard in State court and would use State medical liability tort standards (similar to

way in which Federal Tort Claims Act cases are heard), except where those standards are contrary to federal law.

States that wished to "opt-out" of this federal malpractice action and its limits would need to create State law mechanisms for early offers and medical review boards. The early offer and medical review panel systems adopted by the opting-out States would have to meet certain minimum standards set forth by the federal legislation (outlined below) as further interpreted and certified as compliant by the Secretary of Health and Human Services. The opting-out States would, however, maintain some discretion as to the design and functioning of their early offer and medical review panel systems, so long as the minimum federal guidelines were met.

1. Early offer reforms

Early offers encourage the rapid settlement of cases and provide quick payment of economic compensation in deserving cases and avoid the delay, cost, and emotional distress of litigation.

Within a specified short period after an adverse event or the filing of a claim, a potential or named defendant may make an "early offer" to the claimant. The provider does not have to make an early offer.

The "early offer": The terms of the offer would be set by State statute:

- Net economic damages: The offer would not be for a set dollar amount, but would rather have to include an offer to pay all of the claimant's economic damages (net of collateral sources of recovery) past and future on an accrual basis (e.g., lost wages and health care costs, as more specifically defined in the statute).
- Alternative minimum damages for certain serious injuries: In the case of certain serious injuries that may not cause economic injury, the statute would require the offer of an alternative minimum payment according to a schedule of liability (for injuries such as disfigurement, loss of limbs, or loss of reproductive function). The State system could establish a panel to determine by regulation (with the opportunity for inflation adjusters) what injuries qualify as "serious injuries" and set the schedule for such payments.
- Reasonable attorneys fees to evaluate the offer: The offer would also have to include an offer to pay the claimant's reasonable attorney's fees to evaluate the offer.
- Within the time period for making an early offer, the patient could submit to the provider a statement that it would accept a statutory early offer if made.

In short, the early offer would be an offer to make the claimant whole for the injury. It would not include the payment of non-economic damages such as pain and suffering or loss of consortium or punitive damages (except for the set amount for certain "serious injury" cases).

Acceptance of the early offer: If the provider makes an early offer and the claimant accepts, the case is over. Once the parties reach this agreement, they could

independently make a settlement that precisely lays out the terms of financial liability (such as through the purchase of an annuity by the provider). Alternatively, the accepted early offer could be implemented according to the statutory terms.

- Any disputes that might arise regarding whether particular expenses fit within the statutory definition of the early offer (such as whether a trip to Bermuda for recovery is a bona fide medical expense) or the scope of attorneys fees would be subjected to binding arbitration.
- Although that might still leave uncertainty and some litigation risk, the litigation would relate to damages under a statutory standard, rather than the much more complex issues of liability and future damages calculations.
- Potential co-defendants could join the early offer, with disputes among early offerors as to their respective shares being resolved by binding arbitration if necessary.

Rejection of the early offer: If the provider makes an "early offer" according to the terms of the statute and the claimant refuses it, the provider would have a qualified legal defense in any subsequent state or federal suit or medical review board process.

- The qualified legal defense would provide that the defendant could be held liable only upon clear and convincing evidence of negligence and causation (as opposed to the normal preponderance of the evidence standard).
- The defense would provide that non-economic damages could be awarded only upon clear and convincing evidence of wanton or intentional misconduct by the provider (or, in the alternative, non-economic damages could be limited to $250,000).
- The defense would prohibit the admission into evidence of the fact that an early offer had been made.

Recommendation: Propose federal legislation encouraging States to enact early offer systems for providers to make and patients to accept early offers.

Pros:

- Early offers is a new kind of tort reform that does not involve taking away a vested recovery, as caps on damages do; it gives plaintiffs swift, certain recovery, like workers compensation.
- Leaves States with some flexibility and autonomy in running their tort systems.
- An even stronger form of early offer legislation was first proposed in 1984 by Representatives Richard Gephardt and Henson Moore (it would have applied to Medicare, Medicaid, and other federally funded care in states that did not introduce their own reform, and would have given the plaintiff no option to reject the early offer).
- Would reduce litigation expenses and large non-economic damages awards and permit plaintiffs and defendants and thus ultimately the public to share in the savings.

- Would reduce the number of medical malpractice cases in court.
- A form of early offer was implemented several years ago when a school board purchased an insurance policy providing that if a student suffered serious injury in the course of athletic activities, the insurance company would offer to pay net economic loss as it accrued. Due to risk aversion, in almost every case of serious injury, the student accepted the offer.

Cons:

- Possible continued litigation and uncertainty regarding the exact amount of economic damages liability assumed by the provider making an early offer.
- Plaintiffs' lawyers will argue that it takes away the right to recover non-economic damages in the most serious cases (i.e., the ones where the conduct was so clearly bad that the provider is willing to settle immediately).
- Certain advocacy groups may argue discrimination (i.e., less economic damages for low-income patients) and denial of opportunity to participate in the litigation lottery for large, non-economic damage awards.

2. Early offer demonstration project at federal agencies

A watered-down version of the early offer program could be adopted administratively by federal agencies that are health care providers, such as the VA, DOD, and HHS. Because this version would be implemented without legislation, there could be no "hammer" should a plaintiff refuse the early offer. Patients would be informed that the federal government has an early offer program. Within a set period of time, the government and the patient may file an early offer or acceptance, as the case may be, with a designated neutral third party ("the black box"). Only if both an offer and acceptance are put in the black box will the parties learn of each other's offer and the case would be settled immediately.

Recommendation: The Administration should announce commencement of an early offer demonstration at the time early offer legislation is proposed.

Pros:

- Might provide useful information to see if an early offer program would be popular, speed recovery to deserving victims, and reduce damages paid in these cases.
- Can be implemented without legislation.

Cons:

- Could undercut legislative efforts (i.e, "wait and see).
- Would lack any sanction for refusing an early offer.
- Government malpractice claims already have significant tort liability protections under the Federal Tort Claims Act in that punitive damages cannot be awarded,

trials are before judges, and the government receives the benefit of any liability caps in the jurisdiction.

3. Medical review board systems

Nineteen states currently have some form of medical review panels that may be used prior to litigation. Most of these systems are not mandatory, have little incentive to be efficient, and have no real sanction for challenging the findings of the board. As a result, these systems can simply lead to a dress rehearsal of a second trial in court, at much added expense.

As with encouraging early offers, new federal legislation would encourage State adoption of medical review panel systems by enacting a preemptive federal malpractice action, with damage caps and protections similar to the Health Act (H.R. 4600, see p. 3 and 9). The State medical review panel systems could always provide more stringent standards than provided for by the guidelines under the federal statute, however the minimum standards for such "opt-out" State medical review panel processes would be as follows:

The State medical review board process: Once a claim is filed, a provider would have the option of channeling the claim through the medical review board process. The provider would then have no right to challenge the findings of the board in court, except on the grounds that the findings were clearly erroneous.

- Board composition:
  - Boards would be composed of at least 2 licensed doctors from the State and one lay chairman.
- Board procedures:
  - All costs of the boards, including compensation of members and administration of the system, would be borne by the provider or by the State government or medical licensing board or professional association, at the option of the State. Board members would have the authority to assess costs on claimants with frivolous claims.
  - Participants would have limited discovery rights (i.e., the medical record only, testimony only of those who were eyewitnesses to the conduct at issue, limits on damages discovery) and would be able to put on only essential evidence (e.g., one expert witness per side, all direct testimony submitted in advance in writing, time limits for hearing) before the board.
  - Boards would be required to render decisions within 90 days of the election by the provider of the board process. If a decision is not reached within that time frame, the patient may bring suit without restriction.
  - Deliberations of the panels would be confidential and decisions of the board on 1) causation and liability and 2) damages would be reduced to writing.
  - Board members would be granted qualified legal immunity for private suits for defamation, antitrust, conspiracy, defamation, etc., arising out of their work on the board.

- Board damages awards: The board may award the following damages (subject to any more stringent liability limits adopted by the relevant state or limits set by the early offer program):
  - Past economic damages and future economic damages would be structured for future payment
    - Following such an award, the parties could agree to settle the ongoing economic liability if they wish (such as through the provider's purchasing an annuity for the plaintiff)
  - Unlimited non-economic damages if agreed to by all board members, or $250,000 maximum non-economic damages if agreed to by a majority board members.
    - Damages for future non-economic injury would be paid out on an annual basis, rather than in a lump sum
  - Board must vote unanimously for assessment of any punitive damages

Patient challenges to medical review board findings: If the defendant elects to participate in the review board process, the defendant will be entitled to a qualified legal defense in any subsequent lawsuit:

- The defense would provide that the findings of the board will be admissible in evidence and may be reversed only if clearly erroneous
- The defense would limit non-economic damages to $250,000 (unless a more stringent state limit exists)

Recommendation: Propose federal legislation encouraging States to establish the medical review board process. For States that do not "opt-out" and create such a medical review board process, medical malpractice claims would be preempted by federal law through the creation of a federal medical malpractice tort action, subject to various procedural protections similar to the Health Act.

Pros:

- Would reduce the number of medical liability cases in court
- Would reduce litigation defense costs and damages amounts
- Would offer patients a fast process for an essentially binding liability finding against the provider (if provider submits to panel process)
- Recognizes State sovereignty and State tort law by permitting States to "opt-out" of federal medical malpractice tort action by creating State-run medical review panel process and procedural protections.
- Would automatically enact federal statutory reforms in States that did not "opt-out" and enact their own medical liability reforms including early offer and medical review panel systems.

Cons:

- Could be viewed as adding one more layer of litigation, unless there are real disincentives to continuing with a suit in court
- Success of medical review board systems in States has been mixed
- Past Administrations have promoted the use of medical review boards without much success

c. Option 3: Support the Health Act (H.R. 4600)

In April a bipartisan coalition of 34 congressmen led by Representative Greenwood introduced the Help Efficient, Accessible, Low Cost, Timely Health Care Act ("Health Act") (H.R. 4600), which provides:

- Three year statute of limitations on medical liability lawsuits
- Elimination of joint and several liability
- $250,000 cap on non-economic damages (no cap on economic damages)
- Cap on punitive damages of two times non-economic damages
- No punitive damages could be awarded for FDA compliant products
- Limits on plaintiffs attorney contingency fees
- Future damages are paid out over time rather than in one lump sum

Recommendation: Support the Administration's own innovative approach to medical malpractice liability reform, rather than the Health Act.

Pros of supporting the Health Act:

- Liability caps are the only proven method of reducing liability exposure
- Health Act has bipartisan support in the House, and likely could pass in the House

Cons of supporting the Health Act:

- Old idea, not new.
- Would detract from the Administration's own proposals, which would be more focused on health care quality and targeted, swift recovery to the truly injured
- Past experience suggests that federal caps on liability will not pass in the Senate

d. Option 4: FDA rule preempting state duty to warn claims based on prescription drug labels

Under the Food, Drug, and Cosmetics Act, the FDA comprehensively regulates the labels on prescription drugs. The FDA approves every claim and warning that may be put on the label. Often, the FDA refuses permission to include warnings that the manufacturer or other petitioners would like to have on the label. State duty to warn claims conflict with this comprehensive federal regulatory regime. Public health experts at the FDA believe that excessive warnings can create a health risk by detracting from necessary warnings and by deterring people from taking needed drugs based on unneeded warnings.

Recommendation: The FDA should through notice and comment rulemaking set forth its interpretation of the Act as preempting state duty-to-warn claims based on prescription drug labels.

Pros:

- Could be enacted quickly through administrative action
- Would prevent state tort law interference with a comprehensive federal public health and safety regime

Cons:

- Opponents would argue that the FDA sets a floor on warning, not a ceiling
- Opponents would argue that only those warnings that had been specifically rejected by the FDA should be preempted
- Any preemption argument is susceptible to the claim that it does not accord adequate respect to state regulatory requirements under their general police powers

v. 7/9/02